Northern Ireland Assembly

Windsor Framework Democratic Scrutiny Committee

Inquiry into Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 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

Ordered by the **Windsor Framework Democratic Scrutiny Committee**

to be published 15 August 2024

Report: NIA 47/22-27 Windsor Framework Democratic Scrutiny Committee

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Purpose and Membership

Purpose

The Windsor Framework Democratic Scrutiny Committee is a standing committee of the Northern Ireland Assembly established under Schedule 6B to the Northern Ireland Act 1998.

The purpose of the Committee is to assist with the observation and implementation of Article 13(3a) and Article 13(4) of the Windsor Framework.

The functions of the Committee include:

(a) the examination and consideration of new EU acts and replacement EU acts;
(b) the conduct of inquiries and publication of reports in relation to replacement EU acts;
(c) engagement with businesses, civil society and others as appropriate in relation to replacement EU acts;
(d) engagement with the UK Government in relation to replacement EU acts;
(e) engagement with Ministers and Northern Ireland departments in relation to replacement EU acts;
(f) the collation and publication of evidence collected as part of its other activities; and
(g) dealing with other matters (including legislative proposals which may become new EU acts or replacement EU acts) which the Committee considers to be connected with its purpose or other functions.

A replacement EU act means an EU law which updates, by amending or replacing, any of the relevant[1] EU laws which already apply in Northern Ireland, as listed under Annex 2 of the Windsor Framework. Areas of EU law

[1] Relevant EU laws are those EU instruments referred to in the third subparagraph of Article 5(1) of the Windsor Framework, the first indent of heading 1 of Annex 2 to the Framework or headings 7 to 47 of Annex 2 to the Framework

that apply in Northern Ireland include legislation on goods, animal and plant health rules, rules on agricultural production, VAT and excise on goods, and state aid rules. The EU's Customs Code also applies to goods entering Northern Ireland. There is a procedure by which members of the Assembly may seek to prevent the application of a replacement EU act (an emergency brake mechanism known as the Stormont Brake). Further information on the Stormont Brake can be found here.

A new EU act means a new EU law which falls within the scope of the Windsor Framework, but which neither amends nor replaces an EU act listed in the Annexes. The Northern Ireland Assembly has a role, by means of an "applicability motion", in setting out its position on whether a new EU act should be added to the list of EU laws applicable in Northern Ireland. Further information on Applicability Motions can be found here.

Membership

The Committee has 9 members, including a Chairperson and Deputy Chairperson, and a quorum of five members. The membership of the Committee is as follows:

Mr Philip McGuigan MLA (Chairperson)[2]
Mr David Brooks MLA (Deputy Chairperson)
Mr Eóin Tennyson MLA[3]
Ms Connie Egan MLA[4]
Ms Joanne Bunting MLA
Mr Stephen Dunne MLA[5]
Mr Declan Kearney MLA
Ms Emma Sheerin MLA
Dr Steve Aiken OBE MLA

[2] Mr Philip McGuigan MLA replaced Mr Declan Kearney MLA as Chairperson on the Committee on 9/02/2024

[3] Mr Eóin Tennyson MLA replaced Ms Sorcha Eastwood MLA as a member on the Committee on 22/04/2024

[4] Ms Connie Egan MLA replaced Mr Patrick Brown MLA as a member on the Committee on 20/05/2024

[5] Mr Stephen Dunne MLA replaced Mr Jonathan Buckley MLA as a member on the Committee on 3/06/2024

Introduction

1. This report sets out the conclusions of an inquiry by the Windsor Framework Democratic Scrutiny Committee ('the Committee') into a published replacement EU act: Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 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.

2. The Regulation is a replacement EU act because it repeals and replaces Directives 2002/98/EC and 2004/23/EC, which are listed in the Windsor Framework at Article 5(4), Annex 2, point 22.

3. The replacement EU act applies in Northern Ireland under Article 13(3) of the Windsor Framework but is subject to the mechanism set out in Article 13(3a) of the Windsor Framework. This mechanism provides for a replacement EU act, or relevant parts of a replacement EU act, not to apply in Northern Ireland if the United Kingdom Government ('UK Government') notifies the EU within two months of the act's publication in the EU Official Journal.

4. The UK Government may only make this notification if it is satisfied that the conditions in Article 13(3a) of the Windsor Framework have been met and that the procedures set out in its Unilateral Declaration on the involvement of the institutions of the 1998 Agreement have been followed. These procedures provide, amongst other things, that 30 MLAs from at least two parties (and excluding the Speaker and Deputy Speakers) will need to notify the UK Government of their wish that the emergency brake mechanism should be applied.[6]

5. If the UK Government is satisfied that the necessary conditions have been met, it will notify the EU in the Joint Committee. The EU law will not apply in Northern Ireland in its new form two weeks later. The older version of the EU law will still apply. The relevant law would then be discussed in the EU-UK Joint Committee

[6] The emergency brake mechanism applies to EU acts referred to in the first indent of heading 1 and in headings 7 to 47 of Annex 2 to the Windsor Framework and to Article 2(1)(c) of Council Regulation (EC) 1186/2009 setting up a Community system of reliefs from customs duty.

under the process for new EU laws - Article 13(4). The UK Government must not agree (apart from in exceptional circumstances) to adopt the new law unless the Assembly has passed a motion with cross-community support, known as an applicability motion**.**

6. The replacement EU act in question - Regulation (EU) 2024/1938 - was published in the EU Official Journal on 17 July 2024. The UK Government formally notified the Committee of the act's publication on 18 July 2024.

7. Under paragraph 8(1) of Schedule 6B to the Northern Ireland Act 1998, the Committee must decide no later than five working days after the day on which it was notified of the replacement Regulation whether it wishes to hold an inquiry. In reaching a decision, paragraph 8(2) of Schedule 6B requires the Committee to have regard to whether it appears likely that the replacement EU act:
    - significantly differs (in whole or in part) from the content or scope of the EU instrument which it amends or replaces; and
    - would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist.

8. The Committee may also have regard to any other matters it considers appropriate.

The Replacement EU Act

9. Regulation (EU) 2024/1938 on standards of quality and safety for substances of human origin (SoHO) repeals and replaces Directives 2002/98/EC[7] and 2004/23/EC (BTC Directives)[8]. These Directives are listed in Annex 2 to the Protocol on Ireland/Northern Ireland and so apply in Northern Ireland under the Windsor Framework.

10. The SoHO Regulation is intended to establish "a robust, transparent, up-to-date and sustainable regulatory framework" to ensure the quality and safety of all substances of human origin and which is sufficiently flexible to adapt to scientific and technical developments. The Regulation addresses concerns that the BTC Directives it replaces were implemented differently across the EU, resulting in divergence, which hampered the cross-border exchange of BTC. Member States remain free to introduce more stringent national measures provided they are compatible with EU law and proportionate to the risk to human health.

11. The Regulation is broader in scope than the Directives which it replaces, covering "any substance collected from the human body, whether it contains cells or not and whether those cells are living or not, including SoHO preparations resulting from the processing of such substance". It does not apply to organs for transplantation.

12. The Regulation's provisions include: rigorous safety and quality standards which extend to SoHO donors and to children born from donated eggs, sperm or embryos; requirements for national competent authorities responsible for supervising SoHO-related activities; common EU-wide procedures to authorise

[7] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30)

[8] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).

and assess SoHO preparations; requirements for all entities carrying out activities affecting the safety and quality of SoHO; a new EU-level SoHO Coordination Board and a new IT platform to exchange information; and provisions to ensure continuity of supply and a rapid alert system for serious incidents. The European Commission is empowered to adopt various delegated and implementing acts under the Regulation.

13. The UK Government's Explanatory Memorandum on the proposed Regulation states that reproductive tissues and cells policy is reserved, and blood and non-reproductive tissues and cells policy is devolved.

The Committee's Decision on Whether to Hold an Inquiry

14. The Committee met on 25 July 2024 to decide whether or not to hold an inquiry into Regulation (EU) 2024/1938.

15. To assist it in reaching a decision, the Committee considered legal advice on whether it appeared likely that the replacement EU act differed significantly (in whole or in part) from the content or scope of the Directives which it repeals. The Committee noted that the legal advice indicated that the published replacement act significantly differs, in part, from the content or scope of the EU instruments which it replaces.

16. The Committee also considered whether it appeared likely that the replacement EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist. It did this by: examining an initial assessment of impact provided by the Department of Health (DoH); listening to evidence from DoH officials; considering the UK Government's Explanatory Memorandum (EM) dated 24 July 2024 on the *published* act, and its EM dated 22 September 2022 on the *proposed* act; and considering relevant correspondence published by the House of Lords European Affairs Sub-Committee on the Windsor Framework, and reports published by House of Commons European Scrutiny Committee.

17. The assessment of impact, the EMs and the correspondence published by the Westminster scrutiny committees, can be found at **Appendix B.** The Official Report ('Hansard') of the evidence session can be found at **Appendix C**.

18. Having had regard to whether it appears likely that Regulation (EU) 2024/1938:
    - significantly differs (in whole or in part) from the content or scope of the EU instrument which it amends or replaces; and
    - would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist,

the Committee decided to hold an inquiry into that act. This decision was published on the Committee's webpage.

The Inquiry Process

19. In conducting an inquiry, paragraph 9(2) of Schedule 6B to the Northern Ireland Act 1998, requires the Committee to "seek substantive discussion and engagement" with the UK Government, the relevant Northern Ireland Minister or department, and, to the extent that the Committee considers appropriate, representatives of businesses and civil society affected by the replacement EU act, or who would be affected, if the act was to apply in Northern Ireland. The Committee may also consider any matters it deems appropriate.

20. The Committee had to conclude its inquiry and publish a report setting out its conclusions no later than 15 working days before the end of the two-month scrutiny period. The scrutiny period started when the replacement Regulation was published in the EU Official Journal on 17 July 2024, and therefore ends on 17 September 2024.

21. The Committee considered matters relating to its inquiry, including making a decision on whether to conduct an inquiry, at three meetings. The Minutes of Proceedings can be found at **Appendix A**.

22. At its meeting on 25 July 2024, the Committee agreed to seek substantive discussion and engagement with the UK Government. It therefore wrote to the UK Government to seek its views on whether applying, or not applying, the replacement EU act would have an impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist. In considering the matter of divergence, details of the position in England, Scotland and Wales were also requested. A copy of the Committee's correspondence and the responses from the UK Government dated 7 August 2024 and 14 August 2024, can be found at **Appendix B.**

23. At this meeting, the Committee also agreed to seek substantive discussion and engagement with the relevant Northern Ireland department which is the DoH. Therefore, it requested that DoH officials attend the Committee meeting on 1 August 2024 to give oral evidence. Officials attended as requested and the Hansard of the oral evidence can be found at **Appendix C**.

24. The Committee also agreed to seek substantive discussion and engagement with representatives of business and civil society. It opted to use Citizen Space as a platform to facilitate this engagement. A survey asking for views on the impact of the replacement EU act was launched on 26 July 2024.

25. At its meeting on 25 July 2024, the Committee agreed to write directly to key representatives of business and civil society, identified by the Assembly's Research and Information Service, as being affected, or who would be affected, if the replacement EU act was to apply in Northern Ireland, including regulatory bodies and industry associations, to alert them to the Citizen Space survey. The survey, which was publicised widely, was also open for response by any other representatives of business and civil society as well as members of the public. Four survey responses were received. All respondents agreed that their responses could be published, and these can be found at **Appendix D**.

26. The Committee considered the survey responses at its meeting on 15 August 2024.

27. The Committee deliberated on the evidence received at its meeting on 15 August 2024. The evidence received is not rehearsed in this report; a complete picture of the written and oral evidence can be found in the appendices.

28. At its meeting of 15 August 2024, the Committee agreed its inquiry report and that it should be published.

The Committee's Conclusions

29. In reaching its conclusions, the Committee has carefully considered all the evidence provided to it. The Committee has focused in particular on the two conditions that must be satisfied if the Stormont Brake is to be pulled.

30. In relation to the legal question of whether the replacement EU act significantly differs (in whole or in part) from the content or scope of the EU instrument which it amends or replaces, the Committee noted the legal advice it commissioned which indicated that the published replacement act significantly differs, in part, from the content and scope of the EU instruments which it repeals.

31. The Committee noted that the replacement EU act contains a number of new provisions, which go beyond what was contained in the original EU instruments, including more rigorous safety standards, and the extension of these standards to donors and offspring from medically assisted reproduction.

32. **Having considered its commissioned legal advice, the Committee concluded that the replacement EU act significantly differs, in part, from the content or scope of the EU instruments which it amends or replaces.**

33. In relation to the question of whether the replacement EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist, the Committee considered the written and oral evidence it received from DoH officials, the UK Government's Explanatory Memoranda, and the responses to its Citizen Space survey.

34. In considering this evidence, the Committee took the view that for an act to have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist, that significant impact must be negative.

35. **Having considered the evidence received from the DoH, the UK Government's Explanatory Memoranda, and responses to its Citizen Space survey, the Committee concluded that it was unable to reach a view on**

whether the replacement EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist.

Next Steps

36. Having reached its conclusions, the Committee's Inquiry report will be issued to all Members of the Legislative Assembly for further consideration.

Links to Appendices

Appendix A: Minutes of Proceedings

View Minutes of Proceedings from evidence sessions related to the report

Minutes of Proceedings – 25 July 2024

Minutes of Proceedings – 1 August 2024

Minutes of Proceedings – 15 August 2024

Windsor Framework Democratic Scrutiny Committee - Minutes of Proceedings (niassembly.gov.uk) (Minutes of 15 August can be found here when published)

Appendix B: Memoranda and Other Papers

View Memoranda and Other Papers considered by the Committee

Department of Health Initial Assessment of Impact

UK Government Explanatory Memorandum (published act) – 24 July 2024

UK Government Explanatory Memorandum (proposed act) – 22 September 2022

Extracts from the Ninth and Twentieth Reports of Session 2022-23 from the House of Commons European Scrutiny Committee

Correspondence published by the House of Lords European Affairs Sub-Committee on the Windsor Framework

A response from the UK Government – 7 August 2024

A response from the UK Government – 14 August 2024

Appendix C: Minutes of Evidence

View Minutes of Evidence of Committee meetings related to the report:

Minutes of Evidence – 25 July 2024

Appendix D: Consultation Responses

View responses to the Committee's consultation

Consultation responses here

This Report can be made available in a range of formats including large print, Braille etc. For more information please contact:

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