The FSA commissioned the Advisory Committee on the Microbiological Safety of Food (ACMSF) animal feed and TSE sub-group to review APHA's animal health risk assessment to consider any impact on risks to public health. ACMSF agreed with the conclusions of APHA's risk assessments and advised that those risk assessments provide public health assurance for the UK regarding the current status of imports of non-ruminants from the EU.

It also advised that the risk assessments provide assurance in the case of the non-ruminant UK feed ban rules being relaxed in the future as long as other key controls on limiting entry of TSE infectivity into the food and feed chain, such as surveillance and removal of specified risk material, are in place.

Following consideration of the risk assessments and FSA's advice, I have decided to proceed the review of the livestock feed controls to consultation. The timetable for consultation will depend on other priority work and on completion of preparatory work ahead of the consultation.

In my letter of 14 December 2021, I explained that, following a single case of classical BSE confirmed in Somerset in September 2021, England and Wales would not be able to apply to the World Organisation for Animal Health (WOAH) for official BSE negligible risk status until 2026. I am also pleased to inform you that, following changes to the WOAH rules adopted in its General Session last May, England and Wales will now be able to submit an application for official BSE negligible risk status in summer 2024, for consideration by WOAH General Session in May 2025. The application will be a priority for Defra.

31 July 2023

Letter from the Chair to The Rt Hon Lord Benyon, Minister for Biosecurity, Marine and Rural Affairs, Department for Environment, Food and Rural Affairs

Thank you for your letter, dated 31 July 2023, providing an update on the above Regulation applying to Northern Ireland under the Windsor Framework. The House of Lords Sub-Committee on the Protocol on Ireland/Northern Ireland considered these documents at its meeting on 13 September 2023.

We are grateful for your update on the Food Standards Agency risk assessments and the ability of England and Wales to apply to the World Organisation for Animal Health (WOAH) for official BSE negligible risk status.

We would be grateful for further updates in due course on the Government's plans to consult on the review of livestock feed controls. In the meantime we retain an active interest in these documents.

14 September 2023

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL 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 (11396/22)

Letter from the Chair to the Rt Hon Steve Barclay MP, Secretary of State for Health and Social Care, Department of Health and Social Care

Thank you for the Explanatory Memorandum provided by Rt Hon Robert Jenrick MP, the then Minister of State, dated 28 September 2022, on the above Regulation applying to Northern Ireland within the scope of the Protocol on Ireland/Northern Ireland. The House of Lords Sub-Committee on the Protocol to Ireland/Northern Ireland considered this document at its meeting on 23 November 2022.

As noted in the EM, Substances of Human Origin (SoHo) are used in the life-saving treatment of patients across the UK. As further noted, "GB SoHo establishments will continue to have a strategic supply dependency on some EU Member States." We stress the vital importance of ensuring that the effective

use of SoHo products in medical treatment in Northern Ireland is not adversely affected by this Regulation.

In that context, we would be grateful for your response to the following questions:

1. What assessment has been made of (1) the current movement of SoHo products between Great Britain and Northern Ireland; (2) the scale of such movements between the UK (including Northern Ireland) and the EU; and (3) the potential impact on patients and the wider NI/GB SoHo sector should regulatory divergence between Great Britain and Northern Ireland occur?
2. Will the Regulation, and any regulatory divergence arising between Great Britain and Northern Ireland, adversely affect the availability of SoHo products for patients in Northern Ireland? Pursuant to this point, will there be any implications for the provision of blood transfusions in Northern Ireland? Will such regulatory divergence lead to any delays in the provision of SoHo products to patients in Northern Ireland? What are the implications of this, given the perishability of such items?
3. What update can you give on the likely timetable for the Regulation to come into force? What is the current status of the legislative process within the EU institutions? What will be the practical impact on patients who are undergoing treatment over an extended period of time, including at the moment the Regulation comes into force? What steps will be taken to prevent any interruption to treatment?
4. Given the partially devolved status of SoHo, we note that the devolved governments were consulted in the preparation of this memorandum. What was the outcome of this consultation? In particular, were Ministers and officials of the Northern Ireland Executive consulted? What views did they express about the potential impact of the Regulation on Northern Ireland?
5. While we welcome the Government's commitment to performing a "targeted stakeholder consultation" on the proposed Regulation, we note the absence of relevant organisations in Northern Ireland. When is this consultation expected to commence and will Northern Ireland stakeholders be involved in the process?
6. We note your assessment that the proposed Regulation will have an overall positive impact on the SoHo sector in Northern Ireland, and that the Government is currently reviewing the EU's proposals and will consider whether to introduce similar measures in Great Britain. Can you expand on the likely positive impact of the Regulation for Northern Ireland? In view of this, when can a decision on whether to introduce similar measures in Great Britain be expected? What is your initial assessment regarding the likelihood of adoption these changes? What will be the impact of a temporary period of regulatory divergence between Great Britain and Northern Ireland in the meantime?

We would be grateful for a response to these questions by 8 December 2022. In the meantime, we retain an active interest in this document.

24 November 2022

Letter to the Chair from Will Quince MP, Minister of State, Minister for Health and Secondary Care, Department of Health and Social Care

I would like to thank you for your time in considering the Explanatory Memorandum (EM) on the above proposal, and your letter of 24th November. The Secretary of State has asked me to respond as the Minister responsible for EU-related matters. This reply addresses the questions raised.

Movement of SoHO

Northern Ireland (NI) has a reliance on Great Britain (GB) for the import of Substances of Human Origin (SoHO). However, the scale of movements varies according to the different types of SoHO. For example, NI has a dependency on England for its import of blood, for use in patient transfusions: from

January 2019 to October 2022, NI imported blood and blood products around 53 times from GB and around 5 times from ROI.

At UK-wide level, the UK is largely self-sufficient for organs. The majority of UK organ transplants use organs from UK donors. A small number of organs are imported each year from EU countries. Less than 1% of organs were procured from outside of the UK between 2009/10 and 2020/21. NI is less reliant on imports of organs from Great Britain as only kidney transplants take place in NI. Between 2009/10 and 2020/21 NI received 1 organ from Great Britain.

For non-reproductive tissues and cells, NHS Blood and Transplant (NHSBT) sent 70 tissue items from GB to NI in the first 9 months of 2021. For reproductive tissues and cells, NI based clinics received 22 imports of gametes and/or embryos from GB and sent 2 gametes and/or embryos to GB in 2019.

Nearly all reproductive tissues and cells movements are sperm imports to the UK, split approximately 60/40 between Denmark and the USA respectively. This accounts for about half of the sperm used in the UK. UK reliance on imported stem cell donations is on the up from 57% in 2017/18 to 68% in 2020/21. Work is underway to increase UK self-sufficiency.

Reproductive tissues and cells policy is reserved, and blood and non-reproductive tissues and cells policy is devolved. We recognise that regulatory divergence between Northern Ireland and Great Britain could in principle, lead to issues in the supply of SoHO to UK patients. However, the SoHO Common Frameworks set out a process to ensure the risk is minimised for both devolved and reserved areas. The Frameworks reflect the specific circumstances in Northern Ireland that arise as a result of the Ireland/Northern Ireland Protocol and remains UK wide in its scope. As such decision making and information sharing will always respect the competence of all parties to the Framework and in particular the provisions in Article 18 of the Protocol on democratic consent in Northern Ireland. For devolved areas, section 3 of the Common Frameworks highlights the importance of co-operation across the four governments. As stated in the Joint Ministerial Committee (EU Negotiations) Communique (October 2017) "there will also be close working between the UK Government and the Devolved Governments on reserved and excepted matters that impact significantly on devolved responsibilities". The Frameworks facilitate the continuity of good working relations, open communication and the maintenance of a compatible minimum set of high standards of safety and quality for SoHO, thus making it easier for SoHO to continue to be shared across the UK.

Regulatory divergence and Devolved Governments

Until we receive the final text for the SoHO Regulation, it will be difficult to identify the nature and extent of divergence between GB and NI and resulting implications. We will be contacting the EU Commission to find out when the final text is expected to be agreed. Intra-UK divergence will be managed by the two SoHO Common Frameworks and will be guided by the Joint Ministerial Committee (Europe Negotiations) (JMC(EN)) Common Frameworks principles. The Framework process will include discussions with the national blood services/national transplant services and the relevant regulator, to identify risks to the supply, safety and quality of SoHO. If it is determined that there will be divergence to the minimum safety and quality standards we will work with Devolved Government colleagues to ensure patient safety and supply are maintained. Where rules in NI change in alignment with the EU, the Frameworks will form the basis of a mechanism to ensure consideration by the four Governments of any changes, and will enable them to determine any impacts and subsequent actions arising from these changes.

In addition, the proposed Regulation states that the European Directorate for the Quality of Medicines & HealthCare (EDQM, a Directorate of the Council of Europe) will have a role in providing scientific and technical expertise to shape the standards and guidelines that inform transfusion and transplantation. UK experts in this field have a leadership role on both the European Committee on Organ Transplantation (Co-Chair) and the European Committee on Blood Transfusion, so there is still a route for NI (and GB) views to be considered. This will help to mitigate risks associated with regulatory divergence.

Consultation with Devolved Governments

Under the SoHO Frameworks process, officials across the four Governments meet regularly to discuss policies that may impact each other, including the EU SoHO Regulation. Devolved Government officials, including from the Northern Ireland Executive, were consulted on the EM and the SoHO Regulation was discussed at regular official meetings. The comments they provided were incorporated into the development of the EM. As the legal text may be amended as part of the co-decision process, the proposals have, thus far, only been discussed at official level. As agreed with colleagues in the Devolved Governments, further consultation will take place at both official and Ministerial level once the text is finalised and the EU's proposals are assessed.

SoHO Frameworks set out that the intention is for policy discussions to take place first (and any disagreements to be addressed) at official level. As set out in Appendix II of both SoHO Frameworks, if changes are to be introduced through the Ireland/Northern Ireland Protocol, one or more Government(s) would initiate the Risk Assessment Process. During this phase, the impact of the changes on patient safety and confidence and the JMC(EN) Common Frameworks principles will be fully considered. Frameworks will ensure the full participation of Northern Ireland in discussions such that the views of the relevant Northern Ireland Executive Minister(s) are taken into account in reaching any policy or regulatory decisions by the UK, Scottish or Welsh Governments.

Timeline of SoHO Regulation

The proposal is now being reviewed and discussed by the Council and the European Parliament, and the text will likely be amended as part of the co-decision process. Once the final text is agreed and adopted, it will come into force with a two-year transition period before most provisions apply and a three-year period for some particular provisions. The Commission will adopt a series of Acts implementing certain more detailed provisions, such as import and traceability. The transition period will provide time for stakeholders (e.g. regulators, establishments, healthcare professionals) to prepare legislatively and operationally and this will prevent interruptions to patient treatment. We have been and will continue to engage with SoHO stakeholders and the EU Commission to consider the impacts of the changes and will be working together to ensure that plans are put in place to prevent any interruption to SoHO treatments.

Consultation

The consultation will begin after the legal text is finalised and we have seen the full details of the EU's proposals. The list of stakeholders provided in the EM was not exhaustive and officials in the Devolved Governments and SoHO stakeholders (regulators, establishments and transplant units) will be invited to share views as part of the Frameworks process. Officials across the four Governments will agree on a list of stakeholders to be involved.

Ireland/Northern Ireland Protocol

The proposal provides measures to ensure safety and quality for patients treated with SoHO therapies and those donating SoHO are fully protected from avoidable risks. It also includes measures to mitigate shortages and support innovation by facilitating the development of safe and effective innovative SoHO therapies.

We will conduct a full assessment once the final SoHO Regulation text is agreed which will include engagement with the Devolved Governments. This will consider the impact of the adoption of the changes and potential divergence. Any decision made on the impact of the changes in Northern Ireland, whether to introduce similar changes in Great Britain and/or how to mitigate potential risks will depend on the outcome of the assessment. Decisions will consider a number of factors including: the impact on the minimum safety and quality standards; intra-UK and UK-EU supply of SoHO; innovation within the sector; and health disparities. We will provide a summary of the outcome of our assessment in due course. The Common Frameworks process will be used to manage any divergence that may arise.

I hope this response has been helpful and has answered the committee's questions.

20 December 2022

Letter from the Chair to Will Quince MP, Minister of State for Health and Secondary Care, Department for Health and Social Care

Thank you for your letter, dated 20 December 2022, on the above Regulation with implications for Northern Ireland under the Protocol on Ireland/Northern Ireland. The House of Lords Sub-Committee on the Protocol on Ireland/Northern Ireland considered this document at its meeting on 25 January 2023.

We welcome your detailed response to its questions. We note your assessment that until the Government receives the "final text for the SoHo Regulation, it will be difficult to identify the nature and extent of divergence between GB and NI and resulting implications". We further note that a full assessment of the Regulation will be performed once this text has been received.

Due to the importance of this area, we suggest that you write again once this text has been received and an assessment has been performed—particularly in regard to the impact of potential divergence on Northern Ireland.

We maintain an active interest in this document in the meantime.

26 January 2023

COMMISSION DELEGATED REGULATION (EU) 2022/1636 OF 5.7.2022 SUPPLEMENTING COUNCIL DIRECTIVE (EU) 2020/262 BY ESTABLISHING THE STRUCTURE AND CONTENT OF THE DOCUMENTS EXCHANGED IN THE CONTEXT OF MOVEMENT OF EXCISE GOODS, AND ESTABLISHING A THRESHOLD FOR THE LOSSES DUE TO THE NATURE OF THE GOODS AND COMMISSION IMPLEMENTING REGULATION (EU) 2022/1637 OF 5.7.2022 LAYING DOWN THE RULES FOR THE APPLICATION OF COUNCIL DIRECTIVE (EU) 2020/262 AS REGARDS THE USE OF DOCUMENTS IN THE CONTEXT OF MOVEMENT OF EXCISE GOODS UNDER A DUTY SUSPENSION ARRANGEMENT AND OF MOVEMENT OF EXCISE GOODS AFTER RELEASE FOR CONSUMPTION, AND ESTABLISHING THE FORM TO BE USED FOR THE EXEMPTION CERTIFICATE (UNNUMBERED)

Letter from the Chair to Andrew Griffith MP, Economic Secretary to the Treasury, HM Treasury

Thank you for the Explanatory Memorandum (EM) from your predecessor, Richard Fuller MP, dated 28 September 2022, on the above Delegated and Implementing Regulations applying to Northern Ireland within the scope of the Protocol on Ireland/Northern Ireland. The House of Lords Sub-Committee on the Protocol to Ireland/Northern Ireland considered this document at its meeting on 23 November 2022.

We would be grateful for your response to the following questions:

1. We note that the UK had not transposed Directive 2020/262 by the transposition date of 31 December 2021, given the wider Government position, discussed with the EU, of maintaining the operation of the Protocol on its current basis. We also note that the Commission commenced infraction proceedings against the UK, but agreed an extension of time to respond to the Letters of Formal Notice until 22 November 2022 agreed with the EU Commission. Can you explain in more detail the reasons for the Government choosing not to transpose the Directive? What are the implications for the application of these Delegated and Implementing Regulations to Northern Ireland? Can you update us on the infraction proceedings and the UK's response after the 22 November 2022 deadline passes?
2. We note the Government's statement that "the changes covered here are broadly welcomed as very technical, but logical, changes in line with the aims of the Directive, and are necessary to