

Ministear airson Slàinte Phoblach is Slàinte  
Bhoireannach  
Jenni Minto BPA



Minister for Public Health and Women's Health  
Jenni Minto MSP

T: 0300 244 4000  
E: [scottish.ministers@gov.scot](mailto:scottish.ministers@gov.scot)

Claire Haughey MSP  
Convenor, Health, Social Care and Sport Committee  
Scottish Parliament

[HSCS.Committee@parliament.scot](mailto:HSCS.Committee@parliament.scot)

15 November 2024

Dear Claire,

Thank you for your letter of 1 November 2024 concerning the Blood, Tissues and Cells Regulation and the Blood Safety and Quality Provisional Common Framework.

The EU Substances of Human Origin (SoHO) Regulation 2024/1938 (also referred to as the Blood, Tissues and Cells Regulation) was published in the Official Journal of the EU on 17 July 2024. Given parts of the legislation which the Regulation will replace are over 20 years old, the main aim is to ensure that EU legislation continues to reflect scientific, technical, and medical advancements, as well as future proofing the legislation to allow EU countries to respond more quickly to new technologies and emerging risks (for example if new viruses are discovered). The new Regulation applies to blood components, and all tissues and cells for use by other humans. However it does not apply to organs as the existing Directive (2010/53/EU) and resulting UK Regulations will continue to apply to organs. It is worth noting that the new Regulation is now broader and also includes human breastmilk where it is donated, but not where it is used exclusively to feed one's own child (this is currently covered under food regulations instead), intestinal microbiota (which are faecal matter transplants), and blood preparations that are not used for transfusion, but are used for some sort of treatment for patients (e.g. eye drops).

Following the publication of the Regulation, the Department of Health and Social Care (DHSC) is undertaking a SoHO Regulation Review Programme to seek stakeholder views on the Regulation. This review will take into account a number of factors that may be affected by the proposals, including patient safety; intra-UK and UK-EU supply of SoHO; innovation

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within the sector; and health inequalities. As part of the programme, DHSC will reach out to bodies including the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) and the Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC). One of the key principles of the review is to maintain a compatible minimum set of high standards of safety and quality in these areas in order to protect public health and support the movement of SoHO across the UK.

I have confirmed that the Scottish Government will take part in this review, which is expected to last twelve months. As noted in the EU Law tracker report, the Scottish Government's current general position is to remain aligned and keep pace with EU legislation wherever we can. In line with the Infected Blood Inquiry's final report, it remains critical that we ensure high standards of safety of all SoHO are maintained and improved where possible. In line with the provisions in the Regulation, the intention would be to implement any operational changes and introduce any legislative changes that might be needed ahead of the date on which the Regulation will generally apply, which is 7 August 2027. I would be happy to provide the Committee with a further update once the review has progressed including, as requested in your letter, thoughts on associated implications and costs of maintaining alignment with the rest of the UK in this policy area.

It is worth noting that there are several established provisional Common Frameworks in policy areas covered by the new EU SoHO Regulation, including Food and Feed Safety and Hygiene (for human breast milk), Blood Safety and Quality, and Organs, Tissues and Cells (apart from embryos and gametes). These Common Frameworks will be used to seek to reach a common UK position on the EU Regulation, but will not themselves need to be changed as a consequence of the Regulation.

The above Common Frameworks have not yet been finalised, so I am afraid I am not yet in a position to provide a full response to the Committee's recommendations on Common Frameworks, as set out in its letter of 20 May 2022. The Committee's recommendations, along with those of the other UK legislatures, will need to be considered as part of Four Nations discussions on their finalisation. However, the recommendations made by the Committee for the Blood Safety and Quality and Organs, Tissues and Cells Frameworks are the same as for the Public Health Protection and Health Safety Framework. This Framework is further ahead in the finalisation process and therefore due consideration has already been given to the Committee's recommendations. I can assure the Committee that I am supportive of the Committee's recommendations.

I hope this update is helpful.

Yours sincerely,



**Jenni Minto MSP**

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