

EXPLANATORY MEMORANDUM TO

The Human Tissue (Permitted Materials) Regulations (Northern Ireland)

2023 SR No. 26

1. Introduction

- 1.1. This Explanatory Memorandum has been prepared by the Department of Health to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.
- 1.2. The Statutory Rule is made under sections 3(9A) and 52(4B) and (4C) of the Human Tissue Act 2004 and is subject to the negative resolution procedure.

2. Purpose

- 2.1. [The Statutory Rule will clarify what organs and tissues are considered “permitted material” in Northern Ireland as per the Human Tissue Act 2004 (c.30) (“the 2004 Act”). Section 3 of the 2004 Act makes provision for the interpretation of “appropriate consent”. This term is used in section 1 in relation to an activity involving the body, or material from the body, of a person who is an adult or has died an adult.]

3. Background

- 3.1. Secondary legislation is required for the Organ and Tissue Donation (Deemed Consent) (Act) NI (2022) to come into effect which needs to be laid via the negative resolution procedure, pursuant to section 52 (4B) and (4C) of the Human Tissue Act 2004.
- 3.2. The secondary legislation will clarify what organs and tissues are considered “permitted material” in Northern Ireland as per the Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022

4. Consultation

- 4.1. These matters were consulted on as part of the 2020 public consultation on the Organ and Tissue Donation (Deemed Consent) Bill. The vast majority of respondents were supportive of the proposed changes. The Department considers that no further public consultation on the Statutory Rule is required.

5. Equality Impact

- 5.1. In accordance with guidance produced by the Equality Commission for Northern Ireland, and in keeping with regulation 75 of the Northern Ireland Act 1998, the proposals were screened for equality impact and it has been concluded that a full Equality Impact Assessment is not required.

6. Regulatory Impact

- 6.1. It is not anticipated that there will be any adverse impact on business, charities, social economy or voluntary bodies.

7. Financial Implications

- 7.1. The Department of Finance has approved the Departmental Business Case for the Department to commit resource expenditure of £15,186k in line with the approach set out in the business case.

8. Section 24 of the Northern Ireland Act 1998

- 8.1. Consideration has been given to the human rights implications of these regulations. They are considered compatible with section 24 of the Northern Ireland Act 1998.

9. EU Implications

- 9.1. Not applicable

10. Parity or Replicatory Measure

- 10.1. These regulations extend to Northern Ireland only.

11. Additional Information

- 11.1. Not applicable