The Committee will meet at 9.30 am in the James Clerk Maxwell Room (CR4).

1. **European Union (Withdrawal) Act 2018 - Decision on taking business in private**: The Committee will decide whether to take item 6 in private and all future considerations of evidence received on proposals by the Scottish Government to consent to the UK Government legislating using the powers under the European Union (Withdrawal) Act 2018 in relation to UK statutory instrument proposals.

2. **European Union (Withdrawal) Act 2018**: The Committee will consider a proposal by the Scottish Government to consent to the UK Government legislating using the powers under the Act in relation to the following UK statutory instrument proposals-
   - The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations;
   - The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations; and
   - The Blood Safety and Quality (Amendment) (EU Exit) Regulations.

3. **European Union (Withdrawal) Act 2018**: The Committee will take evidence on the proposal by the Scottish Government to consent to the UK Government legislating using the powers under the Act in relation to the following UK statutory instrument proposals—
   - The General Food Law (EU Exit) Regulations 2018;
   - The General Foodstuffs Hygiene (EU Exit) Regulations 2018;
   - The Specific Foodstuffs (Hygiene) (EU Exit) Regulations 2018;
   - The Contaminants in Food (EU Exit) Regulations 2018; and
   - The Quick-Frozen Food (EU Exit) Regulations 2018

From—
Joe FitzPatrick, Minister for Public Health, Sport and Wellbeing, and Neel Mojee, Solicitor, Legal Directorate, Scottish Government;

Elspeth Macdonald, Head of Strategy and Policy, Food Standards Scotland.

4. **Subordinate legislation:** The Committee will consider the following negative instrument—

The National Health Service (General Dental Services) (Miscellaneous Amendments) (Scotland) Regulations 2018 (SSI 2018/300)

5. **Human Tissue (Authorisation) (Scotland) Bill:** The Committee will take evidence on the Bill at Stage 1 from—

David McColgan, Senior Policy and Public Affairs Manager (Devolved Nations), British Heart Foundation Scotland;

Harpreet Brrang, Information and Research Hub Manager, Children's Liver Disease Foundation;

Gillian Hollis, attending in personal capacity as a lung transplant recipient (2004);

and then from—

Shaben Begum, Director, Scottish Independent Advocacy Alliance;

Fiona Loud, Policy Director, Kidney Care UK;

Dr Gordon Macdonald, Parliamentary Officer, CARE for Scotland.

6. **European Union (Withdrawal) Act 2018:** The Committee will consider the evidence heard earlier in the meeting from Joe FitzPatrick, Minister for Public Health, Sport and Wellbeing and Elspeth Macdonald, Head of Strategy and Policy, Food Standards Scotland on a proposal by the Scottish Government to consent to the UK Government legislating using the powers under the Act in relation to the following UK statutory instrument proposals—

The General Food Law (EU Exit) Regulations 2018;

The General Foodstuffs Hygiene (EU Exit) Regulations 2018;

The Specific Foodstuffs (Hygiene) (EU Exit) Regulations 2018;

The Contaminants in Food (EU Exit) Regulations 2018; and

The Quick-Frozen Food (EU Exit) Regulations 2018

7. **Human Tissue (Authorisation) (Scotland) Bill (in private):** The Committee will consider the evidence heard earlier in the meeting.

8. **Preventative Agenda (in private):** The Committee will consider a revised draft
report.

David Cullum  
Clerk to the Health and Sport Committee  
Room T3.60  
The Scottish Parliament  
Edinburgh  
Tel: 0131 348 5210  
Email: david.cullum@parliament.scot
The papers for this meeting are as follows—

**Agenda item 2**

Note by the Clerk  
HS/S5/18/28/1

**Agenda item 3**

Note by the Clerk  
HS/S5/18/28/2

PRIVATE PAPER  
HS/S5/18/28/3 (P)

**Agenda item 4**

Note by the clerk  
HS/S5/18/28/4

**Agenda item 5**

*Human Tissue (Authorisation) (Scotland) Bill SPICe Briefing*  
HS/S5/18/28/5

PRIVATE PAPER  
HS/S5/18/28/6 (P)

Witness Written Submissions  
HS/S5/18/28/7

**Agenda item 8**

PRIVATE PAPER  
HS/S5/18/28/8 (P)
European Union (Withdrawal) Act 2018
The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations
The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations
The Blood Safety and Quality (Amendment) (EU Exit) Regulations

Background
1. The Committee received notification from the Scottish Government on 28 September 2018 of its intent to consent to UK Ministers making regulations on its behalf in relation to the following:
   • The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations
   • The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations
   • Blood Safety and Quality (Amendment) (EU Exit) Regulations

2. These regulations are being proposed by the UK Government for laying in the UK Parliament in relation to the European Union (Withdrawal) Act 2018 (‘the Act’). A new protocol has been put in place between the Scottish Parliament and the Scottish Government to help Committees deal with these types of instruments.

The Instruments
3. The notification letter states the reasons why the Scottish Government is content that Scottish devolved matters are to be included in these SIs.

4. Under the categorisation proposals set out in the protocol, they have each been categorised by the Scottish Government as having some proposals within them that fall under Category B.

Actions taken to date
5. The Committee agreed at its meeting on 2 October to issue correspondence to relevant stakeholders. Responses were received from:
   • Human Tissue Authority
   • NHS Blood and Transplant
   • Scottish National Blood Transfusion Service
   • Anthony Nolan
   • Medicines and Healthcare Products Regulatory Agency
6. The Committee also agreed on 2 October to write to the Minister for Public Health, Sport and Wellbeing to seek further clarification on what powers to make regulations will sit with UK and which with devolved administrations.

7. The response received from the Minister on 16 October detailed—

“[…] following discussions with the UK Department of Health and Social Care, it has been agreed that in all three of the proposed Regulations, any regulation-making powers would be conferred on both devolved administration Ministers and the Secretary of State for Health and Social Care. This would mean that in each case the SIs will permit Regulations to be made either by Scottish Ministers or, subject to Scottish Ministers providing consent to this, by the Secretary of State. This will ensure there is future flexibility, enabling UK-wide Regulations to be progressed by the Secretary of State for Health and Social Care where is makes sense to do so and there is agreement between the four UK administrations. However, it will also enable the Scottish Government to bring forward its own Regulations in cases where this is considered appropriate, for example where the Scottish position may be different from other parts of the UK.”

8. The Committee considered these responses at its meeting on 23 October and agreed to write to the UK Government for further information.

9. The Convener detailed in his letter issued on 25 October to Jackie Doyle-Price MP, UK Parliamentary Under Secretary for Mental Health and Inequalities (Annexe A) that the Scottish Government was yet to see final versions of the three statutory instruments. The Committee requested confirmation that the final versions of each of the statutory instruments would be provided and when they would be issued to the Scottish Government.

10. The Committee received a response from the UK Parliamentary Under Secretary for Mental Health and Inequalities on 31 October 2018 (Annexe B). In her letter she indicated that the Scottish Government received copies of the updated draft instruments for organs and tissues and cells on 22 October. Final checks were currently being undertaken and further technical modifications to drafts, but no policy changes were expected. She advised that the latest version of the statutory instruments would be sent to the Scottish Government by 2 November.

11. Clerks have spoken to Scottish Government officials who have indicated that the Minister for Public Health, Sport and Wellbeing will provide a response to the correspondence from the UK Parliamentary Under Secretary in advance of today’s committee meeting.
Decision

12. To respond by the deadline of 10 November the Committee is invited to take a decision today on whether it wishes to:
   a. Write to the Scottish Government to confirm it is content for consent for a UK SI to be given.
   b. Take an alternative course of action

Clerk to the Committee November 2018
Dear Parliamentary Under Secretary of State for Mental Health and Inequalities

European Union (Withdrawal) Act 2018

The Committee received correspondence from Joe FitzPatrick, Minister for Public Health, Sport and Wellbeing, Scottish Government on 28 September 2018 detailing the Scottish Government’s intent to consent to UK Ministers making regulations on its behalf in relation to the following:

- The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations
- The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations
- Blood Safety and Quality (Amendment) (EU Exit) Regulations

We understand these three health-related statutory instruments are being proposed by the UK Government for laying in the UK Parliament in relation to the European Union (Withdrawal) Act 2018.

The Committee will be determining if it is content for the Scottish Government to consent to the making of a UK statutory instrument on each of these three-health related areas to be given.

We note the Minister for Public Health Sport and Wellbeing detailed in his letter to us that the Scottish Government was yet to see final versions of these three statutory instruments. We believe it is important this information is provided to the Scottish Government so it can take and then advise us with an informed decision on its
approach. We therefore request confirmation that the final versions of each of the statutory instruments will be provided and when they will be issued to the Scottish Government.

Upon the Scottish Government’s receipt of the final versions of the statutory instruments we expect the Scottish Government to issue us with an update with regard to the proposed regulations. We will then be able to take a decision on whether we are content for the Scottish Government to consent for a UK statutory instrument on these three health-related areas to be given.

The Committee has a very tight timescale for its scrutiny. Therefore, a response to this letter by Wednesday 31 October would be much appreciated.

Yours sincerely

Lewis Macdonald

Lewis Macdonald
Convener, Health and Sport Committee
From Jackie Doyle-Price MP
Parliamentary Under Secretary of State for Mental Health, Inequalities and Suicide Prevention
Department of Health and Social Care
39 Victoria Street
London
SW1H 0EU

Lewis Macdonald MSP
Convener, Health and Sport Committee
Health and Sport Committee
T3.60
The Scottish Parliament
Edinburgh
EH99 1SP

By email only to: healthandsport@parliament.scot

31st October 2018

Dear Lewis,

European Union (Withdrawal) Act 2018

Thank you for your letter in relation to the EU Exit regulations on organs, tissues and cells and blood that the UK Government intends to lay under powers in the European Union (Withdrawal) Act 2018.

The Scottish Government received copies of the updated draft instruments for organs and tissues and cells on 22 October. Final legal checks are currently being undertaken by the Department of Health and Social Care and there will be some technical modifications to those drafts, but these deal with technical issues and are not policy changes. The amended draft instrument for blood was shared on 29 October.

In all instruments, EU Commission powers under the relevant EU Directives have been conferred to appropriate authorities. I can confirm that in each SI the drafting states that in relation to Scotland the “appropriate authority” means:

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  (i) the Scottish Ministers; or
  (ii) the Secretary of State acting with the consent of the Scottish Ministers;
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The regulations also make provision for the Secretary of State to make regulations for the whole of the United Kingdom, “acting with the consent of the Welsh Ministers, the Scottish Ministers and the Department of Health in Northern Ireland.”
I have been advised that the latest version of the statutory instruments will be sent to the Scottish Government by 2 November. This version of the SIs will be submitted for pre-legislative scrutiny to the Joint Committee on Statutory Instruments.

JACKIE DOYLE-PRICE
Health and Sport Committee

28th Meeting, 2018 (Session 5)

Tuesday 6 November 2018

European Union (Withdrawal) Act 2018

The General Food Law (EU Exit) Regulations 2018
The General Foodstuffs Hygiene (EU Exit) Regulations 2018
The Specific Foodstuffs (Hygiene) (EU Exit) Regulations 2018
The Contaminants in Food (EU Exit) Regulations 2018
The Quick Frozen Food (EU Exit) Regulations 2018

Background

1. The Committee received notification from the Scottish Government on 8 October 2018 of its intent to consent to UK Ministers making regulations on its behalf in relation to the following:
   - The General Food Law (EU Exit) Regulations 2018
   - The General Foodstuffs Hygiene (EU Exit) Regulations 2018
   - The Specific Foodstuffs (Hygiene) (EU Exit) Regulations 2018
   - The Contaminants in Food (EU Exit) Regulations 2018
   - The Quick Frozen Food (EU Exit) Regulations 2018

2. These regulations are being proposed by the UK Government for laying in the UK Parliament in relation to the European Union (Withdrawal) Act 2018 ('the Act'). A new protocol has been put in place between the Scottish Parliament and the Scottish Government to help Committees deal with these types of instruments.

The Instruments

3. The notification letter from the Scottish Government states the reasons why the Scottish Government is content that Scottish devolved matters are to be included in these SIs.

4. Under the categorisation proposals set out in the protocol, they have each been categorised by the Scottish Government as falling under Category A.

Actions taken to date

5. On the 18 October 2018 the Convener wrote to Joe FitzPatrick, Minister for Public Health, Sport and Wellbeing (Annexe A) to seek clarification on a range of issues including why the 28 day scrutiny period was not being adhered to and the classification of each instrument as falling within category A.
6. A response was received from the Minister on 23 October (Annexe B).

7. On 25 October 2018 the Convener wrote again to the Minister for Public Health, Sport and Wellbeing (Annexe C) to seek further clarification in relation to any possible implications arising from the recent BSE case in Aberdeenshire in relation to the safety and transferability of food stuffs and whether there is any impact on these proposed regulations.

8. A response was received from the Minister on 31 October (Annexe D) which stated—

   “I am advised by Food Standards Scotland that there is no impact, both in terms of general food safety, or related to the specific instruments currently before the Committee.”

9. The Committee agreed to invite the Minister for Public Health, Sport and Wellbeing to provide oral evidence at today’s meeting, principally in relation to the classification of each instrument as falling within Category A.

Decision

10. Following the Committee’s oral evidence session with the Minister the Committee is invited to:
   a. Write to the Scottish Government to confirm it is content for consent for a UK SI to be given.
   b. Taken an alternative course of action.

Clerk to the Committee November 2018
Via email
Joe FitzPatrick MSP
Minister for Public Health, Sport and Wellbeing

Health and Sport Committee
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The Scottish Parliament
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Email: healthandsport@parliament.scot

18 October 2018

Dear Minister

EU Foodstuffs and Hygiene – EU Exit Regulations

Thank you for your letter of 8 October regarding the EU Food Law etc – EU Exit Regulations.

In advance of the Committee considering this the Committee would find it helpful to have a response to the questions set out in the Annex to this letter. Given the short timescales we are working to we request the response by Tuesday 23 October.

Yours sincerely

Lewis Macdonald
Convener, Health and Sport Committee

c.c. Stephen Hendry, Senior Policy Advisor – Food Labelling & Standards
Food Standards Scotland
ANNEX

NOTIFICATION TO CONSENT – Food Law and Hygiene Regulations
Questions for the Scottish Government

General

- Specifically, in devolved policy areas, do the proposed Regulations make purely technical changes to the EU Regulations or do they include any new policy provisions?

28 day scrutiny period

- Please provide further elaboration of the reason for the time for consideration being shortened from 28 days to 8 days. In particular please indicate the reasons why the request on what are described as non-contentious regulations was only made after the start of the October recess and further details as to the legislative need including potential impact to the sector to lodge between 31 October and 5 November.

Annex B The General Food Law (EU Exit) Regulations

- In the event of no-deal, the UK will leave the RASFF and the European Food Safety Authority, Are provisions being made for a UK wide system to replace these systems and what Parliamentary scrutiny will take place of the establishment of any such systems?

- In addition, what cooperation will take place with the EU in the operation of any new UK systems?

- How will food safety risks be averted in the case of a no-Deal Brexit?

- Please advise why Regulation (EU) No. 16/2011 is revoked.

- Please provide further detail as to the justification for the classification of these instruments as category A. In particular please comment on the appropriate delegation to be given under the protocol for “sub-delegation- transferring EU legislative powers to a UK public authority” and “creating or amending a power to legislate” which would appear to be Category B characteristics.

- In addition please provide your views on whether you consider these regulations are intended (1) “to provide Ministers...with enabling powers to make subordinate legislation for the purpose of applying traceability requirements.” and (2) “the provision of enabling powers...is required to replace existing delegated powers exercised by the Commission at EU level”. Again these would seem to be category B characteristics.

- Please provide detail of the bodies within Scotland whom were consulted and a summary of their responses.
• Has the Scottish Government undertaken any consultation on the proposed provisions in the Regulation, if so please provide the above details?

Annex C The General Foodstuffs Hygiene (EU Exit) Regulations

The Specific Foodstuffs (Hygiene) (EU Exit) Regulations 2018

• Can you provide a short summary of the purpose and effect of the EU Regulations being amended by the UK Regulations?

• Please provide further detail as to the justification for the classification of these instruments as category A. Why has this notification been given a Category A when it is likely to provide delegated powers to Ministers and agencies which are consistent with a Category B notification?

• The Committee would like more information on what additional capacity is required to enable Scottish Ministers to exercise these new functions.

• The Committee would also like to know whether the Scottish Government has undertaken an assessment on what additional capacity is likely to be required?

• Please provide detail of the bodies within Scotland whom were consulted and a summary of their responses.

• Has the Scottish Government undertaken any consultation on the proposed provisions in the Regulation, if so please provide the above details?

Annex D Contaminants in Food (Amendment) (EU EXIT) Regulations 2018

• Can you provide a short summary of the purpose and effect of the EU Regulations being amended by the UK Regulations?

• Please expand upon the general statements in the summary of proposals and provide detail how deficiencies are corrected.

• Why has this notification been given a Category A when it is likely to provide delegated powers to Ministers and agencies which are consistent with a Category B notification?

• Has the Scottish Government undertaken any consultation on the proposed provisions in the Regulation, if so please provide the above details?

• Please provide detail of the bodies within Scotland with whom you consulted and a summary of their responses.
Annexe B

Minister for Public Health, Sport and Wellbeing
Joe FitzPatrick MSP

T: 0300 244 4000
E: scottish.ministers@gov.scot

Via e-mail
Lewis Macdonald MSP
Convenor
Health and Sport Committee
Scottish Parliament
Edinburgh
EH99 1SP

11th October 2018

Dear Lewis,

EU FOODSTUFFS AND HYGIENE – EU EXIT REGULATIONS

Thank you for your letter of 18 October 2018. I wish to apologise for missing your requested response date to allow the Committee to consider this further information during its deliberations today. I understand that the Committee decided today that it was not in a position to consider my recommendation and requires more time to do so. Given our commitment to try, wherever possible, to meet the tight timescale for these UK instruments to ensure a functioning statute book should there be no deal between the EU and UK by 29 March 2019, I would be grateful if the Committee might be able to consider the information attached herein at its meeting next week? I make this request in order to accommodate, if possible, the scheduled laying dates for these instruments the first of which is scheduled for 31 October.

To assist the Committee in its consideration of the notifications to consent to UK Statutory Instruments, following advice from Food Standards Scotland I have replied to your questions as follows:

General

1. The proposed Regulations do not introduce any new policy provisions. The existing EU provisions covered by the instruments are already fully harmonised and directly applicable in all member states. The UK SIs are intended to ensure continuity of this EU law at the point of EU Exit. They remove redundant EU technical references and make the retained legislation workable in a UK context, for
example by replacing references to EU Institutions where necessary, to apply corresponding UK arrangements. This includes limited transfer of functions by replacing 'European Commission' with a form of wording to enable each of the four administrations in the UK to provide for minor amendments to limited parts of retained legislation on food and feed safety in future.

2. In some limited areas, e.g. food contaminants controls, there are proposals to transfer non-legislative functions, currently exercised by EU institutions to Food Standards Scotland. The functions in question are well aligned to the specific functions, ascribed to Food Standards Scotland in the Food Scotland Act 2015, e.g. advice on food safety risks and monitoring such risks within the food supply chain. It was therefore considered there was only one obvious policy option as to which body would provide an opinion to Scottish Ministers and the Scottish Parliament in these areas.

28 day scrutiny period

3. The Cabinet Secretary received a formal request from the UK Government to agree to a series of UK Statutory Instruments regarding food and feed safety, food standards and nutrition related matters on 28 September. Food Standards Scotland was informed by the Food Standards Agency (FSA), shortly before this formal consent request, that these particular instruments had been scheduled for early laying, within the challenging overall programme of UK Instruments that need to be through Westminster by the end of March 2019. Food Standards Scotland expressed concern over the limited time available for their consideration from a Scottish perspective, given that they had not received drafts of all the instruments themselves. Given the probability that this would result in less than the desired 28 days for Scottish Parliamentary scrutiny of the instrument, they requested the UK laying date be deferred to allow this to occur. FSA apologised for the tight deadline, but advised that any rescheduling would be extremely difficult given the overall tight deadline to ensure a functioning statute book for EU Exit next year. They asked that given the degree of policy agreement that had already been reached on the instruments at official level and their commitment to ensure that the limited transfer of functions elements would fully respect the devolution settlement, that the existing Westminster schedule be accommodated.

4. On balance, we agreed with the need to get the SIs laid according to their schedule and Food Standards Scotland then worked as quickly as possible to produce the notifications to the Scottish Parliament based on the information and draft Statutory Instruments available to them. Unfortunately on this occasion we have only been able to afford 8 days for Scottish Parliamentary scrutiny. Further drafts were received late on 19 October but these are still not final drafts. Food Standards Scotland and Scottish Government Legal Directorate are working hard with the FSA to agree the final text.
Annex B - The General Food Law (EU Exit) Regulations 2018

5. The Food Standards Agency and Food Standards Scotland are currently discussing the development of a UK-wide framework for food and feed safety and hygiene, with a view to agreeing new working arrangements and enhanced capacity and capability required to bolster the existing UK and Scottish capacity for incident handling and risk assessment, currently carried out by EU governance arrangements and systems. Where new arrangements require legislative underpinning, such as transfer of functions, the legislation will be subject to the protocol which has been established to ensure that Parliamentary scrutiny of the instrument and consent is given as required.

6. The UK’s future relationship with European Institutions and systems remains subject to ongoing UK/EU negotiations. Both FSA and FSS are seeking to maintain a good relationship with the European Food Safety Authority (EFSA), though the details of how this will be achieved are not expected to be clear until the negotiations are finalised.

7. In the event of a no deal, it is unclear what the cooperation arrangements will be. However, we have been pressing the UK Government to ensure that appropriate information sharing continues, even in the event of a no deal in order to best protect consumers’ interests and Scotland’s reputation in an international context.

8. The proposed legislation maintains the basis of the existing EU legislative provisions which are designed to ensure a high level of public health protection is maintained, and that food businesses in Scotland and the rest of the UK are already operating within. With this in mind, it is therefore important that the necessary functioning statute covering these policy areas is in place before exit day.

9. With regard to Regulation (EU) No 116/2011. This lays down detailed implementing measures for the Rapid Alert System for Food and Feed (RASFF) system. As the UK will no longer participate in this EU system in the event of a no-deal scenario these more detailed rules will become redundant.

10. Category A was chosen on the basis that the main purpose of the instruments is to ensure continuity of law with no significant policy divergence. With respect to transfer of powers from the EU institutions, it is anticipated this will be very limited here and will be consistent with the devolution settlement. In particular, the proposed areas of transfer are considered to fall entirely within areas of devolved competence, as currently delineated within the Scotland Act and the transfer will provide that Scottish Ministers assume those functions of amending the EU law, in so far as those amendments are to be applied within Scotland. There are no proposals to sub-delegate new powers to legislate to public bodies in these instruments, no new fees being provided for, or new financial implications for businesses or the creation of new fines or penalties.
11. As mentioned above the new powers for Ministers to make subordinate legislation with respect to applying traceability requirements are consistent with the devolution settlement and the existing powers of Scottish Ministers to make subordinate legislation for the purposes of ensuring food safety and specifying rules on hygiene contained in the Food Safety Act 1990.

12. The Food Standards Agency carried out a full public consultation across the UK from 4 September until 14 October on the proposed approach to retained EU law for food and feed safety and hygiene. The consultation received 47 responses of which 81% supported or did not disagree with the proposed approach being outlined, with 17% of replies containing mixed comments. The main concerns raised related to the communication of change and ensuring sufficient lead in time is given. One respondent raised concerns about the timeframe for delivering the legislation needed for day one readiness.

Annex C - The General Foodstuffs Hygiene (EU Exit) Regulations 2018

The Specific Foodstuffs Hygiene (EU Exit) Regulations 2018

13. The EU regulations amended by these fixes cover the food chain in its entirety. They set down the responsibilities of food business operators in relation to the hygienic production of food from primary production (such as farming and fishing) through to retail and require such businesses be, depending on their operations, either registered or approved by the competent authority.

14. The regulations set down in law the requirement for all food businesses, except primary producers, to put in place a food safety management system based on ‘Hazard Analysis and Critical Control Point’ (HACCP) principles as well as infrastructure requirements. There are also provisions for the production of guides to good hygiene practice. The regulations also specify additional requirements for establishments placing products of animal origin on the market and the requirement that such establishments carry an identification number as well as, in the case of fresh meat, a health mark which is applied by an official veterinarian of the competent authority. The regulations require that only potable or clean water be used as a decontaminant for meat, unless other substances are approved for such use by the Commission.

15. The Regulations also establish micro-criteria which must either be applied to ensure the safety of the final product (food safety criteria) or to monitor hygiene during processing in establishments (process hygiene criteria).

16. In addition, these regulations set down specific tasks required of competent authorities in relation to approved establishments producing products of animal origin. This includes specific tasks required of official veterinarians in slaughterhouses, as well as requirements for the classification and monitoring of bivalve shellfish production areas. The regulations also provide for the production of
stakeholders in Scotland but has not directly engaged with stakeholders on the UK Government’s approach. Initial findings from this consultation are given with Annex B.

23. Food Standards Scotland issued a specific consultation related to the required replacement provisions for health marking of products of animal origin. This is required since the term EU will no longer be permitted on the health mark applied to UK products once the UK leaves the EU. The proposals were generally supported by stakeholders although concerns were raised by industry about the need for early clarification of the new mark to facilitate modification of existing labelling. FSS also took the opportunity to test stakeholders’ views about the potential ability to provide additional information delineating Scottish establishments at some point after EU exit and there was some support for that idea.

Annex D - The Contaminants in Food (Amendment) (EU Exit) Regulations 2018

24. The regulations make the necessary fixes to ensure that the regulations laying down rules regulating the presence of certain contaminants in food such as PCBs and dioxins will work effectively after EU exit. In particular they modify as necessary the procedures to be applied in future to modify the tolerances for specific contaminants already established at EU level. This includes limits for the same contaminants in different foods, analytical detection limits and sampling and analysis methods to be used.

25. The key feature of the fixing instrument is to replace the current role for these modifications from the Commission to Ministers in the UK countries in so far as they apply in those countries. The fix also provides that the Food Standards Agency in England, Wales and Northern Ireland, and Food Standards Scotland in Scotland, should be consulted by Ministers to provide advice before new technical standards are established and to carry out related functions such as monitoring levels of certain contaminants in certain foods.

26. It is considered that a Category A notification is appropriate given that the necessary transfer of functions is consistent with the devolution settlement. Scottish Ministers already have powers to make regulations prohibiting or regulating the presence in food of any specified substance, of any specified class and generally for regulating the composition of foods under Section 16 of the Food Safety Act 1990. Whilst there are proposals to transfer limited non-legislative functions currently exercised by EU institutions to Food Standards Scotland, the functions in question are well aligned to the specific functions ascribed to Food Standards Scotland in the Food Scotland Act 2015, e.g. advice on food safety risks and monitoring such risks within the food supply chain. It is therefore considered there was only one obvious policy option as to which body would provide an opinion to Scottish Ministers and the Scottish Parliament in these areas, resulting in a Category A rather than Category B notification in accordance with the guidance in the protocol on obtaining approval of the Scottish Parliament.
lists of countries and establishments from which products of animal origin can be imported into the EU.

17. The EU regulations also contain provision for the Commission to amend the regulations through "comitology procedures", which in effect allows for changes to micro criteria and provides for more detailed implementing rules where considered appropriate, as well as allowing for changes to certain import conditions. These powers are repatriated to appropriate authorities in a UK context in the fixing SI, which for Scotland will be Scottish Ministers.

18. Competence for enforcing these regulations in Scotland is set out in the Food Hygiene (Scotland) Regulations 2006 (as amended) and is unchanged as a consequence of the UK fixing SIs.

19. Category A was chosen on the basis that the main purpose of the instruments is to ensure continuity of law with no significant policy divergence. With respect to transfer of powers from the EU institutions, it is anticipated this will be very limited here and will be consistent with the devolution settlement. In particular, the proposed areas of transfer are considered to fall entirely within areas of devolved competence, as currently delineated within the Scotland Act and the transfer will provide that Scottish Ministers assume those functions of amending the EU law, in so far as those amendments are to be applied within Scotland. There are no proposals to sub-delegate new powers to legislative public bodies in these instruments, no new fees being provided for, or new financial implications for businesses or the creation of new fines or penalties.

20. There is existing capacity in microbiological risk assessment in both Food Standards Scotland and the Food Standards Agency. In addition the UK Advisory Committee on the Microbiological Safety of Foods provides general advice on microbiological standards. It is possible that additional risk assessment capacity might be required to support any modifications of the current EU microbiological levels. However, this is not expected to be a frequent or imminent requirement post EU Exit and is expected to be accommodated as part of the current UK frameworks discussions. There is increased capacity being developed within the Food Standards Agency, funded by UKG to address additional capacity needs across the whole of this policy area and FSA has been clear that Scotland will have access to that additional capacity.

21. Food Standards Scotland has a programme of work planning for EU Exit and is currently evaluating issues of future capability and capacity as part of that programme. The capacity requirements are being evaluated in line with that additional capacity being provided to FSA and are also the subject of consideration within the UK food and feed framework which is being developed.

22. A consultation was carried out on a UK basis between the 4 September and 14 October 2018. Food Standards Scotland highlighted the UK consultation to its
27. A consultation was carried out on a UK basis between the 4 September and 14 October 2018. Food Standards Scotland highlighted the UK consultation to its stakeholders in Scotland but has not directly engaged with them on the UK Government’s approach. Initial findings from this consultation are given with Annex B.

I hope this response is helpful.

Yours sincerely,

Joe Fitzpatrick

JOE FITZPATRICK
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25 October 2018

Dear Minister

EU Foodstuffs and Hygiene – EU Exit Regulations

Thank you for your helpful response of 23 October in relation to the above. You may be aware that the Health and Sport Committee this week indicated they were unable to finalise their consideration of the request within the restricted timetable provided. I am hopeful that provision of the undernoted information will however allow us to make a decision in a shorter timeframe than the full 28 days referred to in the protocol.

Before the Committee is able to determine their approach could you provide further clarification in relation to any possible implications arising from the recent BSE case in Aberdeenshire in relation to the safety and transferability of food stuffs and whether there is any impact on these proposed regulations.

I am aware the Cabinet Secretary for the Rural Economy is to update the Rural Economy and Connectivity Committee on a range of issues on Wednesday 31 October but it would be immensely helpful to have a response to this request by 12 noon on Thursday 1 November.
Yours sincerely

Lewis Macdonald

Convener, Health and Sport Committee

cc. Stephen Hendry, Senior Policy Advisor – Food Labelling & Standards

Food Standards Scotland
Dear Lewis

EU FOODSTUFFS AND HYGIENE – EU EXIT REGULATIONS

Thank you for your letter of 25th October regarding the proposed approach to fixing EU food safety and hygiene regulations. You asked specifically for further clarification in relation to any possible implications arising from the recent BSE case in Aberdeenshire in relation to the safety and transferability of food stuffs and whether there is any impact on these proposed regulations.

I am advised by Food Standards Scotland that there is no impact, both in terms of general food safety, or related to the specific instruments currently before the Committee. These instruments lay down requirements for the safe and hygienic production of food; with more detailed obligations set down in relation to establishments producing products of animal origin.

Those additional requirements concern specific hygiene practices and traceability requirements, and the commensurate official controls that must be applied in approved establishments to those products and practices. In relation to cattle, these controls apply irrespective of the BSE status of the country. For example, Regulation (EC) 854/2004 laying down the specific rules for the organisation of official controls on products of animal origin intended for human consumption, specifies that Official Vets of the Competent Authority must declare meat unfit for human consumption if it contains specified risk material (SRM).

However the Committee may wish to be aware that specific rules concerning SRM and BSE more generally, are set down in Regulation (EC) 999/2001 laying down
rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. Whilst the list of SRM to be removed at abattoir changed as a result of the recent BSE case, the process of SRM removal continues to be overseen by FSS.

The Committee may wish to note that the proposed EU fixes for BSE legislation will be covered by the The TSE and Animal By-Product (Amendment etc.) (EU Exit) Regulations (AH09-EU TSE and ABP), these Regulations will be being placed before the Scottish parliament Rural Economy and Connectivity Committee for scrutiny and consent.

Yours sincerely,

Joe Fitzpatrick
Health and Sport Committee  
28th Meeting, 2018 (Session 5)  
Tuesday 6 November 2018  

Negative Subordinate Legislation  

Note by the Clerk  

Overview of instruments  

1. There is one negative instrument for consideration at today’s meeting:  
   - The National Health Service (General Dental Services) (Miscellaneous Amendments) (Scotland) Regulations 2018 (SSI 2018/300)  

Background  

2. These Regulations amend the National Health Service (General Dental Services) (Scotland) Regulations 2010 (“the 2010 Regulations”) and the National Health Service (General Dental Services) (Scotland) Amendment Regulations 2017 (“the 2017 Regulations”).  

3. Regulation 2 amends the date relevant to submission of estimates in paragraphs 20 and 29 of schedule 1 of the 2010 Regulations to mirror the amended commencement dates made by regulation 3. Regulation 3 amends the commencement date of amendments made to the 2010 Regulations by regulations 3(1)(d), 6 and 11(4)(a) of the 2017 Regulations and omits paragraph 3(2) of the 2017 Regulations.  

The Policy Note for the instrument is attached at Annexe A.  

4. An electronic copy of the instrument is available at:  

5. There has been no motion to annul this instrument.  

6. The Committee needs to report by 26 November 2018.  

7. The Delegated Powers Powers and Law Reform Committee considered the instrument at its meeting on 23 October 2018. The Committee determined that it did not need to draw attention of the Parliament to this instrument on any grounds within its remit.  

8. The Committee contacted the Scottish Government ahead of the consideration for further clarification on electronic orthodontic payments being affected by practices not having suitable IT systems in place by 1 January 2019 and the additional cost involved in delaying the coming-into-force date from 1 January 2019 to 1 January 2020. The correspondence is attached at Annexe B.
POLICY NOTE
THE NATIONAL HEALTH SERVICE (GENERAL DENTAL SERVICES) (MISCELLANEOUS AMENDMENTS) (SCOTLAND) REGULATIONS 2018

SSI 2018/300

The above instrument was made in exercise of powers conferred by sections 25(1), 28a(4), 105(7) and 106(a) of the National Health Service (Scotland) Act 1978 and all other powers enabling them to do so.

This instrument is subject to negative procedures.

Policy Objective

The purpose of this instrument is to amend the National Health Service (General Dental Services) (Scotland) Regulations 2010 and the National Health Service (General Dental Services) (Scotland) Amendment Regulations 2017 (“the 2017 Amendment Regulations”) to defer the coming-into-force date for electronic orthodontic payment claim forms and requests for prior approval from 1 January 2019 to 1 January 2020.

Background

The 2017 Amendment Regulations amend the National Health Service (General Dental Services) (Scotland) Regulations 2010 which regulate the provision of General Dental Services in Scotland. One of the purposes of the 2017 Amendment Regulations was to make all claims for payment and requests for prior approval for NHS dental care and treatment electronic (paperless). Prior approval is required where the cost of NHS dental treatment is in excess of £390.

The 2017 Amendment Regulations introduced a phased programme of change to require electronic submission as follows:

- 1 January 2018 - all payment claim forms, with the exception of claims for orthodontic treatment;
- 1 October 2018 - all requests for prior approval, with the exception of orthodontic prior approval requests;
- 1 January 2019 - all orthodontic payment claim forms and requests for prior approval.

Prior to the implementation of this programme around 100 general dental practices in Scotland (out of around 900 practices) relied entirely on paper for the submission of payment claims. Similarly orthodontic payment and all prior approval claims were paper-based. In moving to an electronic system the intention was to reduce processing costs and improve accuracy as well as turn-around periods for prior approval requests.
The first two phases of the programme – payment claims and prior approvals for general dental practices – have either been successfully completed or are on track for completion.

The third and final phase of the programme has been subject to delay. There are around 50 specialist orthodontic practices in Scotland, who rely on two third party system suppliers. In addition to the specialist practices, non-specialised practices also undertake orthodontic treatment and these practices also have a reliance on separate third party suppliers. In discussions with all of these suppliers we have taken the step of deferring the mandating of electronic submission for orthodontic payments and prior approval to allow more time for appropriate electronic systems to be put in place.

Retaining the original date could present the risk of a number of orthodontic specialist practices unable to submit payment and prior approval claims for NHS care and treatment with the potential to delay the provision of orthodontic treatment

Consultation

The British Dental Association (Scotland) has been made aware of these Amendment Regulations.

Impact Assessment

The Minister for Public Health, Sport and Wellbeing confirms that no Equality Impact Assessment is required as this instrument has no adverse effects on patients.

Financial Effects

The Minister for Public Health, Sport and Wellbeing confirms that no Business Regulatory Impact Assessment is necessary as this instrument has no financial effects on the Scottish Government, local government or on business.

Scottish Government
Directorate of Population Health
CDO & Dentistry Division
4 October 2018
Email to David Notman, CDO & Dentistry Division, Directorate of Population Health, Scottish Government – 18 October 2018 – from David Cullum, Clerk

Donaldson L (Lara)

From: Cullum DJ (David)
Sent: 18 October 2018 15:41
To: david.notman@gov.scot
Cc: Macie R (Rebecca); Donaldson L (Lara)
Subject: NHS General Dental Services Regulations

Dear David,

I refer to the SSI (2018/300) submitted for consideration by the Scottish Parliament. This is due to be considered by the Health and Sport Committee and I have been asked to seek additional information to inform their scrutiny.

It is noted the reason for the SSI is “Retaining the original date could present the risk of a number of orthodontic specialist practices unable to submit payment and prior approval claims for NHS care and treatment with the potential to delay the provision of orthodontic treatment.” And that this is required due to the IT systems of specialist orthodontic practices not having appropriate systems in place to comply. Could you indicate the circumstances in which a delay to patients could occur and also the steps that these practices have taken to become compliant and over what timescale they have been aware of this need.

No BRIA has been undertaken because “there are no financial effects on the Scottish Government, local government or on business”. Can you confirm making these IT changes has no financial impact on the businesses concerned and can you indicate what the additional cost to the Scottish Government of maintaining a manual system will be.

It would be helpful to the Committee’s consideration of the instrument to have the above information by Friday 26 October.

I look forward to hearing from you.

David Cullum

David Cullum
Clerk
Health and Sport Committee
Scottish Parliament
Room 7.00
Holyrood
Edinburgh
EH99 1SP
Tel: 031 348 9210
(RND Typetalk calls welcome)
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(Central) Telephone: 0131 348 5415

Follow the Committee on Twitter @SP_HashtagSport
Email from David Notman, CDO & Dentistry Division, Directorate of Population Health, Scottish Government – 24 October 2018 – to David Cullum, Clerk

Donaldson L (Lara)

From: David.Notman@gov.scot
Sent: 24 October 2018 11:27
To: Cullum DJ (David)
Cc: Macdia R (Rebecca); Donaldson L (Lara)
Subject: RE: NHS General Dental Services Regulations

Many thanks David,

We notified practices on 17 March 2017 of the intention to mandate electronic submission of dental, including orthodontic, payment claims and requests for prior approvals. This was followed by the relevant Regulations being laid with a coming-into-force date of 26 October 2017. System suppliers were also provided with specifications from Practitioner Services around the same time as the laying of these Regulations.

By way of background practices that provide NHS dental services are required to submit payment claims forms and prior approval requests. Where the course of treatment for a patient is in excess of £350 then the dentist is required to submit a prior approval request before the treatment may commence. There are around 1,000 dental practices in Scotland providing NHS dental services.

Before the e-dental programme commenced, the majority of general dental practices made electronic payment claims. However prior approval was entirely a paper-based system as were orthodontic payment claims and orthodontic prior approval requests.

The e-dental programme comprised of three phases. Phase 1 to ensure that all general dental practices submit electronic payments claims by 1 January 2018, a second phase that all general dental practices should submit electronic prior approval requests from 1 October 2018, and a final third phase where orthodontic payment claims and prior approval requests should be submitted electronically by 1 January 2019.

Practices have generally worked with their suppliers to become compliant to the implementation timetable for the e-dental programme. The programme requires third party software suppliers to develop and update the software to ensure practices are able to meet the new requirements. Practitioner Services of NHS National Services Scotland are responsible for managing the project and have liaised and supported system suppliers throughout the project. System suppliers have generally been able to meet the development timescales, however, for the final phase of the programme, for orthodontics, suppliers have found the timescale increasingly challenging.

The deferral of mandating electronic orthodontic payment claims and prior approval requests to 1 January 2020 is to allow further time for system suppliers to develop and implement an appropriate solution. If we do not delay it would mean that practices who provide orthodontic care and treatment would not be able to submit payment claims and prior approval requests from 1 January 2019. We envisage that any contingency arrangements that would need to be put in place by Practitioner Services would significantly delay the processing of payment claims and prior approval requests.

We did not provide a Business Regulatory Impact Assessment as we are deferring the date of requiring electronic submission for orthodontic care and treatment. Therefore we do not anticipate any additional cost to practices of deferring the date. The cost of the development work is normally absorbed within the
contractual arrangements that a practice will have with its system supplier, so we do not anticipate that this programme will add to the costs of business.

We do not anticipate additional costs to the Scottish Government of maintaining the status quo for a longer period than anticipated. Payment claims and prior approval requests are processed by Practitioner Services of NHS National Services Scotland. The Scottish Government doesn’t have any direct role in processing claims.

Trust this is helpful, apologies if it is a bit on the long side.

Happy to discuss further,

Kind regards,

David

David Notman
CDO & Dentistry Division
Directorate of Population Health
Scottish Government
0131-244 2467
HEALTH AND SPORT COMMITTEE

HUMAN TISSUE (AUTHORISATION) (SCOTLAND) BILL

SUBMISSION FROM BRITISH HEART FOUNDATION SCOTLAND

The British Heart Foundation is the largest funder of cardiovascular research in Scotland, currently investing £70 million on ground breaking research in Scotland. It is our mission to beat heartbreak forever. Our vision is for a world in which people do not die prematurely or suffer from heart and circulatory disease.

We would like to take this opportunity to thank the Health and Sport committee of the Scottish Parliament for the opportunity to respond to this call for views. We are delighted that the Scottish Government has brought forward the Human Tissue (Authorisation) (Scotland) Bill, which has the potential to transform the lives of the 559 patients awaiting transplants in Scotland.¹

What do you think are they key strengths and weaknesses of the proposals to introduce ‘deemed authorisation’ for those who have not made their wishes on organ donation known?

Strengths

BHF Scotland believes that there are a number of strengths to the deemed authorisation proposal.

Firstly, it allows individuals to be explicit about their views on organ donation, by providing the opportunity to either opt in or out of donation on the organ donor register (ODR). Those who do neither will be giving ‘deemed authorisation’.

This is important, as there is a disparity between those who say that they wish to donate their organs after they die and those who are currently registered on the ODR. Around 80% of people support organ donation², however only 50% of Scots are registered on the ODR.³ The system proposed by the bill will help to close this gap.

Additionally, we believe that deemed authorisation could help the families of potential donors have more confidence in their knowledge of their loved one’s wishes regarding organ donation. As a result of the deemed authorisation legislation in Wales, Specialist

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² NHSBT carries out biannual attitudinal surveys. The fourth wave in 2017, involved 1499 interviews carried out via online self-completion between the 10th and 21st of April 2017. In this wave, 81% of people supported organ donation in principle
Nurses-Organ Donation (SN-ODs) report encountering more instances in which family members were aware of their deceased loved one’s wishes.\(^4\)

We believe that a key strength of the legislation proposed is its potential positive influence on consent rates for organ donation. Results from Wales suggest that the introduction of opt out legislation has positively influenced organ donation consent rates: general Welsh consent rates are the highest in the United Kingdom at 72\%.\(^5\)

Furthermore, as the bill allows those close to the potential donor to inform health care professionals of their relative’s most recent views on organ donation, deemed authorisation ensures that the wishes of individuals in Scotland will be respected upon their deaths.

BHF Scotland believes that the inclusion of a duty for Ministers to inform the public about deemed authorisation is also an important strength of the bill. Ensuring awareness of the legislation is important: firstly to ensure that members of the public to understand the deemed authorisation system, and secondly to encourage them to register their decision to opt in or out on the ODR, and to discuss organ donation with their family. This is integral to the success of the proposed system change and we fully support this aspect of the proposed legislation.

Overall, we strongly believe that the Human Tissue (Authorisation) (Scotland) Bill has a number of strengths and will be a positive step forward for Scotland.

**Weaknesses**

BHF Scotland did not feel that there were any specific weaknesses of the proposed bill but recognises that a deemed authorisation system, while important, is not a panacea.

We believe that, alongside deemed authorisation, continued investment in infrastructure and staff training is necessary. We also believe that campaigns to raise public awareness of organ donation are hugely important.

**What do you think are they key strengths and weaknesses of the plans for authorisation of pre-death procedures?**

BHF Scotland has no comments to make on the key strengths and weaknesses of the plans for authorisation of pre-death procedures.

**Do you have any other comments to make on the Bill?**

Please find below an extensive briefing on BHF Scotland’s position on the bill and the proposals for a deemed authorisation system of organ donation.

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ORGAN DONATION BRIEFING

British Heart Foundation's vision is a world without heart and circulatory disease.

We fund research to keep hearts beating and blood flowing. We are the biggest independent funder of cardiovascular research in Scotland, currently investing £70 million on groundbreaking research in Scotland.

Key Messages

- The need for organs vastly outstrips the number donated.
- During 2017/18, 426 patients throughout the UK died whilst active/suspended on the transplant list or within one year of removal from the list, including 27 people who died while awaiting a heart transplant.
- There is a gap between the number of people who state that they would wish to donate organs and the number who go on to join the Organ Donation Register.
- Countries with soft opt out legislation have on average 13-18 per cent higher organ donation rates than countries with informed consent legislation.
- The Human Tissue (Authorisation) (Scotland) bill, published in June 2018, could increase Scotland’s donation rates.
- BHF Scotland believes that the soft opt out system brought forward by the bill, is an appropriate option for increasing organ donation.
- BHF Scotland also supports continued investment in infrastructure and staff training alongside a campaign to raise public awareness.

The bill will enable those who support organ donation but haven’t registered on the Organ Donor Register to have their wishes recorded.

There is disparity between those who sign up to the organ donor register (ODR) and those who support organ donation and would wish to donate their organs after death.

Around 80% of people support organ donation. However, only 50% of people in Scotland have signed up to the ODR.

The proposed bill will enable those who support organ donation but haven’t registered on the ODR to have their wishes respected, by implementing a system in which those who do not explicitly opt in or out of donation will be deemed to be willing to donate their organs upon their death.

The current system is failing to keep up with the need for organ transplantation. 559 people in Scotland were waiting for an organ at the end of the first quarter of 2018/19. The need for transplants is likely to increase as a result of an ageing demographic.

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6 NHSBT carries out biannual attitudinal surveys. The fourth wave in 2017, involved 1499 interviews carried out via online self-completion between the 10th and 21st of April 2017. In this wave, 81% of people supported organ donation in principle.

During 2017-2018, 426 patients died throughout the UK whilst active/suspended on the transplant list or within one year of removal from the list, including 27 people who died while awaiting a heart transplant⁹.

Each number here represents a life cut short and a family who have lost a loved one where it might have been avoidable. More life-saving transplants could take place each year if the gap between those indicating that they would like to donate, and those taking action to do so was smaller. The proposed bill will help to achieve this.

**The Human Tissue (Authorisation) (Scotland) Bill proposes a system with appropriate checks in place to ensure ethical practices regarding organ donation.**

Firstly, the bill includes requirements to take into account the potential donor’s most recent view about donation.

Secondly, the removal and use of less commonly donated types of organ and tissue, or the removal of commonly donated types for purposes other than transplantation from a potential donor who is subject to deemed authorisation, can only be carried out with authorisation by a nearest relative.

Deemed authorisation will not apply to children under the age of 16; adults who do not have the capacity to understand the implications of deemed authorisation; and those who have resided in Scotland for less than 12 months.

The option will remain available for individuals who fall into one of the two latter groups to opt in or out.

Children aged 12 or above but under 16 will be able to opt in or out, while younger children will require a person with parental rights and responsibilities or another close adult to inform Specialist Nurses-Organ Donation (SN-ODs) about the child’s wishes regarding donation.

**The Human Tissue (Authorisation) (Scotland) Bill emphasises the important role of Specialist Nurses-Organ Donation (SN-ODs).**

The approach made to grieving families to consider the prospect of donating their loved one’s organs needs to be made at an appropriate time by someone with the correct skills and knowledge to support them adequately. SN-ODs are well placed to do this.

In Wales, efforts to ensure a SN-OD is present in all instances of potential donations, have seen consent rates in these situations rise from 94% in 2015/16 to 96% in 2016/17¹⁰. The language of the new Scottish bill emphasises the role of SN-ODs in approaching families to discuss the wishes of their loved one.

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⁸ NHS Blood and Transplant, 2018, Organ Donation and Transplantation Activity Data: SCOTLAND, Annual data for financial years 2013/14 to 2017/18 and data for 2018/19 – first quarter
SN-ODs in Wales report feeling that implementation of the new legislation has gone smoothly. They believed that they had been given sufficient training regarding the new system, and were encountering more instances in which the family knew whether or not their loved one wished to donate their organs\textsuperscript{11}.

The Human Tissue (Authorisation) (Scotland) Bill follows the example of numerous other countries with successful opt-out systems in place.

The results from Wales following the move to an opt-out system on 1st December 2015 have been positive.

General consent rates for organ donation in Wales are currently the highest in the UK, at 72%. Prior to the introduction of the new system in Wales, consent rates were 58% in 2015\textsuperscript{12}. This suggests that opt out legislation has positively influenced consent rates.

Support for the opt-out system in Wales remains high amongst the general public and NHS Staff, and only 6% of the population have opted out\textsuperscript{13}.

In 2017/18, there were a total of 74 deceased donors in Wales, compared to 61 in the previous financial year. 2016/17 saw a decrease of 5% in the number of donors in Wales, down from 64 in 2015/16\textsuperscript{14}, however this can be attributed to changes in the screening procedures used to identify potential donors, rather than an issue with the legislation itself.

Monitoring the implementation of the Welsh bill over time will shed more light on its impact on actual donor numbers; however evidence suggests that it is likely to have a positive impact. International evidence estimates that countries with soft opt out legislation have on average 13-18 per cent higher organ donation rates than countries without\textsuperscript{15}.

Countries such as Israel, Belgium, Norway, Spain & Sweden all operate opt out organ donation systems. Spain introduced their opt-out system in 1979 and has the highest levels of donations per million population in the world\textsuperscript{16}.

\begin{flushleft}
\textsuperscript{14} NHS Blood and Transplant, 2018, Organ Donation and Transplant Activity Data: WALES, Annual data for financial years 2013/14 to 2017/18.
\end{flushleft}
The Human Tissue (Authorisation) (Scotland) Bill could increase consent rates from families, meaning more lifesaving transplants could be performed every year.

BHF Scotland is concerned with the low levels of family authorisation for organ donation in Scotland, which at 58.9% in 2017/18 is the lowest across the UK\(^\text{17}\).

Research has shown that people living in countries with soft opt-out legislation were more likely to report a willingness to authorise the donation of their relatives’ organs compared to respondents living in countries without such legislation\(^\text{18}\).

The system created by the proposed bill ensures that those close to a potential donor retain the right to make health care professionals aware of the most recent views that person held on organ donation.

The opt-out system allows people to be explicit about their wishes, and this can help families be clearer about what their loved one would want.

Consent rates are highest when the potential donor’s decision to donate is known to their family (almost 90%) so it is important that organ donation is normalised and people are comfortable talking about and making decisions on the issue.

An opt-out system along with increased campaigning will help. This has been done successfully in Wales, where The Human Transplantation (Wales) Act 2013 includes an obligation for the Ministers to promote a campaign for the purpose of informing the public about deemed consent at least once every 12 months. 55% of people in Wales reported discussing their wishes around organ donation with family in September 2017, compared with 38% who reported having done so in June 2012\(^\text{19}\).

In recognition of the importance of public awareness relating to consent rates, it will be the duty of the Scottish Ministers to raise public awareness of the terms of the new proposed bill, and specifically what is meant by deemed authorisation for transplant. This is established in section 2 of the proposed bill\(^\text{20}\).

The explanatory notes associated with the proposed bill specify that accessible public information will be produced with targeted information developed for different groups in society\(^\text{21}\). This is in addition to media campaigns and other awareness raising initiatives already required by the 2006 act. This has the potential to create a cultural change

\(^{17}\) NHS Blood and Transplant, 2018, Organ Donation and Transplantation Activity Report 2017/18, p135
regarding organ donation, making it easier for people to discuss their views with family members, driving positive change in consent rates.
HEALTH AND SPORT COMMITTEE

HUMAN TISSUE (AUTHORISATION) (SCOTLAND) BILL

SUBMISSION FROM CHILDREN’S LIVER DISEASE FOUNDATION

1. What do you think are the key strengths and weaknesses of the proposals to introduce ‘deemed authorisation’ for those who have not made their wishes on organ donation known?

Strengths:

Potential for increased numbers of donors as it allows donation to become the default position. Reduces the gap between intent and action.

Inclusion of duty of Scottish ministers to promote information and awareness regarding how authorisation of transplantation may be deemed to be given

Inclusion and emphasis on relatives

Use of “relevant time” instead of “immediately before an adult’s death”. Timing is key when having discussions with relatives and this may provide healthcare professionals with more flexibility about how to approach family. It is also made clear when this “relevant time” may be.

Considers the rights of vulnerable groups – those who may not understand the nature and consequences of deemed authorisation. However, are these discussions undertaken with vulnerable group for a relative to be able to know their views?

Weaknesses:

Still a reliance on family members’ consent even if the individual has not opted out if they can prove that the individual objected to donation but had not recorded this or if there is evidence that they were not capable of making that decision. Also, it is not clear if the relative would have to raise that discussion with the health worker or if they are consulted during the process.

Those who do not wish to donate may not have had an opportunity to opt-out in time or mention it to relatives. They would be considered willing donors.

Regarding awareness and promotion, individuals often do not want to discuss death or preparations for it due to fears, religion, culture, ‘tempting fate’ etc. Therefore, will they engage or listen to messages being communicated?

Affects every individual regardless of language and culture so must consider communication techniques as if the bill is passed and family members are not aware of this it will have a major impact on their emotional wellbeing during an already challenging time.
2. What do you think are the key strengths and weaknesses of the plans for authorisation of pre-death procedures?

**Strengths:**

Clear definition of what is meant by pre-death procedures and types.

Duty to promote information and awareness about the nature of pre-death procedures, when they may be carried out and how they may be authorised.

Inclusion and discussion of relatives in the Bill as it will have an emotional impact on them during a very distressing time.

**Weaknesses:**

Reliance on relative to authorise pre-death procedures and as a result if they are aware of evidence that shows that the individual was opposed to this they may refuse authorisation. This can lead to donation not being made as pre-death procedure not able to take place.

3. Do you have any other comments to make on the Bill?

It has been recognised for some time that the UK compares poorly in terms of donation rates with other countries in Europe. This soft-opt out approach may potentially increase the number of donors in Scotland.

Deemed consent is already in place in Wales and consultations taking place in England. CLDF are pleased that there will hopefully be consistency across all areas of the UK in the near future.

CLDF supports any system which increases the number of organs available for donation, but we need to consider the importance of family consent as donation cannot take place without this even with deemed authorisation. Even though 23 million have signed up to the organ donation register only half have discussed their wishes with their families. Therefore, it is vital for families to have discussions about individual wishes even with deemed authorisation or opt-out systems in place.

Children’s Liver Disease Foundation (CLDF) is the only UK charity dedicated to fighting all childhood liver diseases. We do this by providing information to families and to health professionals, emotional support to young people with liver disease and their families, funds for research and a voice for all affected.
Q1 - What do you think are the key strengths and weaknesses of the proposals to introduce 'deemed authorisation' for those who have not made their wishes on organ donation known?

Key weakness – Presumed consent is presumptuous, and risks alienating people who would have opted to donate freely but not when forced, presumed or expected to donate.
The element of gift that characterises the existing system of organ donation – and is so important to potential donors, donor families and recipients - would be diminished under the proposals. There is a potential backlash from people who object to the state having assumed rights over their bodies. Thus, the proposals may lead to a negative shift in public perception about organ donation, and possibly create a new category of people who would have opted in under the old system but would opt out under the new.

Key weakness – Lack of public trust in the security and accuracy of personal data being held by third parties.
The proposals place greater reliance on the recording of wishes on the organ donor register than the current system, particularly if a person does not wish to donate. Public trust in the security and accuracy of personal data held by third parties has eroded recently. This may lead some people to worry that their wishes may not be followed.

Key weakness – The message is complicated.
As I detail in my response to Q3, I believe the communication of any change in the default position will be crucial to successful implementation. However, I think both the message and language are complicated, offering a significant challenge to the team assigned to raising awareness. “Tell us if you want to donate, tell us if you don’t want to donate, and if you don’t tell us anything we’ll presume you have authorised donation.” “Deemed authorisation” is not an intuitive description, and the use of the phrases opt-in and opt-out invites double negatives. The percentage of Scots signed up to the Organ Donor Register is the highest in the UK, thanks to a combination of Scottish Government funding for awareness raising, excellent campaigns and the generosity of the Scots. However, replacing a simple message with a complicated one risks confusing the public and undermining the good work achieved.

Q2 - What do you think are the key strengths and weaknesses of the plans for authorisation of pre-death procedures?

Key strength – Transparency.
Specifically obtaining authorisation for such procedures ensures that families understand exactly what is going to happen to their loved one, to allow donation to take place.
Key weakness – Quite technical, and risks information overload for donor families at a difficult time.
It increases the burden of information and decision-making on families at a very sensitive time. Most other laypeople to whom I’ve talked assume that the decision to donate is a simple one; the myriad of subsequent information and questions following an initial decision to go ahead comes as a surprise. Adding to this burden should be avoided.

Q3 - Do you have any other comments to make on the Bill?

The importance of raising public awareness and communicating any change in default position, without alienating people already sympathetic to organ donation.
The overall thrust of the Bill is a significant change in the default position. How that message is conveyed to people, should it be necessary, will be extremely important. I think it’s crucial that the element of gift, so central to organ donation under the current system, is maintained.
HEALTH AND SPORT COMMITTEE

HUMAN TISSUE (AUTHORISATION) (SCOTLAND) BILL

SUBMISSION FROM Scottish Independent Advocacy Alliance

Deemed Authorisation

8. The Bill proposes to allow someone to be considered as a potential organ or tissue donor when they have not registered their wishes on the NHS Organ Donor Register or in some other way. This would be known as ‘deemed authorisation’ (sometimes known as ‘presumed consent’)

Please indicate your level of agreement with this proposal

Strongly Agree

Opting Out

9. The Organ Donor Register already allows you to record your wish not to be a donor but the Bill would provide a legal basis for ‘opting out’. Those who did not want to opt-out would still be able to ‘opt in’ as a potential donor

Please indicate your level of agreement with this proposal

Strongly Agree

Exceptions to deemed authorisation

10. Deemed authorisation would not apply to people aged under 16.

Please indicate your level of agreement with this proposal

Disagree

11. Deemed authorisation would not apply to people who have not had the capacity to understand deemed authorisation for some time (e.g. depending on the circumstances, someone with dementia)

Please indicate your level of agreement with this proposal

Strongly Agree

Comments:

People with dementia may well have given consent for donation before becoming unwell.

12. Deemed authorisation would not apply to people who had been resident in Scotland for less than 12 months.

Please indicate your level of agreement with this proposal
Strongly Agree

13. Please add any other comments you have on exceptions to deemed authorisation (optional)

Comments:

**Timing of authorisation**

14. Under the Bill, some donations would still require the authorisation of the nearest relative or a person with parental rights and responsibilities for a child. The Bill would allow there to be more flexibility around when these authorisations could take place.

At the moment this happens once the person has died but the Bill would allow authorisation to happen before a potential donor dies in cases where their death is expected soon.

Please indicate your level of agreement with this proposal

Strongly Agree

**Children**

15. Children aged 12 or over would be allowed to record a decision to opt-out of donating. The law currently allows them to opt-in.

Please indicate your level of agreement with this proposal

Strongly Agree

**Role of the family and next of kin**

16. The Bill has no proposals to allow the wishes of the next of kin to overrule the wishes of the deceased (as recorded in the Organ Donor Register or otherwise)

Please indicate your level of agreement with this proposal

Disagree

17. The Bill would allow someone's next of kin to stop authorisation being deemed if they had information that it was against the wishes of the deceased.

Please indicate your level of agreement with this proposal

Strongly Agree

19. If the deceased person had registered their wishes but had since changed their mind without recording this anywhere, the Bill would allow the next of kin to provide information that their wishes had changed and his would supersede their previously recorded decision.

Please indicate your level of agreement with this proposal
Agree

20. Please add any other comments you have about the role of the family and the next of kin (optional)

Comments:

**Pre-death procedures**

21. The Bill would set out when certain procedures, including tests, can be carried out shortly before a person dies in order to help facilitate and prepare them for donation. The Bill calls this ‘pre-death procedures’.

These pre-death procedures are important when a potential donor is expected to die from circulatory death (i.e. after their heart has stopped beating rather than from brain death). This is because in non-heart beating donations, the organs have to be removed immediately.

Under the Bill, some types of pre-death procedure could be carried out on people whose authorisation is deemed (i.e. they have not opted in or out of being a donor)

Please indicate your level of agreement with this proposal

Agree

22. The Bill would also provide that, where someone has opted in to bring a donor, this is also authorisation for pre-death procedures.

Agree

23. Please add any other comments you have about pre-death procedures (optional).

**Donor Intentions**

24. If the Bill’s proposals become law, do you think it would affect your views on being a donor?
Kidney Care UK is willing to support work that will increase the opportunity for more people to receive transplants and welcomes the move from the Scottish Government in this regard. We are the leading national patient support charity which works to improve quality of life for kidney patients through advocacy, direct grants, educating and informing patients, counselling and funding patient-centred research, healthcare professionals and projects. The charity was established 41 years ago to address the many issues associated with kidney disease and kidney failure. Until 2017 we were known as the British Kidney Patient Association. We are a registered charity in Scotland [www.kidneycareuk.org](http://www.kidneycareuk.org)

What do you think are they key strengths and weaknesses of the proposals to introduce 'deemed authorisation' for those who have not made their wishes on organ donation known?

Advantages:

Deemed authorisation enables families to accept donation rather than have to give permission; some families have commented that knowing their loved one has transformed someone else’s lives can bring some comfort to them.

Changing rules should lead to further training for staff in how to approach families and support them through the donation process and new rules.

The opportunity to increase transplantation by bringing in opt-out, in conjunction with public education and appropriate staffing, has been shown over time to be effective and is welcomed by us.

Disadvantages:

Donation wishes might change but not be recorded, but this is the case in any system, and the option for families to present information on why their loved one would not have wanted to become a donor would be included.

Some people may feel strongly that do not wish for a presumption to donate, but this would be catered for by the opportunity to opt-out online, and it may be that they would never have wished to become donors.

It will be important to learn from Wales about continuing to focus on families and emphasise the importance of an organ donation conversation, whatever the rules.

The differences in age for deemed and self-authorisation will require careful messaging are different to those in other UK countries and could lead to confusion.
What do you think are they key strengths and weaknesses of the plans for authorisation of pre-death procedures?

We do not have any comments.

Do you have any other comments to make on the Bill?

Kidney transplants are the gold standard treatment for kidney failure. For many kidney patients a transplant transforms their lives, returning them to their families, both extending and increasing quality of life. Depending on age, it may enable them to return to work. Study after study attests for better quality of life, whether in younger or older patients, whether with diabetes or not. Kidney Care UK hears from many patients who have benefited from a transplant and share their stories to encourage others https://www.kidneycareuk.org/get-support/your-stories/

As one of them, Kim, recently said 'I can’t put into words what it means to have been given more time and the chance to look into the faces of my beautiful grandchildren’

When disease causes kidney function to drop below the minimum needed to keep an individual alive, there are three possible choices for a patient:

- To undergo a kidney transplant if they are sufficiently fit and a suitable kidney can be found (they will need to receive dialysis whilst they wait for a kidney or receive a transplant pre-emptively, so before their native kidneys stop working).
- To go onto dialysis treatment for the rest of their life if they are not suitable to receive one or choose not to be listed for a transplant.
- To go onto conservative care, in which case they will receive treatment to give them the best possible quality of life in the time remaining until they die.

However there are fewer transplants than there are people waiting - eight out of ten people on the transplant list are waiting for a kidney. One person will die today whilst they wait. The burden on mental health is also difficult. Transplantation makes an enormous difference and means that patients no longer have to go for dialysis, normally at least 3 times a week for four hours at a time. The burden of dialysis and restrictions of kidney failure are very high. It is also very expensive both for the treatment itself, the medications and cost of getting to and from hospital.

We welcome the move by the Scottish Government to increase organ donation and transplantation, and to work with families to do so. We encourage the Scottish government to make adequate funding available for the essential public education to accompany a change in the law.
HEALTH AND SPORT COMMITTEE

HUMAN TISSUE (AUTHORISATION) (SCOTLAND) BILL

SUBMISSION FROM CARE for Scotland

What do you think are the key strengths and weaknesses of the proposals to introduce ‘deemed authorisation’ for those who have not made their wishes on organ donation known?

CARE for Scotland is opposed to the proposed ‘deemed authorisation’ scheme both for ethical reasons and on grounds of practicality. These issues are interconnected as the practical failure of implementation of presumed consent or ‘deemed authorisation’ is often linked to the fact that people respond negatively to the state claiming a right over their bodies.

**Ethical Considerations**

Our primary ethical concern is that the proposal disrespects the personhood of people by considering their bodies to be commodities which the state can acquire without prior consent having been obtained from the individual involved. This runs contrary to the Christian understanding of the human person as being created in the image of God. Human beings possess a measure of autonomy and freedom which cannot be disregarded without our being treated in a degrading, impersonal and dehumanising manner.

The problem with ‘deemed authorisation’ is that it creates a system that treats human beings with a degree of automation and bypasses their personhood. It is good that people choose to donate their organs – this should be encouraged. However, if we introduce an arrangement which results in the taking of people’s organs after death – without direct and honouring engagement with their personhood prior to death – we cannot guarantee that the organs are given freely and with consent and, therefore, the donor’s personhood is potentially disrespected. A new framework and understanding of humanity and our relationship to state power is introduced that will alter the way in which our culture views people generally and not just in relation to organ availability. It promotes a utilitarian ethic in which the state makes a claim to ownership of the bodies of human beings and seeks to use them for the purpose it deems appropriate without the explicit consent of the individual concerned and/or his/her immediate relatives.
Additionally, there are a number of more generic ethical concerns. First, there is a danger that a system of ‘deemed authorisation’ could undermine organ donation as an entirely altruistic gift. In 2008, the Organ Donation Task Force (ODTF) reported that representatives from the Donor Family Network highlight the importance of the gift relationship. They were concerned that a system of ‘deemed authorisation’, however weak, would promote conflict between families and clinical staff, conflict that would rapidly degrade the trust that was vital to decision making. Moreover, recipients and their families are concerned also that donation should always be a genuine gift.¹ The importance of this ‘gift’ aspect is acknowledged by the Scottish Government which states in the Bill’s Policy Memorandum:

“The willingness of donor families to think of other people and the gift of donation at such times makes their generosity all the more special.”²

Second, the concept of ‘deemed authorisation’ is a misnomer. In practice, no authorisation can be assumed to have been given by the donor and his/her family. In some cases the individual concerned may have consented but did not, for any number of reasons, register this view while still alive. However, it is also very likely under the proposed system that organs will be removed from individuals who would not have consented to their removal. For some, this prospect will be of real concern.

Third, the proposed system has the potential to be abused in order to meet the state’s perceptions of the ‘greater good’ whilst the autonomy and discretion of the individual may be violated. For example, there is a danger that in cases where life sustaining treatment is withdrawn of clinical decisions being influenced, in part, by organ transplantation considerations (e.g. the timing of decisions to withdraw treatment). Concerns exist also in relation to those jurisdictions where euthanasia has been legalised in which lack of explicit consent is a common feature and organ donation is practiced in relation to euthanised patients.³ The temptation for clinicians to be unduly influenced by a combination of financial pressures and pressure to meet transplantation demand should not be overlooked. If we are not extremely careful, a commoditised view of the human person could lead to a policy

³ Studies have shown that between 32% and 45% of euthanasia deaths in Belgium are without explicit request or consent. In Belgium, organ donation guidelines have been introduced to apply in cases of euthanasia.
of euthanasia without consent for people with severe neurological conditions who are likely to cost the NHS considerable sums in ongoing care with their organs being harvested for transplantation purposes.

**International Experience**

We are not convinced by the international evidence that the introduction of this system will lead to an increase in organ donation. The debate has been confused because Spain is often claimed to utilise an opt-out system. However, that the country does not in practice utilise such a system. While it may have been legislated for in Spain, there is in practice no way to opt-out as there is no opt-out register. Spain in practice uses an opt-in model and it is the world leader in terms of deceased organ donation. The most successful country in the world, therefore, in terms of organ donation is using an *opt-in* system in practice. Other strongly performing countries in terms of organ donation, such as the USA, also use an opt-in system.

International experience shows that some countries with ‘deemed authorisation’ or presumed consent systems have seen a decline in organ donation. In 2012, Chile moved from a system of informed consent to one of presumed consent. The organ donation figure fell from 8.6 donors per million in 2012 to 5.6 donors per million in 2013. Columbia is another country which operates a presumed consent system which has seen falling organ donation levels in recent years, falling from 12.3 per million in 2010 to 6.8 per million in 2013. Within Europe, Luxembourg, Slovakia and Sweden have all experienced a fall in the level of organ donation over recent years despite operating systems of presumed consent. In those states which have adopted an opt-out system and where levels of organ donation have increased there remains a question as to whether this was caused solely by the introduction of the presumed consent system or by other factors.

It is worth noting that a host of countries which operate opt-out systems have lower levels of organ donation than Scotland. In the year 2013/2014, Scotland’s rate was around 20 donors per million. This was higher than Finland, Latvia, Sweden, Hungary, Poland, Slovakia, Luxembourg, Israel, Greece and Cyprus which all operate opt-out systems. This suggests that there are a number of factors which impact on the level of organ donation within a state. Among these is obtaining the consent of patients and families, but other factors such as training of medical professionals and the availability of specialist health care staff are of equal or greater importance.

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4 [http://www.clinmed.rcpjournal.org/content/14/6/567.full.pdf+html](http://www.clinmed.rcpjournal.org/content/14/6/567.full.pdf+html) and [http://www.bmj.com/content/341/bmj.c4973.long](http://www.bmj.com/content/341/bmj.c4973.long)
Experience in Wales

The Welsh experience in this area needs to be taken into consideration. In the original White Paper introducing their legislation in this area, the Welsh Government stated the aim of the introduction of this policy was “to increase the number of organs available” and claimed that “research suggests that organ donation rates from deceased persons increase by approximately 25% to 30% in countries where an opt-out system applies.”

In Wales, opponents of the proposed change (including CARE) argued that in fact the introduction of an opt-out system did not in and of itself increase the level of organ donation. It was argued that other factors such as the quality of health infrastructure, societal knowledge and the training of specialists played a far greater role with the example of Spain being cited.

Experience in Wales suggests that the expected increase of 25% to 30% in organ donation rates does not automatically materialise following the introduction of the ‘deemed authorisation’ system. In 2013/14 there were 54 deceased donors in Wales and 157 deceased donor transplants occurred. Although by 2018/19 the number of deceased donors had increased to 74, the number of deceased donor transplants had fallen to 137. Moreover, for most of the period (the first four years) after the introduction of their ‘deemed authorisation’ system, there was only a marginal increase in the number of deceased donors (averaging 59.7) and the number of deceased donor transplants varied remarkably from year to year with 128 in 2014/15, 168 in 2015/16 and 135 in 2016/17.

The data from Wales, therefore, presents a mixed and confusing picture. Whether the increase in the number of deceased donors is owing to the introduction of the new system or to other factors is far from clear. Moreover, the fact that the number of deceased donor transplants varies so much from year to year and shows no sign of an overall upward trend, casts doubt on the claimed benefits of introducing a ‘deemed authorisation’ system.


6 “Proposals for Legislation on Organ and Tissue Donation” p4.

7 https://nhsbtdbe.blob.core.windows.net/umbraco-assets/1518/wales-quarterly-stats.pdf
The data from Wales should also be compared with data in other parts of the UK to see if there is any perceptible difference as a result of the introduction of the ‘deemed authorisation’ system. The latest statistics released by NHS Blood and Transplant show that the number of deceased donors in Scotland increased from 98 in 2014/15 to 133 in 2016/17 before falling to 102 in 2017/18. The number of deceased donor transplants in Scotland increased steadily over the period from 300 in 2014/15 to 375 in 2017/18. In England the number of deceased donors increased from 1,076 in 2013/14 to 1,358 in 2017/18 and the number of deceased donor transplants increased from 2,834 in 2014/15 to 3,411 in 2017/18. In Northern Ireland the number of deceased donors fell from 48 in 2014/15 to 40 in 2017/18 and the number of deceased donor transplants increased from 79 in 2014/15 to 115 in 2017/18.

### Deceased Organ Donor Transplants 2014/15-2017/18

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<thead>
<tr>
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<th>2014/15</th>
<th>2015/16</th>
<th>2016/17</th>
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<tr>
<td>Wales</td>
<td>128</td>
<td>168</td>
<td>135</td>
<td>139</td>
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<tr>
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<td>332</td>
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<td>2,834</td>
<td>2,931</td>
<td>3,155</td>
<td>3,411</td>
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<tr>
<td>Northern Ireland</td>
<td>79</td>
<td>100</td>
<td>75</td>
<td>115</td>
</tr>
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</table>

Source NHS Blood and Transplant\(^8\)

Whilst there has been a variable, but overall downward, trend in the number of deceased donor transplants in Wales over the last four years there have been steady increases in the number of deceased donor transplants of 25% in Scotland, 20% in England and up to 45% in Northern Ireland during the same period. This is important because it suggests that the move in Wales to a ‘deemed authorisation’ system has not significantly improved the number organs being made available for transplant from deceased donors whilst precisely the opposite trend is observable in those jurisdictions which have retained an opt-in system.

One other factor it is salient to consider is the number of individuals who have opted out of being organ donors in Wales. The number of people opting out of the organ donor register (ODR) has risen consistently over the last three years since the presumed consent or

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‘deemed authorisation’ system came into force. By the first quarter of 2018, some 182,764 individuals (6% of the population) had opted out of being organ donors in Wales. The organs of these individuals have been lost from the system whereas previously these individuals may have proven to be suitable donors if their families had agreed to donate organs in the situation where deceased individuals had expressed no preference. In contrast to the Welsh situation, in Scotland 5,943 people (0.11% of the population), in Northern Ireland 545 people (0.03% of the population) and in England 416,287 people (0.9% of the population) have opted out of the ODR.

In Wales, by the first quarter of 2018 only 40% of the population had opted into the organ donor system. This compares to 37% in England, 44% in Northern Ireland and 50% in Scotland. Scotland has been much more successful than other parts of the UK in encouraging people to opt into the ODR. It is unclear, therefore, why the Scottish Government is proposing at this time to introduce a ‘deemed authorisation’ system when it has been making so much progress in increasing the rates of deceased donor transplants and in persuading people to opt into the ODR under the current system and the claimed benefit of the ‘deemed authorisation’ system is unproven.

**Conclusion**

In view of the serious ethical issues raised by the proposed opt-out system of organ and tissue donation and doubts about its practical benefit based on both the Welsh and international experiences, CARE for Scotland suggests that the Scottish Parliament should reject this Bill at Stage 1. More resources should be assigned to recruiting and training specialist health care staff and improving transplant management. Initiatives such as these are much more likely to produce the desired result of increasing the number of organs available for transplant than the introduction of the proposed ‘deemed authorisation’ system. We would be pleased to give oral evidence to the Health and Sport Committee during the Stage 1 process.