EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ("the Principal Regulations") to implement Directive 2015/565 of the European Commission ("the coding Directive"), laying down technical requirements for the coding of human tissues and cells. These Regulations also further amend the Principal Regulations and the Human Tissue Act 2004 ("the Act") to implement Directive 2015/566 of the European Commission ("the fourth Directive"), setting out procedures for verifying standards of quality and safety of imported tissues and cells. The coding Directive and the fourth Directive are implemented in so far as they apply to gametes and embryos by the Human Fertilisation and Embryology (Amendment) Regulations 2018 which amend the Human Fertilisation and Embryology Act 1990.

Regulation 2(1) amends references to "import and export" in regulation 2 of the Principal Regulations.

Regulation 2(2) amends regulation 3 of the Principal Regulations and appoints the Human Tissue Authority as the competent authority for the purposes of the fourth Directive.

Regulation 2(3) amends regulation 4 of the Principal Regulations to ensure that all references in those Regulations to the "third Directive" include amendments made to that Directive by the coding Directive and inserts a definition of the fourth Directive.

Regulation 2(4) amends regulation 5 of the Principal Regulations to insert new definitions to reflect amendments made to implement the fourth Directive and, in particular, it introduces the concepts of an "importing licence holder", "third country", "third country premises" and "third country supplier". Regulation 2(4) also includes a definition of "distribution" to clarify that the term only captures the transportation or delivery of tissues or cells intended for human application to the place where those tissues or cells will be used in human application.

Regulation 3(1)(a) amends regulation 7 of the Principal Regulations to require that, subject to the exemptions set out in paragraphs (4) and (5), anyone who imports tissues or cells intended for human application into the United Kingdom from a country which is not an EEA state or Gibraltar (i.e. from a "third country") must have a licence from the Authority to do so.

Regulation 3(1)(d) and (e) amend regulation 7(4) and (5) of the Principal Regulations to clarify the certain circumstances when the Authority can directly authorise, as opposed to requiring a licence for, the distribution, import into the United Kingdom from a third country, or export from the United Kingdom to a third country, of tissues or cells intended for human application.

Regulation 3(2) inserts new regulation 7A into the Principal Regulations, which prohibits import from an EEA state or Gibraltar unless the import is from a regulated tissue establishment, or from the person who is approved to procure those tissues or cells where certain conditions are satisfied.

Regulations 2(4)(a)(ii), 2(5), 3(1)(b),(c) and (f), 3(3)(a) to (c), 5(1), 7(1) and 9(2) and (3) make amendments which are consequential on the changes made by regulations 3(1)(a) and (2).

Regulation 3(3)(a) amends regulation 10 of the Principal Regulations to provide that it is a criminal offence to import tissues or cells intended for human application from a third country without a licence. Regulation 3(3)(b) further amends regulation 10 to provide that it is a criminal offence to import tissues or cells intended for human application from an EEA state or Gibraltar unless the circumstances set out in new regulation 7A apply. Regulation 3(3)(c) makes an amendment that is consequential upon these changes.

Regulation 3(4) amends regulation 11 of the Principal Regulations so that the Authority cannot grant a licence to import tissues or cells for human application from a third country unless they are satisfied that the applicant has complied with the requirements of the fourth Directive by providing specified information and documentation to the Authority. The information and documentation may have been provided with a previous application provided the Authority is satisfied the information and documentation is up to date. Provision is also made to enable the Authority to waive some or all of the documentation requirements in relation to one-off imports.

Regulation 4(1) omits regulation 15 of the Principal Regulations, which is no longer required.

Regulations 4(2) and 8(1) amend regulation 16 and Schedule 2 to the Principal Regulations to require the Authority to give directions to licence holders to secure compliance with the requirements of the fourth Directive and the coding Directive. These include directions in relation to the application of the Single European Code ("SEC") to tissues and cells intended for human application to identify them and to ensure their traceability from donor to recipient, notification of serious adverse events and reactions, the provision of updated information to the Authority, and the review of written agreements between the importing licence holder and any third country supplier.

Regulation 5(2) inserts new regulation 20A into the Principal Regulations to require the Human Tissue Authority ("the Authority") to take certain steps to ensure compliance with requirements imposed by the coding Directive relating to the application of the SEC.

Regulation 5(2) also inserts new regulation 20B into the Principal Regulations to make provision for the Authority to arrange for an inspection of third country premises, or relevant documents held by a third country supplier, or to carry out control measures in relation to an importing licence holder, if the Authority considers that it would be appropriate to do so following a request from a competent authority in an EEA state other than the UK, or in Gibraltar, in whose country the tissues or cells are subsequently distributed. Where a competent authority in another EEA state or in Gibraltar requests an inspection, arrangements must be made for the participation of that authority in the inspection, or reasons given why participation is not appropriate. Provision is also made in new regulation 20B for the Authority to arrange for an inspection of third country premises or relevant documents held by a third country supplier for the purposes of ascertaining whether tissues or cells imported into the United Kingdom for human application from a third country meet standards of quality and safety equivalent to those laid down in the Regulations.

Regulation 5(2) also inserts new regulation 20C into the Principal Regulations to make provision for the Authority to provide a copy of a report or information on any inspection of third country premises or relevant documents carried out under new regulation 20B, as well as information on the exercise of control measures in relation to an importing licence holder, where it considers it appropriate to do so, following a request from the European Commission or a competent authority in an EEA state other than the United Kingdom, or in Gibraltar.

Regulation 6(1) inserts new regulation 21A into the Principal Regulations to make provision for the Authority to inspect documents held by an importing licence holder who has imported tissues or cells intended for human application into the United Kingdom from a third country where there is a request from a competent authority in an EEA state or Gibraltar into whose country the tissues or cells have subsequently been or will be distributed, and where the Authority considers that it would be appropriate to do so.

Regulation 6(2) inserts new regulation 22A into the Principal Regulations to make provision for the Authority to inspect the premises of an importing licence holder following a request from a competent authority in an EEA state, other than the UK, or in Gibraltar into whose country tissues or cells are subsequently distributed, where the Authority considers that it would be appropriate to do so. Provision is also made for the competent authority making the request to participate in any inspection, or for the Authority to give reasons as to why such participation is not appropriate.

Regulation 6(3) amends regulation 27 of the Principal Regulations to make provision for the Authority to give a copy of a report or information on any inspection of records or documents carried

out under regulation 21 or 21A of the Principal Regulations, or on any inspection of premises under regulation 22 of the Principal Regulations to the European Commission or a competent authority in an EEA state, other than the UK, or Gibraltar at their request, where the Authority considers that it would be appropriate to do so. Regulation 6(4) amends regulation 28 of the Principal Regulations to make it an offence to fail without reasonable excuse to comply with a requirement under new regulation 21A.

Regulation 7(2) amends Schedule 1 to the Principal Regulations to require that when the Authority grants a licence authorising the import into the United Kingdom of tissues or cells intended for human application from a third country, it must provide the designated individual in relation to that licence with a certificate in the form set out in Annex II to the fourth Directive.

Regulation 9(2) and (3) amend the Act in consequence of the amendments made to the Principal Regulations. Regulation 9(4) amends paragraph 7 of Schedule 3 to the Act to enable the Authority to revoke a licence where it is not satisfied that any third country premises are suitable for carrying out activities in a manner which secures that tissues or cells imported from a third country will meet standards of safety and quality equivalent to those laid down in the Principal Regulations.

Regulation 10 makes transitional provision in relation to any licence that is in force immediately before the commencement date, where that licence authorises the import into the United Kingdom of tissues or cells intended for human application from a third country. This regulation provides that if the Authority is satisfied that the information and documents required by the fourth Directive have been provided by the licence holder (including those required for one-off imports, where applicable), the licence will be treated as a licence granted under the Principal Regulations as amended, and as authorising activities to which the new regulation 7(1A) applies. Provision is also made to clarify that the licence holder for that licence is to be treated as the importing licence holder for the purposes of the Principal Regulations, as amended. The Authority must provide the licence holder with a certificate in the form set out in Annex II to the fourth Directive.

Regulation 10(9) provides that where tissues or cells are in storage on 29th October 2016 and are transported or delivered to any person before the end of 29th October 2021, the new requirements in the Principal Regulations relating to the SEC, inserted by regulation 8(1)(b) and (c) of these Regulations, will not apply to those tissues or cells.

Regulation 10(11) provides that where tissues or cells were in storage on 29th October 2016 and are transported or delivered to any person on or after 30th October 2021, or where they were placed into storage after 30th October 2016 and are transported or delivered to any person at any time thereafter, the Authority will issue directions requiring application of the rules applicable to small labels in the coding Directive, namely that the SEC must be unambiguously linked to those tissues or cells through the accompanying documentation.

A Regulatory Impact Assessment and a Transposition Note have been prepared for these Regulations and a copy of each has been placed in the library of each House of Parliament. Copies of the Regulatory Impact Assessment and the Transposition Note can be obtained from the Health Ethics Team (Blood, Organ and Tissue Donation), Department of Health, 6th Floor, 39 Victoria Street, London SW1H 0EU.