



Department
of Health

Human Fertilisation and Embryology (Quality and Safety) Regulations 2017

A consultation on new regulations on the coding and
import of reproductive cells

March 2017

You may re-use the text of this document (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit www.nationalarchives.gov.uk/doc/open-government-licence/

© Crown copyright

Published to gov.uk, in PDF format only.

www.gov.uk/dh

Human Fertilisation and Embryology (Quality and Safety) Regulations 2017

A consultation on new regulations on the coding and import of reproductive cells

Contents

Executive summary	5
Chapter 1: Overview	6
Chapter 2: Summary of the Regulations	9
Chapter 3: Summary of Commission Directive (EU) 2015/565 on coding.....	11
Chapter 4: Summary of Commission Directive (EU) 2015/566 on imports.....	16
Chapter 5: Responding to the consultation	20
Annexes	22

Executive summary

The European Union (EU) has published two new Commission Directives. The first establishes a coding system to ensure the traceability of all human tissue and cells intended for human application, at all stages from procurement to final use. The second sets out procedures to verify that human tissue and cells imported from countries outside the EU/European Economic Area (EEA) meets the same quality and safety standards applicable to tissue and cells procured within EU/EEA Member States.

For reproductive cells (sperm, eggs and embryos), the Directives will be implemented by means of amendments made to the Human Fertilisation and Embryology Act 1990 by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2017.

The coding Directive requires an identifying code, in a specified format, to be applied to all reproductive cells at the point of procurement unless they are exempt from the need to be coded, such as a man's sperm used in the fertility treatment of his partner or any reproductive cells that will remain within the same establishment from procurement/creation to final use.

The import Directive requires establishments to be approved by the national competent authority, in the case of reproductive cells the Human Fertilisation and Embryology Authority (HFEA), to import these cells from non-EU/EEA (described in the Directive as "third country") establishments. The Directive sets out the information that must be provided in support of an application for authorisation to import and the duties placed on the HFEA and the United Kingdom Government.

On 23 June 2016, the EU referendum took place and the people of the United Kingdom (UK) voted to leave the European Union. Until exit negotiations are concluded, the UK remains a full member of the EU and all the rights and obligations of EU membership remain in force. During this period the Government will continue to negotiate, implement and apply EU legislation. The outcome of these negotiations will determine what arrangements apply in relation to EU legislation in future once the UK has left the EU.

The Government is aiming to have regulations in place to implement the Directives by Summer 2017.

This consultation document seeks views on a range of questions regarding implementation, including the estimate of the likely cost of implementing both Directives for establishments licensed by the HFEA and for the Authority itself.

Chapter 1: Overview

Introduction

This consultation document seeks views on a range of questions around the implementation of the coding and import Directives. Importantly, we need to test our assumptions of the likely cost of implementing both Directives for centres licensed by the Human Fertilisation and Embryology Authority (HFEA).

Background

Directive 2004/23/EC¹ (described here as the “Mother” Directive) was published in 2004 and set quality and safety standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells intended for human application. This included reproductive cells (sperm, eggs and embryos) intended for use in fertility treatment. The purpose of the Directive was to ensure that wherever a patient was treated within the European Union (EU) or in the Member States of the European Economic Area (EEA)², they could be assured that the human derived tissue and cells used in their treatment met the same quality and safety standards.

The Mother Directive included provision for a number of Commission Directives to be made to implement specific requirements. The first two were Commission Directive 2006/17/EC³ and Commission Directive 2006/86/EC⁴. All three Directives were brought into force, in respect of reproductive cells, by amendments made to the Human Fertilisation and Embryology Act 1990

¹ Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (31 March 2004).

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32004L0023>

² EEA member states include, in addition to the EU member states, Iceland, Lichtenstein and Norway. Although neither a member of the EU or the EEA, Switzerland is also part of the single market.

³ Commission Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (8 February 2006).

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006L0017&from=EN>

⁴ Commission Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (24 October 2006).

<http://eur-lex.europa.eu/legal-content/RO/TXT/?uri=celex:32006L0086>

(1990 Act) in 2007⁵. In section 1A of the 1990 Act they are referred to, respectively, as the “first”, “second” and “third” Directives.

Provision was also made for two further Commission Directives. These covered coding for traceability purposes and the importation of tissue and cells from countries outside the EU/EEA. Commission Directive 2015/565, amends Directive 2006/86/EC (the “third Directive”), and establishes a coding system to ensure traceability of all tissue and cells used within the EU/EEA from its initial procurement (or importation into the EU/EEA) through to final use.

Commission Directive 2015/566, which is freestanding, requires importing establishments to verify that the human tissue and cells imported from countries outside the EU/EEA, known as “third countries”, meets the same quality and safety standards applicable to tissue and cells procured from within EU/EEA Member States.

As before, the two Directives will be implemented by regulations that will amend the 1990 Act. These regulations are made under section 2.2 of the European Communities Act 1972, which provides a mechanism for bringing European legislation into United Kingdom (UK) law.

A draft version of The Human Fertilisation and Embryology (Quality and Safety) Regulations 2017 is at Annex A. Copies of Commission Directive (EU) 2015/565 and Commission Directive (EU) 2015/566 are at Annexes B and C respectively.

Implementation date

On 23 June 2016, the EU referendum took place and the people of the UK voted to leave the EU. Until exit negotiations are concluded, the UK remains a full member of the EU and all the rights and obligations of EU membership remain in force. During this period the Government will continue to negotiate, implement and apply EU legislation. The outcome of these negotiations will determine what arrangements apply in relation to EU legislation in future once the UK has left the EU.

The requirements of the Directives come fully into force on 29 April 2017. The Government is aiming to have regulations in place by Summer 2017

Impact of the Regulations and Directives

Summaries of the impact of the draft regulations and both Directives on the national regulator, the Human Fertilisation and Embryology Authority (HFEA), and licensed centres handling reproductive cells are at Chapters 2, 3 and 4 of this document.

⁵ Amendments were made to the Human Fertilisation and Embryology Act 1990 by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I.2007/1522), which came into force on 5th July 2007.

What will implementation cost

The impact assessment for the coding Directive is at Annex D and the import Directive at Annex E. These give a broad outline of the potential costs to the HFEA of implementing the Regulations and the potential compliance cost for its licensed centres.

Have your say

While the requirements of the two Directives are now fixed and amendments cannot be made, your views are invited on the draft regulations that will implement the Directives, on the two Impact Assessments and on any relevant issues that you feel the consultation document has not covered.

The Directives will be implemented in respect of all other types of human tissue and cells by The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2017. A separate consultation document seeks views on these regulations.

We look forward to receiving your views.

Chapter 2: Summary of The Human Fertilisation and Embryology (Quality and Safety) Regulations 2017

The Regulations amend the 1990 Act to bring the provisions of the coding and import Directives into force in respect of reproductive cells. The Regulations themselves do not set out what licensed centres are required to do to comply with the provisions in the Directives. This detail remains within each Directive and they are summarised at Chapters 3 (coding) and 4 (import). The Regulations are primarily concerned with setting out the duties of the HFEA and providing the Authority with the powers it needs to ensure that licensed centres are informed of what they must do to comply with the Directives and ensure that such compliance is achieved.

In considering the following summary it should be noted that in implementing the provisions of the coding and import Directives, different approaches have been used. As indicated in Chapter 1, the coding Directive solely amends the third Directive, so will not be referred to directly in either these regulations or in the 1990 Act. The import Directive is freestanding and, for that reason, will be described as the “fourth Directive” in both the Regulations and the 1990 Act.

The key provisions of the Regulations are summarised below:

Regulation 1

Citation, commencement and interpretation

Specifies the title of the Regulations, the date they come into force and defines some terms used within the Regulations.

Regulation 2

Designation of the competent authority

Confirms that the HFEA will be the competent authority for the coding and import Directives as they apply to reproductive cells.

Regulation 3

Amendments to the 1990 Act relating to the coding of gametes and embryos

Makes amendments to the 1990 Act to implement the provisions of the coding Directive. It sets out the duty of the HFEA to ensure that the Single European Code is applied to all reproductive cells, where that is necessary, by giving the Authority powers to make directions specifying what licensed centres must do to meet the requirements of the European coding system. It also enables the HFEA to add general conditions to all treatment and storage licences to require compliance with the European coding system.

Regulation 4

Amendments to the 1990 Act relating to the import of gametes and embryos

Determines that the import Directive will be defined as the “fourth Directive” in the 1990 Act.

The Regulation sets out the obligations of the HFEA if asked to carry out an inspection of an establishment by a Competent Authority in another EU/EEA Member State.

The Regulation also determines what requirements directions issued by the HFEA to licensed centres, on importing reproductive cells from third countries, must contain.

Regulation 5

Transitional provision

Any HFEA treatment or storage licence in force immediately before the commencement date of these regulations will be deemed to be subject to the new licence conditions governing the coding and importation of reproductive cells, until arrangements can be made to vary the licence to include the conditions.

Regulation 6

Transitional provision

Any reproductive cells in storage on 29 October 2016, that are distributed for human application, i.e. for use in treatment services, within 5 years of that date, will not be required to have the Single European Code applied to them, provided full traceability can be achieved by other means.

Consultation questions related to the draft regulations

Question 1: Do you have any comments on the draft regulations?

Chapter 3: Summary of the requirements of Commission Directive (EU) 2015/565 on the coding of tissue and cells for traceability purposes

A key principle underpinning the Mother Directive and the third Directive⁶ is that it must be possible to trace all tissue and cells (“tissue”) intended for human application at every stage of their journey from procurement to their final use in treatment. This becomes particularly important where an adverse reaction or adverse event is linked to the tissue.

The primary mechanism for traceability is the application to the tissue of an identifying Single European Code (SEC). Commission Directive 2015/565 (Annex B) amends the third Directive to bring this requirement into force.

The Articles in the Directive are summarised below:

Article 1

Definitions

New definitions are added to Article 2 of the third Directive. These include definitions of:

- Single European Code
- Donation identification sequence
- EU tissue establishment code (*which allows for continued use of existing 4 digit centre identification numbers allocated by the HFEA*).
- Unique donation number (*which allows for continued use of donor identification numbers allocated by individual centres and notified to HFEA. Alternatively, HFEA could choose to use a system generated unique donation number*)
- Product identification sequence
- Product code (*which allows for continued use of existing product codes in databases such as ISBT 128 and Eurocode*)
- Split number
- Expiry date (*for reproductive cells this will be the date that the sperm and egg provider’s consent, including the consent of the providers of the egg and sperm used to create an embryo, to storage or use expires*)
- EU Coding Platform
- EU Tissue Establishment Compendium
- EU Tissue and Cells Product Compendium
- “EUTC”
- Released for circulation
- Within the same centre

⁶ Commission Directive 2006/86/EC

The code must be eye readable. This can be in addition to another format, such as bar coding. The Directive specifies where breaks in the coding sequence should be inserted. The only time a code can be amended after allocation is if an error occurred in co

- Pooling

Traceability

The Article replaces existing provisions in the third Directive related to the traceability of tissue and a European coding system devised for that purpose.

The Single European Code

The principle vehicle for ensuring traceability is the application of the Single European Code. The code, which begins “**SEC**”, consists of the following sequences:

EU establishment code - consisting of the 2 alphabetic character ISO country code, which for the United Kingdom of Great Britain and Northern Ireland is “GB”, and 6 alpha-numeric characters i.e. the existing 4 digit HFEA centre number preceded by two zeros. This element of the code will continue to be provided by the HFEA and recorded centrally on the EU Tissue and Cells Establishment Compendium⁷.

Unique donation number – consisting of 13 alpha-numeric characters. The donation number coding system will be determined by the HFEA, as indicated earlier.

Product code - consisting of 1 alphabetic character product coding system identifier and 7 alpha-numeric characters. The product code will be provided centrally from the EU Tissue and Cells Product Compendium⁸.

Split number - 3 alpha-numeric characters, where this is applicable.

Expiry date - 8 numeric characters, i.e. DD/MM/YYYY.

The code must be eye readable. This can be in addition to another format, such as bar coding. The Directive specifies where breaks in the coding sequence should be inserted. The only time a code can be amended after allocation is if an error occurred in compiling the code. Any change to the code and the reasons for it must be fully documented by the establishment making the change.

The code would normally be applied to the label on the primary container and linked with the accompanying documentation. However, as containers for reproductive cells, such as straws, are likely to be too small for this to happen, the code must appear on accompanying documentation.

⁷ The EU Tissue and Cells Establishment Compendium will be managed centrally by the European Commission.

⁸ The EU Tissue and Cells Product Compendium will be managed centrally by the European Commission.

Application of the Single European Code

A code must be applied by the procuring or importing centre (or one of its third party service suppliers) if the reproductive cells are to be transferred to another establishment. It must not be applied by the receiving establishment or any subsequent establishment handling the cells.

In Transport IVF arrangements, where an IVF patient's eggs are collected at one centre, then taken to a second for the IVF process to be carried out, a code will not have to be applied to the eggs. This is because both establishments operate under the licence of the IVF centre. They are considered, for this purpose, to be one single operation, even though they are at different locations, operating under the supervision of the Person Responsible of the IVF centre.

Exemptions

A code does not have to be applied to:

- sperm used in a wife/partner's treatment (described as "Partner Donation" in the Directive).
- reproductive cells that are procured/collected/created, processed, stored and used within the same HFEA licensed centre, including reproductive cells imported into a licensed centre that remain within that centre where they are then used in treatment.
- reproductive cells in storage on 29 October 2016 that are distributed within 5 years of that date (see *transitional period* below).

There are also exemptions from coding for tissue and cells intended for immediate transplant or imported for emergency treatment. These exemptions are unlikely to apply to reproductive cells.

The HFEA, as the UK national competent authority for the Directive, has the responsibility for ensuring that the coding system is applied correctly by its licensed centres.

Accessibility and maintenance of the European coding system

The European Commission will host the EU coding platform and will be responsible for the EU Tissue and Cells Establishment Compendium and EU Tissue and Cells Product Compendium. It will ensure updates are made as needed. There is also a duty on the UK and other EU/EEA Member States to ensure notification is given to the Commission when either compendium needs updating.

The Directive gives the Commission the power to suspend the use of established coding systems, such as ISBT 128 and Eurocode, if they fail to comply with the requirements of the European coding system.

Documentation

Documentation is also key to traceability. The following data items, as a minimum, must be retained for at least 30 years using an appropriate and readable storage medium:

By the centre providing the reproductive cells for use in treatment, e.g. sperm bank

- Donor identification information, including:
 - Identification of procurement organisation, including contact details

- Unique donation number
- Date of procurement
- Place of procurement
- Type of donation, e.g. single or multiple uses
- Product identification, including:
 - Identification of relevant tissue establishment(s)
 - Type of tissue or cell, e.g. sperm, egg or embryo
 - Pool number (*unlikely to be applicable to reproductive cells*)
 - Split number, if applicable
 - Expiry date
 - Tissue/cell status, e.g. quarantined, released for use etc.
 - Description and origin of the product including the processing steps applied and the materials and additives that have come into contact with the reproductive cells that could have had an effect on their quality and/or safety
 - Identification of the establishment that issued the final label for the reproductive cells
- The Single European Code, if applicable
- Human application identification, including:
 - Date of distribution or disposal
 - Identification of the end user establishment.

By treatment clinic

- Identification of the supplying tissue establishment
- Identification of the end user
- Type of tissue or cells
- Product identification
- Identification of the recipient (*the woman into whom the reproductive cells are placed*)
- Date of application (*date of treatment where the reproductive cells are used*)
- The Single European Code, if applicable.

Transitional period

Application of the SEC will not be retrospective. Reproductive cells in storage on 29 October 2016 are exempt from the coding requirement, providing they are distributed for use within the EU/EEA within 5 years of that date and that full traceability can be achieved by other means.

Articles 2-4

Article 2 sets out the key implementation date of 29 April 2017, as indicated in Chapter 1.

Article 3 specifies the date the Directive came into force (29 April 2015) and Article 4 states that the Directive is addressed to all EU/EEA Member States.

Consultation questions related to coding

Activity

Question 1: Based on your current activities, how many times per year do you envisage applying the SEC to sperm, eggs or embryos at your centre?

Question 2: Can you identify any disadvantages that the coding Directive will bring to your centre?

Question 3: Is it practical to require that accompanying documentation should be sealed within secondary/tertiary packaging? Are there any circumstances where this would not be practical?

Cost implications

Question 4: Our impact assessment of the coding Directive relied on a number of assumptions to estimate the costs that NHS and private sector organisations will bear in complying with the Directive. These assumptions are described in paragraphs 23-44 of the impact assessment at Annex D. We would welcome your feedback on the appropriateness of these assumptions, particularly those that support our estimates of the costs of installing new IT, where required, or upgrading existing IT (paragraphs 34-38).

In responding you may wish to consider the following:

- **Much of the 40-digit alpha-numeric SEC can be generated using the information licensed centres already submit to the HFEA. Therefore, what is the extra cost to your centre of updating the IT system?**
- **For some establishments adding the SEC to accompanying paperwork (rather than the storage container) will require licensed centres to update existing labels and forms to accommodate the SEC. Will this be a cost to your centre?**
- **One-off transitional costs will include items such as dedicated staff time to familiarise themselves with the coding requirements and amending standard operating procedures. What is your estimate of these costs for your centre?**

Chapter 4: Summary of the requirements of Commission Directive (EU) 2015/566 on the import of tissue and cells from non EU/EEA, “third”, countries for human application

The primary purpose of the EU tissue and cells Directives is to give patients the assurance that all human tissue and cells used in their treatment meets the same high quality and safety standards regardless of the country of its origin. For that reason, all tissue and cells imported into EU/EEA countries for human application must meet the same quality and safety standards as that procured within EU/EEA Member States.

Exchanges of tissue and cells increasingly take place on a worldwide basis. The Mother Directive requires that imports of tissue and cells, including reproductive cells, are undertaken by establishments accredited, designated, authorised or licensed by the national Competent Authority, to verify the same level of safety and quality for imported tissue.

Many of the requirements in the import Directive have already been established via the HFEA’s general regulatory process. These include the HFEA carrying out inspections of centres that import reproductive cells, the use of general and special directions to authorise the import and export of reproductive cells and monitoring agreements with third country suppliers. Therefore, current import practices will be updated to take account of any additional requirements specified in the Directive.

The Articles in the Directive are summarised below:

Article 1: Scope

The provisions of the Directive apply to all HFEA licensed centres importing reproductive cells for human application from establishments outside the EU/EEA area, except in the following circumstances:

- one-off imports for use with a named patient, such as imports of a patient’s own sperm, eggs or embryos for use in a new treatment cycle at the importing centre
- imports directly authorised by the HFEA, such as cases of emergency treatment, so this exemption is unlikely to apply to imports of reproductive cells.

Article 2: Definitions

The Directive adds new definitions of:

- Emergency
- Importing tissue establishment
- One-off imports
- Third country supplier

Article 3: accreditation, designation, authorisation, or licensing of importing tissue establishments

Any centre wishing to import reproductive cells from a third country supplier will, in future, need specific authorisation from the HFEA to import from that supplier. The HFEA is proposing to modify the use of the general and special directions system that already regulates the import of reproductive cells, in future requiring centres wishing to import to apply for a direction to do so. The direction will approve import from a specific supplier with any conditions that may be attached to the import.

Once authorised, the centre will need to keep itself aware of any changes in the exporting establishment's practices that might impact on the quality and safety of the imported cells. If such changes occur, it is considered to be a substantial change to the existing authorisation. The HFEA must be notified and approval to continue to import from that establishment obtained.

Imports from any new supplier will also require approval from HFEA, as will any change to the type of reproductive cells the centre wishes to import (one-off imports are not covered by this provision).

The HFEA can revoke its authorisation if, at any time, evidence is found that the requirements of the Directive are no longer being met in relation to any specific import arrangement.

Article 4: Inspection and other control measures

Examination of importing arrangements will become part of the HFEA's inspection of centres holding such an authorisation. The HFEA will also provide information on the findings of inspections and other control measures to the Competent Authorities of other EU/EEA Member States, if requested to do so. HFEA can also inspect on behalf of those authorities.

The HFEA will have the power to inspect the premises of third country suppliers but this is only likely to be exercised in exceptional circumstances.

Article 5: Applications for accreditation, designation, authorisation or licensing as an importing tissue establishment

It will be for the Person Responsible at the importing centre, not the HFEA, to satisfy his or herself that the reproductive cells imported from a third country supplier meets the necessary quality and safety standards. The Person Responsible will be required to give this assurance to the HFEA when making an application for a direction to import.

Applications to import reproductive cells must be supported by the documentation listed in Annexes I and III of the import Directive. The HFEA will publish information on the format of applications and any additional information that needs to be provided.

The HFEA will determine what, if any, notification and/or information will need to be provided to it in respect of one-off imports for named patients.

Article 6: Updated information

As stated above, any changes to importing activities will require approval of the HFEA. Centres should also inform the HFEA if they end any or all import arrangements.

The same arrangement for reporting serious adverse reactions and events will apply to incidents involving imported reproductive cells. A serious adverse event could relate to an incident at the premises of the third country supplier that could affect the quality and safety of the imported tissue.

Centres must also report, without delay, any suspension or revocation of any national domestic authorisation to operate that is applicable to the third country supplier, together with details of any decision related to non-compliance taken by the third country’s national authority, which may be relevant to the quality and safety of the imported reproductive cells.

Article 7: Written agreements

A written agreement between the exporting and importing establishments must be in place, specifying the quality and safety requirements to be met to ensure equivalency with the standards applicable in EU/EEA Member States. The agreement shall include, as a minimum, the information listed at Annex IV of the import Directive. The agreement must also set out the right of the HFEA to inspect the activities, including the premises and facilities, of the third country supplier for the duration of the written agreement and for a period of 2 years following its termination, should it need to do so. A copy of the agreement must be provided to the HFEA.

Article 8: Register of importing tissue establishments

Licensed centres must keep a record of all imports. This includes: the type of reproductive cells imported, their origin and intended use. This information must also be collected for all one-off imports for a named patient’s use.

If approved, import will be added to the list of activities the centre is authorised to carry out on the HFEA’s website.

Article 9: transposition

Article 9 sets out the key implementation date 29 April 2017, as indicated in Chapter 1.

Articles 10 and 11

Article 10 (entry into force) specifies the date the Directive came into force (29 April 2015) and Article 11 (Addresses) that the Directive is addressed to all EU/EEA Member States.

Consultation questions relating to import

Question 1: Substantial changes to import activities, such as a change in third country supplier’s premises, will require prior written approval from the HFEA before imports can continue. What type of change do you think is “substantial” and, therefore, would need approval?

Question 2: It is the duty of the Person Responsible to assure the HFEA that the third country supplier operates to quality and safety standards equivalent to those of EU/EEA approved establishments. What steps do you think your centre will need to take to be able to provide the HFEA with this assurance?

Question 3: Our impact assessment of the import Directive relied on a number of assumptions to estimate the costs the NHS and private sector organisations will bear in complying with the Directive. These assumptions are described in paragraphs 18-36 of the impact assessment at Annex E. We would welcome your feedback on these assumptions, particularly our estimates of the costs of updating written agreements with third party suppliers (Paragraphs 25 – 30).

In responding you might wish to consider the following:

- **One-off transitional costs to licensed centres in order to implement the import Directive. These include: dedicated staff time to familiarise themselves with the requirements, amending standard operating procedures and updating third party agreements. What do you think will be the cost to your centre?**
- **Are there any other one-off or recurring costs that could affect your centre when integrating the import Directive into current practice, such as applying to the HFEA for authorisation? If so, please provide an estimate of these costs for your centre?**
- **The import Directive requires licensed import centres to have a written agreement with any third country supplier and to notify the HFEA when there is a change to the relationship. How many hours do you anticipate it will take your centre to comply with these requirements?**

Chapter 5: Responding to the consultation

The consultation process

This document seeks views on the draft regulations to implement new EU Commission Directives on the coding and import of reproductive cells intended for human application.

The consultation is being run in accordance with the Cabinet Office guidance on consultations, which is available at:

<https://www.gov.uk/government/publications/consultation-principles-guidance>

The closing date for the consultation is **Friday 7 April 2017**.

There is a response form with a full list of the questions we are asking in this consultation at Annex F. When returning the response form, please state whether you are responding as an individual or representing the views of an organisation. If you are responding on behalf of an organisation, please make it clear who the organisation represents.

Please send you responses by email to:

EUTissue&CellsConsultation@dh.gsi.gov.uk

Responses may also be submitted via web form at:

<https://www.gov.uk/government/consultations/coding-and-import-regulations-for-human-tissues-and-cells>

Alternatively by post to:

EU Tissue & Cells Consultation
Department of Health
Room 101/102
Richmond House
79 Whitehall
London SW1A 2NS

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

Consultations Coordinator
Department of Health
2E08, Quarry House
Leeds
LS2 7UE

E-mail: consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health Personal Information Charter, which can be found at:

<https://www.gov.uk/government/organisations/department-of-health/about/personal-information-charter>

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes, primarily the Freedom of Information Act 2000, the Freedom of Information (Scotland) Act 2002, the Data Protection Act 1998 and the Environmental Information Regulations 2004.

If you want the information that you provide to be treated as confidential, please be aware that, under the Freedom of Information Act, there is a statutory Code of Practice with which public authorities must comply and which deals, among other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department of Health.

The Department of Health will process your personal data in accordance with the Data Protection Act and, in most circumstances, this will mean that your personal data will not be disclosed to third parties.

Summary of the consultation

A summary of the responses to this consultation will be made available before or alongside any further action, such as laying legislation before Parliament, and will be placed on the Consultations website.

ANNEXES

This consultation document has the following annexes, which are published separately:

- Annex A: The Human Fertilisation and Embryology (Quality and Safety) Regulations 2017
- Annex B: Commission Directive (EU) 2015/565 on coding
- Annex C: Commission Directive (EU) 2015/566 on imports
- Annex D: Coding Impact Assessment
- Annex E: Import Impact Assessment
- Annex F: Consultation Questions