Title: Transposition of European Commission Directive (EU) 2015/565 as regards certain technical requirements for the coding of human tissues and cells **IA No: 13001** **Lead department or agency:** Department of Health **Other departments or agencies:**	Validation Impact Assessment (IA) **Date:** 12/04/17 **Stage:** Final **Source of intervention: EU** **Type of measure: Secondary Legislation** **Contact for enquiries:** DH Transplant Policy Emma Wilbraham emma.wilbraham@dh.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: GREEN

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANDCB in 2014 prices)	**One-In, Three-Out**	**Business Impact Target Status**
-£4.69m	-£1.42m	£0.17m	Not in scope	Non-qualifying provision

What is the problem under consideration? Why is government intervention necessary?

In 2007, the UK transposed European Directive 2004/23/EC into UK law. This Directive sets quality and safety standards for human tissue and cells intended for human application. It aims to ensure that regardless of where human tissue and cells are procured or used within EU Member States, they meet the same high quality and safety standards. A key requirement of the Directive, in relation to its safety objective, is that all tissue and cells must be traceable. The Directive mentions the Single European Code (SEC) as the key mechanism for achieving full traceability. However, it did not set out the details of how it should work in practice.

What are the policy objectives and the intended effects?

The ultimate aim is to make transplanted human cells and tissues safer by improving their traceability. The specific objective is to make the Single European Code operational in the UK.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 0 - Do nothing. This option has not been considered because of the UK's legal obligation to transpose EU Directives

Option 1 - Transpose European Commission Directive (EU) 2015/565 by copy-out, and therefore without gold-plating

Will the policy be reviewed? It will be reviewed. **If applicable, set review date: 05/22**

Does implementation go beyond minimum EU requirements?		No		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** No	**Large** No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** 0	**Non-traded:** 0	

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister: ..... ***Date:*** 28/11/2017

Summary: Analysis & Evidence

Policy Option 1

- **Description: Transpose European Commission Directive (EU) 2015/565 without gold-plating**
- **FULL ECONOMIC ASSESSMENT**

Price Base Year 2014	PV Base Year 2015	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -3.57	**High: -**5.81	**Best Estimate:-** 4.69

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	3.28	1	0.03	**3.57**
High	5.37		0.05	**5.81**
Best Estimate	4.33		0.04	**4.69**

Description and scale of key monetised costs by 'main affected groups'

The most substantial impacts are the estimated fixed costs of acquiring or upgrading IT. We expect 67 NHS organisations to bear IT total financial costs of £2.29 million, and 25 private sector companies (all small or micro sized) to incur IT costs of £0.85 million

Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low				
High				
Best Estimate				

Description and scale of key monetised benefits by 'main affected groups'

Other key non-monetised benefits by 'main affected groups'

There is currently a small risk that an inability to trace cells and tissue effectively could lead to harm to human health. The risk is possibly growing due to an increasing heterogeneity of cell and tissue sources. We are unable to estimate the benefit that implementing the new Directive would bring in terms of reducing the risk. However, we have estimated that in the UK the Directive would have to prevent between 6 and 10 deaths in order for the benefits to justify the costs.

Key assumptions/sensitivities/risks	**Discount rate (%)**	3.5

- **BUSINESS ASSESSMENT (Option 1)**

Direct impact on business (Equivalent Annual) £m:			
Costs: 0.17	**Benefits:** 0	**Net: 0.17**	**Not in scope of OITO**

Abbreviations used in this Impact Assessment

DIS – Donor Identification Sequence, part of the code that makes up the Single European Code

EU – European Union

EC – European Commission

HFEA - the Human Fertilisation & Embryology Authority, the UK Competent Authority that regulates use of gametes and embryos in fertility treatment and research

HTA - the Human Tissue Authority, The UK Competent Authority that regulates organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public.

IA – Impact Assessment

PIS – Product Identification Sequence, which, along with the DIS, makes up the Single European Code

QALY – Quality Adjusted Life Year, a standardised measure of health that combines information on both the length and quality of life

RPC – The Regulatory Policy Committee. The body that provides the government with external, independent scrutiny of new regulatory and deregulatory proposals.

SEC – Single European Code

TE – Tissue Establishment. A public or private sector organisation that is regulated in the UK either by the Human Tissues Authority or the Human Fertilisation & Embryology Authority

Evidence Base

Final Impact Assessment

1. This Final Impact Assessment includes assumptions that have been revised as a result of feedback from a public consultation that took place in March and early April 2017. Readers who wish to see how the original Consultation IA assumptions have changed may wish to refer directly to paragraphs 24 to 27.

2. On 23 June, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. The Government respected the result and triggered Article 50 of the Treaty on European Union on 29th March 2017 to begin the process of exit. Until exit negotiations are concluded, the UK remains a full member of the European Union 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.

Problem under consideration

3. In July 2007, the UK transposed European Directive 2004/23/EC[1] (referred to in this IA as the "mother Directive") into UK law. The mother Directive sets quality and safety standards for human tissue and cells intended for human application. It has been instrumental in raising operating standards in the UK and across Europe, towards the aim of ensuring that regardless of where human tissue and cells are procured or used within EU Member States, they meet the same high quality and safety standards.

4. A key requirement of the mother Directive, in relation to its safety objective, is that all tissue and cells must be traceable: from the original donor, through all processing and handling stages, to final use in the treatment of the recipient and back again. Such information is important not only for identification purposes but, where a patient suffers a serious adverse reaction, donors and other recipients can be traced quickly in minimise the risk of further harm.

5. The mother Directive mentions the Single European Code (SEC) as the key mechanism for achieving full traceability. However, it does not set out the details of how it should work in practice.

6. The use of identification/traceability codes is widespread in the EU within human tissue donation, although coding is little used in the reproductive sector. Where codes are used, a variety of systems currently exist: from internationally recognised systems such as ISBT 128[2], to nationally applied systems, such as Eurocodes[3] and individual tissue establishments' own coding systems. The lack of a centrally co-ordinated coding framework means that the value of the coding can be limited if the tissue or cells moves to an establishment unfamiliar with the coding system that the supplying establishment uses.

7. Although the UK has not experienced any major incidents involving problems with identification or traceability in the past, tissue and cells now regularly move between tissue establishments and across international borders, making the need for an internationally recognisable identification code more important in order to mitigate future patient safety risks.

Policy objective

8. The ultimate aim of the policy is to make transplanted human cells and tissues safer by improving their traceability. The specific objective is to make the Single European Code operational in the UK.

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

[2] ISBT 128 is a global standard for the identification, labelling, and information transfer of medical products of human origin (including blood, cells, tissues, milk, and organ products) across international borders and disparate health care systems. It is operated by the International Council for Commonality in Blood Banking Automation (ICCBBA), a not for profit organisation based in the USA. Use of the ISBT 128 coding system is mandatory in some EU Member States.

[3] Eurocodes was developed by the European Committee for Standardisation. They are primarily used in Germany.

Description of options considered

Option 0. Do nothing

9. The use of codes to facilitate identification and traceability is not currently subject to any regulatory controls in either the UK or the EU. However, the traceability of cells and tissue in the UK is already effective.

10. With the exception of reproductive cells (sperm, eggs and embryos), coding is already widely used. Although the UK has no mandatory coding system, the most commonly used coding system in the UK is ISBT 128. Some tissue establishments use their own coding systems.

11. Coding has not been adopted in the UK reproductive sector, largely because, with the exception of sperm banks providing donated sperm to HFEA licensed clinics, the movement of gametes and embryos between establishments is on a small scale and usually in response to individual patients wishing to move their own stored material to another clinic. Traceability from donor to recipient and back again is already achieved because of the requirement in the Human Fertilisation & Embryology Act 1990 for every treatment cycle involving the use of donated gametes or embryos to be reported to the national regulator, the Human Fertilisation & Embryology Authority (HFEA). The HFEA maintains a register of every treatment cycle, recording information about the patients treated together with information to allow the donor of gametes or embryos used in their treatment to be identified, including donors of reproductive cells procured from outside the UK. This is to enable donor-conceived people to trace their parentage.

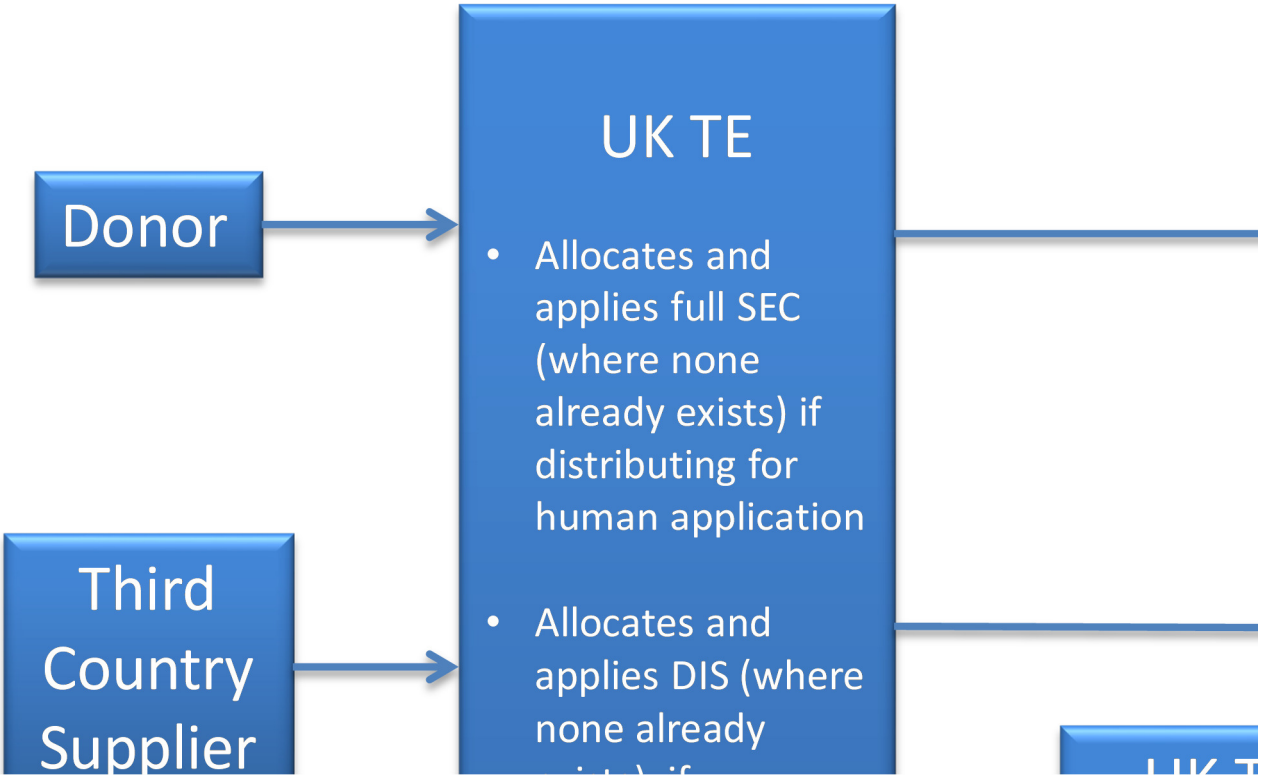
Option 1. Implement Commission Directive (EU) 2015/565

12. Commission Directive (EU) 2015/565 (referred to as the Coding Directive in this IA) sets out the SEC's operational details.

13. Each "tissue establishment"[4] (TE) will be required to allocate and apply an eye-readable SEC to each cell and tissue product that is not exempted by the Directive. The SEC is in two parts. The first part is the "Donation Identification Sequence" (DIS), which uniquely identifies the donation and the EU TE that originally sourced the tissue, either directly from a donor or from a third country supplier. The second part of the SEC is the "Product Identification Sequence", which identifies the type of product (for instance, skin or bone), its expiry date and a "split number" to signify where a single donation has been split for transplant in more than one recipient.

14. The responsibilities of UK TEs for allocating and applying SECs are summarised in the following diagram:

[4] This is the nomenclature used in the Directive and refers to organisations that deal with the sourcing, storage, processing and distribution of human cells and tissues.



15. In cases where a UK TE sources cells and tissues either directly from donors or from third country suppliers (i.e., from outside the EU) but who does not release the products for "human application", the TE is required, as a minimum, to apply the DIS to the product or in accompanying documentation.

16. When a UK TE releases a product for "human application", it must make sure that a full SEC (both the DIS and PIS) has been applied. In some cases either the DIS or full SEC will already have been applied by another UK or EU TE.

17. When a UK TE only has a storage role (ie, it does not source donations directly from a donor or a third country supplier, and does not release products for "human application"), it does not have to do anything provided that a DIS has already been correctly associated with the tissue.

18. The Directive allows for a number of exemptions covering particular circumstances where the DIS or full SEC does not have to be allocated and applied:

    - Reproductive cells from partner donation
    - Tissues and cells distributed directly for immediate transplantation to the recipient
    - Tissues and cells imported in the Union in the case of emergency authorised directly by the competent authority

19. In addition, Member States may allow the following exemptions.

    - Tissues and cells other than reproductive cells for partner donation, when these tissues and cells remain within the same centre

- Tissues and cells that are imported into the Union, when these tissues remain within the same centre from importation to application, provided that the centre comprises a tissue establishment "authorised, designated, accredited, or licensed" to carry out importing activities.

20. The UK will apply these additional exemptions.

21. Where the packaging of products is too small to make the direct application of the DIS or full SEC possible, the Directive allows TEs to apply the code to accompanying documentation.

22. The Directive provides transitional arrangements for products that are already in storage when the transposition period expires. Such products are exempted from the requirement to allocate and apply the SEC provided that they are released for circulation within the EU within five years. Where products remain within deep freeze storage beyond this transition period, the Directive allows the TE to apply the DIS or full SEC to documentation that is linked to the product.

23. The Directive requires competent authorities to keep the EC's database of EU Tissue Establishments (called the Tissue Establishment Compendium) updated when changes occur to the "accreditation, designation, authorisation or licence of a tissue establishment".

Monetised and non-monetised costs and benefits of each option

Feedback from the consultation

24. In March and early April 2017, we conducted a public consultation on the implementation of the Coding Directive. As part of this exercise, we targeted 14 tissue establishments (5 from the private sector) with telephone interviews. These 14 were chosen because they were regarded as being broadly representative of the establishments that will be significantly affected by the Directive. Two of the private sector interviewees were specifically targeted because they had already started implementing the changes and therefore had direct experience of the cost implications.

25. The telephone interviews gained feedback on the assumptions behind the estimated cost impacts reported in the Consultation IA. In particular, the interviews sought information on the assumptions that the Regulatory Policy Committee (RPC) had highlighted as needing verification in its "green rated" opinion on our Consultation IA.

26. In many instances, feedback from consultees and interviewees supported the assumptions made in the Consultation IA. However, there were a number of cases where the feedback prompted us to change our assumptions:

    - The RPC asked us to check our estimates of familiarisation costs. While some stakeholders supported the consultation IA assumption about the time that stakeholders will take to become familiar with the new requirements, a majority felt that the assumption was an underestimate, particularly when taking into account the time taken for developing action plans. From suggestions given by interviewees, we therefore increased its assumption from between 2 and 5 days to between 5 and 15 days. All interviewees supported our original assumption about the cost per day of staff time. The revised familiarisation cost estimate is described in paragraphs 36 to 38.

    - The RPC also asked us to verify our assumption about the costs of changing Standard Operating Procedures. Most interviewees supported our original estimate of £2,000 but some felt that £4,000 was a better estimate. The assumption has therefore now been expressed as a range from £2,000 to £4,000. The revised estimated is described in paragraph 39.

    - The Consultation IA assumed that establishments that use computerised systems for allocating and applying codes would not experience on-going variable costs. The RPC asked for this assumption to be verified. While the majority of interviewees (including the two public sector establishments that will account for the majority of coding activity in the UK) agreed with this assumption, a minority of interviewees mentioned that the labels that they currently use cannot be adapted to accommodate

the new code. Additional labelling may therefore be required in some cases. Our estimates are described in paragraphs 47 to 54.

- For those establishments that opt to code manually, we had previously assumed that generating a new code would take 10 to 15 minutes of staff time. The RPC asked us to verify this assumption. Although stakeholders generally supported our assumption about the unit cost of staff time, some interviewees felt that the task would take longer, particularly because it will involve double checking the accuracy of the code. From feedback gained from consultees we have therefore assumed that the task will take between 10 and 30 minutes. The revised estimate is described in paragraph 46.

- We had previously noted that some establishments might have to purchase new printers. Only a minority of consultation interviewees said that this would be necessary. Based on this feedback, we have assumed that 25% of establishments that will have to apply codes frequently will purchase new printers. Feedback also suggested that the average cost of an appropriate printer is £500. The new estimate is described in paragraph 44.

- The RPC noted that we had mentioned but not included the regulator costs in the Consultation IA. In the case of the HFEA, the incremental costs will be negligible and will not be passed on to establishments. In the case of the HTA, costs will be passed on in the form of marginally increased fees. These incremental costs are described in paragraph 55 to 58.

27. The consultation process confirmed the Government's approach to transposition, which is by copy-out into UK regulations in order to meet the minimum requirements to comply i.e. no gold-plating. The Government will proceed with making the regulations and intends to complete the transposition by the parliamentary Summer Recess 2017.

Option 0 – Do nothing more than is already being done

28. Option 0 is the counterfactual against which the incremental costs of and benefits of Option 1 are measured. Therefore, by definition, no incremental costs and benefits are associated with Option 0. It is interesting to note that in theory, if the UK continued to do nothing to transpose the Directive, the EC would start infraction proceedings, the result of which could be periodic fines that the UK would be required to pay in perpetuity.

Option 1 – transpose and implement the Directive

29. There are two UK competent authorities relevant to the implementation of the Coding Directive.

30. The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator overseeing the use of gametes[5] and embryos in fertility treatment and research. HFEA regulates 79 TEs that will be affected to a greater or lesser extent by the Directive. Of these, 52 are private sector organisations and the remaining 26 are NHS facilities. Information on the size of the private sector organisations is not held by HFEA but the likelihood is that most, if not all, fall into the "small" category. For the purposes of this IA, we have assumed that all 52 companies are small.

31. The other UK competent authority is the Human Tissue Authority (HTA), which regulates organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public. It also gives approval for organ and bone marrow donations from living people. HTA regulates 145 TEs that will be affected by the Directive. Of these, 35[6] are privately operated and the remaining 110 are NHS. We have been informed by an industry source that all of the privately operated TEs fall into the small business category.

32. In total, therefore, there will be 224 TEs affected by the Directive, 137 of which are NHS, and the remaining 87 are small private businesses.

[5] Gametes are reproductive cells that unite at fertilization to form a new cell called a zygote.

[6] Figure from 2015. Figures fluctuate but 2015 was a reasonably representative year.

33. Among the 224 TEs there is considerable variability in the extent to which individual TEs will be affected by the Directive. Of the TEs regulated by the HFEA, only 4[7] (all private) are expected to have to allocate and apply DISs or full SECs on a frequent basis. The remaining 75 TEs will benefit from the "same partner" exemption and will either have to apply SECs rarely (two or three times in a typical year) or not at all. In the absence of further disaggregated information and to avoid under-estimating costs, we have assumed that all 75 TEs that benefit from exemptions will code two or three times a year.

34. The HTA has estimated that 31 (15 private) of the TEs it regulates will frequently have to allocate and apply either a DIS or the full SEC. A further 33 (6 private) are expected to have to code rarely (two to three times in a typical year) and 24 (6 private) are expected not to have to code at all. The remaining 57 (6 private) will have to undertake a currently unknown level of coding because much of their activities are likely to be covered by exemptions, such as the "same centre" exemption. In the Consultation IA, for the sake of avoiding under-estimates, we assumed that all of these 57 would fall into the "frequent coding" category. In this Final IA, we have maintained this assumption because in many cases, it is unlikely that all of a TE's products will be covered by exemptions. Given that the variable incremental costs of coding using automated systems are very small, a reasonable response by TEs in such cases would be to apply a code to all their products to avoid the costs of maintaining separate labelling processes.

35. Table 1 provides a summary of these categorisations.

Table 1. UK Tissue Establishments affected by the Coding Directive

	Total		Frequent coding		Rare coding		No coding	
	NHS	Private	NHS	Private	NHS	Private	NHS	Private
HFEA regulated TEs	27	52	0	4	27	48	0	0
HTA regulated TEs	110	35	67	21	27	6	18	6
Total TEs	137	87	67	25	54	54	18	6

Familiarisation

36. The Directive is a technical document that cannot be understood in a short period. We have therefore assumed each of the 224 TEs will have to spend between 5 and 15 days[8] of staff time familiarising themselves with the requirements, even if they consequently discover that their activities are exempt from the Directive's requirements. We have assumed a full staff cost (salary and non-salary costs) per day of £263[9] for both the NHS and the private sector. These assumptions yield one-off estimated costs of between £180,000 and £540,000 for the NHS, and between £114,000 and £343,000 for the private sector.

37. Department of Health impact assessment guidance requires that Quality Adjusted Life Year (QALY) opportunity costs should be used in the analysis of cost impacts on the NHS. Recent research indicates that at the margin, the NHS[10] loses 1 QALY for every £15,000 it has to divert away from spending on curative treatment. The costs associated with complying with the Coding Directive have an impact on the NHS England, NHS Scotland, NHS Wales and NHS Northern Ireland budgets that are available for funding treatment.

38. The opportunity costs of the resources that the NHS spends on familiarising itself with the Coding Directive can therefore be measured as being approximately between 12 and 36 QALYs.

[7] There are five large centres but we expect that the activities of one them will be covered entirely by the "same partner" exemption.

[8] This assumption was increased after conversations with stakeholders during the public consultation. The original assumption was 2 to 5 days.

[9] Derived from ASHE (2014 provisional) SOC10 2462 "Quality Assurance and regulatory professional". We assumed 225 working days a year and added 30% to account for non-salary costs. This cost assumption was verified during the public consultation in March and April 2017

[10] The research focussed on the NHS in England. We have assumed that the same applies to the NHS in the Devolved Administrations.

Changes to Standard Operating Procedures, Service Level Agreements and Staff Training

39. We currently expect that of the 224 TEs that familiarise themselves with the requirements, 200 (121 NHS and 79 private) will discover that they will have to take further action. Feedback from the public consultation indicated that the costs of changing Standard Operating Procedures and Service Level Agreements, and training staff would be between £2,000 and £4,000[11]. The estimated costs are therefore between £242,000 and £484,000 for the NHS and between £158,000 and £316,000 for the private sector. The opportunity cost for the NHS is between 16 and 32 QALYs.

Code allocation

40. Although in practice, code allocation and application of the code to the product will often occur as part of the same process, it is easier to treat them as separate processes for the purposes of estimating cost impacts. A TE that has to allocate either DISs and/or full SECs will have to generate the relevant code through some type of repeatable process. The sophistication of that process will depend on the frequency that a TE has to allocate a code. Among the private and public sector that we consulted during the preparation of this Final IA, the unanimous opinion was that in cases where code allocation would have to be performed frequently, a computerised system would be required. By contrast, where codes will be allocated rarely, manual systems, possibly aided by a simple spreadsheet, would be adopted.

41. In table 1, we reported our estimate that 92 TEs (25 private) will have to allocate codes frequently. In discussions with TEs, we discovered that all of the data inputs that an SEC-ready system needs in order to generate the relevant code is either already routinely recorded by TEs on their existing IT systems or would only have to be recorded once because the relevant part of the code does not vary between individual SECs issued by a single TE. We therefore have assumed that, for TEs that will have to code frequently, there are no incremental variable costs associated with code allocation. The only incremental costs are the fixed costs of acquiring new IT systems or upgrading existing IT systems. This finding was verified through interviews with 15 TEs (5 private sector) during the public consultation.

42. Our discussions with TEs also revealed that there is considerable heterogeneity among TEs in terms of both the type of IT systems that the TEs currently operate and the extent to which the existing IT can be upgraded. We have therefore assumed a range of possible costs and applied it to each TE.

43. We estimate that there are 92 TEs (of which 25 are private) that will seek an IT solution to allocating codes. During interviews with TEs conducted during the public consultation, we received widespread agreement that the IT cost assumptions used in the consultation IA reflect reality. We have therefore stuck with the following assumptions. The cost of upgrading existing IT systems to become SEC capable is £8,000. The cost installing new SEC capable software is £20,000. The cost of setting up and validating both new and upgraded software is £20,000. We have assumed that the range £28,000 to £40,000 covers the costs of achieving SEC capability from the two possible starting points – either upgrading existing IT costs or installing new IT. Our estimate of the IT costs ranges from £1,876,000 to £2,680,000 for the NHS and from £700,000 to £1,000,000 for the private sector. The QALY opportunity cost to the NHS is between 125 and 179 QALYs.

44. Feedback from the consultation interviewees revealed that a minority of TEs that will code frequently will purchase a new printer. While the majority will use their existing printers, 3 out of the 14 interviewees (all of whom will be coding frequently) said that a new printer would be necessary. The cost of the printers was quoted as being between £400 to £1,000, although the more expensive printers would have greater functionality and would be used for purposes other than just printing SEC codes. We have therefore assumed that 25% of TEs that code frequently will purchase a new printer at a unit cost of £500. These assumptions give rise to an estimated printer purchasing cost of £8,000 for the NHS and £3,000 for the private sector. The opportunity cost to the NHS is less than 1 QALY.

45. While TEs are not obliged to adopt any particular coding standard for allocating the SEC, we became aware during our informal consultations that the ISBT 128 coding standard is widely used. Use of the ISBT 128 standard requires the payment of an annual licence fee, which ranges from US$218 to US$346 (£136 to

[11] The consultation IA assumption was £2,000.

£216[12]), depending on the scale of the TE's operations. We have assumed that these fees are representative of fees charged by other IT coding standards organisations. The estimated annual cost of licence fees is therefore between £9,000 and £15,000 for the NHS and between £3,000 and £5,000 for the private sector. The opportunity cost for the NHS is 1 QALY.

46. For the 108 (54 private) TEs that we expect will only have to allocate SECs two or three times a year, we have assumed that the only incremental costs associated with allocating SECs will be the variable costs of manually generating a code each time one is needed. The validity of this assumption was confirmed during the interviews that we conducted during the public consultation. Based on additional feedback from the consultation interviews, we have assumed that each code allocation performed manually takes between ten and thirty minutes[13], and that the staff cost per minute for relevant NHS and private sector staff is £0.40[14]. Our estimate of the annual incremental variable costs for manual coding therefore ranges from £500 to £1,900 for both the NHS and the private sector.

Table 2 presents the mid-point estimates for code allocation.

	First year	Each subsequent year
NHS opportunity costs (QALYs)	153	1
Private sector costs	£858,000	£6,000

Code application

47. The unanimous view among the TEs that we interviewed during the public consultation is that the incremental variable costs of applying codes to products will be either non-existent or small[15]. All TEs already have to apply existing identification codes either to packaging or accompanying documentation. In most cases there will be no additional variable cost in physically applying them to products or documentation.

48. However, the consultation interviews revealed that a minority of TEs may incur incremental on-going costs. These costs will arise because existing labels cannot be adapted to accommodate the SEC code. In such cases additional labels may need to be attached to product packaging.

49. These additional labelling costs will not apply to HFEA regulated TEs. The size of packaging used in the human reproductive sector is small and hence codes will be included in accompanying documentation.

50. The situation regarding HTA regulated TEs is less clear. HTA has confirmed that the "accompanying documentation" solution will be available for TEs whose existing product labels cannot be adapted to accommodate the SEC. However, there are other circumstances where an additional label might be required. To avoid under-estimating costs, we have taken a liberal approach to estimating the number of additional labels that will in practice be required.

51. Importantly, NHSBT, which is the largest public sector TE in the UK, has reported to us that it will not have to adopt the additional label solution. Excluding NHSBT's product units, HTA has estimated that approximately 87,000 product units are produced annually in the UK by HTA regulated TEs. HTA estimates that at least 64,000 of these product units will not require an additional label either because of exemptions provided in the Coding Directive or because the "accompanying documentation" solution will apply. We have assumed that all the remaining product units will require additional labels. This is a worst case scenario but fits with our approach of avoiding underestimated costs.

[12] Converted using HMRC annual average exchange rate to 31 March 2015.

[13] This assumption was increased as a result of responses from several interviewees during the consultation. The original assumption was 10 to 15 minutes. While some interviewees agreed that the original was about correct, others felt that double-checking the code would take a longer time.

[14] NHSBT provided a figure of £40,000 as the salary and non-salary staff cost of a relevant member of staff. We have assumed 225 working days a year and 450 working minutes a day. This assumption was broadly supported by interviewees during the public consultation.

[15] The consultation IA mentioned the possibility that TEs might have to find ways of applying codes to the packaging of tissues that have already been deep frozen. This would have presented technical challenges and the risk of damage to products. However, the HTA has adopted a pragmatic approach that allows TEs to apply codes to accompanying documentation. This removes substantial difficulty and cost.

52. Private sector TEs account for approximately 31% of the HTA-regulated sector and hence, under our liberal assumptions, they will have to apply approximately 7,000 additional labels a year. Non-NHSBT public sector TEs that code frequently will have to apply codes to approximately 16,000 additional labels a year.

53. Interviewees suggested that the cost per additional label ranges from 40 to 63 pence. This includes the costs of the label, printer consumables and the staff cost of printing and applying the label.

54. These assumptions lead us to estimate that private sector costs of applying additional labels will range from £3,000 to £5,000 a year, while the costs to the NHS will be between £7,000 and £10,000 a year. The opportunity cost to the NHS is less than 1 QALY.

Competent Authority responsibilities

55. HFEA has assessed the extra responsibilities that the Directive imposes on competent authorities and believes that the incremental costs will be insignificant in its case.

56. HTA has identified the following additional activities that the Coding Directive will require it to perform:

    - Dealing with SEC related enquiries
    - Updating the EC compendium
    - General administrative work
    - On-going policy work

57. From performing these activities, HTA has estimated that it will bear an annual incremental staff cost of approximately £9,000. Because HTA is a government trading fund, it will be obliged to recover these incremental costs through fees charged to TEs. The private sector will bear approximately £3,000 of the annual incremental costs, while the NHS will bear approximately £6,000. The opportunity cost to the NHS is less than 1 QALY.

58. Over the coming years HTA expects to operate within its current resources. It will therefore seek efficiencies in other fee areas within the Human Application sector to offset the fee increases made necessary by the Coding Directive. The effect of this fee balancing is not included in this IA.

Cost summary

59. Table 3 summarises the opportunity costs impact of the Coding Directive on the NHS. The first part collates the QALY impact information that appears in earlier sections of this IA, and adds ten year present values. The second part reports the conversion of the QALY impact into monetary terms using DH's standard willingness to pay QALY valuation of £60,000.

Table 3. Summary of NHS Opportunity Costs

NHS Opportunity Cost	First year	Each subsequent year	10 year Present Value (1.5% discount rate)
QALY opportunity costs			
Lower estimate	155	2	168
Higher estimate	250	2	268
Midpoint estimate	202	2	218
£ Opportunity costs			
Lower estimate	£9,314,000	£90,000	£10,068,000
Higher estimate	£14,974,000	£133,000	£16,083,000
Midpoint estimate	£12,144,000	£111,000	£13,075,000

60. Table 4 reports the Coding Directive cost impact on the private sector, including ten year present values and the Equivalent Annual Net Cost to Business. All costs reported in the table are direct costs.

Table 4. Summary of Private Sector Costs

Private Sector Cost	First year	Each subsequent year	10 year Present Value (3.5% discount rate)	EANCB
Lower estimate	£985,000	£10,000	£1,058,000	£123,000
Higher estimate	£1,675,000	£15,000	£1,787,000	£208,000
Midpoint estimate	£1,330,000	£12,000	£1,422,000	£165,000

Table 5. Summary of NHS Opportunity Costs and Private Costs

	First year	Each subsequent year	10 year Present Value (1.5 % and 3.5% discount rates)
Lower estimate	£10,298,000	£100,000	£11,125,000
Higher estimate	£16,649,000	£147,000	£17,870,000
Midpoint estimate	£13,474,000	£124,000	£14,498,000

Table 6. Summary of NHS and Private Sector Financial Costs

	First year	Each subsequent year	10 year Present Value (3.5% discount rates)
Lower estimate	£3,313,000	£32,000	£3,575,000
Higher estimate	£5,418,000	£48,000	£5,808,000
Midpoint estimate	£4,366,000	£40,000	£4,691,000

Benefits

61. It is likely that the implementation of the Coding Directive will provide only minimal increased benefit to patients in terms of quality and safety, including those treated in the reproductive sector, because existing arrangements largely fulfil the aims of the Directive.

62. Paragraph 7 of this IA notes that the UK has not yet experienced any major incidents involving problems associated with the traceability of cells and tissues. However, the growing complexity of global trade in human cells and tissues means that the risks could be growing.

63. Without knowing the future probability of a major incident occurring in the UK, the health and wider economic impacts that it would have, and the reduction in risk that implementing the Coding Directive would bring, it is impossible to estimate the Coding Directive's UK benefits. However, by making a number of assumptions, one can exemplify the health impact of a major incident. Let us assume that the incident causes the death of a person who is of the UK average age (37) and who enjoys the average health of a person of that age. The Department of Health has estimated that such a person could have expected to enjoy 30 more Quality Adjusted Life Years (QALYs) had death not occurred. DH has also estimated that society values a QALY at £60,000. Hence the cost to society of this premature death would be £1.8 million.

64. This figure suggests that the implementation of the Coding Directive in the UK would have to prevent between 6 and 10 such deaths over 10 years in order to justify its costs[16]. We are not in a position to comments on the likelihood of this happening.

65. The TEs that we have consulted were unable to identify any business benefits that compliance with the Coding Directive will bring.

Rationale and evidence that justify the level of analysis used in the IA

66. For this Final IA, we have used consultation responses and worked with the UK competent authorities (HFEA and HTA), 9 NHS TEs and 5 TEs to verify and improve the estimates that we presented in the Consultation IA. We have concentrated our resources on reviewing the estimates that the RPC specifically asked us to verify and any other estimates that contribute substantially to the overall cost burden. We have therefore spent the greatest proportion of our time checking our estimates of:

    - Familiarisation costs
    - Costs of changing Standard Operating Procedures
    - The existence of recurrent costs for TEs that will code frequently
    - The costs of upgrading or acquiring new IT equipment
    - The time taken to manually code an SEC
    - The costs that the Competent Authorities will incur and pass on to TEs

Risks and assumptions

67. Significant remaining uncertainties have been incorporated into our analysis by adopting wide ranges for important assumptions.

68. In the Consultation IA, we noted that there was a risk that the legal interpretation of the Coding Directive would prevent the HTA from allowing its TEs from applying the SEC to accompanying documentation of products that have already been deep-frozen. This would have substantially increased costs and risked harm to brittle, deep frozen products. It is now clear that TEs will be allowed to apply the SEC to accompanying documentation.

Direct costs and benefits to business calculations (following OITO methodology)

69. We have estimated that that Equivalent Annual Net Cost to Business (EANCB) ranges from £123,000 to £208,000 (midpoint £165,000). This impact falls out of scope of OITO because it relates to the transposition of an EU Directive, and no gold-plating has been applied.

Wider impacts

Small and micro businesses

70. We have been informed by private sector stakeholders that all the 87 private sector TEs that will be affected by the Coding Directive fall into the small and micro business categories. Our estimates show that by far the greatest cost impact will be felt in terms of fixed IT costs. We have estimated that the average IT cost for each of the 65 private sector TEs that we expect will adopt an IT based coding solution will range from £28,000 to £40,000.

71. The TEs that we have consulted suggested that the greatest disproportionate impact will be felt in terms of temporarily diverting specialist staff's time away from their daily activities towards understanding, planning

[16] To simplify this estimate, we have used undiscounted figures. We have also excluded the benefits that would accrue because GDP losses would be avoided.

and implementing the SEC. While larger organisations tend to employ staff who are specifically assigned these tasks, smaller organisations do not have this luxury. We have estimated that the cost of familiarisation per company will be between £1,000 and £4,000, while the cost of updating SOPs (for the 79 companies that we expect will have to allocate and apply SECs) will be between £2,000 and £4,000.

72. We have not conducted a full Small and Medium Business Assessment (SaMBA) because EU Directives fall out of scope and we are not able to adapt the provisions depending on the type of business involved. However the Competent Authorities have discussed detailed operational aspects with the full range of TEs, including small businesses, to make sure the accompanying guidance fully reflects the way their businesses operate.

Competition assessment

73. Does the Directive:

1. Directly limit the number or range of suppliers?

No. The Directive places no direct limit on who can compete in the market

2. Indirectly limit the number or range of suppliers?

No. The Directive will treat all TEs equally, regardless of whether they are existing suppliers or new. The costs associated with the Directive do not pose a significant barrier to entry into the market.

3. Limit the ability of suppliers to compete?

No. The Directive places no controls on price, product characteristics, quality standards, innovation, geographical coverage, advertisement, production processes or organisational form.

4. Reduce suppliers' incentives to compete vigorously?

No. The Directive does not exempt suppliers from general competition law, introduce or amend intellectual property regime, require or encourage the exchange between suppliers, or publication, of information on prices, costs, sales or outputs, or increase the costs to customers of switching between suppliers.