Title: Transposition of European Commission Directive (EU) 2015/565 as regards certain technical requirements for the coding of human tissues and cells **IA No:** **Lead department or agency:** Department of Health **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 23/09/15 **Stage:** Consultation **Source of intervention:** EU **Type of measure:** Secondary legislation **Contact for enquiries:** Triona Norman triona.norman@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** (EANCB on 2009 prices)	**In scope of One-In, Two-Out?**	**Measure qualifies as**
£-12.18m	£-1.09m	£0.13m	No	NA

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 by 29 April 2017 (the deadline for transposition).

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:** 05/2022

Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** 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, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: _____ Date: _____

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2015	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 10.05	**High:** 14.26	**Best Estimate:** 12.14

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	9.70		0.04	**10.05**
High	13.74		0.07	**14.31**
Best Estimate	11.72		0.06	**12.18**

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 opportunity costs of £10.6 million, and 25 private sector companies (all small or micro sized) to incur IT costs of £0.9 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	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
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 8 deaths in order for the benefits to justify the costs.

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

We have used discount rates of 1.5% for NHS QALY opportunity costs, and 3.5% for private sector costs. The key uncertainty is the cost of upgrading or acquiring IT. The key risk is that Tissue Establishments that receive products that are already deep frozen will not be allowed to apply codes to accompanying documentation. If this was to happen, significant incremental variable costs would arise. Legal opinion on this issue is currently being sought.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 0.13	**Benefits:** 0	**Net:** -0.13	No	NA

Evidence Base

Problem under consideration

1. 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.

2. 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 to the use of the tissue or cells in their treatment or a serious adverse incident occurs involving the material, donors and other recipients can be traced. This would enable tissue banked for example from an individual donor to be traced quickly before use if tissue from that same donor is found to cause a serious reaction.

3. 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.

4. 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 procuring establishment uses.

5. 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

6. 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 by 29 April 2017 (the deadline for transposition). Since this impact assessment was drafted, on the 23 June 2016, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. Until exit negotiations are concluded, the UK remains a full member of the European Union (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.

[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

7. 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.

8. 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, while some tissue establishments use their own coding structures.

9. 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 young people to have information about their genetic origins.

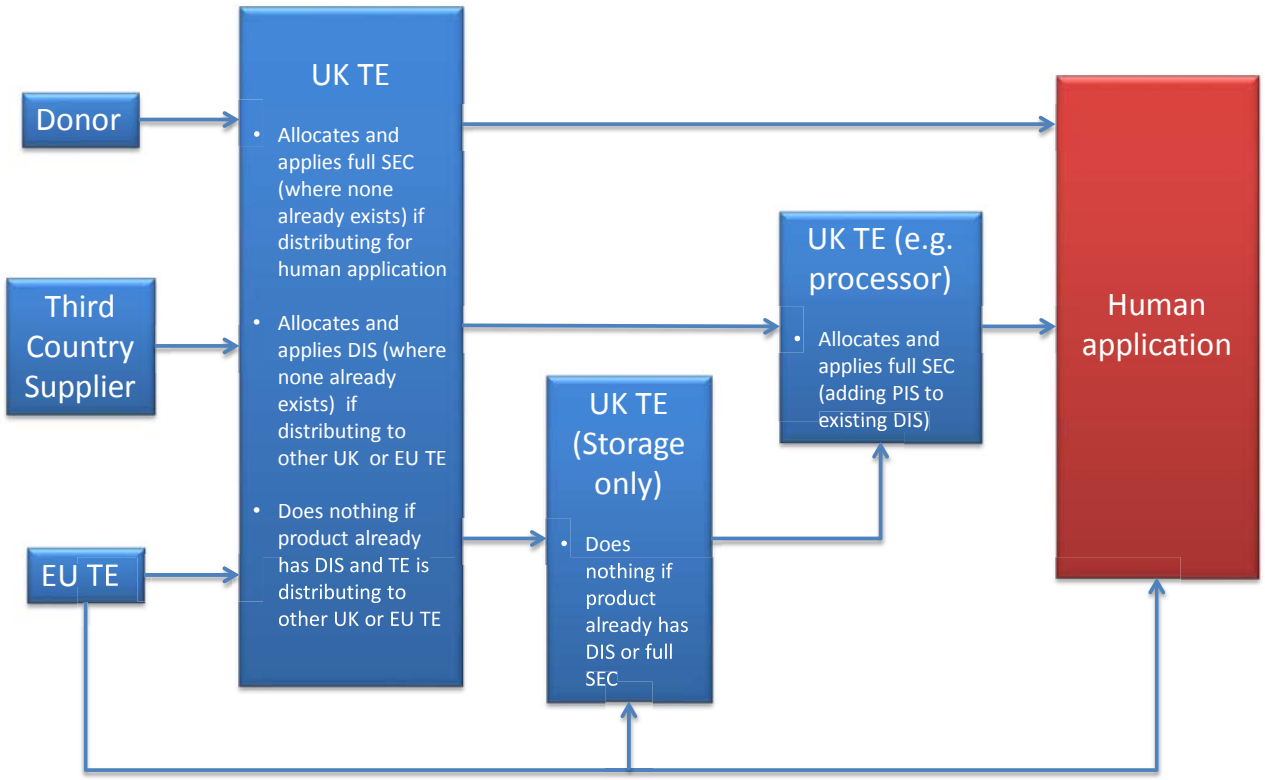
Option 1. Implement Commission Directive (EU) 2015/565

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

11. 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.

12. 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.



13. 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.

14. 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.

15. 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.

16. 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

17. 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.

18. The UK will apply these additional exemptions.

19. 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.

20. 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.

21. 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

Option 0 – Do nothing more than is already being done

22. 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

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

24. 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, we have assumed that all 52 companies are small.

25. The other UK competent authority is the Human Tissues 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 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.

26. 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.

27. 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[6] (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.

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

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

28. 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. However, the strict legal interpretation of what falls into the scope of various exemptions has yet to be given by UK government lawyers. In order to avoid underestimating the cost impact of the Directive, we have included these 57 TEs in the "Frequent coding" category, to give a total of 88 (31 plus 57) TEs in this category. We will revisit this assumption and include better estimates in the final IA when legal clarity is available. 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 regulatated 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

29. The Coding Directive was published in April 2015, and is therefore a relatively new development for TEs. Nearly all TEs are currently in the early stages of assessing how they will respond to its requirements. All but two of the TEs that we consulted during the preparation of this consultation IA were unable to provide cost estimates. We will use the public consultation to improve our knowledge of costs.

Familiarisation

30. 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 two and five days 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[7] for both the NHS and the private sector. These assumptions yield one-off estimated costs of between £72,000 and £180,000 for the NHS, and between £46,000 and £114,000 for the private sector.

31. 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[8] 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.

32. 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 5 and 12 QALYs.

Changes to Standard Operating Procedures

33. 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. Two of the TEs that we informally consulted (one NHS and one private) were able to estimate the costs of changing Standard Operating Procedure documentation. Both estimated the costs at £2,000. TEs regarded the costs of Staff training as

[7] 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.

[8] The research focussed on the NHS in England. We have assumed that the same

negligible. The estimated costs are therefore £242,000 for the NHS and £158,000 for the private sector. The opportunity cost for the NHS is 16 QALYs.

Code allocation

34. 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 system. The sophistication of that system will usually depend on the frequency that a TE has to allocate a code. In preparing this consultation IA, we discussed code allocation with 7 TEs, 3 of which are private sector. The consensus of 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 probably be adopted.

35. In table 1, we reported our estimate that 92 TEs (25 private) will have to allocate codes frequently. In discussions with TEs during the preparation of this IA, 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.

36. 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. Without greater knowledge about upgrade and acquisition costs for different types of software, and about what proportion of relevant TEs have upgradeable IT and what proportion will have to acquire new software, we have been left with considerable uncertainty about how to estimate the fixed IT costs. We have therefore assumed a range of possible costs and applied it to each TE. We will refine these estimates following feedback from the public consultation.

37. With the exception of the NHSBT (the NHS's blood and transplant service) and SNBTS (the Scottish equivalent of NHSBT), the consulted TEs who will have to code frequently are currently in the early stages of assessing how they will respond to the Directive, and were unable to provide us with IT cost estimates. NHSBT, has already upgraded, and where necessary, installed and tested software that allocates SECs. We have therefore used NHSBT's estimates of the upgrade and installation costs in our own estimates for the sector as a whole. This approach is subject to bias for three reasons. Firstly, NHS unit costs are likely to vary from private sector unit costs. Secondly, NHSBT uses a particular coding standard (ISBT 128). The costs are likely to vary from the costs of installing and/or upgrading the systems that other TEs currently use and intend to upgrade. Thirdly, NHSBT is one of the biggest operators in the sector and will therefore have to allocate codes on a very frequent basis. Its IT solutions might therefore have to be more robust than those implemented by many other TEs. We will use the public consultation to gather better data on IT costs.

38. We estimate that there are 92 TEs (of which 25 are private) that will seek an IT solution to allocating codes. NHSBT told us that it spent £8,000 on upgrading one of its existing IT systems to become SEC capable. It also spent £20,000 on installing new SEC capable software in two of its centres that previously did not have any. NHSBT also spent an additional £20,000 on testing the systems to ensure that they were reliable. 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.

39. 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 seems to be a front-runner. Use of the ISBT 128 standard requires the payment of an annual licence fee, which ranges from US$218 to US$346 (£136 to £216[9]), depending on the scale of the TE's operations. We have assumed that these fees are

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

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.

40. 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. We have further assumed that each code allocation performed manually takes between ten and fifteen minutes, and that the staff cost per minute for relevant NHS and private sector staff is £0.40[10]. Our estimate of the annual incremental variable costs for manual coding therefore ranges from £500 to £1,000 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	£854,000	£5,000

Code application

41. The consensus among the 7 TEs that we have already informally consulted is that, with one potential exception, the incremental variable costs of applying codes to products will be negligible. All TEs already have to apply other identification codes either to packaging or in accompanying documentation. Labels and forms therefore already exist and although they will have to be adapted to accommodate the SEC, there will be no additional variable cost in physically applying them to products or documentation.

42. The exception to this could occur if TEs are required to apply codes directly to packaging of products that have already been deep-frozen for storage. Such products are brittle and should not be removed from freezers for lengthy periods. Furthermore, the frozen packaging does not provide a suitable surface for sticky labels to adhere to. This is not an issue for HFEA regulated TEs because the small size of gamete and embryo packaging means that all codes will be applied to accompanying documentation. For its TEs, HTA wants to implement the Directive in such a way that TEs can also use accompanying documentation to apply codes in the case of products that have already been frozen. The HTA's interpretation of what the Directive allows is still subject to government legal opinion, which had not been issued at the time of writing this IA. If the accompanying documentation solution is not deemed permissible, some HTA regulated TEs would have to find additional means of applying SECs to frozen packs, possibly involving extra outer packaging. We will revisit this issue when there is legal clarity on whether the accompanying documentation solution is permissible.

43. TEs will need to modify existing labels and forms to accommodate the SEC. All of the TEs that we have consulted so far believed that the costs of doing this would be negligible. We will explore this issue further in the public consultation.

44. Some TEs may have to invest in new printers. However, most of the TEs that we have consulted so far believe that their existing printers will be sufficient. Where new printers are required, the unit cost is expected to be approximately £1,000 (information provided by NHSBT). We will use the public consultation to investigate further how many TEs will need to purchase printers.

Competent Authority responsibilities

45. 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.

46. HTA's assessment of its incremental costs suggests that there will be incremental one-off costs associated with updating guidance and training staff and stakeholders. There will also be an incremental on-going cost

[10] 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.

of updating the EU Compendium of Tissue Establishments. HTA is currently unable to estimate these costs. Because HTA is a government trading fund, it will be obliged to recover these incremental costs through fees charged to TEs. We will include these costs in the post-consultation final version of this IA. However, we expect that the inclusion of these costs will add little to the overall costs that TEs will bear.

Cost summary

47. 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	147	1	152
Higher estimate	208	1	216
Midpoint estimate	177	1	184
£ Opportunity costs			
Lower estimate	£8,796,000	£38,000	£9,116,000
Higher estimate	£12,466,000	£62,000	£12,983,000
Midpoint estimate	£10,631,000	£50,000	£11,050,000

48. 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

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	£907,000	£4,000	£936,000	£109,000
Higher estimate	£1,278,000	£6,000	£1,326,000	£154,000
Midpoint estimate	£1,092,000	£5,000	£1,131,000	£131,000

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	£9,704,000	£42,000	£10,053,000
Higher estimate	£13,743,000	£68,000	£14,309,000
Midpoint estimate	£11,724,000	£55,000	£12,181,000

Benefits

49. 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.

50. Paragraph 5 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.

51. 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.

52. This figure suggests that the implementation of the Coding Directive in the UK would have to prevent between 6 and 8 such deaths in order to justify its costs[11]. We are not in a position to comment on the likelihood of this happening.

53. The TEs that we have consulted so far 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

54. We have worked with the UK competent authorities (HFEA and HTA) and several NHS and private sector Tissue Establishments to identify impacts and provide indicative estimates of costs. The purpose of doing this has been to ensure that stakeholders who engage with the public consultation have a good starting point from which to provide their comments. We believe that we have provided indicative estimates for all of the most significant areas of impact, and where gaps in our estimates exist, it is because many Tissue Establishments are still in the early stages of working out how they will respond the Coding Directive in practice. We intend to use the public consultation to gain the information that will allow us to fill these gaps and refine our existing estimates.

Risks and assumptions

55. The most significant uncertainties in our estimates all relate to the calculation of fixed IT costs. Our knowledge of how many TEs will decide that they have to invest in new IT systems and how many TEs will decide to upgrade existing IT systems will be improved through engaging with stakeholder in the public consultation. Furthermore, by the time of the consultation, many more TEs will also have assessed their incremental IT costs, and we will be able to provide better unit cost estimates in the Final IA.

56. The greatest risk is that the legal interpretation of the Coding Directive will prevent the HTA from allowing its TEs from applying the SEC to accompanying documentation of products that have already been deep-frozen. If this was to happen, TEs would have to find potentially expensive alternative solutions such as adding outer packaging. There would also be an increase in the risk of damage deep-frozen, and therefore brittle products that would have to be removed temporarily from storage in order for codes to be applied. We have not been able to estimate the associated costs because no TEs have yet identified appropriate technical solutions.

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

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

57. We have estimated that that Equivalent Annual Net Cost to Business (EANCB) ranges from £109,000 to £154,000 (midpoint £131,000). 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

58. 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 indicative estimates indicate 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 TEs that we expect will adopt an IT based coding solution will range from £28,000 to £40,000.

59. 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 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 approximately £1,000, while the cost of updating SOPs (for the 79 companies that we expect will have to allocate and apply SECs) will be £2,000.

60. We have not conducted a full Small and Medium Business Assessment (SaMBA) because EU Directives fall out of scope.

Competition assessment

61. 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.