Title: Transposition of European Commission Directive 2015/566 as regards to the quality and safety of imported tissues and cells **IA No:** **Lead department or agency:** Department of Health (DH) **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 14/09/2015 **Stage:** Consultation **Source of intervention:** EU **Type of measure:** Secondary legislation **Contact for enquiries:** DH Transplant Policy Triona Norman triana.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**
£-2.34m	£-0.61m	£0.071m	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 tissues and cells are procured or used within EU Member States they meet the same high quality and safety standards. The principle of ensuring consistently high quality and safety standards should also apply to any tissues or cells imported into the EU from non-EU countries. The Commission Directive 2015/566 introduces the mechanisms for assuring this.

What are the policy objectives and the intended effects?

The aim is to make transplanted human cells and tissues safer by tightening up controls especially on information and better traceability and accountability. The specific objective is to make the requirements of the Commission Directive operational in the UK by 29 April 2017.

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

Option 0 – Do nothing. The UK would continue to import tissues and cells under current regulations without implementing the additional requirements set out in the Directive. This option has not been considered because of the UK's legal obligation to transpose EU Directives.

Option 1 – Transpose European Directive 2015/566 by copy-out into UK regulations in order to meet the minimum requirements to comply i.e. no 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: 1.56	**High:** 3.13	**Best Estimate:** 2.34

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	1.56		0	**1.56**
High	3.13		0	**3.13**
Best Estimate	2.34		0	**2.34**

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

The most substantial impacts are the estimated one-off costs of altering and authorising written agreements with Third Country suppliers. We expect 43 NHS organisations to bear opportunity costs of £1.2 million, and 65 private sector companies (all small or micro sized) to incur costs of £0.4 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 importation of inferior material 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 1 and 2 deaths in order for the benefits to justify the costs.

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

The key uncertainty is the costs of re-writing and authorising agreements with Third Country suppliers. The key risk is the definition of Third Country supplier in relation to clearing houses. This could increase the one-off costs of altering written agreements. Legal opinion on the issue is currently being sought.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 0.071	**Benefits: 0**	**Net:** -0.071	No	NA

Evidence Base

Background

1. European Commission Directive 2015/566, implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells, was published in the Official Journal of the European Union on 9 April 2015. The UK, along with other Member States, is required to transpose the Directive into domestic law by 29 October 2016.

The problem under consideration

2. 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 set quality and safety standards for human tissues 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 tissues and cells are procured or used within the EU Member States, they meet the same high quality and safety standards.

3. These principles and standards should also apply to any tissue or cells imported into the EU from non-EU countries (described as "Third Countries"). Tissues and cells are moving more frequently and across a wider variety of international borders, making the need for equivalency in standards more important in order to mitigate future patient safety risks. The new Commission Directive 2015/566 (referred to in this IA as the "Import Directive") introduces the mechanisms for assuring equivalence of Third Country imports to EU standards.

4. Imports of tissues and cells from Third Countries are already tightly regulated in the UK by two Competent Authorities, the Human Tissue Authority (HTA) and the Human Fertilisation & Embryology Authority (HFEA). Following transposition of the 2004 Directive[2], both the HTA and the HFEA introduced regulatory controls to ensure that imported tissue and cells met the standards of the 2004 Directive and its supporting Commission Directives[3]. Any material that cannot meet these standards or where there are uncertainties about the standards applied in the Third Country exporting establishment cannot be imported for human application.

Policy objective

5. The ultimate aim is to make transplanted human cells and tissues safer by tightening up controls especially on information and better traceability and accountability. The specific objective is to make the requirements of the Import Directive operational in the UK by 29 April 2017. 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,

[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] The Directive and supporting Commission Directives were transposed into UK law in July 2007. For reproductive cells this was by means of the Human Fertilisation and Embryology (Quality and Safety) Regulation 2007 that amended the Human Fertilisation and Embryology Act 1990 to implement the provisions of the Directives. For all other human tissue and cells, the Directive were implemented by freestanding regulations: the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

[3] Commission Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells and Commission Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and 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.

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.

Option 0 – Do nothing

6. To do nothing would mean that the Government does not take any measures to transpose the Directive, so effectively this would maintain the status quo. Although systems controlling imports are already in place and working effectively in the UK, additional steps will need to be taken to ensure full compliance with the Import Directive. The do nothing option would mean that the UK would be in breach of European law.

7. Central coordination is necessary to create a single set of standards against which imports could operate. It is therefore highly unlikely that the policy objective would be met in full without intervention by the European Commission and implementation by Member States.

Option 1 – Implement measures set out in Commission Directive 2015/566

8. Option 1 constitutes the implementation of the Import Directive. Under this option, where given any flexibility on implementation, the UK will choose the option least burdensome to business. Since the import of tissues and cells is already tightly regulated in the UK, there will only need to be a few changes to existing protocols to ensure the terms of the Import Directive are met in full.

9. The Directive means that importing tissue establishments (ITEs) in the UK will hold more quality and safety information about their suppliers and will require a greater depth of knowledge about international regulatory requirements. Tissue establishments will be required to provide this information to the HTA and HFEA as part of the licensing arrangements.

10. The Import Directive applies to all human tissues and cells intended for human application and manufactured products derived from human tissues and cells intended for human applications, where not covered by other Union legislation.

Exemptions and Definitions

11. The Directive does not apply to:
    - the import into the EU of tissues and cells authorised directly by authorities such as those distributed directly for immediate transplantation;
    - the import of tissues and cells which are directly authorised in case of emergencies;
    - blood and blood components; and
    - organs or parts of organs.

12. Member states are also allowed to exempt ‘one-off imports’ for named individuals from the requirements of the Directive. The use of this exemption is limited to situations where a person has had tissues or cells stored in a Third Country for their future use and wishes to have such tissues or cells imported into the Union on their behalf – for example, cases of partner donations of reproductive cells, of autologous donations, the import of peripheral blood stem cells via registries, or donations directed to close relatives. ‘One-off imports’ should not take place on regular basis from the same Third Country supplier or for any given recipient.

13. A Third Country Supplier (3CS) refers to a tissue establishment or another body, established in a Third Country, which is responsible for the export to the EU of tissues and cells it supplies to an

importing tissue establishment. In some circumstances, tissues are supplied by a clearing centre or organ procurement organisation. However, the tissues can be supplied to the clearing centre by a number of different tissue banks or hospitals and testing is performed locally. For the purposes of the IA it is assumed that clearing houses and similar organisations are the 3CS rather than hospitals/donating centres supplying the clearing house. Since the strict legal interpretation of a 3CS has yet to be given by UK government lawyers there is a risk that this assumption could be incorrect. We will revisit this assumption in the final IA when legal clarity is available.

Competent Authorities

14. The use of tissues in the UK is licensed by two Competent Authorities (CA). The Human Tissue Authority (HTA) regulates organisations that remove, store and use human tissue. The Human Fertilisation and Embryology Authority (HFEA) oversees the use of gametes and embryos in fertility treatment and research.

15. Tissue establishments, with the exception of those in the reproductive sector, must apply for and be granted separate licenses by the HTA for specific activities. Therefore, those wishing to import tissues and cells must first hold an import licence from the HTA to do so. Applications for a licence require the tissue establishment to provide assurances on a range of issues, such as the quality and safety standards adopted by the 3CS.

16. In the reproductive sector, imports of gametes and embryos are governed by Directions rather than an establishment being specifically licenced for this purpose. The HFEA has issued a General Direction[4] on imports. If licenced establishments intending to import reproductive cells can meet the conditions in that Direction, including evidence of the quality and safety standards adopted by the 3CS, they do not need specific approval for the import. If any of the conditions in the General Direction cannot be met, establishments must apply to the HFEA for a Special Direction to authorise that specific import.

Assessment of the impact of Option 0 (Do nothing)

17. Option 0 is the counterfactual against which the incremental costs and benefits of Option 1 are measured. Therefore, by definition, no incremental costs are associated with Option 0. However, failure to adequately transpose the Directive would be contrary to European law. This would lead to infraction proceedings before the European Court of Justice (ECJ) resulting in substantial fines against the UK. It is not possible to predict the level of payments before any ECJ ruling as it will depend on the Courts assessment of the severity of the breach among other aspects.

Assessment of the impact of Option 1 (Implementation of the Import Directive)

Costs of Option 1

Tissue Establishments and Sector Information

18. The HTA regulates 145 tissue establishments (TEs) in the Human Application Sector. A subset of 41 of these establishments will be affected by the Import Directive. Of these, 22 are privately operated and the remaining 19 are NHS bodies. The HTA does not hold information on the number and sizes of organisations but we have been informed by an industry source that all of the privately operated TEs fall into the “small” business category.

[4] Under the Human Fertilisation and Embryology Act 1990, the HFEA has the power to issue Directions - or rules. General Directions apply to all treatment centres. Centres are required to comply with Directions; if a centre fails to do so this would amount to a breach of a statutory licence condition, which might lead to the variation, suspension or revocation of a clinics licence.

19. The HFEA regulates 116 clinics in the UK. Based on 2014 data from importing centres, 67 clinics will be affected by the Import Directive. Of these, 43 are private sector organisations and the remaining 24 are NHS facilities. Information on the size of the private sector organisations is not held by the HFEA but the likelihood is that most, if not all, fall into the "small" category.

20. Table 1 provides a summary of the TEs affected. In total, there will be 108 TEs impacted by the Directive, 43 of which are NHS, and the remaining 65 are small private businesses. However, there are a number of exemptions to the Import Directive which might mean that TEs are affected by a greater or lesser extent.

Table 1: UK Tissue Establishments affected by the Import Directive

	NHS	Private	Total
HFEA regulated TEs	24	43	67
HTA regulated TES	19	22	41
Total TEs	**43**	**65**	**108**

Transition Costs

21. Information gained from TEs indicates that all of the impacts of implementing the Import Directive are one-off transitional costs with no recurring costs.

Familiarisation

22. The Directive is a technical document that cannot be understood in a short period. We have therefore assumed each of the 108 ITEs 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[5] for both NHS and private sector. These assumptions yield one-off estimated costs of between £23,000 and £56,000 for the NHS, and between £34,000 and £85,000 for the private sector.

23. Department of Health impact assessment guidance requires that the Quality Adjusted Life Year (QALY) opportunity cost should be used in the analysis of cost impacts on the NHS. Recent research indicates that at the margin, the NHS loses 1 QALY for every £15,000 it has to divert away from spending on curative treatment. The costs associated with complying with the Import Directive have a direct impact on the budget that is available for funding treatment.

24. The opportunity costs of the resources that the NHS spends on familiarising itself with the Import Directive can therefore be measured as being approximately between 2 and 4 QALYs.

Changes to Standard Operating Procedures

25. We currently expect that all of the 108 TEs that familiarise themselves with the requirement 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 negligible. The estimated

[5] 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.

costs are therefore £86,000 for the NHS and £130,000 for the private sector. The opportunity cost for the NHS is 6 QALYs.

Third Party Agreements, Contracts, and Licensing

26. ITEs in the UK already have written agreements in place with suppliers. A lot of the information required by the Directive[6] should already be encompassed by the information tissue establishments seek from 3CS to assure themselves of the quality and safety standards in operation at the exporting establishments. Similarly, we would already expect the agreements to document the operating standards and responsibilities, again meeting the requirements of the Directive[7]. However, all current agreements would need to be edited by all UK based establishments seeking authorisation to import tissues and cells.

27. When discussing with ITEs, the change of third party agreements is the area which they feel will have the biggest impact. Most did not envisage there being significant issues in getting 3CS to agree to new terms of the Directive. It was felt that being able to import into the UK provides 3CS with the opportunity to expand business, and they would be likely to assist in the supply of information for written agreements.

28. The majority of imports of tissues and cells into the UK presently come from the US. Stakeholders suggest that in the US, the competent authority is well established with recognised standards, and multiple audits conducted by the FDA (Food and Drug Administration) throughout the year. Conversely, in some countries inspections by the regulator do not happen and there could be a reticence among some 3CS because local institutions do not require much of the information required by this Directive. There is a small risk that in extreme cases, termination of agreements might become necessary or rationalisation of the number of 3CS. However, this Import Directive would apply EU wide, so any supplier not willing to cooperate would not be able to supply any EU Member State. It is therefore perhaps unlikely that 3CS would refuse to provide the required information.

29. In Table 1, we reported our estimate that 108 TEs currently import tissues and cells. In discussions with TEs there was variation in the number 3CS that each TE deals with. Based on those discussions, we expect HTA regulated tissue establishments to currently have 3 to 10 agreements with 3CS. It was reported that donor sperm or eggs are generally imported from a limited number of clinics outside the EU, and we have therefore assumed that each of those tissue establishments regulated by the HFEA have 2 to 3 agreements with 3CS.

30. The consulted TEs were still in the early stages of assessing how they will respond to the Directive, and were unable to provide us with cost estimates for rewriting agreements. We have assumed that each agreement will require input from solicitors[8] (1 day), clerical staff[9] (1 day), and compliance or senior managers[6] (5 days). We have assumed the same full staff costs (salary and non-salary costs) for both NHS and private sector. These assumptions result in an average cost of £1,700 to amend each written agreement. We will refine these estimates following feedback from the public consultation. These assumptions yield one-off estimated costs of between £176,000 and £439,000 for the NHS, and between £255,000 and £585,000 for the private sector. The QALY opportunity cost to the NHS is between 12 and 29 QALYs.

[6] Set out in Annex I and III of the Import Directive.

[7] Annex IV of the Import Directive.

[8] Derived from ASHE (2014 provisional) SOC10 2413 “Solicitors”

[9] Derived from ASHE (2014 provisional) SOC10 4159 “Other Administrative Occupations N.E.C”

31. Table 2 : Mid-point estimates for Third Party Agreements

	First year
NHS opportunity costs (QALYs)	20
Private sector costs	£420,000

Audits and Inspections

32. The Directive provides authority for the Competent Authorities to inspect both importing tissue establishments and 3CS, and for suppliers to allow Importing TEs to audit their records regularly.

33. CAs will begin drafting their guidance on audits later in the year, and this will state how often the audits should occur. Discussions showed that most Importing TEs conduct desk based reviews of suppliers every 1-2 years, or in between for any arising matters. Some Importing TEs do conduct site visits voluntarily to ensure they are happy with procedures. The Directive doesn't require ITEs to go on suppliers' sites so there should be no additional impact.

Record Keeping and Reporting

34. The Directive requires ITEs to keep records of the types and quantities of tissues and cells imported with their origin and destination. They will have to report any changes to their import activities, serious adverse events in 3CS, and any non-compliance findings.

35. ITEs already submit annual reports to the HTA on import activity and the HTA will try to make use of current activity data and minimise any data collection.

36. For HFEA regulated TEs, even those clinics not importing from donor banks outside of the EU will need to register "one-off" imports that it makes. However, these imports are already recorded on the HFEA register through the Electronic Data Interchange system. The HFEA will try to make use of this activity data and minimise any data collection.

Competent Authority Responsibilities

37. For the HFEA, it is anticipated that processes would generally continue as they are, but updated to accommodate requirements in the Directive. In general, changes are anticipated to affect application forms, licensing procedures to be merged into existing systems, and new procedures for the HFEA inspection team to verify that the importing clinics meet requirements of the Directive. Incremental costs will be insignificant, and fees are not anticipated to change as a result of the Directive.

38. All licenses to importing tissue establishments will need to be reissued by the HTA. HTA have suggested that the fees for those establishments are likely to increase but are yet to determine the value of this increase and whether it will be through charging an application fee, or through annual fees. HTA also suggest that that there will be one-off costs associated with updating guidance and staff and stakeholder training. We will include these costs in the post-consultation final version of this IA.

Summary Costs of Option 1

39. Table 3 summarises the opportunity costs impact of the Import Directive on the NHS. The first part collates the QALY impact information that appears in earlier sections of this IA. 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. All costs incurred are one-off costs in the first year.

Table 3: Summary of NHS Opportunity Costs

	First year
QALY opportunity costs	
Lower estimate	19
Higher estimate	39
Midpoint estimate	29
£ Opportunity costs	
Lower estimate	£1,138,000
Higher estimate	£2,326,000
Midpoint estimate	£1,732,000

40. Table 4 reports the Import Directive cost impact on the private sector and the Equivalent Annual Net Cost to Business. Table 5 provides total summary costs.

Table 4: Summary of Private Sector Costs

	First year	EANCB
Lower estimate	£419,000	£49,000
Higher estimate	£800,000	£93,000
Midpoint estimate	£610,000	£71,000

Table 5: Summary of NHS Opportunity Costs and Private Costs

	First year

Lower estimate	£1,557,000
Higher estimate	£3,126,000
Midpoint estimate	£2,342,000

Benefits of Option 1

41. It is likely that the implementation of the Import Directive will provide only minimal increased benefit to patients in terms of quality and safety because existing arrangements largely fulfil the aims of Directive. The UK has not yet experienced any major incidents involving problems associated with the importation of tissues and cells. However, the growing complexity of global trade in human tissues and cells means that the risks could be growing.

42. 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 Import Directive would bring, it is impossible to estimate the Import 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 have enjoyed 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.

43. This figure suggests that implementing of the Import Directive in the UK would have to prevent between 1 and 2 such deaths in order to justify its costs[10]. We are not in a position to comment on the likelihood of this happening.

44. The TEs that we have consulted so far were unable to identify any business benefits that compliance with the Import Directive will bring.

Rationale and evidence that justify the level of analysis used

45. We have worked with the UK competent authorities (HTA and HFEA) and several NHS and private sector Tissue Establishments to provide indicative estimates of costs. The purpose of doing this has been to try to ensure that stakeholders who engage with the public consultation have a good starting point from which to provide their comments. However, gaps in our estimates do exist where Tissue Establishments are still in the early stages of working out how they will respond to the Import Directive in practice. In particular, the resources involved in rewriting and authorising agreements with 3CS have been highlighted as having the biggest impact on tissue establishments. However, we have struggled to obtain a reliable estimate of the costs involved in doing this. We intend to use the public consultation to gain the information that will allow us to fill these gaps and refine our existing estimates.

Sensitivity and Risk Analysis

46. The calculations in this IA remain a preliminary assessment of the potential implications of the import Directive. As highlighted, the greatest uncertainty relates to the alteration of written agreement.

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

47. There is a risk regarding the legal interpretation of Third Country Supplier for circumstances where tissues are supplied by a clearing centre or organ procurement organisation. For the purposes of the IA it is assumed that clearing houses and similar organisations are the 3CS. However, if the hospitals supplying the clearing centres were deemed to be the 3CS then this could have a great impact on some ITEs. ITEs would need to have relationships directly with the hospitals/donating centres and form written agreements from scratch with a larger number of suppliers. We have not been able to estimate the associated costs because we do not have information the numbers of suppliers to clearing centres.

48. We have not been able to quantify the benefits of implementing the Import Directive. There is currently a small risk that importation of inferior material 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 1 and 2 deaths in order for the benefits to justify the costs.

One in Two Out

49. We have estimated that the Equivalent Annual Net Cost to Business (EANCB) ranges from £49,000 to £93,000 (midpoint £71,000). However, transposition of EU policy and implementing the import Directive at a minimum cost to business (Option 1) is exempt from OITO.

Wider Impacts

Small and micro businesses

50. We have been informed by private sector stakeholders that all the 65 private sector TEs who will be affected by the Import 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 rewriting and authorising agreements. We have estimated that the average cost for each of the TEs will range from £4,000 to £9,000.
51. 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 Import Directive. While larger organisations tend to employ staff who are specifically assigned tasks such as regulatory matters, quality control and compliance issues, smaller organisations do not have this luxury. In particular, there are likely to be smaller auditing teams. We have estimated that the cost of familiarisation per company will be approximately £1,000 while the cost of updating SOPs will be £2,000.
52. We have not conducted a full Small and Medium Business Assessment (SaMBA) because EU Directives fall out of scope.

Competition assessment

53. 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.