

Title: Tobacco Products Directive (TPD) IA No: 3131 Lead department or agency: Department of Health (DH) Other departments or agencies: MHRA	Impact Assessment (IA)		
	Date: 29/06/2015		
	Stage: Consultation		
	Source of intervention: EU		
	Type of measure: Secondary legislation		
			Contact for enquiries: DH Tobacco Programme
Summary: Intervention and Options			RPC Opinion: AMBER

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
£11,459m	-£130.07m	£11.07m of which £0.02m in scope	Yes (Gold-plating only)	In

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

Tobacco use remains one of the most significant challenges to public health across the United Kingdom and is the leading cause of premature death in the UK. The Government remains concerned about the take up of smoking by young people, the difficulty that adult smokers have in quitting smoking, high levels of relapse of those smokers that do attempt to quit and the consequences for the health of others from exposure to second hand smoke (SHS). Action is required to harmonize certain aspects of tobacco control policies across the European Union and update earlier legislation to account for newly developed products. The UK is required to transpose the Tobacco Products Directive into domestic legislation by 20th May 2016.

What are the policy objectives and the intended effects?

The Tobacco Products Directive was formulated with the intention to:

- Update harmonised European Union tobacco control rules which has not been done since 2001
- Introduce harmonised rules for novel tobacco products, herbals products for smoking and electronic cigarettes (e-cigarettes)
- Prevent distortion of the market as Member States consider their implementation of the global Framework Convention on Tobacco Control
- Improve the function of the internal market whilst maintaining a high level of health protection

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

Domestic legislation and enforcement provisions to implement the EU TPD must be put in place. We must also decide which optional national measures to adopt.

Option 1: Implement the TPD at a minimum cost to business (do minimum)

Option 2: Implement some selected optional elements of TPD (preferred option)

Will the policy be reviewed? It Will be reviewed. If applicable, set review date: 05/2021

1 Does implementation go beyond minimum EU requirements?			Yes		
2 Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.		Micro Yes	< 20 Yes	Small Yes	Medium Yes
3 What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded:		Non-traded:

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:

Date:

Summary: Analysis & Evidence

Policy Option 1

Description: Transpose the Revised Tobacco Products Directive at a minimum cost to business

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2016	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 11,458

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate				2,201

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

Appraisal is 10 years' of policy implementation (consequential lifetime tax costs are discounted back to the year of behaviour change). Expected costs include losses to the exchequer of £2.2bn, spread over the lifespan of smokers who quit. Transition costs to the UK for manufacturers are estimated at £6.3m (of which £0.67m is on UK based business activity). Ongoing labelling requirements will impose a discounted cost of £0.84m (£0.74m) over 10 years. There is a £0.22m discounted cost to Government for data handling.

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

A reduction in the ability of tobacco companies to compete through offering products with certain characteristics (flavouring, pack size etc.). Potential loss of revenue streams from non-TPD2 compliant manufacturing equipment or additional costs of adjusting said equipment. Costs to e-cigarette manufacturers of meeting TPD2 physical and chemical standards. Further ongoing staff and transitional costs to Government for data processing.

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				13,659

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

Appraisal is of 10 years' policy implementation with consequential lifetime health gains discounted back to the year of behaviour change. Expected benefits are the health benefits that would accrue from improved smoking quit rates of life years valued at £13.7bn. Manufacturing cost savings are estimated at £5.7m (of which £0.45m is on UK based business activity).

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

Key assumptions/sensitivities/risks	Discount rate (%)	1.5/3.5
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Assumptions / sensitivities: The estimated impact on smoking consumption

Risks: Development of quality and safety standards in e-cigarette market may not occur as expected

Discount rate: 1½ % for health impacts denominated in life years and 3½% for monetised impacts.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 11.1	Benefits: 0.0	Net: -11.1	No	N/A

Summary: Analysis & Evidence

Policy Option 2

Description: Transpose the Revised TPD taking account of additional flexibilities

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2016	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 11,459

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate				2,202

Description and scale of key monetised costs by 'main affected groups'
 Costs are as identified under Option 1, except: £1.8m of additional discounted costs through additional fees for tobacco and e-cigarette manufacturers over 10 years (of which £0.14m is on U K based business activity). £0.17m cost to Government of peer reviewing additives.
 £0.25m of transition costs and £0.74m of additional discounted costs to pipe and cigar manufacturers for implementing pictorial warnings (of which £0.03m and £0.08m respectively fall on UK based activity).

Other key non-monetised costs by 'main affected groups'
 Non-monetised costs are as identified under Option 1

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				13,661

Description and scale of key monetised benefits by 'main affected groups'
 Benefits are as identified under Option 1, except:
 £1.8m of revenue to the UK Government from fees.

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

Key assumptions/sensitivities/risks	Discount rate (%)	1.5/3.5
Key assumptions / sensitivities / risks / discount rate are as identified under Option 1		

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 11.1 (0.02)	Benefits: 0.0	Net: -11.1 (-0.02)	Yes (marginal only)	IN

Evidence Base (for summary sheets)

Background

1. The European Commission published a proposed revision to the 2001 Tobacco Products Directive (Directive 2001/37/EC) (henceforth referred to as TPD1) on 19 December 2012, the revised Tobacco Products Directive (2014/40/EU) (henceforth referred to as TPD2). Domestically, the UK Government's position on this proposal was secured via a write-round to the European Affairs Committee (EAC) and the devolved administrations in spring 2013. At a meeting of the EU Health Council on 21 June 2013, Member States 'voted' (through signalling support rather than via a formal vote) to agree a General Approach to the Directive, following lengthy and complex negotiations over six months. The UK Government supported the General Approach to the Directive although inevitable compromises to some of the UK's preferred positions were made to help to achieve agreement.
2. On 18 December 2013 EU Member States and the European Parliament approved additions and amendments to the initial proposal and the European Parliament and the Council formally approved the TPD2 in early 2014.
3. The TPD2 was published in the Official Journal of the European Union on 29 April 2014. This new directive will apply from 20 May 2016. EU Member States must have transposed the TPD2 into domestic law by this time.
4. The TPD2 contains several flexibilities that Member States can opt to take up and these flexibilities are considered in this consultation stage impact assessment.

The problem under consideration

5. Tobacco use remains one of the most significant challenges to public health across the United Kingdom and Europe and is the leading cause of premature death in the UK. Smoking is the primary cause of preventable morbidity and premature death, accounting for over 100,000 deaths in the UK each year¹. One out of two long term smokers will die of a smoking-related disease². While rates of smoking have declined over past decades, in recent years the rate of this decline has slowed. The Government remains concerned about the take up of smoking by young people, the difficulty that adult smokers have in quitting smoking, high levels of relapse of those smokers that do attempt to quit and the consequences for the health of others from exposure to second hand smoke (SHS). Tobacco use also contributes significantly to health inequalities.
6. While smoking prevalence has fallen steadily since its peak in the mid-20th century, smoking rates are today higher than average among particular groups meaning that smoking has emerged as one of the most significant contributors to health inequalities, accounting for approximately half of the difference in life expectancy between the lowest and highest income groups³. Smoking is most common among those who earn the least, and least common among those who earn the most. In 2010, smoking prevalence was more than twice as high among people in routine and manual occupations compared with managerial and professional occupations. Smoking rates are high in particular ethnic and social groups. Smoking rates among people with mental health problems are also significantly higher than among the general population⁴.
7. Smoking rates are today broadly the same among men and women. Around two-thirds of smokers say that they started smoking regularly before the age of 18. In 2009, the Public Health Research Consortium (PHRC) published a review of young people and smoking in England. The review found that the onset of smoking is a function of individual factors (e.g. self-image), social and community factors (e.g. family circumstances) and societal factors (e.g. tobacco marketing)⁵.

¹ Action on Smoking and Health. Smoking Statistics – Illness and Death. November 2014.

² Doll, R, Peto, R, Boreham, J., Sutherland, I "Mortality in relation to smoking: 50 years' observations on male British doctors," British Medical Journal 2004, vol 328, pp. 1519–27.

³ Marmot, M. et al. (2010). Fair Society, Healthy Lives: Strategic review of health inequalities in England post-2010. Marmot review secretariat, London.

⁴ Department of Health (2008). Consultation on the future of tobacco control. Department of Health, London.

⁵ Public Health Research Consortium (2009). A Review of Young People and Smoking in England. PHRC, York

8. Tobacco control policy across the UK aims to reduce youth uptake of smoking, and to encourage and support quitting amongst smokers who wish to quit; implementation of the TPD2 is expected to have a positive impact on both.
9. The TPD2 seeks to improve the functioning of the internal market and achieve a high standard of health by regulating tobacco products (TPs) in a way that reflects its characteristics as an addictive product with proven negative health consequences linked to its consumption. As such the TPD2 aims to achieve a harmonised approach to the regulation of ingredients to reduce obstacles to smooth functioning of the internal market and ensure that ingredients and product presentation do not encourage or facilitate smoking uptake by young people and that consumers are able to take informed decisions about tobacco and related products.
10. The TPD2 focuses on initiation of tobacco consumption, in particular by young people, taking into account that 70% of smokers in Europe start before the age of 18 and 94% before the age of 25 years⁶. This picture is reflected in the UK where it is estimated that each year around 207,000 children start smoking⁷. Most adult smokers take up smoking before the age of 20 with 40% taking up smoking regularly before the age of 16⁸.
11. Smoking initiation is associated with a wide range of factors including: parental and sibling smoking, the ease of obtaining cigarettes, smoking by friends and peer group members, socioeconomic status, exposure to tobacco marketing, and depictions of smoking in films, television and other media⁹. The TPD2 contains provisions to control the ingredients of tobacco products to reduce their palatability to minors, among other things, and strengthen existing harmonised labelling rules to better inform consumers about the health risks of tobacco products.
12. It is recognised that peer pressure and familial smoking patterns are most responsible for take up of tobacco consumption by young people. However, there is evidence to suggest that the appeal of flavoured tobacco does play a role in some individuals' decisions to start smoking. Eurobarometer data reports that 4% of UK current and ex-smokers identify mentholated cigarettes as one of the 3 main reasons they started smoking, with a further 1% identifying 'sweet, fruity or spicy' flavouring.
13. As well as potentially encouraging smoking uptake, menthol cigarettes may currently mislead some consumers over their health effects. 11% of UK individuals surveyed in 2012 thought that menthol brands were less harmful than others. This could result in people underestimating the health cost associated with smoking and over-consuming relative to their true preferences.

Rationale for Intervention

14. Government (and EU) intervention is justified in several ways:
 - to correct an information asymmetry by regulating to ensure that governments have access to more information about the products in scope of the TPD2 and to make more information publicly available to better inform consumer choice.
 - to harmonise the EU market such that Member States cannot gain a competitive advantage by undermining public health benefits
 - to regulate products which especially appeal to children, who are unable to make a fully informed choice about consuming a product which creates a future addiction.
 - To reduce obstacles to trade in tobacco and related products within the EU by reducing differences between the regulatory regimes in different EU Member States.

Policy objective

15. The Tobacco Products Directive was formulated with the intention to improve the functioning of the internal market and improve health protection by:

⁶ Eurobarometer 2012

⁷ Hopkinson, NS., Lester-George, A., Ormiston-Smith, N., Cox, A. & Arnott, D. Child uptake of smoking by area across the UK. *Thorax* 2013. doi:10.1136/thoraxjnl-2013-204379

⁸ Office for National Statistics. General Lifestyle Survey Overview: A report on the 2011 General Lifestyle Survey. 2013.

⁹ Passive smoking and children. Royal College of Physicians, London, 2010 (pdf).

- Updating harmonised EU tobacco control rules not done since 2001
- Introducing harmonised rules for tobacco related products including herbal products for smoking, novel tobacco products and electronic cigarettes
- Preventing distortion of the market as Member States consider their implementation of the global Framework Convention on Tobacco Control
- Maintaining a high level of health protection

Improve the functioning of the internal market

16. The TPD2 will update already harmonised areas, thereby overcoming the obstacles for the UK in bringing national legislation in line with new market, scientific and international developments. It will also address product related measures not yet covered by the TPD1 insofar as heterogeneous development in Member States has led to, or is likely to lead to, fragmentation of the internal market. Finally, the proposal seeks to ensure that the provisions of the Directive are not circumvented by placing on the market of products not compliant with the TPD. The proposal will also ensure a harmonised implementation of international obligations following from the FCTC, which is binding for the EU and all Member States, and a consistent approach to non-binding FCTC commitments, if there is a risk of diverging national transposition.

Health protection

17. A high level of health protection has been considered in developing the TPD2. Over time the proposed measures are expected to impact on peoples' awareness of the risks associated with tobacco products, which in turn will lead to a change in behaviour. Fewer young people will start smoking and some adults will successfully quit smoking. This is expected to lead to an overall reduction of smoking consumption/prevalence.
18. The TPD2 seeks to regulate tobacco products in a way that reflects its characteristics as an addictive product with proven negative health consequences linked to its consumption (including mouth, throat and lung cancer, cardiovascular diseases including heart attacks, strokes, clogged arteries, increased risk of blindness, impotence, lower fertility and impacts on the unborn child).
19. Current legislation results in a framework that may confuse or mislead consumers over the health risks of certain products. The lack of mandated health warnings for herbal products for smoking, alongside the 'natural' style advertising for these products may lead people to underestimate their health risks. The TPD2 aims to create a comprehensive framework that encapsulates smoked and smokeless tobacco, nicotine containing products and other smoked products. The TPD2 removes the requirement to provide information on levels of tar, nicotine and carbon monoxide on packs, which some consumers are using as a relative-risk tool.
20. The revision focuses on initiation of tobacco consumption, in particular by young people, taking into account that the majority of adults start smoking before the age of 20 years. Tobacco control policy across the UK aims to reduce youth uptake of smoking and to encourage and support quitting amongst smokers who wish to quit; implementation of the TPD is expected to have a positive impact on both.

Decrease in illicit trade

21. The measures in the TPD2 dealing with cross-border distance sales and traceability and security features are expected to contribute to a drop in consumption, in particular in the illicit segment of the market. Part of this demand would be expected to return to the legal supply chain, which is more expensive and therefore may encourage some consumers to not start smoking, to smoke less or to quit. This effect will be most noticeable amongst groups who are more sensitive to changes in prices, such as young people and those on low incomes¹⁰ where the burden of ill health due to tobacco smoking currently falls most heavily. Moreover, consumers are better informed of the health risks of tobacco products and other products for smoking (e.g. herbal products) because they carry the information required by the TPD2.

Counterfactual (Option 0)

¹⁰ http://www.who.int/tobacco/economics/meetings/dublin_demand_for_tob_feb2012.pdf

22. As an EU directive, the TPD2 must be transposed into domestic legislation by the 20th May 2016. However, in order to assess the impacts of this policy, a counterfactual needs to be established. In the case of EU legislation, the agreed counterfactual for Impact Assessment purposes is a state in which the EU had not passed legislation.
23. The expected counterfactual evolution of key variables is identified in the relevant sections of the assessment of Option 1's costs and benefits. There is however a great deal of uncertainty surrounding the counterfactual for the electronic cigarette industry. This is because the market is evolving rapidly, industry-led safety and quality standards that are currently under development, the drafts of which show partial coverage of the provisions set out in the TPD. Given the amount of negative publicity on the safety of e-cigarettes it is likely that this developing industry would have continued to work on best practice standards, over time, to deflect some of the criticism and to allow companies to differentiate their products. However such standards could not be enforced and it is difficult to make an assessment of the degree to which the market would adopt them. In addition, many e-cigarette firms are new, and sales outside the traditional channels are not accurately tracked. For these reasons, no definitive counterfactual is estimated. An assessment of potential changes to the electronic cigarette market is presented in Annex B. **We would welcome any further information or data that would enable us to develop this analysis.**

Implementing TPD2 at minimum regulatory burden (Option 1)

24. Option 1 constitutes the implementation of the revised Tobacco Products Directive consistent with a minimal overall impact on business. Implementation of the TPD2 is required by 20 May 2016, except where specific extensions have been allowed. This involves¹¹:
- Ingredients and emissions
 - Maximum emission levels for tar, nicotine, carbon monoxide (TNCO) and other yields (Article 3)
 - Measurement methods (Article 4)
 - Reporting of ingredients and emissions (Article 5)
 - Priority list of additives and enhanced reporting obligations (Article 6)
 - Regulation of ingredients (Article 7)
 - Labelling and Packaging
 - General provisions (Article 8)
 - General warning and information messages on tobacco products for smoking (Article 9)
 - Combined health warnings for tobacco products for smoking (Article 10)
 - Labelling of tobacco products for smoking other than factory made cigarettes, roll-your-own tobacco and waterpipe tobacco (Article 11)
 - Labelling of smokeless tobacco products (Article 12)
 - Product presentation (Article 13)
 - Appearance and content of unit packs (Article 14)
 - Track and Trace (Illicit trade)
 - Traceability (Article 15)
 - Security feature (Article 16)
 - Tobacco for oral use, cross border-distance sales of tobacco products and novel tobacco products
 - Tobacco for oral use (Article 17)
 - Cross-border distance sales of tobacco products (Article 18)
 - Notification of novel tobacco products (Article 19)
 - Electronic cigarettes and herbal products for smoking
 - Electronic cigarettes (Article 20)

¹¹ The description of the TPD2 contained in this IA is not a full and complete account of the Directive or the UK Government's approach to its transposition. This description is intended to highlight requirements that are most likely to result in costs and benefits to businesses, individuals and the Government. The Directive, as annexed to the accompanying consultation document, should be used for determining specific legal requirements.

- Herbal products for smoking (Article 21)
 - Reporting of ingredients of herbal products for smoking (Article 22)
 - Transitional provision (Article 30)
25. Under this option, where given any flexibility on implementation, the UK will choose the option least burdensome to business. For the purposes of this consultation stage IA the following options are considered least burdensome to industry:
- i. To adopt transitional periods to allow for the sell through of old stock at retail level not in compliance with the TPD2 including tobacco products, herbal products and e-cigarettes until May 2017 (the latest allowed by the TPD2).
 - ii. To exempt tobacco products other than cigarettes, RYO and waterpipe tobacco from carrying the information message and combined health warning and require them to carry a text-only warning instead.
 - iii. We consider the choice of one written health warning over another (a choice of two options for both tobacco products and e-cigarettes) is cost neutral and either would be a lowest cost option.
 - iv. To implement a notification system versus an authorisation system of novel tobacco products.
 - v. To adopt a registration scheme for companies wishing to sell to consumers outside of the UK and require them to adopt an age verification scheme rather than ban sales of TPs, e-cigarettes and refills that are sold to consumers across UK borders.
 - vi. Not to require peer review of the comprehensive scientific studies into certain additives that manufacturers will be required to carry out.
 - vii. Not to charge the industry directly for the proportionate cost of the following services:
 - a. The verification of TNCO levels in cigarettes
 - b. The receiving, storing, handling, analysis and publishing information on ingredients and emissions of tobacco products
 - c. The receiving, storing, handling and analysing information submitted to them on e-cigarettes
 - d. If the UK chooses to implement an authorisation system for novel TPs then a fee can be charged for that authorisation (Option 1 would implement a notification scheme, so this charge is not relevant)
 - e. The peer review of scientific studies on additives undertaken by the tobacco industry.
26. Maximum levels of tar, nicotine and carbon monoxide were agreed under the TPD1. The TPD2 imposes the same maximum levels, keeping this requirement unchanged. The revised Tobacco Products Directive provides the EU with the power to adopt delegated acts to adapt the currently agreed maximum levels, taking into account scientific developments.
27. The TPD1 requires TNCO emissions to be verified in laboratories which are approved and monitored by the competent authorities of Member States. The TPD2 imposes an additional requirement over TPD1 that these laboratories shall not be owned or controlled directly or indirectly by the tobacco industry. This requirement is already met by the UK, requiring no changes as a result of this article.
28. Tobacco manufacturers and importers are currently required to report product ingredients and emissions to Member State competent authorities on an annual basis. The TPD2 removes this burden, instead requiring a one-off reporting of existing products and new or modified products prior to placing on the market.
29. The TPD2 imposes an additional reporting requirement for information on emission levels other than TNCO – for cigarettes and emissions from other tobacco products where these are available.
30. In addition to ingredient and emission data, manufacturers will be required to submit, where they are available, internal and external studies on market research and summary results from market surveys.
31. Manufacturers and importers will be required to provide data on sales volumes per brand and variant on an annual basis.

32. The data provided under this act shall be made publically available on a website. Member States shall take the need to protect trade secrets into account.
33. Further reporting requirements will be imposed on a s pecific set of commonly used or potentially hazardous additives. This list is yet to be determined, but will be agreed and adopted by 20 May 2016 and shall contain at least 15 additives.
34. For these additives, manufacturers and importers of cigarettes and RYO tobacco will be required to carry out comprehensive studies assessing toxicological, flavouring, nicotine uptake and C MR effects. The results of these studies must be reported to the relevant competent authority within 18 months of the additive being added to the priority list.
35. Small and Medium Enterprises (SMEs) are exempted from the obligations of this article if a report on an additive is prepared by another manufacturer or importer.
36. The revised Tobacco Products Directive requires Member States to prohibit the placing on t he market of cigarettes and roll-your-own tobacco with a characterising flavour, or any tobacco product that contains the following additives:
- Vitamins or other additives that imply a health benefit
 - Caffeine, taurine or other stimulant compounds associated with energy and vitality
 - Those with colouring properties for emission
 - Those that facilitate inhalation or nicotine uptake
 - Those that have carcinogenic, mutagenic and reprotoxic (CMR) properties in unburnt form.
37. Member states must also prohibit the placing on the market of any cigarette and RYO tobacco product containing flavourings in any of their components (filters, papers, capsules etc.).
38. The provisions of this article shall only apply from 20 May 2020 for tobacco products with a characterising flavour whose Union-wide sales volumes represent 3% or more in a particular product category. Based on c urrent market data, this temporary exemption only applies to mentholated cigarettes. Member States are required to notify the Commission when they deem a product to have a characterising flavour and further Implementing Acts are expected from the Commission on how characterising flavours should be determined and the setting up of an EU advisory panel.
39. The TPD2 reinforces and expands upon the labelling requirements of 2001/37/EC. These changes include the following requirements:
- Health warnings must remain intact upon opening packets, except in the case of flip-top lids (subject to graphical integrity and clarity)
 - Unit packets must contain the information message ‘Tobacco smoke contains over 70 substances known to cause cancer’ and a general warning “smoking kills – quit now” and a graphical warning
 - Size requirements for general warnings, information messages and graphical warnings
 - An increase in the size of graphical health warnings to 65% of the front and back surfaces and introduce minimum dimensions of warning labels on packets of cigarettes
 - Combined health warnings must be rotated on an annual basis. Warnings are grouped into 3 sets, and each set shall be used in a given year
40. The TPD2 allows Member States to choose to provide for less onerous labelling requirements for tobacco products for smoking other than cigarettes, RYO and waterpipe tobacco. These lesser requirements are similar to those of the TPD1. If the UK Government took this option up, the general and text warnings on those products would still be required to appear on the two most visible surfaces of the unit packaging. For products in packets with hinged lids the second most visible surface is defined as the one that becomes visible on opening. These warnings will also be required for individually wrapped (single) cigars which are currently exempt from labelling in the UK.
41. Requirements for smokeless tobacco products remain largely unchanged. Whilst the surface coverage of warning messages remains at 30% (for a single official language country), there will be a new requirement for warnings to appear on the two largest surfaces of unit products rather than one as previously required.

42. The TPD2 restricts certain marketing claims and features as part of tobacco product presentation. These include messages that:
- Promotes a tobacco product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions. Labels may not contain any information about the nicotine, tar or carbon monoxide of the product
 - Suggest that a particular product is less harmful than others or aims to reduce the effect of some harmful component of smoke, or has vitalising, energetic, healing, rejuvenating, natural / organic properties or other health or lifestyle benefits.
 - Refer to taste, smell, flavouring or other additives or absence thereof
 - Resemble a food or cosmetic product
 - Suggest improved biodegradability or other environmental benefits
 - Suggest economic advantages by providing discounts.
43. Unit packets of cigarettes will be required to have a cuboid shape; unit packets of RYO tobacco either cuboid, cylindrical or pouch. Cigarette packs may contain no fewer than 20 cigarettes, and RYO tobacco packets must contain at least 30g of tobacco.
44. Unit packets of cigarettes may not be re-sealable except for flip-top and shoulder box hinged lids.
45. Member States will be required to ensure that all tobacco products must be marked by a unique identifier. This feature shall be used in conjunction with tracking equipment to monitor the movement of products. This requirement will apply to cigarettes and RYO tobacco from 20 May 2019, and all other tobacco products from 20 May 2024. In addition to the unique identifier, all products will require tamperproof security features.
46. **Track and trace systems and the provision of security features are not assessed as part of this Impact Assessment. HMRC will be responsible for the implementation of Articles 15 and 16 and will conduct an independent impact assessment once further detail of the required scheme and technical specifications for security features have been set out by the Commission in relevant Implementing and Delegated Acts.**
47. Tobacco for oral use remains banned without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.
48. The TPD2 gives Member States two options in relation to cross-border distance sales to consumers – either to prohibit such sales or to require sellers to register with the competent authorities in Member States where actual or potential customers are located. This registration requires the reporting of minimal amounts of information about the company. Sellers must receive receipt of confirmation of registering prior to placing items for sale. If a registration scheme is implemented, retail outlets must implement an age verification system to ensure that purchasers of tobacco products are above the minimum legal age for consumption in the Member State for destination. The Directive defines ‘age verification system’ as ‘a computing system that unambiguously confirms the consumer’s age electronically in accordance with national provisions’.
49. Member states shall require manufacturers and importers of novel tobacco products to submit a notification to the competent authority 6 months prior to the product being placed on the market. This notification should contain information as required under Article 5, and any further available information on toxicological and addictive effects, consumer studies and market research, and the additional information indicated at Article 19.
50. The introductory text to paragraph 2 of Article 20 on electronic cigarettes reads:
- “Manufacturers and importers of electronic cigarettes and refill containers shall submit a notification to the competent authorities of the Member States of any such products which they intend to place on the market. The notification shall be submitted in electronic form six months before the intended placing on the market... A new notification shall be submitted for each substantial modification of the product.”*
51. The Directive’s text that specifies the information that needs to be included in each notification can be found under Article 20 (2). Along with the information required for tobacco and herbal products,

the EC will adopt an Implementing Act to specify the form in which information should be notified to competent authorities.

52. Member States are required to restrict the volume and strength of nicotine containing liquids. Dedicated refill containers may not exceed 10ml; disposable e-cigarettes, single use cartridges or tanks may not exceed 2ml. Nicotine containing liquid may not contain nicotine in excess of 20mg/ml, additives listed under Article 7(6), ingredients must be of high quality and (other than nicotine) must not pose a risk to human health. E-cigarettes must deliver nicotine doses at consistent levels under normal use, and e-cigarettes and refill containers must be child and tamper proof. The EC will adopt an Implementing Act setting out the technical standards for the refill mechanism of these products.
53. Manufacturers are required to provide an information leaflet with unit packets of e-cigarettes and refill containers. These leaflets must contain information on toxicity and addictiveness and a number of other pieces of information. Unit packets must display information on ingredients and one of two health warnings to be decided by the Member State (see Option 2) among other prohibitions and requirements.
54. The TPD2 requires Member States to prohibit all commercial communications (advertisement, product placement etc.) of e-cigarettes and refill containers in information society services, in the press and other printed publications, (except in trade publications and publications which are printed and published in third countries, where those publications are not principally intended for the European Union market) on the radio, on TV as well as certain types of sponsorship.
55. The UK Government shall publish the information received in e-cigarette notifications on a website, having taken the need to protect trade secrets into account.
56. Manufacturers and importers of e-cigarettes are required to submit annual data on sales volumes, consumer preferences, modes of sale and summaries of any market surveys undertaken.
57. Manufacturers, importers and distributors will also be required to maintain a system for collecting information on the potential adverse events on human health of e-cigarettes and refill containers. Businesses will be required to take corrective action where electronic cigarettes or refill containers, are not safe or are not of good quality, to withdraw or to recall them, as appropriate. They will also be required to inform the central competent authority giving details, in particular, of the risk to human health and safety and of any corrective action taken, and of the results of such corrective action. The central competent authority also has powers to take appropriate provisional measures to deal with any e-cigarettes or refill containers that pose a serious risk to human health. The Commission will be notified and must determine whether the measures taken are justified.
58. Member States may also request additional information from the economic operators, for example on the safety and quality of the product or any adverse effects of e-cigarettes or refill containers.
59. Herbal products for smoking were not covered by the TPD1. The TPD2 would require the inclusion of health warnings on unit packaging, compliant with Article 9 and covering at least 30% of the surface area of the unit pack in countries with one official language.
60. Herbal products for smoking must also be compliant with parts of Article 13 on how products can be presented and may not make claims to be free of additives or flavouring.
61. Member States shall require all manufacturers and importers of herbal products for smoking to submit lists of product ingredients to the central competent authority.
62. Member States shall make the information submitted by manufacturers of herbal products for smoking and e-cigarettes publically available on a website.
63. The TPD2 offers Member States the option to allow products that are compliant with the TPD2 and are manufactured prior to 20 May 2016 may be sold until 20 May 2017.

Table 1: TPD2 and additional provisions with an impact on Business/Central Government/Enforcement Community

<i>TPD2 Article</i>	Additional provisions with an impact on Business/Central Government/Enforcement Community
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<i>4 - Measurement methods</i>	Current measurement methods for emissions of tar, nicotine and carbon dioxide (TNCO) remain the same. Member States will be required to notify the Commission of any measurement methods they use for emissions from cigarettes other than TNCO emissions and for emissions from tobacco products other than cigarettes. The UK does not currently require testing of cigarettes beyond TNCO emissions.
<i>5 - Reporting of ingredients and emissions</i>	Manufacturers and importers of tobacco products will be required to provide additional information on ingredients and emissions as well as submit available market research studies and data on sales volumes on a yearly basis. Member States (MS) will be required to publish a wider range of data on ingredients and emissions.
<i>6 - Priority list of additives and enhanced reporting obligations</i>	Enhanced reporting obligations for manufacturers will apply to certain additives contained in cigarettes and roll-your-own tobacco that are included in a priority list of 15 additives (to be announced in an Implementing Act); if manufacturers have products containing an additive in this list they must carry out studies examining toxicity, addictiveness, flavour etc.
<i>7 - Regulation of ingredients</i>	The placing on the market of cigarettes and RYO tobacco with a characterising flavour and tobacco products with certain additives will be prohibited.
<i>8 - General provisions</i>	There are changes to the general provisions relating to the position, size, and formatting of the written health warnings.
<i>9 - General warning and information messages on tobacco products for smoking</i>	Changes to the general warning and information messages on tobacco products for smoking relating to their position, wording and surface coverage.
<i>10 - Combined health warnings for tobacco products for smoking</i>	Graphical warnings will be mandatory and must appear on the front and back of the pack and increase in size to 65% of each surface. Further requirements regarding the layout, design and shape of graphical health warnings to be defined by the Commission in Implementing Acts.
<i>11 - Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco</i>	Provides the possibility for MS to exempt tobacco products for smoking other than cigarettes, RYO and waterpipe tobacco, from some of the labelling requirements in articles 9 and 10 and to impose an alternative regime.
<i>12 - Labelling of smokeless tobacco products</i>	Specific requirements regarding the position, size and format of health warnings for smokeless products.
<i>13 - Product presentation</i>	Whilst the text implementing this Article was included in the draft SI for the Standardised Packaging Legislation (SPoT) issued on 26th June 2014 for consultation, this Impact Assessment includes the costs and benefits accruing from the TPD2 provisions. The SPoT Impact Assessment covers the additional costs of standardised packaging over and above the TPD2 provisions which include restrictions on misleading elements/features of labels, for example that the product has health or lifestyle benefits and must not refer to taste, smell or flavourings.
<i>14 - Appearance and content of unit packets</i>	Whilst the text implementing this Article was included in the draft SI for the SPoT issued on 26th June 2014 for consultation, this Impact Assessment includes the costs and benefits accruing from the TPD2 provisions. The SPoT Impact Assessment covers the additional costs of standardised

	packaging over and above the TPD2 provisions which include prescribing shape, closure mechanisms and materials that can be used for packaging materials. TPD2 also imposes minimum content levels e.g. 20 cigarettes or 30g of roll your own tobacco.
15 - Traceability	<i>Enhanced traceability system. Commission Implementing Act to further set out specification for the system to be adopted and detail of indelible unique identifier what that identifier must reveal.</i>
16 - Security feature	<i>All unit packets of tobacco products which are placed on the market must carry a tamper proof security feature, composed of visible and invisible elements. Commission to define in Implementing Act technical standards for security feature including any need for rotation.</i>
18 - Cross-border distance sales of tobacco products	Provisions that allow MS to ban cross border distance sales or to introduce a registration scheme and age verification requirement for cross border distance sale of TPs, e-cigarettes and refills.
19 - Notification of novel tobacco products	Manufacturers and importers of novel tobacco products must submit a notification in electronic form accompanied by a detailed description of the novel tobacco product, along with studies on its addictiveness etc. Option for MS to introduce an authorisation scheme.
20 - Electronic cigarettes	Requirements relating to the composition, labelling, advertising and reporting of e-cigarettes and refills. MS required to make certain information available to the public, other MS and the Commission.
21 - Herbal products for smoking	Requirements for herbal products for smoking including health warnings and their position.
22 - Reporting of ingredients of herbal products for smoking	Manufacturers and importers of herbal products for smoking must submit to their competent authorities a list of all ingredients used and quantities thereof. MS to make available this information to the public.

Implementing TPD2 with additional flexibilities (Option 2)

64. As stated in the accompanying consultation document, with regards to the flexibilities available in transposing the TPD2 the Government is currently minded to:

- Adopt transition periods to allow the sell through of old stock (tobacco products, e-cigarettes and herbal products for smoking);
- Consult on whether to adopt less onerous labelling requirements for individually wrapped cigars and cigarillos, requesting information on other products currently on the market which will have difficulty applying full labelling;
- Consult on the choice of health warnings to be applied to tobacco products, steering towards our preference "Smoking kills – quit now";
- Adopt measures that would allow the Government to obtain peer reviews on tobacco industry's studies
- Consult on our preferred option to adopt a notification scheme rather than an authorisation scheme for novel tobacco products;
- Consult on our preferred option to introduce a registration system for cross border distance sales with an age verification requirement; if this is determined to be the least burdensome option (i.e. less burdensome than an outright ban); and

- Consult openly without preference on the principle of charging industry proportionate fees to recover costs associated with TPD2 activities
65. For the purposes of this IA, with the intention to provide as much information as possible rather than to indicate preference (except where a clear preference has been indicated), we assume the following :
- Transitional periods are adopted (I.e. Unchanged from Option 1)
 - Other tobacco products (except individually wrapped cigars and cigarillos) are **not** exempted from the full labelling requirements
 - The tobacco health warning reads “Smoking kills – quit now”
 - Measures are adopted to allow the Government to obtain peer reviews on tobacco industry’s studies
 - A notification scheme for novel tobacco products is adopted (I.e. Unchanged from Option 1)
 - A registration system is introduced for cross border distance sales of tobacco and e-cigarettes (I.e. Unchanged from Option 1)
 - Industry is charged proportionate fees to recover costs associated with TPD2 activities

Assessment of the impact of Option 1

Benefits of Option 1

66. The European Commission Impact Assessment on the revised Tobacco Products Directive estimated the reduction in cigarette / RYO tobacco consumption following the implementation of the TPD2. This decrease was estimated to be approximately between 1.7% and 2.6% across the European Union. This assumption is deemed to be in line with expectation and experiences of other tobacco control agencies which have observed similar drops for comparable policy measures¹². All policy areas are expected to make a contribution to the overall consumption drop with the main contributions expected from the mutually reinforcing policy areas on packaging and ingredients (see Figure 1 and extracts from the EU IA in Annex C).

Figure 1: Tentative contributions of individual policy areas¹³ to the projected decrease of cigarette/RYO consumption¹³

¹² Commission Staff Working Document – Impact Assessment accompanying the document Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and tobacco related products, 2012 – Section 5.7

¹³ STP refers to Smokeless Tobacco Products, NCP to Nicotine Containing Products

Policy area		Foreseen contribution to the decrease in %
Scope	(STP)	0.2-0.3
	NCP	
	(Herbal)	
Packaging & Labelling		1-1.5
Ingredients		0.5-0.8
TOTAL		1.7-2.6%
Cross-border distance sales + Illicit trade		Additional decrease of consumption, however not in the legal supply chain. (Decreases in illicit consumption could mitigate the decrease in the legal chain).

67. However, this considers the impact of introducing the TPD2 across the European Union. The UK has pursued the public health agenda more thoroughly than some other countries – notably on requiring picture warnings for unit packets of cigarettes (since 2009) and other tobacco products (since 2010).
68. The estimated impact of picture warnings expressed in the European TPD IA is partly based on evidence from the 2007 UK Regulatory Impact Assessment on warnings. The UK is, therefore, likely to have already experienced some of the reduction in smoking prevalence associated with visual health warnings (although the UK's implementation of graphical warnings was only on one side of tobacco product packaging compared to the TPD2's two-sided requirement and the label is a smaller size).
69. The TPD2 as adopted differs slightly from the options assessed in the European TPD IA. The IA assumed warnings would cover 75% of the packets and that slim cigarette sticks would be banned (the impact of a ban on slim cigarettes falling under the 'Packaging and Labelling' heading in figure 1). The TPD2 as adopted has the coverage slightly reduced to 65% and slim cigarettes are not prohibited.
70. As such, we expect the reduction in consumption due to packaging & labelling to be at the lower end of the expected range, i.e. 1%. This leads to an overall expected decrease of 1.7%-2.1%, from which the central figure of 1.9% is taken. This figure is consistent with that used in the Impact Assessment for Standardised Packaging of Tobacco Products¹⁴.
71. Assuming, as per the EU IA, that the decreased consumption of tobacco is achieved over 5 years, and that reductions are made in a linear way, we would expect that, from May 2016, tobacco consumption would decrease by 0.38% in the first year, or (assuming that consumption is linearly related to prevalence) that prevalence would fall by around 0.08 percentage points.

Value of reduced prevalence

72. We value the health benefits gained from reduced prevalence in a similar way to the IAs on the legislation to stop the sale of tobacco from vending machines, legislation to end the display of tobacco display in shops and the introduction of standardised packaging. The detailed methodology is shown in Annex A.
73. We start by considering the amount of smoking we expect for the baseline when the TPD2 is due to be enforced. This baseline includes the impact of the tobacco display ban. The General Lifestyle Survey/Opinions and Lifestyle Survey for 2012 found a prevalence of 19.9%. We expect the result of the display ban to be a reduction in this proportion to around 19.8% (To reach this figure, we have applied an annual 0.04 percentage point decrease, taken from the IA for the ending of tobacco displays). This suggests the prevalence in 2016 would be about 19.7%.
74. Applying the 1.9% reduction (as calculated above) to the 19.7% prevalence gives a reduction after 5 years of 0.38 percentage points due to the TPD2. Applying this reduction (in a linear manner) to the UK population aged 16 and over from 2016 - 2020 corresponds to around 200,000 fewer smokers, over and above the benefit attributed to the display ban.

¹⁴ Standardised Packaging of Tobacco Impact Assessment

75. In total, applying the reduction in smoking consumption from the EU IA (as adjusted to the UK environment) to equivalent estimates of smoking prevalence reductions over the 5 years of the TPD post implementation gives lifetime health benefits of £13.7 bn.

Reduced reporting and labelling burden

76. The TPD1 requires manufacturers and importers of tobacco products to submit ingredient and quantity data on an annual basis, and manufacturers and importers of cigarettes to submit TNCO data on an annual basis. The TPD2 replaces this with a requirement for the ingredients information to be submitted only upon a product entering the market, or upon a product being changed. Sales and market survey data will be required on an annual basis, however this will likely be less burdensome and so there may be a marginal reduction in administrative costs as a result of the removed annual burden.
77. The TPD1 requires cigarette labels to contain printed TNCO information. This will be prohibited by the TPD2. The one-off costs of TPD2 labelling changes are identified under 'Costs of Option 1', but here we calculate the estimated reduction in enduring costs to manufacturers from no longer printing TNCO information on unit packets.
78. RAND Europe¹⁵ consulted three large European cigarette manufacturers on the ongoing administrative burden caused by requiring TNCO labelling. Annual costs were reported at £670 - £1,400 per year per SKU¹⁶: taking the mid-point of this gives a central cost estimate of £1,050. Nielsen ScanTrack data indicates that there are currently 626 cigarette SKUs for sale in the UK market. Implementation of the TPD2 would therefore result in an overall annual reduction in administrative burden of £660,000. Over 10 years, this gives a total discounted reduction in costs of £5.7m.

Costs of Option 1

79. The costs of Option 1 can be categorised in the following way:
- A. Enduring costs in the form of reduced profits to tobacco manufacturers, wholesalers and UK retailers of lower tobacco consumption
 - B. Enduring and one off costs to tobacco and e-cigarette manufacturers in reporting more information
 - C. Enduring costs to the UK government in processing, storing and publishing information received from manufacturers
 - D. One-off/transitional costs to manufacturers in adjusting to new labelling and product presentation requirements, product restrictions, and familiarising with regulations
 - E. Costs to the e-cigarette industry of banning certain types of advertising
 - F. Enduring costs to the Exchequer of lower tobacco consumption.

Enduring costs in the form of reduced profits to tobacco manufacturers, wholesalers and UK retailers of lower tobacco consumption

80. The main benefit identified from implementing TPD2 is lower consumption of tobacco by, on average, 1.9% in the UK. This lower consumption will mean, all else equal, that fewer profits will be made by tobacco manufacturers, wholesalers and retailers, offset by more profits made by manufacturers, wholesalers and retailers of other goods and services as spend is diverted elsewhere.
81. Only direct impacts on business should be counted for OITO purposes. Losses of profits to tobacco companies and others in the supply chain due to reduced consumption of tobacco are contingent on the changed behaviour of smokers and so were excluded from OITO calculations in previous tobacco IAs. The Regulatory Policy Committee have now advised that policies which ban or severely restrict a particular activity, that explicitly prohibit a form of promotional activity, and have a primary objective to reduce sales (even if by promoting behaviour change) should be considered as

¹⁵ 'Assessing the impacts of revising the Tobacco Products Directive: Study to support DG SANCO Impact Assessment', RAND, 2011
Henceforth referred to as the 'RAND Europe' report / consultation

¹⁶ All RAND costs were reported in Euros. These have been converted into GBP using the average 2011 (or 2004 where appropriate) exchange rate, and inflated to 2014 prices.

having a direct impact on businesses. Whilst the primary reason for the TPD2 is to harmonise rules across the EU, this legislation is explicitly attempting to maintain a high level of health protection. In this IA we therefore treat profit losses resulting from the expected reduction in tobacco consumption as a direct impact for OITO purposes. We note that the Better Regulation Executive's Framework review is considering the question of the definition of "Direct" for OITO purposes.

82. The expected offsetting increase in spend for other products is however indirect, and so will not be considered in terms of direct cost to business. This will however be accounted for in our assessment of NPV. This offsetting (from an NPV perspective) is broadly consistent with the assessment made by the EU on the impacts of the revised TPD¹⁷. We therefore conclude there is no overall impact on the NPV of Option 1 from switching spending from one sector of the economy to another, but there will be a direct impact on cost to businesses.
83. It may be deemed that the direct cost to business would be reflected by the entire lost profit stream for those product lines that are banned by the TPD2. However, in reality this would grossly overestimate the cost to business, as the large majority of those lost profits would be regained through increased sales of other tobacco products by the same business. This is because tobacco is a highly addictive product and we can expect the majority of existing consumers to continue to purchase even if flavours and certain pack formats are removed from the market. With the exception noted below (on which we seek additional information), we assume the banned products lie within the same product range of the same businesses that also supply the tobacco products that will be switched to, thus making the direct impact of the TPD2 the overall reduction of 1.9%.
84. An assessment of the extent of this loss can be made by using tobacco market size estimates based on Office for Budget Responsibility (OBR) forecasts and then applying the decrease in prevalence expected from the TPD2 of 0.38 percentage points. This volume loss can be applied:
- To an average profit of 30p per pack¹⁸ for tobacco manufacturers to give a total discounted loss of £78m over 10 years (not all of this profit loss is to the UK).
 - To an average profit loss of 16p per pack¹⁹ for wholesalers to give a total discounted loss of £41m over 10 years.
 - To an average profit loss of 32p per pack²⁰ for retailers to give a total discounted loss of £82m over 10 years.
85. This calculation explicitly assumes that the reduction in consumption caused by the TPD2 occurs solely in the cigarette and RYO tobacco markets. This is deemed reasonable given the relative size of these markets and the population groups expected to be affected.
86. The above assessment refers purely to the reduced profit as a result of the overall reduction in tobacco consumption. There may be further effects as a result of the changed product mix following implementation of the TPD2. The restriction on certain products (cigarette packs containing fewer than 20 cigarettes, RYO tobacco containing less than 30g, menthol flavoured cigarettes), will result in part of the overall 1.9% reduction in consumption quantified above. However, the majority of consumers of these products will be expected to continue consuming tobacco in forms that are TPD2 compliant²¹.

¹⁷ Actually the EU assessment goes one step further and uses input output ratios to estimate that any reduction in the final demand for tobacco products is likely to be more than offset by increased economic activity in other sectors. Against this, there may be some loss in brand value associated with TPD2, particularly in relation to menthol and small pack sized brands, which would be an economic loss not recovered elsewhere. This would already be included within the direct costs calculated within this IA for OITO, and are not pertinent to the decision whether to pursue Option 2 rather than Option 1, so they are not material to the decisions being supported by this IA.

¹⁸ This estimate is informed by Tobacco manufacturers' annual reports. "Pack" refers to 20 factory made cigarette sticks. The same profit margin per unit weight of tobacco i.e. 14g is used is for HRT.

¹⁹ This estimate is informed by Wholesalers' annual reports. "Pack" refers to 20 factory made cigarette sticks. The same profit margin per unit weight of tobacco i.e. 14g is used is for HRT.

²⁰ This estimate is informed by evidence from the retail sector of the retailers' margin on cigarettes and HRT. "Pack" refers to 20 factory made cigarette sticks. The same profit margin per unit weight of tobacco i.e. 14g is used is for HRT.

²¹ Both the restriction on smaller unit packages of tobacco and the restriction on menthol flavoured cigarettes are expected to have a greater impact on reducing the take-up of smoking than on encouraging current smokers to quit. In a number of countries research has found that flavoured tobacco products are preferred by children and adolescents as well as experimenting smokers (Ashare et al. 'Smoking expectancies for flavoured and non-flavoured cigarettes among college students', 2013; Hersey et al. 'Are menthol cigarettes a starter product for youth?', 2006).

87. Manufacturers and retailers may therefore face changes in profits if, for example, an equal amount of monetary spend on 20 pack cigarettes generates a different profit to an equal spend on 10 pack cigarettes. As we currently have no evidence on the relative profit margins of different tobacco products for manufacturers, wholesalers and retailers, it is not possible to estimate a change in profit. **We would welcome further information from the industry on relative profit margins.**
88. There are currently a number of RYO tobacco brands that only supply products in non-TPD2 compliant sized packs. There is the potential that these brands may lose customers to those brands with an established presence in the otherwise TPD2 compliant market. This would not represent an overall loss of profit to the industry, but a transfer across businesses. Nevertheless, for those businesses in this position it would represent a cost – and consistently with the treatment of other losses in this IA, it would be direct for OITO purposes. **We would welcome information from the industry on the extent of this potential cost.**

Enduring and one off costs to tobacco and e-cigarette manufacturers in reporting more information

89. The TPD2 requires manufacturers of tobacco products, novel tobacco products, herbal products for smoking and e-cigarettes to report varying degrees of information on their products.

Tobacco

90. Excluding the requirements outlined under the priority additive list section below, tobacco product manufacturers are only required to additionally report “where available”, information on cigarette emissions other than TNCO and emissions from other tobacco products and their levels. We expect there to be minimal administrative costs associated with this task given the ongoing requirement to report a much wider range of information. For the purposes of this IA, we take this cost to be £1,000 per product category.
91. This costing assumption is used in order to generate an indicative burden to industry for the purposes of this consultation. **Information from manufacturers is welcomed so that this estimate may be revised for the final IA.** This figure is not deemed unreasonable, as it would represent approximately 1-2 weeks of staff costs for an employee earning £25,000 per annum, but it is recognised that there will be considerable uncertainty around the below calculations.
92. Approximately 160 cigarette formulations are currently reported to the DH, with a further 40 having been notified. Assuming all of these products are on the market on 20th May 2016 implies a total reporting cost of £200,000. In addition to factory manufactured cigarettes, there are an estimated 1000 cigar, 30 fine cut (RYO) tobacco and 160 pipe tobacco products available. Assuming the same £1,000 cost would imply an additional £1.2m cost, or £1.4m in total.
93. There will be further costs faced by manufacturers upon bringing new products to market after 2016. These are expected to be equally small, but estimation of the total costs to industry is difficult given the uncertainty around future product creation. Inclusion of the 40 cigarette products currently notified to the DH as potentially entering the market in the future will likely capture some of this cost, as it is probable that many will not have entered the market by 2016 or may never do so.

Priority additive list

94. A priority list of additives, containing no fewer than 15 additives, will be adopted by the EU prior to 20 May 2016. We are awaiting a Delegated Act that will set out precisely what, and how many, additives will be included. In order to provide some estimate of cost we operate under the assumption that 15 additives will be placed on this list.
95. Manufacturers will need to produce a comprehensive study on any additives placed on the priority list covering emissions, toxicological and flavouring characteristics and report their findings to the government and the Commission. These studies can be done jointly between manufacturers and a report on the results of these studies needs to be submitted no later 18 months after an additive has been placed on the additive list. Depending on the current state of the evidence base for the chosen additives, it may be possible for manufacturers and industry to satisfy this requirement with a literature review. However, it is also possible that further data collection and analysis would be required. Lacking details of the additives to be chosen, we assume a cost of £50,000 per additive for

each study and report²². For 15 additives this would give a total one off cost of £750,000 – we assume this cost is incurred in 2016.

96. As with the estimate for general information reporting costs, the assumption of £50,000 has been made to generate a plausible estimate of costs to industry for this consultation. **We welcome any estimates from industry on expected costs during the consultation**, but recognise that this will be difficult without the relevant EU Implementing Act being passed. This estimate will therefore be revised as and when further details arise.

Herbal products for smoking

97. Importers and manufacturers of herbal products for smoking will be required to submit information on their ingredients and quantities thereof. There is currently no systematic evidence on the number of herbal products for smoking available in the UK, or any trade body representing a significant proportion of relevant businesses. However, a 2012 HMRC consultation²³ on herbal products liability to tobacco products duty received responses from a small number of producers and retailers. A total of 30 herbal products for smoking related to these organisations were identified as being available for purchase in the UK²⁴.
98. Whilst the manufacturers of these products are not currently required to report ingredient data, it is expected that this information will already be known. As such, a £1,000 administrative cost per product category is applied (the same estimate as was made in the previous section for tobacco products), resulting in a total expected cost of £30,000.
99. It is recognised that this may only be a partial assessment of the herbal products for smoking market, so **any relevant information on both the expected costs of reporting and the total number of organisations and products is welcomed**.

Electronic cigarettes – Product notification

100. Annex B explains why there is huge uncertainty about the number of companies that will be affected by notification requirements. There is even greater uncertainty about the number of products that will be put forward for notification, not least because we anticipate that the costs of generating notification information may deter many companies from putting all of their products through the notification process (i.e. there will be a rationalisation of existing product lines with some being withdrawn from the market). We will use this public consultation and targeted engagement to further investigate these issues.
101. Article 20 of the TPD2 does not specify the methods that should be used to generate the technical information required for notification. This presents a significant challenge to both industry and national authorities in determining the testing standard that should be applied. The e-cigarette industry is working with the British Standards Institute (BSI) to develop a Publicly Available Specification (PAS) to raise industry standards in this sector. Whilst it is a voluntary standard, the PAS appears to reflect the ongoing changes to quality and safety expectations in the e-cigarette market. The PAS may ultimately not be followed by the e-cigarette industry, but the content is deemed indicative of what could be expected to comply with some aspects of the TPD2. A draft of the PAS was released for public consultation in November 2014 and BSI expects to be able to publish the finalised PAS in March 2015.
102. Annex B explains why we have decided to assume that the PAS would not have emerged in its current form or to its current timing without the influence of the TPD2. We therefore do not consider that the PAS should form part of our 'no TPD2' counterfactual.
103. The substantial on-going uncertainty about what standards should be applied in generating notification information means that we are currently unable to accurately estimate compliance costs. Our difficulties are compounded by the absence of information from the "highly fragmented" e-cigarette industry on the standards currently applied across companies. We will continue to engage

²² This figure is deemed reasonable given the current experience of costs incurred in creating peer reviews for chemical regulatory submissions to Government scientific advisory committees (see the assessment of Option 2 costs for further details). These peer reviews often require literature reviews and analysis of study findings to a similar level of the original reports being assessed. The central cost estimate of reviewing, £24,000, is just under half of our assumed cost to tobacco manufacturers – reflecting that the initial report will require additional resource.

²³ <http://www.hmrc.gov.uk/budget-updates/11dec12/4755.pdf>

²⁴ Based on a web search for products supplied by the relevant organisations

with ECITA, the industry trade body, and individual companies in order to provide estimates for the Final Impact Assessment.

104. Our reading of the draft PAS suggests that a proportion of the required TPD2 notification information will be generated through compliance with the PAS. We will use the published draft of the PAS (expected in March 2015) and information gathered during the consultation to assess compliance costs with all TPD2 notification requirements.

Electronic cigarettes – Reporting sales information

105. We are currently assuming that companies will already have the information on sales volumes and therefore there will be no incremental costs of gathering the information. The only incremental costs will therefore be those of collating and send the information to the competent authority. We anticipate that these costs may prove more burdensome for smaller companies, whose existing systems for collating sales information are unlikely to be sophisticated. We will explore this further in future stakeholder engagement when details on the reporting requirements are established by the European Commission.

Electronic cigarettes – Adverse effects reporting

106. Article 20, Paragraph 9 makes it the responsibility of manufacturers, importers and distributors to monitor adverse effects, take appropriate corrective action (including product recall and withdrawal) and to inform Member States “market surveillance authorities” where the products are sold.
107. The draft BSI PAS recommends that the “technical dossier” for each product should contain “Records of customer complaints and/or reports of adverse events relating to the product”. The draft PAS also outlines the circumstances under which products should be recalled and withdrawn, and the procedures for doing so. It also specifies that the competent authorities should be informed of adverse health effects. However, the draft PAS does not include recommendations for establishing and maintaining adverse health effect monitoring systems. We will use the published version of the PAS and information gathered during the public consultation to estimate the incremental adverse effect reporting costs imposed by the TPD2.

E-cigarettes – Summary

108. As stated above, there is currently a great deal of uncertainty surrounding the e-cigarette market that makes accurate estimation of TPD2 compliance costs impossible. In order to generate a possible order of magnitude for these costs, we assign the same £1,000 per SKU cost applied to the other product categories. This is purely based on assumption, and we intend to revise this in light of consultation responses and the evolution of the PAS.
109. There is also uncertainty around the number of products available. Nielsen ScanTrack data suggests that the number of e-cigarette related products available in the UK is at least 1,300. The actual number of product notifications will depend both on the precise requirements for notification (for example, whether different flavours of the same e-cigarette will require individual notifications), and a more refined estimate of the number of products (to be aided by the consultation process). With these caveats in mind, we therefore provide the very approximate estimate of annual costs of £1.3m. **We welcome any information on the above issues regarding e-cigarettes.**

Cross-border sellers – tobacco products and electronic cigarettes

110. Cross-border sellers of tobacco products and electronic cigarettes will be required to register basic information with Member States prior to trading, if the UK takes up the registration option. The level of information required is very limited, so administrative costs will be negligible. We do not currently have an estimate for the number of UK based cross-border sellers, so are unable to generate a plausible total burden of costs. We do know that internet retailing accounts for 0.3% of cigarette sales²⁵, of which cross-border sales will form some unknown subset.
111. Cross-border sellers will also be required to implement age-verification schemes. The Directive requires that sellers verify ‘at the time of sale that the consumer complies with the minimum age requirements provided for under the national law of the Member State of destination’. **We seek**

²⁵ Cigarettes in the United Kingdom, Euromonitor 2014

costing information from tobacco and e-cigarette manufacturers who currently have such systems in place on product websites.

Summary

112. We estimate that costs to the e-cigarette industry may be in the order of £1.3m, although note that there is a high degree of uncertainty around this figure. There is an estimated further £1.4m cost of additional reporting for tobacco products, and a £750k one-off cost for the required studies on additives.

Enduring costs to the UK government in processing, storing and publishing information received from manufacturers

113. All information supplied by manufacturers will need to be received, processed, published and stored by the UK government. We estimate, for the purposes of this IA, that these costs will be lower than the costs to industry of sending the information, as only one set of back office infrastructure is needed, rather than multiple that originate from multiple firms submitting information.
114. The Electronic Model Tobacco Control (EMTOC) web-based reporting system has been developed to aid Member States in collecting ingredient data. This system is not currently used in the UK, but would have cost the UK £11,150 per year to use in 2013-2014. Assuming this real cost is constant, this fee would be faced on an annual basis. DH has estimated that there would be an initial £15,000 set-up cost for joining the system.
115. However, this system would not be fully sufficient for the recording of additional information required by the TPD2. The EC are developing a new system, but there are currently no indications as to what this will cost. Given the additional complexities, it is deemed likely that the costs will be substantially higher.
116. Germany does not currently subscribe to EMTOC, but do publish TNCO data on a website. This requires a 0.3 FTE staff member for data processing and publication²⁶. Assuming that this task was performed by an HEO level civil servant would result in an annual cost of £12,600²⁷. This cost is neither additive nor directly comparable to the cost of EMTOC subscription, as it does not include the infrastructure costs necessary to support data publication. However, it does support the general order of magnitude of costs identified²⁸.
117. DH are continuing to refine their cost estimates of the staffing requirement for receiving, storing, handling, analysing and publishing information on tobacco products. These will depend on the outputs in the Implementing Act on reporting and the degree to which an IT platform for reporting is developed that can be adopted by MS, as anticipated in the Commission's specification for the contractor working on this area at European level. Costs are likely to be higher in the first year when a full set of data for all products is submitted and support will be required for businesses submitting data for the first time. IT support demands are also expected to be higher in the early stages. Staff resource needs are expected to be lower in subsequent years when less data is submitted and companies are more familiar with the system.
118. The UK Government does not currently collect data about electronic cigarettes that have not been granted medicinal status. An additional data handling system will therefore be required. The precise format of such a system is yet to be determined, but for a preliminary estimate of costs it may be assumed to be similar to the system used for tobacco products. It is likely that the costs incurred due to this system will be at least as great as for other tobacco products – and most probably higher as a scheme must be fully developed rather than adopted from the EC and will include gathering and monitoring adverse event notifications.
119. With no further information, we apply the same expected costs of EMTOC to an e-cigarette data management system. It is recognised that this is a preliminary and partial estimate, and we will revise this as more details of the system's requirements and functionality arise during the consultation period. Our overall estimate is therefore a total set-up cost of £30,000, with a recurring annual cost of £22,000.

²⁶ Communication with the Bundesministerium für Ernährung und Landwirtschaft

²⁷ Based on average DH London staffing costs

²⁸ This figure is not included in our total assessment of potential costs to the UK of implementing the TPD2

One-off/transitional costs to manufacturers in adjusting to new labelling and product presentation requirements, product restrictions, and familiarising with regulations

120. The TPD2 will require manufacturers to redesign packaging for a number of reasons, including larger health warnings and removal of certain claims, elements and features.
121. RAND Europe assessed the potential one-off costs faced by manufacturers in order to redesign packaging. It was noted that general labelling redesigns tend to occur every 2 years for cigarette Stock Keeping Units (SKUs), and every 5-7 years for cigar SKUs. As compliance with the TPD is required by 20 May 2016, it is likely that many of the non-compliant packs will redesign packaging in the intervening window as part of natural ongoing business. Therefore, there is an argument that the incremental costs of the TPD2 are zero. However, numerous technical aspects of the packaging requirements are still to be determined by the European Commission, with some Implementing Acts not expected until 2015 Q4²⁹. The changes required by the TPD2 may also necessitate a more expensive redesign process than is usual. As such, we estimate the potential total costs faced of adjusting all non-compliant SKUs.

Cigarettes and RYO tobacco

122. RAND Europe's consultation of tobacco manufacturers received one response in request for estimated costs of redesigning packaging to allow for pictorial warnings. This gave an estimated cost per SKU of £16,600 - £18,700³⁰. However, pictorial warnings are already required in the UK, so the labelling redesign required is likely far less extensive. Evidence from the food industry suggests the cost of a small labelling redesign to be £1,700 - £3,400 per SKU, and an extensive redesign to be £5,900 - £7,500.
123. We have estimated that approximately 323 cigarette (202 otherwise TPD2 compliant, 64 currently making labelling claims and 57 mentholated) SKUs and 81 RYO tobacco (37 otherwise TPD2 compliant, 6 making labelling / flavour claims, and 38 from brands that are currently only available in packs of less than 30g) SKUs may require redesigning once non-compliant SKUs are discontinued³¹. The majority of these are expected to be relatively simple redesigns, costing £2,500 (midpoint of food industry estimate). It is recognised that mentholated packs and those making labelling claims may be subject to more extensive redesign requirements, as rather than just requiring minor technical changes, it will be necessary to adjust branding for TPD2 compliance. As such, we assume costs of £6,700 (the mid-point of the food industry extensive redesign) are required per SKU for these changes³². This higher cost is also applied to those RYO tobacco brands that currently do not produce any packs in a TPD2 compliant size. This results in a total cost of £1.7m, which we assume is faced in 2016.
124. The European Commission IA reported industry estimates of 1.3-1.5% cost increases associated with the introduction of pictorial warnings across the EU. This ongoing cost increase has not been applied in this IA because of the current requirement for pictorial warnings in the UK. It is possible that the larger size requirements for TPD2 pictorial warnings (relative to current UK warnings) may increase marginal running costs. **We welcome any information from industry as to the extent of any such cost.**
125. Manufacturers of cigarettes and RYO tobacco (and their packaging) may face costs in addition to those identified above. Whilst the above calculations consider costs associated with design change, administrative burdens and the replacement of printing plates, there is the potential that businesses will be required to adjust or scrap machinery – specifically for those currently producing smaller packs or flavoured cigarettes. It is likely that manufacturers of smaller packages will be able to

²⁹ http://ec.europa.eu/health/tobacco/docs/implementation_plan_en.pdf - Accessed December 2014

³⁰ All RAND costs were reported in Euros. These have been converted into GBP using the average 2011 (or 2004 where appropriate) exchange rate, and inflated to 2014 prices.

³¹ Based on an assessment of Nielsen ScanTrack Data. This (and other uses of ScanTrack data) does not represent a valid legal assessment of these items, but is a preliminary analytical estimate necessary to generate potential costs.

³² Section 5.3.1 of the European Commission's IA for the TPD2 identified the expected costs of achieving labelling compliance (with the TPD2 as it was defined in 2011/12) for factory manufactured cigarettes and RYO tobacco. These estimates were 14,500 – 50,000 EUR per cigarette SKU and 2,500 – 9,000 EUR per RYO tobacco SKU. These figures have not been used in this IA due to the current requirement for (less substantial) pictorial warnings in the UK, and the expectation that much of this adjustment cost would therefore not apply to products created for the UK market. Whilst the cost reported in the EC IA for cigarettes is substantially higher than that used in this IA, the costs for redesigning RYO tobacco packs are of a similar magnitude.

adjust machinery (at cost) to produce TPD2 compliant packs, but there may be less flexibility for the production of flavour 'capsules'.

126. Euromonitor data suggests that flavour capsule cigarettes accounted for 2% of UK cigarette sales in 2013 – with forecasts that this may rise to 5% by 2018³³. It is not clear what investment in capital has been required for this market, but if this cannot be repurposed it will require scrapping once the May 2020 ban on mentholated cigarettes comes into force.
127. The packaging requirements of the TPD2 may result in losses of brand value to tobacco manufacturers. This could occur through two channels: firstly by restricting the range of allowed products, and secondly by reducing the surface area available for branding on packages. The second of these impacts is likely to be small, as manufacturers will still be able to apply branding to unit packs, just on a marginally reduced area. The loss of brand value for flavoured tobacco products may however be considerable. In addition to the 2% market share of flavour capsule cigarettes, menthol cigarettes accounted for a further 8.5% of cigarette sales in 2013³⁴. Goodwill associated with the brands behind these sales may partially transfer to non-flavoured alternatives produced by the tobacco manufacturers, but there will be a loss nonetheless. There may also be a loss of brand value due to the minimum size restrictions on packs. We do not expect this to apply in cases where a brand currently offers both compliant and non-compliant sized packs. However, we have identified 38 RYO tobacco brands that are currently only available in non-compliant sizes. Whilst creating TPD2 compliant SKUs for these brands would likely maintain any brand value, it is recognised that there may be a loss.
128. The TPD2 will prohibit products benefiting from the transitional arrangements (menthol cigarettes) or exemption from the ban on characterising flavours (pipe tobacco etc.), from being labelled with any reference to taste, smell or flavouring. For example, a brand of menthol cigarettes may continue to be sold until May 2020, but will not be able to be labelled as '<Brand X> Menthol'. **Through this consultation IA we are seeking more impact as to the impact of this provision.**
129. A further potential issue exists around the production of specialist packaging, such as Glide Tec cigarette packages. It is likely that these will be deemed non-compliant under TPD2. **We welcome information from manufacturers on the sunk costs associated with the production of Glide Tec.**
130. **We welcome any information on the potential costs associated with adjusting or scrapping machinery required for the production of other non-TPD2 compliant products**, and will revise our cost estimates in light of the consultation findings.
131. The European Commission Impact Assessment on the TPD2 reported an estimated cost of an ingredient driven product redesign to be 1m EUR per brand. As far as we are aware, the only brands that would need a redesign to comply with the TPD2's ingredient restrictions are those that are currently branded as flavoured. As flavoured versions of otherwise TPD2 compliant brands, it is not expected that these would need to be redesigned (i.e. manufacturers would simply increase production of the non-flavoured version of the brand). **We welcome any information from manufacturers of products where this is not the case, alongside any further estimates of product reformulation costs.**

Other tobacco products for smoking

132. Nielsen ScanTrack data identifies 161 cigar SKUs with non-zero sales in the UK market for the year to June 2014. The TPD2 requirements as per Article 11 generally require only minor adjustments for TPD1 compliant products, but we are aware of some specific industry concerns. Although under this option tobacco products other than cigarettes, RYO and waterpipe tobacco are exempt from carrying the information message and combined health warning, text warnings will be required on the two most visible surfaces. For cigar cases with a hinged lid, the directive requires the text warning to be printed on the inside surface of the packet.
133. This printing requirement means that many cigar pack manufacturing processes may need to be substantially revised, with the potential scrapping of current machinery. Discussion with the Imported Tobacco Products Advisory Council (ITPAC) has revealed that industry bodies are yet to generate

³³ Cigarettes in the United Kingdom, Euromonitor International, July 2014

³⁴ Ibid.

robust estimates of the potential costs faced, so **we intend to explore this issue further during the consultation period, and welcome any relevant information.**

134. More substantial adjustments will be required for individually wrapped cigars, which were exempt from labelling requirements under the TPD1 but will need to comply with Article 11 of the TPD2.
135. Of the 161 cigar SKUs identified, 59 are for products identified as containing only one cigar – and thus will require health warnings for the first time. For these products we apply the cost of an extensive labelling redesign from the food industry, £6,700. For those products (102 SKUs) that currently require health warnings, we apply the lower adjustment cost from the food industry of £2,500 per SKU. This results in a total transition cost of £650,000.
136. There will be an increase in ongoing administrative costs for manufacturers of individually wrapped cigars as a result of the labelling requirements. Responses to the RAND Europe consultation from cigar manufacturers suggested that requiring textual warnings imposes a burden of £150-£300 per SKU per year. We take the mid-point of this value, £225, and apply it to the 59 relevant SKUs. This results in a total annual cost of £13,000.
137. Data submitted by manufacturers of tobacco products to DH suggests that 160 pipe tobacco products are available in the UK. Assuming that these are each available in 1 SKU provides an estimate of how many packages may require adapting. Applying the central cost estimate of £2,500 per SKU implies a relabeling cost of £400,000. **We seek further information clarifying the number of pipe tobacco SKUs currently available on the UK market.**

Herbal products for smoking

138. Herbal products for smoking will be required to include text health warning messages for the first time. We have identified 30 relevant SKUs currently available in the UK market. The specific cost of relabeling would be expected to fall in the £1,700 - £3,400 range of a small relabeling change per product as identified by RAND. Applying the central cost of £2,500 results in a total cost to industry of £75,000.
139. RAND Europe's consultation of tobacco manufacturers identified an ongoing administrative cost associated with the requirement for textual health warnings. This was identified as £1,800 - £8,900 per SKU by cigarette manufacturers and £150 - £300 per SKU by cigar manufacturers. The stark difference between these estimates results in considerable uncertainty around the potential cost to manufacturers of herbal products for smoking. For the purposes of this consultation, we take the crude average of the two ranges' mid-points, £2,800 per SKU per year, as the cost of requiring textual health warnings. Applied to the 30 identified SKUs results in total annual costs of £84,000. **We seek further information from manufacturers of herbal products for smoking on both the number of products that will be affected and any estimated costs of compliance.**

Electronic cigarettes

140. The TPD2 requires Member States to ensure that information leaflets are provided with e-cigarettes and the packaging contains specified information including a prescribed health warning. As noted in Annex B, neither we nor the industry as a whole has credible information on the number of affected products because of the fast pace of development in this market. The costs of (re)designing information leaflets and packaging (and introducing information leaflets where applicable) are also uncertain because the industry is still considering how it will respond to the TPD2 requirements. **We will explore this further in future targeted stakeholder engagement and would welcome any information provided through this consultation.** The TPD2 imposes a number of restrictions on the composition of e-cigarettes and nicotine containing liquid, including:
- Only ingredients of high purity are used in the manufacturer of the nicotine-containing liquid;
 - Except for nicotine, only ingredients are used in the nicotine-containing liquid that do not pose a risk to human health in heated or unheated form;
 - Electronic cigarettes deliver the nicotine doses at consistent levels under normal conditions of use;
 - Electronic cigarettes and refill containers are child and tamper-proof, are protected against breakage and leakage and have a mechanism that ensures refilling without leakage;

- Nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10ml, in disposable electronic cigarettes or single use cartridges and that the cartridges or tanks do not exceed a volume of 2ml;
 - The nicotine-containing liquid does not contain nicotine in excess of 20mg/ml;
 - The nicotine-containing liquid does not contain additives listed in Article 7(6).
141. The additives mentioned in the final bullet point relate to such substances as vitamins, caffeine, colourants and those that enhance nicotine uptake. As far as we know, no e-cigarettes currently, or likely to be placed on the UK market, contain these substances.
142. We understand that most e-cigarette liquid is already sold in refill containers of 10ml or less and that cartridges or tanks of 2ml or less are commonly used because these are the standards that already exist in some EU markets that several UK brands sell into.
143. The industry is aware of concerns regarding the quality of ingredients in their products and the emissions generated by them. There is a move, as indicated in the draft BSI PAS, towards the use of pharmaceutical grade nicotine solution and food grade flavours. We understand that current standards of ingredients used in the industry are variable.
144. From the limited data we have from Nielsen, we believe that the 20mg/ml nicotine concentration restriction will affect only a few suppliers. ECigIntelligence analysts have suggested that less than one in five products will be affected.
145. Current standards applied by the industry regarding tamper and child-proof e-cigarettes and containers are not known. However, there are existing ISO international standards on these aspects.
146. As far as we currently know, nobody in the industry has yet developed a standard to meet the TPD2's requirement for consistent nicotine dose.
147. We will use future targeted stakeholder engagement to explore all of these issues further and generate an estimate of costs for the final IA.

Summary

148. We therefore make an estimate of transition costs due to redesigning packaging of tobacco and herbal products for smoking of £2.8m. There will be enduring costs to manufacturers of herbal products for smoking and individually wrapped cigars of £97,000 per year. **We seek evidence on the number of e-cigarette products that require information leaflets and compliance costs imposed by chemical and physical restrictions on e-cigarettes and related products.**

Costs to the e-cigarette industry of banning certain types of advertising

149. The effect of advertising on tobacco consumption was assessed by the 1992 Smee Report. This found that "The balance of evidence supports the conclusion that advertising does have a positive impact on consumption" and when other countries have implemented bans, these were "followed by a fall in smoking on a scale which cannot reasonably be attributed to other factors". The 2002 consultation document on the Tobacco Advertising and Promotion Act estimated the long term reduction in smoking due to the Act at 2.5%. This was presented as an approximate figure, and there must be further caution in applying it to the e-cigarette market. The wider tobacco industry was thoroughly developed by 2002, with a long history of marketing, but e-cigarettes are an emerging and rapidly evolving industry. Regardless, the evidence implies that a ban on e-cigarette advertising may restrict future growth in the market and reduce consumption.
150. There are two distinct groups that e-cigarette advertising may influence – current nicotine consumers (whether tobacco smokers, e-cigarette users or others) and non-tobacco users including children. There is a clear public health risk if e-cigarettes were to act as a gateway to nicotine addiction by attracting non-tobacco users. Survey data suggests that this is not currently an issue, as less than 1% of never smokers have ever tried e-cigarettes and virtually none continue to use them³⁵. The Committee of Advertising Practice also introduced rules on e-cigarette marketing in November 2014, directly prohibiting advertisements that target non-smokers.

³⁵ ASH / YouGov Survey

151. It therefore seems likely that the impact of a ban on e-cigarette advertising will influence current nicotine consumers. The cost to business as a result of this will depend on to what extent advertising currently influences tobacco product users to switch to e-cigarettes, and to what extent it strengthens individual e-cigarette brands and captures sales from other e-cigarette manufacturers. If the former effect dominates, a restriction on advertising will reduce e-cigarette manufacturer profits. If the latter effect dominates, by concurrently prohibiting all e-cigarette manufacturers from advertising, the e-cigarette industry may not experience significant falls in sales, but will benefit from savings in terms of reduced expenditure on advertising. After discussion with the RPC, and in an approach consistent with that used for the IA on Standardised Packaging of Tobacco, we deem any such impact on the profits of e-cigarette manufacturers, wholesalers and retailers resulting from changed behaviour in light of an advertising ban to be direct.
152. The new and evolving nature of the e-cigarette market makes it extremely difficult to estimate any potential effect of an advertising ban. Because of this difficulty, the European Commission IA on TPD did not generate a potential effect. However, we do have data on the size of the e-cigarette advertising market, and so can consider the scale of any impact.

Impact on marketing agencies

153. The total advertising budget of 4 major e-cigarette companies (Skycig, Vype, Gammuci and E-lites) for 2013 was found to be just under £8.4m³⁶. EcigIntelligence note various industry reports of total 2013 advertising spend at £10m - £11.5m. Since this time, Skycig alone have announced a £20m investment in a new marketing campaign.
154. The direct impact of an advertising ban would be to remove the entire marketing spend of the e-cigarette industry in respect of the types of advertising covered by the TPD (including press, TV, internet). Whilst the latest estimates of total advertising spend are just over £10m, this is likely to be a substantial underestimate of expenditure in 2015 or beyond.
155. At this stage we are unable to calculate a sufficiently accurate estimate for the expected size of the e-cigarette advertising market under our counterfactual Option 0 for the assessment period. This is due to complexities with assessing not only the expected future size of the e-cigarette market, but also changes in how this market utilises advertising. **We welcome any information on the expected impacts of a ban on certain types of e-cigarette advertising, including on manufacturer, wholesaler and retailer profits, and the expected growth in the value of the e-cigarette advertising market.** We expect to present a fully quantified assessment of these costs in the Final Impact Assessment.

Potential health implications

156. Whilst the scientific evidence on the effectiveness of e-cigarettes as a cessation tool is limited³⁷, data from ASH indicates that in March 2014 there were 2.1 million users of e-cigarettes; a third of whom were both sole users and ex-smokers and data from the Smoking Toolkit Study, reports that 30% of quit attempts now involve the use of e-cigarettes making them the most popular method of stopping smoking³⁸. It is possible that an advertising ban may have health costs resulting from smokers not being informed of the availability of products that would reduce the harm of their addiction to nicotine. However, any effect is likely to be limited as awareness of e-cigarettes is already very high in the general population - over 95% amongst smokers and 90 % in non-smokers³⁹.

Enduring costs to the Exchequer of lower tobacco consumption

157. Tobacco products have higher levels of tax and duty applied than other goods and services in the economy. Therefore any reduction in tobacco consumption, even if it is matched by increased expenditure elsewhere in the economy (which we would expect to occur), is likely to lead to a reduction in government tax and duty receipts.

³⁶ E-cigarette uptake and marketing, PHE

³⁷ McRobbie H, Bullen C, Hartmann-Boyce J, Hajek P. Electronic cigarettes for smoking cessation and reduction. Cochrane Database of Systematic Reviews 2014, Issue 11. Art. No.: CD010216. DOI:10.1002/14651858.CD010216.pub2.

³⁸ Smoking Toolkit Study. Trends in electronic cigarette use in England. October 2014

³⁹ ASH Fact Sheet on the use of electronic cigarettes in Great Britain. October 2014

158. For changes in tobacco consumption, we report a potential lifetime impact on duty consistent with the magnitude of the impact on health. The estimates of lost duty have been updated since previous tobacco policy Impact Assessments and use the same methodology as for health benefits. For every additional adult smoker who quits, there is an average discounted lifetime loss of duty of around £11,700. These estimates allow for mortality, consumption of non-UK duty paid tobacco, and the probability that those quitting as a result of the TPD2 would have quit at some point in the future. The methodology employed is detailed in Annex A.
159. We estimate that this reduction, following the assumed 1.9% reduction from the EU IA (discussed at the start of the Benefits of Option 1 section), will result in tax losses totalling £2.2bn over the lifetime of those affected during the standard 10 year assessment period. This lower level of consumption due to TPD will be endured after the 10 year appraisal period. These estimates of lost receipts are indicative and do not allow for future changes in: rates of duty, smoking patterns, the illicit market, and cross border shopping.
160. One can view impacts on tax as transfer payments: for example when the Exchequer loses tax revenue individuals/ businesses will gain an equal amount, so the effects can be seen to offset each other. Most changes in tax revenues are transfer payments, and as such have zero net effect on the NPV (ignoring distributional impacts). However, when considering policies that transfer spending from higher taxed goods to lower taxed goods, DH identify an adverse impact since if the Government decides to maintain public spending additional tax would have to be raised and the public would lose benefit. Therefore, when considering policies that transfer spending from higher taxed goods to lower taxed goods, DH attributes an adverse impact to such a policy, affecting its NPV. In this case, it is the estimate of £2.2bn. It is important to take into account various factors such as the overall impact on society, distributional impacts and the affordability of policy options in terms of government spending and tax. Therefore, whether the tax loss is considered a transfer payment or not, in terms of the public finances if the government loses tax revenue it is an important consideration for the financial feasibility of any policy.
161. The loss of duty mentioned above is for illustrative net present value purposes. This is likely to differ significantly from any Exchequer impact that will eventually be incorporated into the Public Finances, which will have to be certified by the Office for Budget Responsibility (OBR). In part the differences will be down to issues that are not appropriate for inclusion in this Impact Assessment e.g. not discounting, different relevant timeframes etc. In addition consideration will be given to various behavioural responses which are relevant to both the Public Finances and the Impact Assessment. There are significant elements of judgement involved in the applicable behavioural responses around which the OBR will take their own view. In addition over time as more evidence becomes available this may impact on relevant estimates. We therefore expect that the figure that will eventually be incorporated into the Public Finances will differ significantly in light of appropriateness of inclusion (e.g. discounting), OBR judgements and any future evidence.

Illicit and cross-border shipping

162. There are expected to be no significant increases in the consumption of illicit tobacco. The EU IA states:
- With respect to illicit trade, it is also worth noting that none of the preferred options are expected to lead to a (noteworthy) increase in illicit trade beyond the baseline and will therefore not shift additional revenues from the legal to the illicit supply chain.*
163. Cross-border shopping is thought to currently represent a very small market in tobacco products given the level of duty paid in the UK. If there are likely to be any effects, one may expect less cross border shopping as the appeal of cigarettes manufactured for the EU market diminishes relative to domestically sold cigarettes when they have the same picture warnings and labelling regime.
164. Full assessment of the costs and benefits of the track and trace provisions in Article 15 and 16 will be undertaken in an Impact Assessment by HMRC when further details are published by the Commission. It is these aspects of the TPD2 that are expected to have the greatest impact on the illicit consumption of tobacco. **We welcome any relevant information to help inform HMRC's Impact Assessment.**

Apportionment of costs and benefits to NPV and EANCB

165. The figures presented throughout the assessment of Option 1 have related to the total societal and business costs resulting from changes to UK consumer behaviour under the implementation of the TPD2. However, the impact of these changes will not fall entirely upon either the UK population or UK businesses. As such it is necessary to adjust these estimates so that only the UK specific impact is recorded.
166. For EANCB and OITO purposes we adopt a “GDP approach” of attributing costs and benefits. In other words, we assess the proportion of direct costs and benefits that fall on UK-based business activity regardless of where profits are repatriated. For example, 100% of direct costs imposed on retailers are considered in scope (whilst cross-border distance sales will mean this figure is actually lower, the proportion of these is very small).
167. In attributing a share of impact to the UK, we require an assessment of the proportion of the gross value added by UK based activity. For wholesalers and retailers we assume 100% of the profits come from companies with 100% UK based activity. For the manufacturing of tobacco related products, the estimate of the share of value added that is UK based is more complex.
168. There are two multinational tobacco manufacturing companies with UK-based cigarette production, the Imperial factory in Nottingham and the JTI factory in Lisnafillan. These two companies supply around 44% and 41% of the UK tobacco market respectively⁴⁰. We assume that all the value added by tobacco manufacturing comes from factory production (ignoring both any exports from these plants and any value added by importers – as most of the latter would be attributable to wholesalers and retailers.). Therefore, using these market share figures, we attribute 85% of current gross manufacturing value added consumed in the UK to UK based producers.
169. Imperial has announced the closure of this factory, and it is not scheduled to be producing when the TPD2 is implemented⁴¹. JTI have also announced the closure of its factory and we anticipate that all manufacture would cease by mid-2017⁴², one year after the introduction of the TPD2. Therefore, in the 10 year period after the introduction of the TPD2 the proportion of UK consumed tobacco that comes from UK-based production from these factories is around 4.1%.
170. Such an approach implicitly assumes that the decision to close these factories is unrelated to the proposal to implement the TPD2. One takes the projected share of UK value added of manufactured tobacco products that is produced in the UK to be invariant between Option 0 (our counterfactual in which the TPD2 does not exist) and Option 1 (where the TPD2 is implemented). However, it may be argued that the success of tobacco control policies in general, including the TPD2, must be relevant to the decision where to locate production. Although tobacco manufacturing is global and tobacco consumed in the UK does not have to be manufactured in the UK (and vice versa), clearly any expected reduction in branded tobacco consumption in the UK will have weakened the case for maintaining production within the UK, notwithstanding that other factors are also critical in choosing a location for production (for example, relative shipping and labour costs).
171. To resolve this issue, we propose to assume that the decision to close these factories is influenced by the TPD2 but only in proportion to its expected impact upon smoking prevalence in the UK. In contextualising the contribution that anticipation of this policy change might have had on these closure decisions, a decision time frame must be selected. We suggest that it is implausible that changes in smoking prevalence that took place more than a decade ago are having a significant influence upon location decisions now: factories rendered unviable by changes in smoking behaviour that long ago would in general already have been relocated or closed.

⁴⁰ ASH factsheet 18 tobacco Industry, quoting Annual Cigarette Synopsis. Citi Research, 25 March 2014 as original source. Available at http://www.ash.org.uk/files/documents/ASH_123.pdf. Note that although 85% of the UK market may be supplied by them some of that production may be non-UK based. The Imperial factory produces around 17 billion sticks per year i.e. equivalent to around 46% of the 37 billion in the UK market (see Imperial press release 15/4/2014 available at <http://www.imperial-tobacco.co.uk/index.asp?page=78&newsid=2000>). The proportion exported is not known.

⁴¹ Closure date May 2016. Nottingham Post 18/6/2014 available at <http://www.nottinghampost.com/Redundancy-package-agreed-Imperial-Tobacco-staff/story-21255473-detail/story.htm>

⁴² Correspondence from JTI to Northern Ireland Office 7/10/14 “all manufacture at Lisnafillan ceasing by the second quarter of 2017”. Consistent with JTI press release 7/10/14 which discusses closure of this factory as well as one in Belgium stating “factory closures completed between 2016 and 2018.”

172. Conversely, we cannot be confident that the decision has not been influenced by more recent changes in prevalence. It is clear that an unexpected drop in actual or projected prevalence will not lead to the immediate closure of a factory. For production will continue at an unviable factory if revenue exceeds variable costs. It is only at the point that major renewal of capital is required that the cumulative impact of recent declines in profitability will be brought to bear on the decision whether or not to persist with the current location.
173. The precise timeframe will depend upon discount rates and the life expectancy of the fixed capital employed in tobacco manufacturing. Ten years seems a reasonable estimate, and creates a not implausible weight for the impact of this particular intervention.
174. Suppose therefore that the decision to close is therefore affected by changes in consumption over the last decade, as well as by prospective changes in the near future.
175. We note that smoking prevalence has decreased by around 7 percentage points over 10 years⁴³, and this policy is expected to decrease smoking prevalence by around 0.38 percentage points. If there is an equal chance that any particular decrement in prevalence would have tipped the decision against the continued UK location of these factories, then there is a one in twenty chance that this policy was critical to the decision.
176. Against that background, to estimate the statistically expected impact upon UK business, we reckon a one twentieth chance in the absence of these policies the factories would have stayed open. In which case there is a one twentieth chance that 85% of the tobacco manufacturing profits are UK-based. But there is a nineteen twentieths chance that they would have closed anyway, in which case, as above 4.1% of the tobacco manufacturing profits are UK-based. Weighting these possibilities together gives an expected proportion of profits that are UK based of 8% over the period. This 8% is applied to the profit loss of the cigarette and RYO tobacco manufacturers to derive a direct UK-based figure from these factories for OITO and EANCB purposes.
177. The above apportionment is applied to costs and profit losses for cigarette and RYO tobacco products. This market is substantially different to others covered by the TPD – cigars, e-cigarettes and herbal products for smoking. We have therefore estimated a different UK proportion of manufacturing activity for each of these industries.
178. To assess the proportion of cigar manufacturing activity that is UK based, we use Nielsen ScanTrack data to identify the market shares of JTI, Imperial, STG, and other manufacturers. It is not clear if Imperial and JTI produce their cigars for the UK market at their factories mentioned above. For the sake of this assessment, we assume that 100% of their UK cigar sales are produced at these factories. For this proportion of the market, we therefore apply the same methodology used above in assessing the probability that the TPD2 may be responsible for their closure. It is acknowledged that this methodology relies on the changes to total smoking prevalence, which is determined far more by cigarette and RYO tobacco consumption than cigars. However, in pursuing cost minimisation, it is likely that cigar production will be co-located with cigarette production where possible. It is therefore not unreasonable to assume that the decision of where to manufacture cigars for Imperial and JTI is largely influenced by the larger market.
179. According to Nielsen ScanTrack data, JTI and ITL account for 36% and 18% of UK cigar sales respectively. Following from the above logic, in the 10 year period after the introduction of the TPD2 the proportion of UK consumed cigars that comes from UK-based production from these factories is around 3.6%. We then estimate the statistically expected level of production, with a 1 in 20 chance of these factories producing 54% of sales and a 19 in 20 chance of them producing 3.6%. This results in an expected UK share of cigar manufacturing of 6%.
180. The third major producer of cigars for the UK market, STG group (with 36% of UK sales), does not have any manufacturing locations within the UK. In assessing the remaining 10% of UK cigar sales, DH note that excluding the 2 large factories discussed above, we are aware of fewer than 5 small tobacco manufacturers with UK based production (based on product notifications). Given the highly fragmented and niche nature of the market outside of the major producers, it is therefore unlikely that much of the remaining cigar production occurs in the UK. For the purposes of this IA, and so as not to underestimate the potential impact on UK business, we assume that half of this

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Based on Integrated Household Survey data for smokers aged 18+ in 2013 and 2003

production occurs in the UK. This proportion is a pure assumption that we aim to revise downward in light of responses to this consultation.

181. The total estimate for the expected UK share of cigar manufacturing is therefore 11%, which is applied to all expected costs to the cigar market. This figure is also applied to the pipe tobacco market, a niche market that is most similar to cigars. DH has no information on the production of pipe tobacco in the UK beyond inferences possible from the very small number of tobacco manufacturers notified to us, as discussed above. **We seek further information on the presence of wider tobacco manufacturing processes within the UK and welcome any comments.**
182. Detailed data on e-cigarette production is not available – related business activity is not uniquely identified in national accounts, nor can e-cigarettes and e-liquid be distinguished from other products in trade data (both fall under miscellaneous trade codes that encompass a variety of products). Unlike in the case of tobacco, manufacturers of e-cigarettes and e-liquid are not required to specifically register with DH or HMRC for specific tax purposes. We therefore do not have any systematic information on the number of manufacturers located within the UK.
183. ECigIntelligence report that the vast majority of e-cigarettes and e-liquids are currently produced in the Shenzhen region of China. They have also produced an assessment of the UK market for e-cigarettes⁴⁴, which lists the top 30 e-cigarette brands as compiled by Alexa. It is recognised that this list does not reflect the top 30 by market size, but by online brand presence. EcigIntelligence assessed the top 20 of these brands to check for claims that they manufacture their e-liquid in the UK. Of the 20 brands, 12 claim to produce e-liquid in the UK, while 8 do not. To assess the proportion of activity that occurs within the UK, we then linked these brands to Nielsen ScanTrack data on smoking control products. Of the 12 brands that claimed UK-based productions, 6 could be successfully linked to Nielsen data, while data for 5 of the 8 brands that did not claim UK production could be found. That the data linkage is not a simple process reflects the fragmented nature of the market and the difficulty in monitoring sales occurring through non-conventional channels.
184. 41% of total e-cigarette sales⁴⁵ as identified by Nielsen related to the 11 brands that could be linked. The 6 brands claiming to produce in the UK accounted for 16% of the sales identified for the top 20, or 7% of total sales. The remaining 84% are from non-UK producers, accounting for 33% of total sales.
185. Due to the design of the list, some of the largest manufacturers of e-cigarettes for the UK market were excluded. The two largest of these, E-lites and Nicolites, account for 43% of sales as identified by Nielsen. Based on the available evidence, it appears that neither of these manufacture product within the UK^{46,47}.
186. We can therefore estimate that 7% of UK e-cigarette sales do contain e-liquid manufactured in the UK and 78% do not, with the remaining 16% being unclear. Assuming that the distribution of location for these unknowns is the same as for those we do know results in an estimate of 92% of manufacturing occurring outside of the UK.
187. It should be noted that these assessments relate to the production of e-liquid – it is generally noted that the vast majority, if not all, hardware is manufactured in China. As such, applying these proportions may overestimate the proportion of value-added activity that occurs in the UK. On the other hand, many of these e-cigarette firms maintain their head office and marketing teams in the UK, which would lead to these figures underestimating the UK burden. Any attempt to adjust our estimates to account for these factors would require detailed knowledge of the internal workings of e-cigarette manufacturers. It seems plausible that the value-add associated with the creation of e-cigarette hardware is at least as great as that added by UK-based service, not least because UK e-cigarette consumers commonly use disposable products⁴⁸ for which the hardware will likely account for a considerable proportion of the cost.
188. We therefore estimate that 8% of costs to the e-cigarette industry fall on UK-based business activity.

⁴⁴ <http://ecigintelligence.com/data-in-depth-uk-e-cig-brands-products-pricing-analysis/>

⁴⁵ Sales data relate to all identified e-cigarette related products, including disposables and e-liquid refill vials.

⁴⁶ <http://www.birminghampost.co.uk/business/bromsgrove-electronic-cigarettes-firm-e-lites-3907715>

⁴⁷ <http://grocerytrader.co.uk/?p=17905>

⁴⁸ As reported by ECigIntelligence

189. We do not currently have information on where the production of herbal products for smoking occurs. Given the smaller nature of these businesses, and in order to not underestimate the potential impact on UK business, we make the conservative assumption that 100% occurs within the UK.
190. These figures represent our current assessment of the location of production of tobacco, e-cigarette and herbal products for smoking manufacturers. **We welcome any information that can help to refine these estimates, and will adjust our calculations accordingly for the final IA.**
191. In the case of NPV, we have apportioned costs and benefits with respect to the people who are ultimately affected. Health benefits to UK consumers and changes in costs to the UK Government are therefore valued at 100%. Changes in industry profits are apportioned on the basis of shareholder residence. For the tobacco industry, this has been estimated at 10%⁴⁹. This assumption is also applied to the e-cigarette industry, where the major tobacco manufacturers are establishing a growing presence. There is little information on the shareholders of herbal products for smoking, but it is expected that these are more likely to be domestic. We therefore make the conservative assumption that 100% of profits for herbal products for smoking will accrue to UK shareholders. **We welcome any information on the proportion of UK shareholders of relevant companies.**

⁴⁹ The 10% is not based on any one specific source, but was stated clearly during the consultations on Standardised Packaging of Tobacco. However, it does draw on 3 pieces of information. Firstly 10% is a figure used for previous IAs for the proportion of multinational profits that should be considered in the NPV. Secondly there is some information on the shareholdings of multinational tobacco companies, however, this is information about the institutional shareholdings rather than the individual shareholdings. Thirdly, if one was to assume a perfectly globalised market where all companies were multinational, then the proportion of profits received by UK shareholders would be approximately the ratio of GDP for the UK to that of the world which is around 3-4% (IMF – World Economic Outlook Database) using current prices and 2014 figures.

Summary of Option 1 Costs and Benefits, showing the proportions included in the estimates of cost to business and social NPV

			Total Present Value	Proportion included in direct net cost to business	Proportion included in NPV
Product Packaging			£2,100,000	-£610,000	-£520,000
	Transitional				
		Cigarettes	-£1,300,000	8%	10%
		RYO tobacco	-£390,000	8%	10%
		Cigars	-£650,000	11%	10%
		Pipe tobacco	-£400,000	11%	10%
		Herbal products for smoking	-£75,000	100%	100%
	Recurring				
		Cigarette TNCO labelling (removal of requirement)	£5,700,000	8%	10%
		Herbal products textual health warnings	-£720,000	100%	100%
	Individually wrapped cigars textual health warnings	-£110,000	11%	10%	
Information reporting			-£3,500,000	-£340,000	-£370,000
	Transitional				
		Cigarettes	-£200,000	8%	10%
		RYO tobacco	-£30,000	8%	10%
		Cigars	-£1,000,000	11%	10%
		Pipe tobacco	-£160,000	11%	10%
		Herbal Products for smoking	-£30,000	100%	100%
		Tobacco priority additives	-£750,000	8%	10%
		E-cigarettes	-£1,300,000	8%	10%
Government data processing			-£220,000	£0	-£220,000
	Transitional				
		Tobacco reporting set-up (partial)	-£15,000	0%	100%
		E-cigarette reporting set-up (partial)	-£15,000	0%	100%
	Recurring				
		Tobacco reporting (partial)	-£96,000	0%	100%
		E-cigarette reporting (partial)	-£96,000	0%	100%
Tobacco profits			-£201,000,000	-£129,000,000	-£130,000,000
	Recurring				
		Manufacturers	-£78,000,000	8%	10%
		Wholesalers	-£41,000,000	100%	100%
		Retailers	-£82,000,000	100%	100%
Other industry profits			£201,000,000	£0	£130,000,000
	Recurring				
		Manufacturers	£78,000,000	0%	10%
		Wholesalers	£41,000,000	0%	100%
		Retailers	£82,000,000	0%	100%

Additional life years		£13,700,000,000	0%	100%
Tobacco duty		-£2,200,000,000	0%	100%
Total		£11,500,000,000	-£130,000,000	£11,500,000,000
Unquantified effects				
	Reduction in advertising industry profit	Negative (direct cost to business)		
	E-cigarette profits (due to advertising) – Retailers / Wholesalers / Manufacturers	Ambiguous (direct impact on business)		
	Tobacco profits (due to product restrictions redistributing sales)	Negative (direct cost to business)		
	Annual tobacco information reporting (removal of requirement)	Positive (direct cost saving for business)		
	E-cigarette product adjustments & labelling changes	Negative (direct cost to business)		
	Cross-border retailers of e-cigarettes and tobacco products (registration & age-verification costs)	Negative (direct cost to business)		
	Tobacco and e-cigarette Government data handling (partial)	Negative (not a cost to business)		
	Redundant machinery scrapped as a result of TPD2 product restrictions (flavouring & packaging)	Negative (direct cost to business)		

192. The above table summarises the expected impacts of implementing the TPD2 under a copy-out basis (at a minimum cost to business). A number of effects, both direct and indirect, remain unquantified in this consultation stage assessment. Each of these are discussed in their relevant sections above, and for each of these areas additional information is being sought through the accompanying consultation. These impacts will be quantified in the Final Impact Assessment.

Implementing TPD with additional flexibilities (Option 2)

193. This option sets out the costs and benefits of the Governments preferred approach to implementation (subject to consultation). Under this option we would implement the TPD2 in full and take the following options.

Transitional provisions for Tobacco Products (TPs), e-cigarettes and herbal products (Article 30)

194. The TPD2 permits Member States to allow the sell through of old stock at retail level until May 2017, so long as the tobacco or herbal product was produced before May 2016, and that the product is compliant with the old regulatory regime or for e-cigarette that was produced before November 2016. **We intend to adopt this provision to minimise costs to business in changing their packaging to meet the new requirements.**

195. Implementing these transitional provisions is preferred as it allows retailers to sell stock they have already paid for which would otherwise become obsolete. This may be of particular benefit to small and micro businesses with lower, less consistent sales volumes. The additional cost is that it may be possible for old packs of fewer than 20 cigarettes or old labelling to persist which may undermine the health benefits. We expect this effect to be small relative to the NPV of the policy given what we expect to be a relatively short sell through period compared to the enduring timescale for benefits.

196. As this approach to the flexibility is unchanged to that of implementation at a minimum cost to business, the costs and benefits are implicitly included in Option 1.

Exempt TPs other than cigarettes, roll your own tobacco (RYO) and water pipe tobacco from carrying the information message and combined health warning (Article 11)

197. Option 1 exploits the flexibility allowed by the TPD2 in requiring a less onerous labelling regime (i.e. smaller labels without pictures) on TPs other than cigarettes, RYO and water pipe tobacco (i.e. cigars, pipe tobacco etc.) on the basis that these products are generally not attractive to children. The reduced labelling regime would include the general warning 'Smoking Kills' or 'Smoking Kills – Quit Now', one of the text warnings from the combined warning list but no picture, and cessation information; these warnings to be provided in specified sizes and positions on packs and outer wrapping. Current UK legislation requires picture and text warnings on all tobacco products except for individually wrapped cigars and cigarillos. The Government is minded to do so in the case of individually wrapped cigars and cigarillos and to derogate these products from the full labelling regime. The reduced labelling regime under Article 11 still represent a strengthening of the current requirements and would result in clearer labels on these products.

198. Requiring the more extensive health warnings for other tobacco products would impose an additional burden on manufacturers. RAND Europe consulted cigar manufacturers on the estimated cost of adjusting production to comply with pictorial warnings. Estimated costs ranged from £220 to £1300 per SKU. Using a central estimate of £780 applied to the previously identified 161 cigar SKUs results in a total one-off cost of £125,000.

199. There may also be an enduring increase in costs as a result of requiring picture warnings. The same RAND study received estimates of this annual burden to be £170 - £370 per cigar SKU, totalling £43,000 for the entire market.

200. These costs have been applied to individually wrapped cigars and cigarillos as well as packs of cigars. Individually wrapped items account for 59 of the total 161 identified SKUs. Although individually wrapped items are exempted from the requirement of pictorial warnings they will still require an adjustment to packaging. Given a lack of data on costs specifically associated with repackaging these items, it has been deemed prudent to apply the potentially higher estimate of adjusting to pictorial warnings.

201. The cost derived from the RAND consultation for cigars is significantly lower than the estimate provided for cigarettes, and lower than the previously used evidence from the food industry. The RAND report noted that costs reported by cigar manufacturers were consistently lower on a per SKU basis, but could not establish why this would be the case. As such any information on the expected burden to cigar manufacturers, and why this figure may differ from that for other tobacco products, is welcomed.

202. As stated in the assessment of labelling burdens under Option 1, concerns have been raised by some manufacturers about the additional costs associated with applying both exemption and non-

exemption labelling requirements to cigars due to specific packaging issues. Through discussion facilitated by ITPAC we have received an estimate of the costs expected by one major manufacturer, but are unable to use this further due to the commercially sensitive and preliminary nature of the estimate. These potential costs therefore remain unquantified in this assessment. **We will explore this issue further during the consultation period and welcome any relevant information.**

203. The costs to business of not exempting TPs other than cigarettes, RYO tobacco and water pipe tobacco will depend upon the actions taken by other MS. Concerted action across the EU would naturally result in a lower burden for UK related activity than if the UK acted alone in implementing the more extensive requirements. It is not currently known how other MS intend to transpose the TPD2, so no estimate of this effect can be generated at this time.
204. DH Registration data suggests that 160 pipe tobacco formulations are available in the UK. Assuming that these are each available in 1 SKU provides an estimate of how many packages may require adapting. The RAND Europe study did not consult manufacturers of pipe tobacco for estimates of adjusting packages to display pictorial warnings, so we assume an equal cost to that faced by cigar manufacturers. This results in a total one-off cost of £124,000 and annual costs of £43,000.
205. This suggests that not exempting other tobacco products from Article 11 would likely result in an additional one-off cost to industry of £250,000, with further annual costs of £85,000. **These costs are included in the assessment of Option 2 as they do represent a cost that businesses may potentially face.** These calculations are a preliminary assessment intended to inform the consultation, and will be revised on the basis of additional information received.

Choice of health warnings: e-cigarettes and TPs (Article 9, Article 20)

206. The TPD2 provides a number of options on the wording prescribed in the health warnings:
- For tobacco products
 - a. 'Smoking kills': or
 - b. 'Smoking kills – quit now'
 - And for e-cigarettes
 - a. 'This product contains nicotine which is a highly addictive substance'; or
 - b. 'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'
207. **The Government is minded to adopt option b in both cases subject to consultation** because these options support other policies to encourage smokers to quit and position e-cigarettes at an alternative to smoking and not a general consumer product.
208. The costs of either option are deemed to be the same but adopting option b in both cases would, in our opinion, strengthen the public health message and give the best chance for the health benefits to be realised.

Authorisation/notification of novel TPs (Article 19)

209. The TPD2 provides for Member States to implement either a notification scheme or a prior authorisation scheme for novel TPs. An authorisation scheme would introduce significant costs for both the industry and any organisation charged with administering the scheme.
210. A Notification of a novel TP requires information on new products to be submitted 6 months in advance of placing the product on the market and will be supported by the existing strong consumer protection enforcement regime which will allow the withdrawal of products that evidence demonstrates not to be safe.
211. **The Government is minded, subject to consultation, to adopt a notification scheme** as the protections this provides are likely to mean that the additional benefit of a prior authorisation scheme would be outweighed by the cost it imposes.
212. As this approach to the flexibility is unchanged to that of implementation at a minimum cost to business, the costs and benefits are implicitly included in Option 1.

Cross border distance sales of Tobacco Products (TP), e-cigarettes and refills (Article 18)

213. There is the option to ban sales of TPs, e-cigarettes and refills that cross Member States borders e.g. internet sales or to introduce a registration scheme and age verification requirement.
214. Introducing such a ban is likely to harm legitimate businesses and put these at a competitive disadvantage compared to business in member states who do not adopt the ban.
215. We have no evidence that there is a significant amount of illicit trade on-line or that cross border sales form a significant route for the sale of cigarettes to minors. **The Government is therefore minded, subject to consultation, to adopt a registration scheme if this is determined to be the least burdensome option (i.e. less burdensome than an outright ban) and meets all Government policy objectives.**
216. As this approach to the flexibility is unchanged to that of implementation at a minimum cost to business, the costs and benefits are implicitly included in Option 1.

Peer review (Article 6)

217. The TPD2 will bring new Member State responsibilities for banning products containing additives that have been shown to increase the toxic or addictive effect, or carcinogenic, mutagenic or reprotoxic properties of tobacco products. To aid them in making those decisions the TPD2 provides that manufacturers will be required to carry out comprehensive scientific studies into certain additives and submit their studies to Member States and to the Commission.
218. Member States will then have the option to require the scientific reports “to be peer reviewed by an independent scientific body, in particular as regards their comprehensiveness, methodology and conclusions.”
219. **The Government propose to adopt this provision and on a case by case basis seek peer review of any reports submitted.**
220. Additional costs arise to government from this option, but we believe the benefit of being assured that the evidence presented is high quality, accurate and trustworthy will outweigh these costs, and may be negated by reclaiming costs from industry – see ‘Charging’ below.
221. It is expected that in most cases the Government will be satisfied with the European Commission using EU scientific committees to assess the quality of reports. As such, we do not expect that all of the expected 15 additives will require Government commissioned peer review. For this IA we assume that approximately half of the additives, 7, will require additional peer review.
222. The precise cost of peer review will depend on how robust an assessment is required. However, we can estimate the approximate order of magnitude of costs. Government peer review would be expected to use the Committee on Toxicity (COT), Committee on Carcinogenicity (COC) and Committee on Mutagenicity (COM) as appropriate. Based on current contractor costs for preparing reviewing information and papers for the committees we estimate the cost of preparing papers for such a review by the committees to be £19,000 - £27,000. A further cost will be associated with the sitting of the three committees to discuss the findings of each peer review. We estimate the costs for attendance and reading fees for chairmen and committee members at £800 - £2,400 per review. Taking the central points of these two costs results in a total cost per additive of £24,600. Across 7 additives this results in a total cost to Government of £170,000. These are very initial estimates as we do not know the size of the studies that will be submitted.

Charging (Articles 4, 6, 7, 19, 20)

223. The Directive provides that the industry may be charged directly for the cost of the regulatory regime in some areas. These include:
- The verification of the levels of tar, nicotine and carbon monoxide (TNCO) in cigarettes (*Article 4*)
 - The receiving, storage, handling, analysis and publishing information on ingredients and emissions of TPs including novel tobacco products (*Article 7*)
 - The receiving, storing and handling and analysing information submitted to them on e-cigarettes (*Article 20*)

- If the UK chooses to implement an authorisation system for novel TPs then a fee can be charged for that authorisation (*Article 19*)⁵⁰
 - The peer review of scientific studies and additives undertaken by the tobacco industry (*Article 6*)
224. Charging the tobacco industry for the cost of the regulatory regime in these areas will transfer costs from the Government to large multinational companies, of which UK shareholders are estimated to own 10%, and with UK based production estimated at 8%⁵¹. Therefore any shifting of cost burdens is likely to represent value for money for the UK taxpayer. There is precedent for such charging of industry for regulatory functions in other sectors including pharmaceuticals.
225. Some costs would also fall on the e-cigarette manufacturers who are not owned by the tobacco industry. Over the last couple of years the big tobacco firms have acquired a large stake in the e-cigarette industry and we believe the proportion of UK based e-cigarette and e-liquid manufacturing to be low – 8% of the total consumed in the UK. **We seek evidence and confirmation from the consultation on the number and size of firms affected in this market and will add any estimates to the costs calculated in this section.**
226. The contract for verification of TNCO data currently costs the DH £130,000 per year, with a further cost for contract management and monitoring contact with companies. We estimate this cost annually at £30,000. Assuming that these costs remain constant in real terms means that charging for Article 4 would impose an annual cost on industry of £160,000.
227. The costs of information handling, storage and publishing of tobacco products and e-cigarettes were estimated under Option 1. Charging would naturally transfer these costs to industry – resulting in an annual cost of £22,000 and one-off costs of £30,000. As stated earlier (in the assessment under Option 1) this may underestimate costs, notably to the e-cigarette industry, as details of the required reporting systems are yet to be determined.
228. As calculated above, it is estimated that the peer review of studies for additives identified on the priority additive list will be approximately £170,000.
229. Implementing all charging options would therefore transfer annual costs of approximately £180,000 from Government to industry, with a further £200,000 one-off transfer of costs.
- 230. The Government are openly consulting on the adoption of these provisions and the proportionate charging of industry to cover the services listed above. These costs are included in the assessment of Option 2 as they reflect costs that may be faced by business. We will engage with stakeholders further on the likely charging levels before finalising this IA.**

Benefits of Option 2

231. In the assessment above the only quantified benefits relate to Government savings achieved through the charging of industry. However, it is expected that pursuing these options, such as requiring peer review of studies for additives, will have further benefits. We will attempt to quantify these impacts during the consultation period, and provide a full assessment for the Final IA.

⁵⁰ This is not being considered as we are minded to adopt a notification scheme

⁵¹ A full assessment of the extent of UK based production is contained in the 'Apportionment of costs and benefits to NPV and EANCB' section earlier in the document. The same proportions of UK-based activity as estimated in this section have been applied to our expected costs under Option 2.

Summary of Incremental Costs and Benefits of Option 2 Beyond Option 1

		Total Present Value	Proportion included in direct net cost to business	Proportion included in NPV
Product Packaging		-£980,000	-£108,000	-£98,000
	Transitional			
	Cigars	-£120,000	11%	10%
	Pipe tobacco	-£120,000	11%	10%
	Recurring			
	Cigars	-£370,000	11%	10%
	Pipe tobacco	-£370,000	11%	10%
Additive peer review		-£170,000	£0	-£170,000
Charging (Industry cost)		-£1,800,000	-£144,000	-£180,000
	Transitional			
	Additive peer review	-£170,000	8%	10%
	Tobacco reporting set-up (partial)	-£20,000	8%	10%
	E-cigarette reporting set-up (partial)	-£20,000	8%	10%
	Recurring			
	Tobacco reporting (partial)	-£100,000	8%	10%
	E-cigarette reporting (partial)	-£100,000	8%	10%
	TNCO verification	-£1,400,000	8%	10%
Charging (Government revenue)		£1,800,000	£0	£1,800,000
	Transitional			
	Additive peer review	£170,000	0%	100%
	Tobacco reporting set-up (partial)	£20,000	0%	100%
	E-cigarette reporting set-up (partial)	£20,000	0%	100%
	Recurring			
	Tobacco reporting (partial)	£100,000	0%	100%
	E-cigarette reporting (partial)	£100,000	0%	100%
	TNCO verification	£1,400,000	0%	100%
Total		-£1,150,000	-£252,000	£1,300,000
Unquantified effects				
	Improved quality of evidence as a result of peer review	Positive (not a business impact)		

231. The above table summarises the expected **incremental** impacts of implementing the TPD2 under Option 2 over those expected under implementation at a minimum cost to business. The positive UK-attributed NPV results from shifting costs faced by the UK Government to costs faced by multi-national companies, for whom UK residents represent only a small proportion of shareholders.

Rationale and evidence that justify the level of analysis used – proportionality approach

232. The revised Tobacco Products Directive contains many areas where further Implementing Acts and Delegating Acts are required to establish detail that will be necessary for full implementation. Thorough and specific assessment of the costs and benefits associated with implementation is therefore not possible in many cases. A summary of these required acts is presented below. This IA has attempted to identify the scale of the impacts possible under a plausible interpretation of the Directive.

Implementing Acts

- Common reporting format for ingredients and emission data of tobacco products and e-cigarettes (Articles 5(5) and 20(13))
- Establish a list of priority additives for which enhanced reporting obligations shall apply (Article 6(1))
- Establish procedure for determining products with a characterising flavour (Article 7(3))
- Determine precise position of the general health warning and information message on RYO tobacco marketed in pouches (Article 9(6))
- Define the technical specifications for the layout, design and shape of the combined health warning. (Article 10(4))
- Determine technical standards for the operation of a track and trace system (Article 15(11))
- Determine technical standards for the security feature (Article 16(2))
- Determine technical standards for the refill mechanisms of e-cigarettes (Article 20(13))

Delegated Acts

- Establish the picture warning library (Article 10(3))
- Determine key elements of the data storage contracts established under the track and trace system (Article 15(12))

233. The nature of the markets affected, notably e-cigarettes and herbal products for smoking, mean that there is currently insufficient data to robustly assess certain impacts of TPD2. This consultation process and further targeted engagement is being used to gain input from relevant groups and the wider tobacco industry so that a full assessment can be made as part of the final IA.

234. A full list of the areas in which we are seeking additional information is presented in Annex E.

One in Two Out Calculation

235. We estimate the total EANCB of Option 2 to be £11.07m in 2009 prices and discounted to 2010. However, as transposition of EU policy, implementing the TPD at a minimum cost to business (Option 1) is exempt from OITO. Only the additional direct costs associated with Option 2 (gold-plating) are in scope. We estimate this marginal EANCB of Option 2 to be £0.02m.

236. This is only a partial quantification of the expected direct impacts of the TPD2. Insufficient information is currently available to quantify a number of impacts, including the costs to e-cigarette manufacturers from product requirements, lost profits for the advertising industry, and potential lost profits to manufacturers of restricted tobacco brands. We will use the consultation to further develop our estimate of these figures, and provide a full assessment for the Final IA.

Sensitivity and Risk Analysis

237. The calculations in this IA remain a preliminary assessment of the potential implications of the TPD2. It is recognised that a great deal of uncertainty exists around estimates of costs to business,

with these calculations due to be updated, and a more formal assessment of this uncertainty to be completed, as more information becomes available during this consultation process.

238. The magnitude of these costs is however small in comparison to the expected health benefit. Whilst the valuation of this benefit depends on a variety of assumptions, the most important factor is the expected reduction in consumption as a result of the TPD2. Adjusting this reduction shows that the NPV of the TPD2 is expected to be positive for virtually any reduction – even if there are only 1% of the expected number of quitters (a 0.019% reduction), we would still expect to see £137m in discounted health benefits, far greater than the relevant costs.

Specific Impact Tests

Small and Micro Business Assessment

239. Implementation of the TPD2 under Option 1 will generally impact upon the large multi-national manufacturers of tobacco products. However a number of products, especially those in niche markets, may be produced by smaller businesses. DH tobacco notification data suggests that there are fewer than 5 small manufacturers of tobacco products located in the UK. There may be further producers of herbal products for smoking and electronic cigarettes in the UK, although market intelligence suggests the vast majority of the latter products are imports from China.
240. We assume that design and branding functions of tobacco manufacturers are within the company structure and do not rely on independent contracted firms. Therefore all costs associated with branding, design and packaging requirement fall on large firms (bar the fewer than 5 small manufacturers identified above). **We are seeking any further information that would help us to develop this analysis.**
241. In recent years the big tobacco firms have acquired a large portion of the e-cigarette market (in terms of sales volumes), mainly through acquisitions and buy-outs. Many of these firms were previously regarded as being small and micro businesses, but we are now considering these as part of a large multinational firm, even though they may retain their original name and branding. We therefore consider a number of the UK based e-cigarette manufacturers are part of large firms, and so not in scope of this SaMBA.
242. There may still be a significant portion of the e-cigarette market which is UK based and independently owned. Whilst many of the biggest brands are now owned by the large tobacco manufacturers, there are a number of smaller manufacturers. **We seek further information on the number of small and micro e-cigarette manufacturers.** A full discussion of the market is included in Annex B. It is likely that some portion of these will be classified as small or micro, and therefore will be affected by these regulations.
243. Small and micro UK advertising firms may experience reduced business as a result of the ban on e-cigarette advertising. We currently have no information on whether or not such firms are currently used, or what proportion of e-cigarette advertising spend they may account for. **We seek information on any such firms likely to be affected.**
244. We are also aware of concerns raised by the cigar industry around the potential difficulties associated with implementing additional health warnings as required by the TPD2. The relative costs of redesigning packaging will be higher for lower volume products, which may impose a greater burden on small and micro businesses.
245. Using a 2011 market research report⁵², we estimate that 46% of cigarette and RYO tobacco sales occurred in small and micro retailers. The niche nature of cigars, pipe tobacco and electronic cigarettes means it is likely that a higher proportion of these sales also occur among small retailers. The main effect on small and micro retailers is likely to be due to changes in profits due to reduced tobacco consumption after the effects of the TPD2 are fully realised. Implementation of the TPD2 is expected to reduce retailer revenue from tobacco by £82m over 10 years, of which we would expect £38m to fall on small and micro retailers.
246. We would expect this loss in retailer revenue to be offset by an indirect increase in consumption for other goods, but it is possible that not all of these sales will occur in small and micro retailers.

⁵² "Cigarettes in the United Kingdom", Euromonitor International, 2011

Many specialist retailers will stock mainly tobacco products and related paraphernalia, and not the other goods that consumption will switch to. **We seek information on the number of specialist retailers of tobacco products and e-cigarettes, and the potential impact of the TPD2 on their operation.**

247. We do not believe that the health benefits identified, or the unquantified improvement in market functioning due to harmonisation across the EU, could be realised by exempting small and micro retailers and manufacturers from the regulations as they are contingent on consistent application. It would not be possible, therefore, for the benefits to be realised if consumers could still purchase prohibited tobacco products from small manufacturers and retailers.
248. Whilst most aspects of the TPD2 apply to organisations of all sizes, SMEs are exempt from the requirements of Article 6 (priority additive reporting list) if the relevant additive is being studied by another organisation. This should help to reduce costs to small and micro businesses.
249. The implementation of the TPD2 under Option 2 is likely to be the least costly for small and micro businesses, with the possible exception of cigar manufacturers depending on the outcome of the consultation on the labelling requirements of tobacco products for smoking other than cigarettes. We encourage respondents to the consultation to have this in mind when considering the extent to which regulations should be extended to cigars.
250. Not banning cross border selling is likely to be a benefit to small specialist distributors who may continue to operate in this area.
251. No other flexibilities that are suggested are likely to impact on small and micro organisations, but large tobacco manufacturers.
252. The TPD2 therefore impacts directly on some small manufacturers (mainly e-cigarette and cigar manufacturers), and those small and micro retailers who sell tobacco products. We believe that the retailers will see indirect increases in demand for other goods and services to offset this reduction in tobacco demand, although do accept that there may be a footfall effect where the purchase of tobacco prompts sales of other goods in the shop. Where demand for tobacco reduces it is possible that these prompted sales will also fall. We look to implement, where possible, flexibilities that will help to reduce burdens on small and micro businesses, for example for sell through periods, and are looking to openly consult on the extent to which cigar (and other) manufacturers will be subject to the labelling regulations, some of which will be small firms.

Equality Test

253. Neither implementation through copy-out nor any of the flexibilities are thought to impact on equalities. Overall, in its assessment of the impact on equality of this measure⁵³, the Department of Health has concluded that the policy would not lead to any unlawful discrimination, harassment or victimisation of any particular group by gender, race, religion, ethnicity, sexuality, sexual orientation or disability. It is a wide-ranging policy which has potential to advance equality of opportunity by reducing health inequalities.

Competition Test

254. Implementing the TPD2 as per Option 1 will impact upon competition. The TPD2 directly prohibits a number of product characteristics that could previously be used to compete on. Much of the recent innovation in the tobacco industry has occurred in the areas of packaging design and product flavouring – such as the introduction of flavour capsules. These aspects of non-price competition may be replaced by further price competition. Restrictions on the advertisement of electronic cigarettes will also restrict competition in this market.
255. The harmonisation of rules across EU Member States is intended to improve the functioning of the internal market, and as such may increase competitive pressures within the EU.
256. None of the flexibilities under Option 2 are thought to impact on competition, apart from not banning cross border sales which is likely to enhance competition and not put UK businesses at a competitive disadvantage.

⁵³ Tobacco Products Directive, Consultation Equalities Impact Assessment, DH

Sustainability Test

257. Neither implementation of the TPD2 at a minimum nor any of the flexibilities are thought to impact on sustainability.

Environmental Test

258. Neither implementation of the TPD2 at a minimum nor any of the flexibilities are thought to impact on the environment.

Annex A: Life Years Gained and Money Not Spent from Reduced Smoking Prevalence

259. This Annex describes the method and data sources behind the estimation of:

- The discounted number of life years saved for a randomly chosen adult who quits smoking today.
- The discounted amount of money not spent per £1 spent on a 20 -pack of cigarettes for a randomly chosen adult who quits smoking today. This value can be applied to find estimates such as the lost duty per adult quitter.

260. Estimates take account of the fact that many smokers quit during their lifetime, thus reducing the expected number of life years lost from starting to smoke in the first place, and reducing the expected number of life years gained by quitting today. There is a similar effect for monetary estimates.

261. The following main sources of data are used:

- Opinions and Lifestyle Survey (OLS, 2012) source data used to identify the age distribution of smokers and the relationship between age and the percentage of smokers who have quit. It is also used to estimate the average daily cigarette consumption.
- Doll, Peto, Boreham and Sutherland (2004), 'Mortality in relation to smoking: 50 years' observations on male British doctors' (BMJ 2004;328;1519) reports the impact of smoking on mortality, split by age of quitting smoking (if applicable).
- Office for National Statistics (ONS) National life tables, United Kingdom, 2010-12, report population mortality estimates used to transform the outputs of the doctors' study into life years saved.

262. The following steps are followed:

- **1. Identify an estimate of the percentage of smokers who have quit by each year of age.** We use data from OLS (2012) which reports the numbers of those who have never smoked (never smokers), current smokers and ex-smokers, by single year of age. Over time, quitting behaviour results in a decline in the proportion of current smokers among those who have ever smoked (ever smokers). This percentage declines at a fairly steady and constant rate as age increases. A linear relationship was estimated between age and the percentage of ever smokers who are currently smoking⁵⁴; the results imply that 35% of ever smokers have already quit by age 35, with 1.1 percentage points of ever smokers quitting in each year thereafter. This is broadly consistent with a quit rate among current smokers of 2.5% per annum, a figure used in the literature as the background rate of quitting.
- **2. Estimate the proportion of children, who take up smoking, that will quit at various ages.** We assume that children who take up smoking now will quit at the same rate as the historical data above. The results are shown below in table A1. This is important as mortality amongst ex-smokers depends on the age at which they quit. The results are collated into different age bands defined by when they quit (alongside "lifelong smokers"), described below as the "Quit age band".

Table A1: Proportion of children, who take up smoking, that quit in the given quit age bands, or are 'Lifelong Smokers' and never quit (note may not sum to 100 due to rounding)

Quit age band	
Under 35	35%
35 to 44	11%

⁵⁴ This is done using the 75 data points from those aged 16 to 89 inclusive. Ages over 89 are excluded so this value is not overly affected by variations due to small numbers in older ages (note the linear relationship is not very sensitive to this choice).

45 to 54	11%
55 to 64	11%
Lifelong Smokers	33%

- 3. Estimate the proportion of smokers that will quit at various ages.** We consider 5 age bands of current adult smokers. We use the information in table A1 to produce this estimate. We note that for a current smoker to be picked at random, they need to have already reached their age category. For example a current smoker picked at random aged 55 to 64 could not have quit at 40, since that would mean they are not a current smoker, and could not have been picked. This is also taken into account for age bands with corresponding quit age bands. For example if a 35 year old smoker is picked from the age band 35 to 44 the chances they quit in the quit age band 35 to 44 is $11\%/(11\%+11\%+11\%+33\%)= 17\%$. However, if a 44 year old was picked the day before their 45th Birthday, there is a near 0% chance they will quit in the 35 to 44 age band. Therefore, the corresponding value in table A2 of 9% is around half of 17% (when you consider rounding).

Table A2: Proportion smokers that quit in the given quit age bands, or are 'Lifelong Smokers' and never quit

Quit age band	Smoker age				
	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	21%				
35 to 44	13%	9%			
45 to 54	13%	18%	11%		
55 to 64	13%	18%	22%	14%	
Lifelong Smokers	40%	55%	67%	86%	100%

- 4. Identify mortality data (by year of age and sex) for lifelong non-smokers and for the five “quit age bands”.** Mortality data are taken from Doll, Peto, Boreham and Sutherland (2004, Table 5), which lists number of deaths per 1,000 people at ages 35-44, 45-54, 55-64, 65-74 and 75-84. This information is presented at these age bands for lifelong non-smokers, as well as:
 - those who have quit between age 35-44,
 - those who have quit between age 45-54,
 - those who have quit between age 55-64, and
 - those who continue to smoke beyond age 65

These categories of smoker correspond to our quit age bands (alongside an “Under 35” band). The data are converted into relative risks by dividing the number of deaths per 1,000 in each of these four categories by the equivalent number of deaths (i.e. the number of deaths in the same age band) for the lifelong non-smokers. The Doll et al. (2004) study does not report results for all ages and quit bands and so we assume:

- The relative risk of smokers aged Under 35 is 1.
- The relative risk of those in the Under 35 quit band is 1.
- The relative risk of those in the same age as quit band (e.g. a smoker aged 45-54 in the quit band 45-54) is the same as a smoker in that age band.
- The relative risk of smokers aged 85 or over is 1.

We then observe that the average mortality rate observed in the population is made up from the mortality rates of any subpopulations weighted by the size of each sub population. We also observe that we have defined relative risk, relative to never-smokers. For any year of age and sex, these observations provide

us with 6 simultaneous equations and 6 unknown mortality rates. Solving these gives us the following formulae:

- $M_{ns} = M / (P_{ns} + R_{qu35} P_{qu35} + R_{q40} P_{q40} + R_{q50} P_{q50} + R_{q60} P_{q60} + R_{ll} P_{ll})$
- $M_{qu35} = M R_{qu35} / (P_{ns} + R_{qu35} P_{qu35} + R_{q40} P_{q40} + R_{q50} P_{q50} + R_{q60} P_{q60} + R_{ll} P_{ll})$
- $M_{q40} = M R_{q40} / (P_{ns} + R_{qu35} P_{qu35} + R_{q40} P_{q40} + R_{q50} P_{q50} + R_{q60} P_{q60} + R_{ll} P_{ll})$
- $M_{q50} = M R_{q50} / (P_{ns} + R_{qu35} P_{qu35} + R_{q40} P_{q40} + R_{q50} P_{q50} + R_{q60} P_{q60} + R_{ll} P_{ll})$
- $M_{q60} = M R_{q60} / (P_{ns} + R_{qu35} P_{qu35} + R_{q40} P_{q40} + R_{q50} P_{q50} + R_{q60} P_{q60} + R_{ll} P_{ll})$
- $M_{ll} = M R_{ll} / (P_{ns} + R_{qu35} P_{qu35} + R_{q40} P_{q40} + R_{q50} P_{q50} + R_{q60} P_{q60} + R_{ll} P_{ll})$

Where:

- M is the mortality estimate from the ONS life tables
 - The subscripts represent the quit age bands:
 - ns for lifetime non-smoker
 - qu35 for a smoker who quits before they are 35
 - q40 for a smoker who quits between age 35-44 (i.e. around 40)
 - q50 for a smoker who quits between age 45-54 (i.e. around 50)
 - q60 for a smoker who quits between age 55-64 (i.e. around 60)
 - qll for a lifelong smoker
 - R is the relative risk of mortality compared to a lifelong non-smoker estimated using the Doll et al study
 - P is the proportion that this subpopulation represents. P_{ns} is assumed to be the simple average of this value for those aged 16-90⁵⁵ of 59%. The remaining 41% of the population is split by the values in table A1 to derive the other P values.
5. Identify the number of life years lived from now by adults (by age band and sex), and for the five “quit age bands”. For each combination of quit age band (or lifelong non-smokers) and sex, life tables are calculated following the method of Chiang (1984). These life tables are used to model the expected number of life years lived per capita for each combination of sex, quit age band, and age band: Under 35, 35-44, 45-54, 55-64, and Over 65. This is done by representing the age band by approximately the median age in each of these age bands of 25, 40, 50, 60 and 70 respectively. The results for males are seen in table A3 below and the results for females are similar and are not displayed for presentational reasons, however they are considered separately throughout this analysis.

Table A3: Life years lived from now – Male

Quit age band	Smoker age				
	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	56.2				
35 to 44	55.0	40.8			
45 to 54	51.9	37.7	28.8		
55 to 64	50.7	36.3	27.4	19.6	
Lifelong Smokers	48.9	34.5	25.6	17.5	11.0

- 6. Identify the amount of money spent, per £1 spent on a 20-pack of cigarettes by adults (by age band and sex), for lifelong non-smokers and for the five “quit age bands”. The life tables described above are used to estimate the expected number of packs bought each year from now per capita for each of the various combinations. Two further assumptions are needed:

⁵⁵

i.e. the average of the 75 data points from those aged 16 to 89 inclusive. Older ages are excluded so this value is not overly affected by variations due to small numbers in older ages (note the average is not very sensitive to this choice).

First, Opinions and Lifestyle Survey data is used for the average daily cigarette consumption. Secondly we assume that people in the quit age bands Under 35, 35-44, 45-54, and 55-64, quit on their 25th, 40th, 50th, and 60th birthdays respectively. The sum of these values across all future years of age equals the total number of packets bought. This value is multiplied by £1 so that a per £1 spent on a pack figure is derived. This is done so that the outputs from this model can be used to easily estimate any value that is proportionate to the number of packs bought. The results for males are seen in table A4 below and the results for females are similar.

Table A4: Money spent, per £1 spent on a 20-pack of cigarette – Male (values rounded to nearest £100)

Quit age band	Smoker age				
	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	-				
35 to 44	3,200	-			
45 to 54	5,300	2,100	-		
55 to 64	7,200	4,100	2,100	-	
Lifelong Smokers	10,400	7,400	5,500	3,700	2,400

- 7. Discount the numbers of year of life lived and money spent.** As the life years occur in the future, they should be discounted appropriately. The money spent discount rates used are equal to those in the Treasury Green Book⁵⁶. For life years the discount rates used are equal to Green Book rates minus 2%. The 'minus 2%' takes account of the fact that the monetary value per life-year can be expected to grow at the same rate as real economic growth. The 2% figure for this is taken from the Social Rate of Time Preference assumptions underlying the Green Book discount rates. In the short to medium term, life years are discounted at 1.5% per annum (3.5% less 2%) but this declines for survival gains occurring more than 30 years into the future. The sum of the discounted amount of money spent at each year of age equals the discounted amount of money spent by the specified combination of quit age band and sex. The sum of the discounted numbers of life years lived at each year of age equals the discounted number of life years lived by the specified combination of quit age band and sex. This gives corresponding values to those in tables A3 and A4 which are shown below in tables A5 and A6 respectively. The results for females are similar.

Table A5: Discounted life years lived from now – Male

Quit age band	Smoker age				
	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	38.8				
35 to 44	38.1	30.4			
45 to 54	36.5	28.5	23.0		
55 to 64	35.8	27.7	22.1	16.6	
Lifelong Smokers	35.0	26.7	20.9	15.1	9.9

Table A6: Discounted money spent from now, per £1 spent on a 20 -pack of cigarette – Male (values rounded to nearest £100)

Quit age band	Smoker age				
	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	-				
35 to 44	2,500	-			
45 to 54	3,600	1,800	-		

⁵⁶ 3.5% p.a. reducing into the future. Green Book available at <https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-government>

55 to 64	4,300	3,000	1,800	-	
Lifelong Smokers	5,100	4,200	3,500	2,700	1,900

- 8. Identify the life years and money saved per quitter (by age band and sex), for the five “quit age bands”. The difference between the life years lived for each quit age band and the life years lived if a smoker quit at their current age in table A5 is used to estimate these values. For example, table A3 suggests a 40 year old who is going to be a lifelong smoker expects to live for another 34.5 years, but if they were to quit now they would expect to live for another 40.8 years. Therefore the difference of 6.2 years is the life year gain for that quit age band. Similarly this is done for the money saved due to quitting, and repeated for corresponding discounted values as well. The results are presented in tables A7 to A10. The results for females are similar.

Table A7: Life years saved by quitting – Male

	Smoker age				
Quit age band, before intervention	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	0.0				
35 to 44	1.3	0.0			
45 to 54	4.3	3.1	0.0		
55 to 64	5.6	4.4	1.4	0.0	
Lifelong Smokers	7.4	6.2	3.2	2.0	0.0

Table A8: Discounted life years saved by quitting – Male

	Smoker age				
Quit age band, before intervention	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	0.0				
35 to 44	0.7	0.0			
45 to 54	2.3	1.9	0.0		
55 to 64	3.0	2.7	0.9	0.0	
Lifelong Smokers	3.8	3.7	2.1	1.5	0.0

Table A9: Money saved per quitter, per £1 spent on a 20-pack of cigarette – Male (values rounded to nearest £100)

Quit age band, before intervention	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	-				
35 to 44	3,200	-			
45 to 54	5,300	2,100	-		
55 to 64	7,200	4,100	2,100	-	
Lifelong Smokers	10,400	7,400	5,500	3,700	-

Table A10: Discounted money saved per quitter, per £1 spent on a 20-pack of cigarette – Male (values rounded to nearest £100)

	Smoker age				
Quit age band, before intervention	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	-				

35 to 44	2,500	-			
45 to 54	3,600	1,800	-		
55 to 64	4,300	3,000	1,800	-	
Lifelong Smokers	5,100	4,200	3,500	2,700	-

- **9. Estimate the proportion of current smokers by the 5 age categories.** This is done using OLS 2012 and is used to provide an estimate of the probability of the age of a current smoker picked at random. The results are shown in table A11.

Table A11: Proportion of current smokers by age.

Smoker age				
Under 35	35 to 44	45 to 54	55 to 64	Over 65
39%	20%	18%	12%	11%

- **10. Estimate the life years and money saved per quitter and their discounted values.** Male and female estimates of life years gained and discounted life years gained are then downscaled to 65% and 61% of their calculated value respectively. This reflects the fact that the median doctor from the doctors' study smoked 18 cigarettes per day, whereas current averages for men and women are lower: 11.7 and 10.9, respectively (OLS 2012). Current smokers can therefore be expected to experience less harm and hence quitting or not starting means less health benefit. Note that the money values are not downscaled since they already use the current OLS figures. The final numbers are then calculated by weighting the downscaled values in tables A7 to A10 (and corresponding female ones) by the values in the corresponding tables A2 and A11. The male and female results are then averaged to give the following main results:

- **The discounted number of life years saved for a randomly chosen adult who quits smoking today of 1.2 (2.0 not discounted)**
- **The discounted amount of money not spent per £1 spent on a 20-pack of cigarettes, for a randomly chosen adult who quits smoking today of £2,700 (£4,600 not discounted)**

263. The following factors may bias the central estimate of benefit presented above downwards (factors a-d) or upwards (factors e-f):

- a. They do not take account of the improved quality of life that results from quitting smoking. For example, quitters may escape diseases that reduce their quality of life as well as reduce their life expectancy (such as chronic obstructive pulmonary disease).
- b. It is assumed that no harm is incurred by smoking over the age of 84. There is likely to be some harm here (which would increase the measured benefits if counted), but there is a lack of precise data. In any case, as the cohort is fairly small by this age, the results are not particularly sensitive to this assumption.
- c. It is assumed that no harm is incurred by smoking under the age of 35. Again, there is likely to be a benefit from not smoking at this age, but there is a lack of precise data. It is worth noting that means that health benefits for children who do not take up smoking, under this modelling assumption, therefore take some time to develop, and more time than an adult who quits. Therefore when discounting this causes the discounted life years saved to be larger for adult quitters than for children who do not take up smoking.

- d. It is assumed that quitting after the age of 65 yields no health benefit. There is also likely to be a small benefit here, but again, there is a lack of precise data.
- e. By assuming that all adults who are smoking at age 65 go on to be lifelong smokers, the benefits of quitting and not taking up smoking are slightly overestimated.
- f. The Doll, Peto, Boreham and Sutherland (2004) study does not explicitly adjust for confounding factors (although it does control for social class, given that its sample consists only of doctors). For example, if smokers are also more likely to drink heavily, this may exaggerate the mortality impact of smoking. However, a similar cohort study (based in The Netherlands) does adjust for a long list of confounding factors, including socioeconomic status, alcohol use and body mass index. The authors conclude that adjusting for confounding factors reduces the estimated number of (undiscounted) life years lost due to smoking by half a year out of seven years. Given that the estimates presented in this annex are discounted and take account of future quit propensities, any reduction to take account of confounding factors would be considerably less than half a life year.

264. Other limitations of the estimate include:

- a. It is assumed that the same smoking mortality impacts hold for both men and women. The Doll, Peto, Boreham and Sutherland (2004) study only covers male doctors.
- b. It is assumed that the number of life years lost is linearly related to the average daily number of cigarettes smoked throughout life. The relationship is unlikely to be perfectly linear in practice.
- c. It is assumed that the average daily number of cigarettes smoked throughout life remains constant.

Lost tax revenues

265. Using price data supplied by a cigarette manufacturer for the standardised packaging of tobacco products IA we estimate the amount of specific tax and ad valorem duty that is charged per 20-pack of factory made cigarettes based on 2014 tax rates. This gives an average total duty for a 20-pack of factory made cigarettes of £4.93.

266. The discounted amount of money not spent, per £1 spent on a 20 -pack of cigarettes, for a randomly chosen adult who quits smoking today was estimated above at £2,700. This estimate cannot simply be multiplied by the £4.93 duty per pack, since such an estimate would imply that all quitters would have been purchasing UK duty paid tobacco. This is not the case since the share of the factory made cigarette market which is duty paid is 88%⁵⁷. We use this value to reduce the estimate losses to reflect that those consuming non-UK duty paid tobacco will not have been paying duty in the first instance.

267. Taking the 3 figures in the last paragraph, we estimate that £11,700 in tax is lost per adult quitter. This is a discounted value over the course of each person's lifetime.

268. We note that this estimate takes the modelling choice not to account for Roll Your Own (RYO) tobacco. This choice has a minor effect on the estimate since RYO is the minority of the market, and

⁵⁷ 2012/13 figures from Tax gap data available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/249543/131009_Publication_of_Tobacco_Tax_Gap_estimates_2012-13.pdf as well as correspondence with HMRC. Published in table 4 of the standardised packaging of tobacco products 2014 consultation IA available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/323518/impact_assessment.pdf

it does incur duty payments (albeit lower per gram). This choice suggests this may be a slight overestimate of the tax loss. It should also be noted that this is an estimate of the net tax lost, and that although VAT is also lost when spending is transferred from tobacco to other goods and service, VAT is also gained from those other goods and services. This modelling choice to not explicitly model VAT only has a minor effect since the VAT gained from other goods and services will be of comparable size but not exactly the same as the VAT lost from tobacco. This choice suggests that this may be a slight underestimate of the tax lost, since on average goods and services are subject to a lower VAT rate. As is the aim and nature of such modelling choices, these choices tend to cancel each other out and are of a size that does not materially affect the decision that needs to be taken.

Changes since the 2014 Consultation IA on Standardised Packaging of Tobacco Products

269. The method described above is similar to that used in the 2014 consultation IA on Standardised Packaging of Tobacco Products. The main difference is that the 2014 consultation IA on Standardised Packaging of Tobacco Products followed various non-smoking / smoking / quitting cohorts, from birth, and estimated the discounted life years saved by quitting. The method above follows various non-smoking / smoking / quitting cohorts, from various ages, not just from birth.
270. Once the 2014 consultation IA on Standardised Packaging of Tobacco Products had followed these birth cohorts, it controlled for the fact that a smoker picked at random, aged for example 50 cannot have quit aged 35 to 44. Since the 2014 consultation IA on Standardised Packaging of Tobacco Products followed all cohorts from birth, the intermediate values are an estimate of the life years saved (or tax amounts) between new-borns who become smokers who we know smoke to a certain age, and may quit in the future and new-borns who become smokers who we know smoke to a certain age, and quit at that certain age. For example, an intermediate estimate was made for the discounted life years saved for a child who smokes to around 50 (the 45 to 54 band) and then quits, and a child who smokes to around 50 (the 45 to 54 band) and then has various chances of quitting as they get older (or remaining a lifelong smoker).
271. Without discounting, the results of both methods are very similar. However, with discounting, the results vary, with the duty and tax results varying more since the discount rate of 3.5% is larger than the health discount rate of 1.5%.

Annex B: Electronic cigarette market

History and current situation

272. The first generation of e-cigarettes appeared in the UK in 2008. Consumption has since grown rapidly. Although nobody knows for certain how big the UK markets for e-cigarettes are, ECigIntelligence has recently estimated that there are currently 2.5 million UK vapers (consumers who use e-cigarettes at least once a week), and that the value of the market in 2014 will be worth between £225 million and £300 million. This compares with ECigIntelligence's 2013 market value estimate of between £160 million and £250 million.
273. An estimated 60% of the UK market by value is currently taken up by the "cigalike" form of e-cigarette⁵⁸. These products mimic the appearance of conventional ready-made cigarettes and can be disposable, or rechargeable and refillable.
274. The other estimated 40% is accounted for by refillable tank products. These make no attempt at mimicry, have greater battery and power capacities and some later generation products are available with interchangeable components so that vapers can tailor the vaping experience to their particular needs.
275. Nielsen ScanTrack data suggests that in the twelve months to November 2014, approximately 1,300 e-cigarette related products from at least 63 trading companies were sold in UK retail outlets. These are almost certainly significant under-estimates. Analysts from ECigIntelligence believe that there are at least 100 companies that import and/or manufacture e-cigarette products and suggest that the total could be several hundred more. They also suggest that when all flavour and strength combinations are taken into account, the total number of products is likely to be several thousand more than the Nielsen estimate. The difficulty of arriving at even very rough estimates of company and product numbers has been explained to DH by several industry insiders in terms of the "highly fragmented" nature of the industry.
276. There is a large number of small e-cigarette companies that have physical retail ("vape store") or internet presences, or both. Little is currently known in aggregate about these companies other than they concentrate on the refillable tank form and often import e-cigarette hardware and liquid. Information on smaller brands is currently unavailable because many of these companies are new, do not sell through traditional retail channels (which are tracked by market information companies such as Nielsen), and they are generally not represented by the industry's trade body. We will use the public consultation to discover more about these smaller companies.
277. As far as we know, manufacturing in the UK has so far been largely restricted to the production of liquids (albeit most liquid is reportedly still imported). Nearly all hardware is still imported, particularly from China.
278. In 2013 and early 2014 several of the largest e-cigarette cigalike brands were acquired by global tobacco companies, who saw the opportunity to diversify their product ranges and exploit economies of scale from their cigarette marketing and distribution expertise and infrastructure. We understand that revenues from e-cigarettes still represent a small part of global tobacco companies' overall revenue.
279. Some global tobacco are also developing their own e-cigarette products and other "harm reduction" products, such as "heat not burn" products that avoid some of the toxicity of tobacco smoke by using chemical reactions to heat tobacco in order to release nicotine without combustion.
280. Several large tobacco and pharmaceutical companies are showing interest in licensing e-cigarettes as medicines. This relatively costly route⁵⁹ allows suppliers to differentiate their products from non-medicinal e-cigarettes, with potential advantages of greater consumer confidence. A medicines licence also allows suppliers to make marketing claims relating to harm reduction and smoking cessation. An additional bonus is that VAT can be minimised. Non-prescription medicines can be advertised to healthcare professionals and to the public. These differences would to some

⁵⁸ ECigIntelligence report October 2014

⁵⁹ In 2013, MHRA estimated that the annualised cost of acquiring and maintaining a licence for a single e-cigarette would be between £87,000 and £266,000 based on a 3.5% discount rate and a ten year appraisal period. This estimate did not include the costs of meeting the strict standards for pharmaceutical good manufacturing practice.

extent mitigate the cost disadvantage of having to satisfy strict licensing standards relating to standards of quality efficacy and safety, and potentially make the licenced products competitive with non-licenced products. However the licensing route is generally only open to larger companies that can finance the upfront licensing costs before a marketing authorisation is granted. MHRA has recently licensed one nicotine inhaler (non-electronic) that mimics a conventional cigarette, and is considering an application for one e-cigarette (that uses an electrically powered heating process to create vapour).

281. The UK market split between cigalike and tank forms has been changing over recent years, with a move towards greater use of the tank form⁶⁰. A pattern seems to be emerging whereby vapers tend to start vaping using the cigalike form because it is convenient and readily available. These consumers either stop using e-cigarettes, perhaps because they have managed to quit smoking and overcome their nicotine addictions, or they tend to graduate onto tank based systems because this form allows the vaping experience to be tuned to create better, more consistent nicotine delivery, and satisfy consumer demand for multiple flavours and lower cost. Although the tank market has to date been largely supplied by smaller companies, the main cigalike brands are beginning to take note of this market development and some are offering tank systems of their own.

How would the market for e-cigarettes have developed in the absence of the TPD2?

282. This question is difficult to answer because the market is evolving so quickly and could have developed in future in numerous directions. However it is possible to draw some broad conclusions by identifying non-Article 20 factors that are likely to shape the market:

a. Continued move towards tank based systems.

283. Consumer preferences are likely to continue to shift towards greater use of tank based systems, which hitherto have largely been the preserve of numerous smaller specialist companies. However, the marketing and distribution power of the major cigalike brands (backed by global tobacco companies), combined with the likelihood that cigalikes will continue to act as the introduction to vaping to most new consumers, will probably mean that the cigalike form will continue to hold a major market share. Furthermore, the large brands are likely to continue making inroads into the tank system market by offering their own tank products. The effect of this is that, in the “no TPD2” scenario, one might expect the number of suppliers to decrease and the average size of company to increase.

b. Acquisitions and consolidation

284. As previously noted, the trend towards larger supplier size has already started in the cigalike market, with several acquisitions in 2013 and early 2014. However, industry observers suggest that all the obvious targets have been acquired and so, for the time being, further acquisitions in the cigalike market are unlikely. Widespread acquisitions in the tank markets are perhaps less likely given the smaller sizes of potential acquisition targets. However some consolidation might be expected to occur in the tank market, as smaller companies merge to exploit economies of scale and counter increasing competition from the major brands. This provides further reason to believe that the average size of e-cigarette suppliers will increase and the total number of companies will decrease in the future, regardless of the effect of the TPD2.

c. Quality improvements and the emergence of formal standards

285. As noted by the Parliamentary Office for Science and Technology⁶¹, there are signs that e-cigarettes manufacturing standards, particularly among larger suppliers, are improving. This is to be expected in a maturing market as suppliers seek to differentiate their products from those of competitors.

286. An industry-led formal quality and safety standard is also emerging. ECITA (The Electronic Cigarette Industry Trade Association) has been developing a formal standard for several years. Most recently it asked the British Standards Institute to develop a Publicly Available Specification

⁶⁰ Interestingly this development is also happening in parallel in the US market, which is often regarded as being of a similar nature to the UK market.

⁶¹ <http://www.parliament.uk/business/publications/research/briefing-papers/POST-PN-455/electronic-cigarettes>

(PAS)⁶². The e-cigarette PAS covers “recommendations for the manufacture, importation, labelling, marketing and sale of vaping products”. A draft of the PAS was put out to consultation in November 2014. Current plans are to publish the finalised PAS in March 2015.

287. It is not clear to what extent the emergence of this PAS is due to industry expectations of the TPD2. There are clear non-TPD2 factors that would encourage the development of such a standard, notably the recent public debate and press coverage around e-cigarette safety. Information provided by ECITA clearly indicates that the current PAS has been influenced by article 20 of the TPD2. It is also clear that ECITA would have pursued industry standards backed by national and/or European standards institutes regardless of the existence of Article 20 but would have done so to a longer timescale and using different design criteria.
288. According to the British Standards Institute, the reach of the PAS is likely to be considerable across the UK e-cigarette market. Trading Standards Officers will refer to the standard in investigating e-cigarette safety and quality and so, whilst voluntary, the pressure on suppliers to comply with the PAS will be strong.
289. The involvement of BSI should result in a rigorous standard, if agreement can be attained between all stakeholders. It will however require investment on the part of suppliers to achieve compliance. It therefore seems likely that the effect of the PAS will be to reduce the number of suppliers and increase the average size of company. We believe that this effect would almost certainly have been felt sooner or later without the influence of the TPD2.
290. The PAS should have the effect of raising quality and safety standards, and in-so-doing, it should have some effect on reducing harm to health. However, the lack of a substantial body of evidence on the ill health effects of current e-cigarettes means that we are unable to estimate the PAS’s beneficial effect on health.
291. The PAS’s place in the counterfactual is difficult to gauge. For the sake of avoiding underestimates of the incremental costs imposed by the TPD2, it seems sensible at this stage to discount the PAS’s influence during the appraisal period. This assumption is conservative because it seems highly likely that an industry standard in some form would have emerged as part of the counterfactual.

d. *Medicines licensing*

292. A step beyond the PAS is full medicines licensing. This requires more rigorous pre-market testing and trialling, more robust manufacturing practices and the obligation to conduct “pharmacovigilance” (activities designed to monitor the safety and effectiveness of medicines once they have been released onto the market). In addition distributors of licensed medicines are required to hold medicines Wholesaler Dealers Licences. Whether many e-cigarette suppliers will view the incremental benefits of licensing as outweighing the incremental costs is currently uncertain. However, if medicines licensing becomes widespread, and licensed products gain significant market share, the expectation will be that the average size of companies in the sector will further increase.

e. *Other factors*

293. We can be less certain of the role that other factors may play in shaping the counterfactual. For instance, technologies that could potentially compete with e-cigarettes to satisfy nicotine cravings, such as “heat not burn” products, may in future affect the e-cigarette market. Also taxation and restrictions on where vaping can take place may in future be used as tools to control e-cigarette consumption.

⁶² A PAS has many of the features of a full British Standard, and in fact, a PAS can become a full British Standard after two years after publication and a review.

5.7. INDIRECT EFFECTS / HEALTH IMPACTS

294. As explained the various policy options are expected to impact the economic stakeholders and Governments not only in a direct manner (e.g. costs/benefits associated with the implementation of the measure), but also in an indirect manner. Over time the proposed measures are expected to impact on peoples' awareness on the risks associated with tobacco products, which in turn will lead to a change in behaviour. Less young people will start smoking and some adults will successfully quit smoking. This is expected to lead to a reduction of smoking consumption/prevalence.
295. When comparing with international experiences, it is assumed for the purpose of this impact assessment that the combination of the preferred policy options will lead to a **reduction of consumption of around 2 %** (1.7-2.6% see figure 14 below) within a five year period after transposition beyond the baseline for FMCs and RYO. This corresponds to a reduction of 2.4 million smokers in the EU. It has to be stressed that this figure is a best effort estimation.
296. The assumption of 2% is mainly based on experiences and estimations from other jurisdictions. All policy areas are expected to make a contribution to the overall consumption drop, albeit not to the same degree. The main contributions are expected from the policy areas on packaging and ingredients which are mutually reinforcing.
297. Several independent studies have assessed and attempted to quantify the impacts of **packaging and labelling measures**. Practically all reached the conclusion that such measures impact on the awareness of consumers, which over time changes also smoking behaviour but there was some divergence as to the exact level. The prevalence of adult smoking in Canada has declined approximately 6% since the implementation of large pictorial warnings in 2001, which is at least partially attributable to the picture warnings⁶³. Another study prepared for Health Canada assessing a set of policy measures on labelling similar to the ones proposed in option 1 under packaging and labelling estimated a rather small reduction of 0.3 percent to 0.8 percent in the number of smokers within ten years⁶⁴. Assuming uniform quit rates across smokers with different consumption levels this corresponds to a comparable drop in consumption of about 0.3-0.8% resulting from those quitting⁶⁵. It should be emphasized that at the time of the Canadian assessment picture-based warnings were already in use which could limit the additional impact to be expected. A cost-benefit analysis prepared for the Australian Government estimated that introducing pictorial warnings covering 50% of the front and back of the packets would result in a 1.3% decline in smoking prevalence rate per annum (12.3% decrease in 10 years) and a 3% decrease in tobacco consumption per capita per annum (26.3% decrease in 10 years)⁶⁶. The UK Department of Health's impact assessment (2007) estimated that the introduction of pictorial warnings would result in a 0.5% decrease in smoking prevalence in the long term compared to 0.05 percent decrease in consumption if the status quo (text warnings only) were maintained⁶⁷. Finally, a more recent US impact assessment estimated the reduction in smoking prevalence as a result of introducing nine pictorial warnings, occupying 50% of both display areas, including a mandatory reference to a toll-free quitline⁶⁸. The reduction in the US smoking population in 2013 was estimated at 213,000 persons (corresponding to a prevalence reduction of 0.45%), with small subsequent effects.
298. In its opinion from 2010, SCENIHR concluded that the use of fruit and candy flavours seems to favour smoking initiation in young people and that some additives decrease the harshness and increase the smoothness of the smoke⁶⁹. The US FDA Tobacco Products Scientific Advisory

⁶³ Health Canada. Canadian Tobacco Use Monitoring Survey (CTUMS). Ottawa: Health Canada; 2008. www.hc-sc.gc.ca/hc-ps/tobac-tabac/research-recherche/stat/ctums-esutc_2008-eng.php (accessed 06 Nov 2012) as referenced in Hammond D. Health warning messages on tobacco products: a review. *Tob Control* 2011; 20:327-3.

⁶⁴ Industrial Economics Incorporated (IEC). Economic evaluation of Health Canada's proposal to amend the tobacco product information regulations: Final report. Cambridge, MA: IEC; 2009. (Report for Health Canada).

⁶⁵ As a result of the measures proposed, an additional reduction in consumption levels can also be expected for those who keep smoking

⁶⁶ Applied Economics. Cost-benefit analysis of proposed new health warnings on tobacco products. Canberra: Applied Economics; 2003. (Report prepared for the Commonwealth Department of Health and Ageing, Australia)

⁶⁷ UK Department of Health (UK DoH). The Introduction of Picture Warnings on Tobacco Packs – Final Regulatory Impact Assessment. London: UK DoH; 2007.

⁶⁸ US Dept. of Health and Human Services. Required Warnings for Cigarette Packages and Advertisements. 2011 Federal Register Vol. 76, 22 June 2011/Rules and Regulations, pp.36628-36777.

⁶⁹ SCENIHR 2010.

Committee confirmed, on the basis of the extensive review of all available information, that the evidence was sufficient to conclude that it is more likely than not that the availability of menthol FMC increases the likelihood of experimentation and regular smoking beyond the anticipated prevalence if such FMC were not available⁷⁰.

299. The contribution to the reduced smoking prevalence from policy area “**STP and extension of the product scope**” is primarily expected to result from the possibility that e-cigarettes can develop a potential as a smoking cessation aid under the preferred option.
300. Also the measures in the policy areas dealing with **cross-border distance sales⁷¹ and traceability & security features** are expected to contribute to a drop in consumption, in particular in the illicit segment of the market. Part of this demand will return to the legal supply chain, which is however more expensive and therefore it is expected to encourage some consumers not to start smoking/stop smoking or smoke less, in particular in parts of society with lower revenues such as young people. Also, consumers are better informed by the health risks of tobacco products fully compatible with the TPD.
301. Figure 14 provides a tentative break-down of the contributions of individual policy areas. More information is provided in Annex 5. While 2% is estimated reasonable, it needs to be underlined that even a lower drop in consumption remains beneficial from a macro-economic and Governmental/societal perspective (see section 6.2.4 and Annex 5). It needs also to be stressed that conclusive empirical data is lacking for some of the measures, including NCP (where no electronic cigarettes have been authorised, at this stage, under the medicinal products’ legislation).

Figure 14: Tentative contributions of individual policy areas to the projected decrease of cigarette/RYO consumption

Policy area		Foreseen contribution to the decrease in %
Scope	(STP)	0.2-0.3
	NCP	
	(Herbal)	
Packaging & Labelling		1-1.5
Ingredients		0.5-0.8
TOTAL		1.7-2.6%
Cross-border distance sales + Illicit trade		Additional decrease of consumption, however not in the legal supply chain. (Decreases in illicit consumption could mitigate the decrease in the legal chain).

302. In addition to the predicted drop in smoking prevalence, the preferred options are also likely to result in reduced uptake of **STP and herbal products for smoking**. In particular, it is expected that STP use will remain limited to specific population groups already using these products and that recruitment of new users will become more difficult. However, it is difficult to quantify this effect, also in the light of increased use of smoke-free environments.

A.5.2. SOCIO-ECONOMIC IMPACT ASSOCIATED WITH A REDUCTION OF TOBACCO CONSUMPTION

A.5.2.1. Methodological approach

303. The main objective of the analysis in this annex is to quantify socio-economic impacts linked to a drop in cigarette/RYO prevalence and consumption, as a result of the implementation of the proposed preferred policy options. For this, our analysis was based on the assumption that the **combination of the envisaged policy options would lead to a drop of tobacco consumption of 2% for cigarettes and RYO⁷²** beyond the baseline in 5 years. In absolute figures, such a drop in tobacco consumption corresponds to **2.4 million Europeans** that would either not start smoking or successfully manage to quit smoking.

⁷⁰ Tobacco Products Scientific Advisory Committee (TPSAC). Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations. Rockville, MD: US Food and Drug Administration; 2011.

⁷¹ In an experimental Californian study from 2004 96.7% of participating minors were successful in finding and ordering tobacco on the internet. Jensen JA, Hickman NJ 3rd, Landrine H, Klonoff EA. Availability of tobacco to youth via the Internet. JAMA 2004; 291(15):1837.

⁷² The focus on cigarettes and RYO is due to the fact that the preferred policy options focus on these segments and concrete measures are proposed for them whilst for other tobacco products (pipe and cigars) the preferred options foresee delegated powers. For smokeless tobacco and herbal products intended for smoking, the reference is made to the analysis on policy area 1 (scope).

304. The expected impacts are analysed for the **fifth year after transposition** of the envisaged directive, i.e. at a time when the measures are expected to develop their major impact in terms of decreased consumption. This should not be understood to mean that there are no **impacts on consumption** before or after "year five". On the contrary, the drop in tobacco consumption is expected to develop gradually, starting already in year one and continuing beyond year five. This is for example due to the fact that some provisions (e.g. new mandatory picture warnings) are expected to initially affect actual and potential smokers awareness before leading to a change in smoking behaviour, while other provisions (e.g. the ban of characterizing flavours) may have a more direct/immediate effect on smoking behaviour. Overall, the measures are expected in particular to affect the uptake of smoking in young people leading to a continuous reduction in smoking consumption in the long run. This effect develops and reinforces itself over time⁷³.
305. Some **benefits of reduced tobacco consumption on public health** will also only develop over time. While improvement for certain tobacco related acute diseases (e.g. respiratory illnesses) are expected to be seen within short time period, the effect on some other diseases (e.g. cancer) may take several decades to fully materialise. A scientific study from 1997 suggests that maximum health benefits from tobacco control policies are observed five years after a tobacco control measure is introduced⁷⁴. In this light, "year five after transposition" was selected as a good proxy for the analysis of the effects. The long term benefits (e.g. reduced cancer rates) are anticipated to allow for a fair comparison. Social discounting is used where appropriate.
306. As indicated the preferred policy measures are – in combination - expected to lead to a **decrease of consumption of 2% compared to the baseline**⁷⁵. This assumption is in line with expectation and experiences of other tobacco control agencies which have observed similar drops for comparable policy measures. According to these, the main contributions are expected from the policy areas on packaging and labelling and ingredients. Whilst the details how each policy area contributes to the decrease of consumption are set out in the introductory part of section 5.7 of the IA report, the following table contains an overview:
- [Repeated table omitted, see 'Figure 14' above]*
307. The figures in the above table should be interpreted with caution. Firstly, the proposed measures are mutually reinforcing. For example, improved health warnings and an improved ingredients policy both have the public health objective of making it less attractive for young people to start smoking⁷⁶. The combination of these measures is expected to have a better effect than the sum of each individual measure. Secondly, from an *ex post* perspective it is sometimes not straight forward to fully disentangle the impact of the different measures.
308. Typically **tobacco regulators introduce a variety of measures at the same time**. This is due to the fact that there is not one single policy measure that could make the introduction of all other tobacco control measures redundant. Tobacco control policy measures include among others price/tax policies, smokefree environments, information campaigns, advertising bans/limitations, health warnings. The task to say with precision which measure contributed to the success and to which degree is further complicated by the fact that certain measures require time to take full effect (see above). Lastly, the success of many of the policy measures implemented in other jurisdictions needs to be judged against the backdrop of existing measures, national/cultural differences and the economic situation of the country concerned. The same applies to the situation in the different Member States.
309. In the light of the arguments above, it seems preferable to work on the basis of the assumption that the **combination of the envisaged measures will lead to a drop of consumption of 2% in 5 years' time**.

⁷³ In this respect it is considered that more than 80% of smokers start smoking when they are under age (teenagers) and that nicotine contained in tobacco has addictive properties, which makes smoking cessation a challenge. It is also considered that people, who do not start smoking under age, are less likely to start smoking at a later stage and that children of smokers are significantly more likely to start smoking
- Anne Charlton, Youth and Cigarette Smoking, <http://www.globalink.org/en/youth.shtml>, accessed on 11 March 2012

- Meg Riordan, Campaign for Tobacco-Free Kids; www.tobaccofreekids.org/research/factsheets/pdf/0127.pdf, accessed on 11 March 2012

- U.S. Department of Health and Human Services, Preventing tobacco use among young people; <http://profiles.nlm.nih.gov/ps/access/NNBCLQ.ocr>, accessed on 11 March 2012

⁷⁴ Jan J. Barendregt, M.A., Luc Bonneux, M.D., and Paul J. van der Maas, Ph.D. N Engl J Med 1997; 337:1052-1057

⁷⁵ For description of the base line see section 2.3 of the main report.

⁷⁶ Although the main objective of the revised directive is the improvement of the internal market, when it comes to the assessment of the effects of the proposed options, the drop of consumption needs to be assessed in line with the objective of a high level of public health.

310. For the sake of clarity and transparency, annex 5 provides not only the calculations for a 2% reduction, but also **calculations based on higher and lower impact scenarios**. This is done to show that more stringent measures could have even bigger impact (e.g. plain packaging, full ban of additives, full ban of displays, which could lead to a reduction of consumption of up to 5%), but also to show - if the current expectations prove not to be correct - that even smaller decreases in tobacco consumption are beneficial and therefore make sense from an impact assessment point of view. This simplified sensitivity analysis did **not suggest any significant variation of qualitative outcomes within the broad range of the assumed consumption drop**.
311. In order to bring our range into perspective, a comparison can be made with various global targets. For example, the WHO envisages a 40% relative reduction in prevalence of current tobacco smoking by the year 2025, taking 2010 as a base year. In comparison to these figures, the projected consumption drop is not overly ambitious, even if tobacco product regulation is just one tool of many and other tobacco control measures may also contribute to decreasing smoking prevalence.
312. One last **important caveat** should be remembered, **collecting data and presenting it in a coherent form was a challenge** when preparing the IA report. Whilst all possible efforts were made to gather the most comprehensive data, some challenges remain. For example, some stakeholders either did not provide the requested information or did not provide the information in a usable format. Furthermore, information received from economic stakeholders could not always be reconciled with publicly available data (e.g. Eurostat). The data sets received from industry were also not always fully consistent when comparing data of different market participants (here every effort was made to reconcile the data to the extent possible). In order to ensure overall quality, some key data was verified with associated services (e.g. tax revenues) and/or industry (e.g. turnover generated with tobacco products and the allocation of shares across stakeholders along the value chain). Finally, information on the illicit part of the market was difficult to establish in a robust form taking into account the nature of these activities.
313. As explained above, this annex addresses the expectation of how reduced tobacco consumption impacts on various stakeholders. It does not address other (for example direct) impacts associated with a change of regulation (e.g. costs/benefits associated with implementing the new regulatory requirements on labelling). These are described in the respective sections of section 5.5 of the IA report.

Annex D: Questions for consultation

To better understand the likely costs and benefits of implementing the TPD2, and to develop the consultation-stage impact assessment, we are seeking further evidence on the following questions:

- What is the likely cost of reassigning or retiring capital and adjusting manufacturing processes in response to the restrictions on certain product lines and requirements for additional health warnings?
- What are the likely marginal impacts of implementing the TPD2 on e-cigarette manufacturers?
- We are aware that tobacco products that benefit from transitional arrangements (menthol), or are exempt from the ban on characterising flavours, will no longer be able to provide a reference to the flavour on the packet. We would be interested to receive views on the impact of this provision.
- Do you have any further information that may inform the calculations in this IA, specifically in those areas outlined in Annex E?
- Do you have any further comments on the approach taken in this IA?

Annex E: Full list of areas in which additional information is being sought

1. The expected evolution of the electronic cigarette market in the absence of the TPD2;
2. The expected loss in profits as a result of product restrictions, including information on the relative profit margins of TPD2 compliant / non-compliant products;
3. Whether the product restrictions will reduce profits of specific businesses who may not experience offsetting increases in consumption due to their brand portfolio;
4. Expected administrative costs to tobacco, e-cigarette and herbal products for smoking manufacturers of reporting information, including product notifications;
5. Expected costs of generating and collating sufficient evidence on the additives (to be) listed on the priority additives list;
6. The number of companies and products in the e-cigarette, herbal products for smoking and 'other tobacco products' markets;
7. The costs of implementing and maintaining an age-verification system for online sales;
8. If there will be a marginal increase in printing costs associated with larger pictorial warnings;
9. The expected impacts of differing transitional arrangements for product flavouring and product promotion;
10. Costs of complying with packaging and product requirements under Option 1, including losses related to specific packaging types (e.g. GlideTec), and costs specific to manufacturers of 'other tobacco products';
11. If any products are expected to require reformulation to comply with the TPD2;
12. The number of pipe tobacco and herbal products for smoking SKUs available in the UK;
13. The expected costs of requiring textual warnings on herbal products for smoking and individually wrapped cigars;
14. Expected effects of a ban on e-cigarette advertising;
15. Expected costs of requiring information leaflets in e-cigarette products;
16. The number of e-cigarette products, and the expected costs of achieving compliance with TPD2 physical and chemical minimum standards;
17. Any expected impacts on illicit and cross border shipping of tobacco products;
18. The extent to which relevant business activity (especially for NTPs, herbal products for smoking and e-cigarettes) is occurring in the UK, including upstream processes, and specifying small and

micro businesses. Any further details on the closure of the remaining two large UK cigarette manufacturing plants;

19. The extent to which tobacco and tobacco related product company shareholders are UK residents;
20. The number of, and expected impact on, small specialist retailers of tobacco and e-cigarette products;
21. The proportion of e-cigarette advertising that is accounted for by small and micro UK firms;
22. Expected costs of complying with packaging requirements for 'other tobacco products' under Option 2.