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Consultation on implementation of the revised Tobacco Products Directive (2014/40/EU)

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1. Purpose of this consultation

- 1.1. Directive 2001/37/EC¹ lays down rules at EU level on the regulation of tobacco products. These rules have been in place for over a decade and in order to reflect scientific and market developments, and also international agreements under the World Health Organisation (WHO) Framework Convention on Tobacco Control (FCTC)², the European Commission published a proposal in 2012 to update and replace the Directive³. Following negotiations between the European Council and European Parliament, Directive 2014/40/EU was adopted and published in the Official Journal of the European Union on 29 April 2014⁴. Member States must transpose the revised TPD into domestic law by 20 May 2016.
- 1.2. Directive 2001/37/EC is implemented in the UK by The Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002⁵. In order to transpose Directive 2014/40/EU, the Government proposes to revoke and replace the current UK Regulations. Legislation in this area is by and large not devolved. In keeping with the extent of the current legislation therefore, the Health Departments in England, Scotland, Wales and Northern Ireland are content for the UK Government to transpose the Directive in Regulations which will apply to the whole of the UK. A draft of the proposed Statutory Instrument has been prepared and published alongside this document.
- 1.3. The revised Directive aims to harmonise the regulation of tobacco and related products across the EU, and there is little scope for the Member States to deviate from its provisions. The Government will explore, in this consultation, the pros and cons of the options in certain areas where the Directive provides flexibilities for Member States to opt for certain provisions and areas where further clarity or elaboration is required. These issues are considered in this consultation document and the draft impact assessment published alongside this document. The consultation does not cover standardised packaging of tobacco products, which has been subject to a separate Government consultation⁶.
- 1.4. There are areas of the revised Directive that are yet to be determined by the EU. This further detail will be set out in Implementing Acts and Delegated Acts, which are further pieces of EU legislation. Each of these areas is highlighted in this consultation and accompanying documents. Whilst the Government will be conducting targeted stakeholder engagement on these measures, given that they may be published close to the implementation deadline of 20 May 2016, we would encourage interested parties to engage with the European Stakeholder consultation to ensure any proposals best reflect their views (see section 4.9).

2. Background to consultation

Tobacco Products Directive 2001/37/EC

- 2.1. The Tobacco Products Directive 2001/37/EC (hereafter referred to as 'TPD1'), set down rules at the EU level concerning the composition and labelling of tobacco products. This forms part of a wider package of tobacco control measures to ensure the smooth functioning of the single market and a high level of health protection.
- 2.2. The TPD1's main provisions established reporting requirements for emissions and ingredients in tobacco products; required Member States to verify emissions of cigarettes and set labelling requirements including text warnings and optional picture warnings.
- 2.3. More than ten years have passed since the adoption of the TPD1, making it necessary to update the Directive in order to bring it in line with market, scientific and international developments in the tobacco sector.

Tobacco Products Directive 2014/40/EU

- 2.4. The European Commission published a proposed revision to the TPD1 on 19 December 2012, the revised Tobacco Products Directive (2014/40/EU) (hereafter referred to as 'TPD2'). The TPD2 has the main aim of contributing to the smooth functioning of the internal market for tobacco products and also in related products, such as herbal products for smoking and e-cigarettes.
- 2.5. In early 2014 the European Council and European Parliament formally approved the TPD2. The TPD2 was adopted by the EU on 29 April 2014 and must be transposed into the law of EU member states including the UK by 20 May 2016.
- 2.6. The main new provisions of Directive 2014/40/EU:
 - a) Introduce a minimum pack size of 20 cigarettes and minimum weight of 30g for roll-your-own tobacco (RYO);
 - b) Continue, and enhance in some areas, the reporting of ingredients and emissions of tobacco products, including the introduction of a harmonised reporting format;
 - c) Increase the size of combined health warnings consisting of a text and photograph warning and cessation information, increased in size to cover 65% of front and back of pack (previously 30% on front of pack and 40% on back of pack);
 - d) Ban certain descriptors, such as "natural" or "organic";
 - e) Ban cigarettes and RYO tobacco containing characterising flavours such as menthol (with a transition period to 2020 for products whose Union-wide sales volumes represent 3% or more);
 - f) Introduce a traceability system and security features to track and trace tobacco products, to strengthen the fight against illicit trade;
 - g) Regulate electronic cigarettes and associated refill cartridges;
 - h) Regulate herbal cigarettes;

- i) Introduce a notification (or authorisation) system for novel tobacco products.
- 2.7. A detailed summary of the new provisions is provided in **Table 1 of the draft Impact Assessment**.
- 2.8. In order to understand how the TPD2 requirements apply to the different types of products captured within the scope of the Directive, a quick reference table is provided in **Appendix A**.

3. Policy Objectives

Update harmonised tobacco control legislation

- 3.1. The TPD2 aims to update rules which are already harmonised, in line with new market, scientific and international developments. Over the last decade the market has changed significantly including the introduction of innovative new products, particularly in the area of electronic cigarettes (also known as vapourisers, e-cigarettes, Nicotine Inhaling Products or electronic nicotine devices(ENDS)), where Member States have taken different approaches to regulation. The TPD2 ensures the regulation of these products is harmonised and prevents the distortion of trade in the single market. Member States will continue to be able to monitor new products placed on the market including novel tobacco products and e-cigarettes to ensure they meet safety and marketing standards.

Tackling Illicit Trade

- 3.2. HM Revenue and Customs (HMRC) and Border Force have been highly effective in reducing the illicit cigarette trade from 22 per cent in 2000-01 to 10 per cent in 2013-14, and from 61 per cent to 39 per cent for RYO/hand-rolling tobacco⁷. Success in reducing the illicit share of the tobacco market helps to reduce consumption, reduce organised crime in local communities, prevent young people accessing tobacco, reduce revenue loss to the HM Treasury and support legitimate retailers. The TPD2 includes strong measures against illicit trade of tobacco products, by introducing an EU-wide tracking and tracing system for the legal supply chain and a security feature combining both visible and invisible elements (e.g. holograms) which should strengthen the tracking of legitimate products through the supply chain, facilitate law enforcement and help detect counterfeit products.

Health protection

- 3.3. Tobacco use remains one of the most significant challenges to public health in the UK. Smoking is the primary cause of preventable morbidity and premature death, accounting each year for over 100,000 deaths⁸. One out of two long-term smokers will die of a smoking-related disease.⁹ In 1974 almost half of the UK population smoked. Smoking rates have fallen significantly, but 18.7%¹⁰ of adults still smoke in the United Kingdom.
- 3.4. While smoking prevalence has fallen steadily since its peak in the mid-20th century, prevalence in certain sections of society means 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 groups¹¹. 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 also high in particular ethnic and social groups. Research demonstrates that smoking rates amongst people with mental health disorders are significantly higher than in the general population and there is growing evidence to show a strong association between smoking and mental health disorders.¹²
13 14 15
- 3.5. The Department of Health and Devolved Administrations (hereafter referred to as the 'Government') are particularly focused on taking action to reduce the uptake of smoking

by young people. 207,000 children still take up smoking each year, which equates to 600 children (aged between 11-15 years) starting smoking in the UK each day. Most adult smokers take up smoking before the age of 20 with 40% taking up smoking before the age of 16¹⁶. Preventing initiation of smoking therefore forms an important strand of any tobacco control strategy.

- 3.6. The TPD2 is aligned with UK policy in this area and focused on prevention, with provisions aimed at ensuring 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 the risks associated with tobacco and related products.

International considerations – World Health Organisation's Framework Convention on Tobacco Control (FCTC)

- 3.7. There are also wider policy considerations which have been taken into account in the development of the TPD2. The European Union and the UK are party to the World Health Organisation's Framework Convention on Tobacco Control (FCTC). The FCTC is the world's first public health treaty. It places legal obligations on all parties to meet the treaty objectives to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke and to implement comprehensive tobacco control strategies. The TPD2 takes account of the FCTC and the obligations it places on the European Union and its Member States, preventing barriers to trade arising, by harmonising Member States' approaches to the Treaty's implementation.

4. Approach to implementation

- 4.1. The Government proposes to give effect to the TPD2 in the UK by revoking and replacing the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002. The proposed regulations will apply across the whole of the UK and will sit alongside other tobacco control legislation. Certain elements of TPD2 are already implemented by the Standardised Packaging of Tobacco Regulations (S.I.2015/829) (see section 5.2).
- 4.2. The TPD2 continues the EU ban on the sale of tobacco for oral use. It is therefore proposed that the Tobacco for Oral Use (Safety) Regulations 1992 (S.I. 1992/3134), which implemented the original ban in the UK, will be maintained.
- 4.3. The Government intends to implement requirements within the TPD2 in line with its EU Transposition Principles and Better Regulation Framework. In addition, the revised Directive contains several flexibilities that Member States can opt to take up. These flexibilities are the main focus of this consultation and are considered in this document and accompanying consultation stage impact assessment.

Competent Authority Roles

- 4.4. The TPD2 requires Member States to designate a competent authority to implement and enforce the provisions of the Directive. Whilst Department of Health and Health Departments of the Devolved Administrations have overall responsibility for implementation of the TPD2 into domestic law, the complexity of the Directive and the division of responsibilities within the UK makes it necessary to work closely with other Government Departments. These roles are outlined below:
 - Track and trace and security features – Secretary of State for Health working closely with HM Revenue & Customs (HMRC)
 - Electronic cigarettes - the Secretary of State for Health acting through the Medicines and Healthcare products Regulatory Agency (MHRA)
 - Enforcement – Local Authority Trading Standards, HMRC and Border Force UK.

Timetable for implementation

- 4.5. Member States must transpose the TPD2 by 20 May 2016. Some elements have already been transposed – see section 5.2. In order for the Government to achieve this it is necessary to consult now on the options provided to Member States and seek views on the draft UK regulations and gather information to inform the impact assessment. The Government has taken this opportunity to share with stakeholders a draft of the implementing regulations which indicates how it intends to implement the remaining provisions of the Directive itself.
- 4.6. It is important to highlight at this stage that the TPD2 sets out the main requirements and obligations that will apply to tobacco and related products. There are however, a number of significant areas which are yet to be agreed at EU level. The TPD2 confers powers to the European Commission to adopt Implementing Acts and Delegated Acts, to supplement or amend certain non-essential elements or to implement uniform conditions.
- 4.7. A summary of the key EU acts that are required is provided in **Table 1**.

Table 1. Summary of key TPD2 Implementing and Delegated Acts

<p>Implementing Acts</p> <ul style="list-style-type: none"> • 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) and 7(4)) • 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))
<p>Delegated Acts</p> <ul style="list-style-type: none"> • 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))

- 4.8. The Commission has published a timetable for the publication of the Implementing and Delegated Acts on their website¹⁷. The timetable includes detail on how they will engage with interested parties in the development of these acts. Whilst the Government will be conducting targeted stakeholder engagement on these acts, given that they will be published quite close to the implementation deadline of 20 May 2016, we would encourage all interested parties to engage with the European stakeholder consultation to ensure that any proposals best reflect their views. Stakeholders will note that Acts specified in articles 15 and 16 relating to track and trace and security features will not be published until after the transposition deadline. Documents relating to the Implementing and Delegated Acts can be found on the European Commission website¹⁸.
- 4.9. To ensure that the Government is best placed to implement the Directive by 20 May 2016, it is consulting interested parties now on the options that Member States have and on the proposed implementation of the majority of its provisions. It is proposed that further targeted engagement with stakeholders that have identified themselves as having an interest through this consultation; will be conducted as and when details on the Implementing and Delegated Acts emerge from the Commission. These engagements may be short in nature, to enable the Government to effectively influence negotiations

with the Commission and other Member States and consider its approach to implementing these further Acts.

IMPORTANT. Interested Parties, who wish to engage further with the Government on any of the areas impacted by any of the Implementing and Delegated Acts listed above, are invited to provide their contact details and indicate their areas of interest by completing the online form referenced in Section 9. When we have further details of these Acts, we will use these details to seek further views as necessary.

5. Draft UK Implementing Regulations

- 5.1. Draft regulations have been prepared and published alongside this document. The draft regulations set out proposed requirements to transpose the majority of provisions of the TPD2. These regulations will be revised following consultation and publication of the Implementing and Delegated Acts. Those areas where Implementing and Delegated Acts are yet to be adopted are highlighted in the draft regulation. These elements are drafted on what is known at the present time, or are left blank. These areas will be subject to further targeted stakeholder engagement when details emerge from the Commission – see section 4.9.
- 5.2. Please note that Articles 13 and 14, and one element of Article 9.3, of the TPD2 are not included in these regulations. These articles relate to the presentation and appearance of products and their packaging, including their shape, minimum unit quantities (i.e. minimise pack size of 20 cigarettes and 30g of RYO) and banning of certain descriptors such as ‘natural’ or ‘organic’. These are implemented by in the Standardised Packaging of Tobacco Products Regulations (SI 2015/829) which were consulted on in a UK consultation that ran from 26 June 2014 to 7 August 2014 and laid before Parliament on 19 March 2015.
- 5.3. Provisions on a track and trace system and security features (Article 15-16) and prohibition of certain forms of advertising of e-cigarettes (Article 20(5)) are not yet included in the draft regulations. Further information on the track and trace provisions is provided at section 5.41-42.
- 5.4. Whilst we welcome views on any aspect of the draft regulations, where we are seeking views on specific areas, consultation questions are set out in this section and summarised at **appendix B**.

Overview of the draft regulations

- 5.5. The draft regulations follow the Directive closely in most areas, only differing where clarification is required to ensure clear and effective transposition into UK law. The regulations are also structured to be as user-friendly as possible, in line with good drafting principles and Better Regulation principles.
- 5.6. The main focus of this consultation is on certain areas where Member States have flexibility to choose from a number of options provided for in the TPD2. These flexibilities are set out in the following section.

Ingredients and Emissions (TPD2 Articles 4-7; Draft UK Regs 12-16)

- 5.7. As in the previous Directive, the TPD2 continues the requirement for manufacturers to test emission levels of tar, nicotine, carbon monoxide (TNCO) in cigarettes, against maximum levels (10mg for tar, 1mg of nicotine, and 10 mg of carbon monoxide per cigarette). There is no longer a requirement for manufacturers to declare TNCO levels on packets, but data will be published and made available to the public, subject to consideration of trade secrets.
- 5.8. The TPD2 requires Member States to require manufacturers and importers of any tobacco product, to report information on ingredients and emissions for each product via

a standardised electronic format. Enhanced reporting obligations will be required for certain frequently used substances found in cigarettes and RYO tobacco (a 'priority list of additives'). This will enable regulators to gain more information on the ingredients contained in tobacco products and their effects on health and addiction.

- 5.9. The Commission must adopt a standardised reporting format for tobacco products and e-cigarettes by means of an Implementing Act. The Commission has not released details on the form this may take or specific data requirements, therefore this will be subject to further targeted stakeholder engagement when details emerge – see section 4.9.
- 5.10. The TPD2 requires Member States to prohibit the placing on the market of cigarettes and RYO tobacco containing a characterising flavouring and certain additives, including vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks; caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality; additives having colouring properties for emissions; for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake; and additives that have carcinogenic, mutagenic or reprotoxic (CMR) properties in unburnt form.
- 5.11. The Department of Health currently operates a *Voluntary Agreement on the Approval and use of Additives in Tobacco Products in the UK*, dated March 1997 (The 'Agreement') and a list of *Permitted Additives to Tobacco Products in the United Kingdom*, dated October 2003¹⁹, which was agreed by the representatives of tobacco manufacturers and importers and the four UK Health Departments. Other Member States have taken different approaches to allowing or prohibiting additives and ingredients, which has negative impacts on the free movement of goods in the EU. The TPD2 harmonises the regulation of additives and ingredients and will supersede this agreement.
- 5.12. The European Commission will establish a priority list of additives (further details in section 5.13) and in doing so will review the positive and negative lists of additives used in Member States and seek the views of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).

Priority list of additives – peer review of industry reports (TPD2 Article 6)

- 5.13. 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. The Commission will establish a priority list of additives by May 2016. To assist regulators, the Directive provides that manufacturers will be required to carry out comprehensive scientific studies into these 'priority' additives and submit their studies to Member States and to the Commission. Small and Medium Enterprises (SMEs) are exempt from the obligations of this article if a report on an additive is prepared by another manufacturer.
- 5.14. Member States and the Commission may require the scientific reports to be peer reviewed by an independent scientific body, in particular as regards to their comprehensiveness, methodology and conclusions.
- 5.15. We are minded to request the peer review of industry reports as and when required.

Q1 Should the Government request peer review of any reports submitted by the industry in relation to certain additives contained in a priority list of additives?
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Ban on characterising flavours (TPD2 Article 7)

- 5.16. The TPD2 requires Member States to prohibit cigarettes and RYO tobacco with a characterising flavour. This is defined as a ‘clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives (see further detail in definition (Article 2(25)))’. Products with more than 3% share of the EU market are provided with a transition period of four years. The EU Impact Assessment suggests that menthol cigarettes represent approximately 4% of the EU market, ranging from 25% in Finland to 0.1% in Greece²⁰. The market share of menthol cigarettes in the UK has been rising year on year and in 2013 stood at 8.5%.²¹
- 5.17. Other tobacco products, such as cigars, cigarillos, pipe tobacco, waterpipe and smokeless tobacco products are exempted from the ban on characterising flavours. The Commission is empowered to remove this exemption if there is a substantial change in circumstances for any of these products (in terms of sales volumes or prevalence levels among young people).
- 5.18. To assist Member States and the Commission to determine whether a product has a characterising flavour, the Commission will establish an independent advisory panel at EU level. In the UK it is envisaged that referral to the European Panel will be managed through existing enforcement liaison mechanisms. Trading Standards will then take appropriate enforcement action following the outcome of the Panel’s assessment.
- 5.19. The TPD2 will prohibit products benefiting from the transitional arrangements (menthol cigarettes) or exemption from characterising flavours (pipe tobacco etc.), from being labelled with any reference to taste, smell or flavouring. For example, a brand of menthol flavoured cigarettes may continue to be sold until May 2020, but will not be able to be labelled as ‘Brand X Menthol’. Through this consultation we are seeking more information as to the impact of this provision – see accompanying impact assessment.

Labelling and Health Warnings (TPD2 Article 8-12; Draft UK Regs 5-11)

- 5.20. The TPD2 enhances and strengthens existing labelling requirements for tobacco products. This includes increasing size and prominence of health warnings and mandating combined text and picture health warnings for tobacco products. There are also a number of areas where Member States are given flexibilities or options to consider when implementing domestically. These are explored in detail below:

Images of packets targeting consumers (TPD2 Article 8)

- 5.21. At Article 8(8) the Directive requires Member States to ensure that any images of packs and outside packaging of tobacco products ‘targeting consumers in the Union’ are compliant with the Directive’s labelling provisions. Tobacco advertising in the UK is prohibited already. The Government is considering how to define the scope of images which are ‘targeted at consumers’, whilst seeking not to restrict journalistic, literary, political, academic and cultural freedom of expression. Initial thinking is that the requirement will be focused on those images that are associated with the purchase of tobacco products.

Q2 The Government intends to implement this provision of the Directive to mean images, targeted at consumers, that are used to promote the sale of products, such as retailer websites offering products for sale. Do you agree with this approach?

General warning and information message (TPD2 Article 9)

- 5.22. The TPD2 stipulates technical specifications on the precise size, shape and appearance of the general warning ('Smoking kills' or 'Smoking kills - quit now') and information message ('Tobacco smoke contains over 70 substances known to cause cancer') on packets of tobacco products.
- 5.23. For cuboid packets, the TPD2 sets out that the general warning must appear on the bottom part of one of the "lateral" surfaces of the unit packets, and the information message must appear on the bottom part of the other lateral surface. "Lateral" is not defined, but the objective is clearly for these secondary warnings to be as visible as possible and to appear on a different surface to the surface on which the picture warnings appear.
- 5.24. Accordingly, in order to provide a simple, clear, enforceable and least burdensome rule, we propose to transpose 'lateral surfaces' as 'secondary surfaces' which are defined as 'the next two largest surfaces of the pack, after the front and the back surfaces (of the surfaces that are visible before the pack is opened).' The 'front and back surfaces' are defined as the 'largest two surfaces of the pack'. We believe this makes the labelling provisions easier to interpret for all shapes of unit packs or container packs (where one or more unit packs are inserted into outer packaging intended for sale to the consumer and full labelling is required).

Q3 The TPD2 stipulates where health warnings should appear on packs including that the general warning should appear on the lateral surface. The Government propose to transpose 'lateral' (Article 9) as 'secondary' (defined as the next two largest surfaces of the pack, after the front and the back surfaces) in our domestic legislation. Can you tell us of any packaging shapes where this interpretation would not be the most effective approach / would not work as intended?

- 5.25. For packets in the form of a shoulder box with a hinged lid that will result in the lateral surfaces being split into two when the packet is open, the general warning and the information message shall appear in their entirety on the larger parts of those split surfaces. The general warning shall also appear on the inside of the top surface that is visible when the packet is open (Article 9(3)). The lateral surfaces of this type of packet shall have a height of not less than 16mm. This latter provision is transposed in the Standardised Packaging of Tobacco Regulations.
- 5.26. For tobacco products marketed in pouches, the general warning and information message shall appear on surfaces that ensure the full visibility of those health warnings. For RYO marketed in cylindrical packets the general warning shall appear on the outside surface of the lid and information message on the inside surface of the lid.
- 5.27. In all the above cases the general warning and information message shall cover 50% of the surface on which they are printed.

Choice of health warnings (TPD2 Article 9)

- 5.28. The TPD1 required the health warnings 'Smoking kills' and 'Smoking seriously harms you and those around you', to be rotated to ensure regular appearance across all tobacco products. The TPD2 requires one of the following statements to be applied to all tobacco products (i.e. no rotation of message as under TPD1):
- a. 'Smoking kills': or
 - b. 'Smoking kills – quit now'
- 5.29. The Government is minded to adopt option b, subject to responses to this consultation. This option best fits with wider tobacco policies in the 4 nations which are aimed at restricting access to tobacco products and supporting those who want to quit to do so.

Q4 The TPD2 requires Member States to choose between the warnings 'Smoking kills' or 'Smoking kills – quit now'. The Government is minded to require that tobacco products be labelled with the warning 'Smoking kills – quit now' to align with UK smoking cessation messaging. Do you have any information/evidence that would inform this choice?

Combined Health Warnings (TPD2 Article 10)

- 5.30. Combined text and picture health warnings have been compulsory in the UK since 2008. The health warnings in the TPD1 were updated in light of new scientific evidence on the health effects of smoking tobacco and to refresh their impact. The new text warnings adopted under Directive 2012/39/EU²² are incorporated in Annex I of the TPD2 and Commission Delegated Directive 2014/109/EU²³ concerning picture warnings amends Annex II of the TPD2. The text and picture warnings have been reproduced in the Schedule at the end of the attached draft Regulations. The detailed conditions on the use of the combined health warnings are explored further in this section.

Size, shape and appearance (TPD2 Article 10)

- 5.31. The TPD2 mandates the inclusion of a combined text and picture warning and cessation information, to cover 65% of front and back of pack (previously 40% on back of pack) for cigarettes, RYO and waterpipe tobacco. This provides for a much more prominent health warning.
- 5.32. The placement of the combined health warning on the front and back of the pack is straightforward for cuboid cigarette packs, which accounts for nearly 100% of the market for these products. For cylindrical packets of RYO tobacco, the combined health warnings must be positioned equidistant from each other, each covering 65% of their respective half of the curved surface. For some squat cylindrical packets there may be insufficient depth to print the combined health warning in a form that both complies with the 65% rule and is clearly legible.
- 5.33. Whilst we are aware that the Commission is working on technical specifications for the layout, design and shape of the combined health warnings on various shaped packaging, we would be interested to identify any further shapes of packaging for cigarettes, RYO and waterpipe tobacco, other than squat tins and pouches, on which it will prove challenging to attain full compliance with the health warning requirements.

5.34. The labelling of tobacco products other than cigarettes, RYO and waterpipe tobacco is examined further in section 5.39.

Q5 Are there any other pack shapes for cigarettes, Roll Your Own (RYO) and waterpipe tobacco on the market, other than pouches and squat cylindrical tins/tubs, where there may be technical difficulties in applying any of the new health warnings under Articles 9 and 10?

Rotation of combined health warning (TPD2 Article 10)

5.35. The picture warning must be taken from a library of 42 images, which are grouped into three sets. Member States are required to ensure that images are rotated on an annual basis. To ensure this process is harmonised across the Union, the Commission is encouraging Member States to rotate the same set of picture warnings, ensuring the same picture warnings are used by all Member States simultaneously (e.g. set 1 in 2016, set 2 in 2017 and set 3 in 2018).

5.36. It is proposed that this requirement applies at the point of manufacture, to enable old stock to be sold through at retail, i.e. products with low turnover will not be required to be relabelled at point of sale, by retailers, with the current set of warnings. Importers will be required to take reasonable steps to ensure that the correct warnings were applied at the time of manufacture. The Government believes that retailers (including specialist tobacconists) who repackage, for example, loose cigars or tobacco at the point of sale, should be responsible for ensuring packaging meets the TPD2 provisions, including rotation of the warnings. This may include repackaging products in packaging/labels provided by the manufacturer. The Government is minded to alter the draft regulations to this end, and seeks further information on the practicalities and likely costs of meeting this requirement.

5.37. It is proposed that, in any one year, each of the images in a set shall appear on between 1/24 (4.16%) and 1/12 (8.33%) of products in each brand, mirroring the current requirements.

Q6 To ensure the combined health warnings are applied evenly across each brand of tobacco product, it is proposed that images should appear on between 1/24 (4.15%) and 1/12 (8.33%) of products and each set of images in the TPD2 picture library should be rotated on an annual basis. Are there any additional costs, above and beyond the current regime, imposed by this proposal?

Q7 The draft regulations require producers/manufacturers to ensure the correct health warning is applied to tobacco products. We are minded to treat retailers who repackage tobacco products at the point of sale the same as producers. For example, loose tobacco packaged at point of sale, should comply with the full labelling provisions, including the rotation of the combined health warning. Do you agree with this approach?

We also seek further details on the costs and practicalities of such businesses meeting these requirements.

Information on Smoking Cessation (TPD2 Article 10)

- 5.38. The TPD2 requires all tobacco products to be labelled with smoking cessation information. The Government is minded to require tobacco products to be labelled with cessation information consisting of a reference to a website such as “<http://www.nhs.uk/smokefree>”. Once the labelling requirements within the TPD2 have been finalised the precise wording of the reference will be agreed and embedded into the combined health warning. It is envisaged that this will be a UK-wide solution, with referral to the appropriate cessation services in each of the four nations.

Whether to exempt tobacco products for smoking other than cigarettes, RYO and water pipe tobacco from carrying the information message and combined health warning (Article 11)

- 5.39. The TPD2 allows for Member States to opt for a less onerous labelling regime (i.e. labels without pictures) on tobacco products other than cigarettes, RYO and waterpipe tobacco (i.e. cigars, pipe tobacco etc.). 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 a reference to the smoking cessation information. If the 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 and to occupy 30% and 40% of the surface in each case. For products in packets with hinged lids the second most visible surface is defined as the one that becomes visible on opening.
- 5.40. Current UK legislation requires picture and text warnings on all tobacco products except for individually wrapped cigars and cigarillos. As drafted the regulations do not take advantage of the article 11 derogations. However 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 provisions which would apply under Article 11 still represent a strengthening of the current requirements and would result in clearer labels on these products.

<p>Q8 The Government is minded to derogate individually wrapped cigars and cigarillos from the full labelling regime, requiring only the general warning ‘Smoking kills’ or ‘Smoking kills – quit now’; one of the text warnings from the combined warning list but no picture; and a reference to the smoking cessation information. Do you agree with this approach?</p>
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Illicit Trade – track & trace system and security feature (TPD2 Articles 15 and 16)

- 5.41. The TPD2 introduces a traceability system and security features to track and trace tobacco products, to strengthen the fight against illicit trade. While the Acts specified in articles 15 and 16 relating to track and trace and security features remain unpublished, the Department of Health will lead on implementation of these features in the UK, however HMRC are continuing to support this and have competent authority for it with

Department of Health. Information obtained from this consultation will be shared with HMRC.

- 5.42. A further consultation on the implementation of these aspects of the TPD2 when further detail of the proposed pan-EU approach and specification has been set out by the Commission. As outlined in section 4.9 above, time for this exercise may be limited so interested parties are invited to provide their contact details and notice of their interest in these areas when completing the online form (see section 9).

- Q9 The Government is seeking evidence and information on the supply chains currently used to distribute tobacco products in the UK, such as the number of links in the chain and the number of businesses affected.**
- Q10 The Government would welcome initial views on how track and trace and security markings may impact on business, and what the key issues for business will be.**

Cross border distance sales of Tobacco Products, e-cigarettes and refills to consumers (TPD2 Article 18; Draft UK Regs 42)

- 5.43. The TPD2 applies the same rules on cross-border distance sales to both tobacco products and e-cigarettes (including refill containers). The TPD2 provides Member States with the option to prohibit cross-border distance sales of tobacco products and e-cigarettes in and out of the UK, i.e. to ban businesses in the UK from selling these products to consumers in other EU Member States, for example via internet, telephone or mail order; and businesses based in EU Member States from selling them to consumers in the UK.
- 5.44. If the Government does not take up the option of prohibiting cross-border distance sales then the TPD2 obliges Member States to implement a registration scheme for all retailers that engage in cross-border distance sales both into and out of the UK. If a registration scheme is introduced, UK retailers selling tobacco products, electronic cigarettes and refill containers to consumers in other Member States (that have not imposed a ban) via distance selling arrangements, will be required to register with the UK authorities and the authorities in the Member State where the consumer is based; and conversely all non-UK businesses wishing to sell to UK consumers via distance selling arrangements must register with the UK authorities.
- 5.45. Retailers would need to provide contact details of their business; starting date of their activities; details of the website(s) used for the purpose of cross-border sales; and a description of the details and functioning of the age verification system used. The Directive gives the UK flexibility to require businesses selling into the UK to nominate an individual to be responsible for verifying that the product complies with the provisions of the UK regulations implementing the TPD2 that are relevant to the particular product, before the product is supplied to the consumer.
- 5.46. Retailers engaged in cross-border distance selling arrangements 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'. The Directive further defines 'age verification system' as 'a computing system that unambiguously confirms the consumer's age electronically in accordance with national provisions'. Current domestic guidance on age verification for distance sales includes:

(a) Payment by credit card

At the moment, credit cards are generally available only to those over 18, although some pre-paid cards may be available to under 18s. Payment or verification of the purchaser using a credit (as opposed to a debit) card could serve to verify that the principal cardholder for the credit card is over 18. Other Member States may have different finance rules.

(b) Age verification on delivery

Retailers could use age verification checks at the point of delivery by ensuring that delivery drivers request a valid proof of age to confirm that the purchaser is over the minimum age to buy the product in question. Third-party couriers may not accept responsibility for age verification and this may not be practicable for deliveries in other Member States.

(c) Online age verification checks

A simple 'click to enter' approach (if 18 or relevant age in other Member States) is unlikely to satisfy the requirements of the directive. Online age verification software is available that makes use of various sources of information in order to verify both age and identity during the ordering process. These checks include using the electoral register and/or credit reference agencies, but may not cover all other Member States. There are also businesses that offer online access to electoral register information, which could be used to verify a purchaser's age, but again this method may not be available in all other Member States.

- 5.47. We do not have enough evidence to determine the size of this sub-section of the market nor which type of consumers use this mode of purchase. We wish to use this consultation to gather evidence to inform the impact assessment. Information including sales volumes and types of products (e.g. cigarettes, cigars, e-cigarettes etc.) traded across the UK border via distance selling arrangements direct to consumers and whether any growth in trade of this type is foreseen, is welcomed.
- 5.48. The Government is minded 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. The draft regulations that accompany this consultation provide for the way in which the registration system would operate.

Q11 If a registration scheme were introduced for cross-border distance sales, the Government is minded to require the nomination of an individual to be responsible for verifying that the product complies with the provisions in the UK regulations, before the product is supplied to the consumer. Do you agree with this approach?

- Q12 Should cross-border distance sales of tobacco products to consumers be prohibited?**
- Q13 Should cross-border distance sales of e-cigarettes and refills to consumers be prohibited?**
- Q14 What systems to verify the age of customers are available to, or currently used by, businesses involved in distance sales to other EU Member States?**

Authorisation/notification of novel tobacco products (TPD2 Article 19; Draft UK Regs 25)

- 5.49. The TPD2 requires Member States to implement either a notification scheme or a prior authorisation scheme for novel tobacco products. A prior authorisation scheme would introduce significant costs for both the industry and any organisation charged with administering the scheme and we are not convinced the benefits outweigh the costs of this approach. The Government is therefore minded to introduce a notifications scheme.
- 5.50. Notification of a novel tobacco product requires detailed information on new products to be submitted to a competent authority 6 months in advance of placing the product on the market.
- 5.51. The Government is minded, subject to consultation, to adopt a notification scheme. The attached draft regulations reflect this intention.
- 5.52. The TPD2 requires businesses to provide available information on:
- a. the toxicity of the product, its ingredients and emissions;
 - b. the addictiveness of the product, its ingredients and emissions;
 - c. the expected effects of the product on the cessation of tobacco consumption by existing users of tobacco products;
 - d. the perception of the product by consumers or potential consumers (or predictions as to how the product will be perceived), including the attractiveness of the product;
 - e. the preferences of consumer groups, including young people and current smokers, in respect of the product; and
 - f. the risks and benefits of the product.
- 5.53. The Directive also allows Member States to require businesses to carry out additional tests or submit additional information. The regulations as drafted for consultation require information on points a) to d) to be submitted with a notification. This reflects that the Government believes information on toxicity, addictiveness, expected impact on smoking rates and consumer perceptions should be available before the launch of a novel tobacco product, and should be information readily available to a producer. This would mean the producer either has to identify existing research on those issues or commission new research or studies ahead of notification. Information on points e) and f) will only be required where available.

Q15 Should novel tobacco products be subject to a notification scheme? If “No”, please explain why you think an authorisation scheme would be preferable?

Q16 Under a notification scheme the Government is minded to include provision to require manufacturers or importers of novel tobacco products to provide, with any notification, information on:

- a. the toxicity of the product, its ingredients and emissions;
- b. the addictiveness of the product, its ingredients and emissions;
- c. the expected effects of the product on the cessation of tobacco consumption by existing users of tobacco products; and
- d. the perception of the product by consumers or potential consumers (or predictions as to how the product will be perceived), including the attractiveness of the product.

The Government believes that this information should and will be available to manufacturers and importers prior to launching all new products. Do you agree with this approach?

Electronic Cigarettes (TPD2 Article 20; Draft UK Regs 30-41)

- 5.54. In the UK, any nicotine-containing products (NCP), including e-cigarettes, which claims or implies that it can be used for cutting down, quitting and reducing harm is considered to be a medicinal product and must be licensed as a medicine by the Medicines and Healthcare products Regulatory Agency (MHRA). Licensed medicines are subject to separate regulatory rules that cover the safety, quality and efficacy of the products along with other aspects such as advertising, product presentation, post-marketing surveillance, to whom medicines can be supplied, and other aspects relating to their sale and supply.
- 5.55. From May 2016, the TPD2 will establish new rules for the safety, quality, composition and presentation of consumer electronic cigarettes not subject to medicines licensing. The TPD2 requires manufacturers and importers of electronic cigarettes to submit an electronic notification to the competent authority of the Member States in which they intend to place their product on the market. The TPD2 regulatory framework for these products will sit alongside existing legislation that applies to the manufacture and supply of the various components and ingredients of e-cigarettes.
- 5.56. The provisions regulating electronic cigarettes and refill containers can be found in article 20 of the TPD2. Broadly speaking, the provisions cover: a notification scheme for electronic cigarettes and refill containers (paragraph 2), product requirements (paragraph 3), requirements as to the information that must accompany electronic cigarettes or form part of their packaging (paragraph 4), advertising restrictions (paragraph 5), an annual reporting requirement (paragraph 7), monitoring requirements (paragraph 9) and powers for Member States to take steps in relation to products that pose a serious threat to human health (paragraph 11).

- 5.57. The Commission is required by means of an Implementing Act, to lay down a common reporting format for the notification of new and modified products.
- 5.58. The competent authority for electronic cigarettes in the UK will be the MHRA on behalf of the Secretary of State. The MHRA will conduct further stakeholder engagement around the practicalities of notification. Details of how to register your interest and receive further information on future stakeholder engagement in this area is provided in section 9.

Definitions

- 5.59. The TPD2 provides definitions for 'electronic cigarette' and 'refill container'. The Government consulted on draft regulations to introduce a minimum age of sale of 18 years for nicotine inhaling products²⁴ from 17 December 2014 to 28 January 2015. This contains definitions for 'nicotine inhaling products', 'nicotine cartridge' and 'nicotine refill substances'. Using these definitions in the transposing regulations for the TPD2 would have the benefit of consistency in national legislation. Using the age of sale definitions would however mean that certain products, e.g. products producing nicotine in a powder form, that are not covered by the definitions in the TPD2 would have to comply with the rules for electronic cigarettes. Similarly, some components that are covered by the definitions in the TPD2, e.g. 'tanks', would not be covered by the age of sale definitions.

Q17 The Government is minded to use the TPD2 definitions of an 'electronic cigarette' and 'refill container'. Do you foresee any problems with inconsistency with the definitions in The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations?

Publication of notifications

- 5.60. The TPD2 requires Member States to make the information contained in notifications for electronic cigarettes and refill containers publicly available but to protect trade secrets.

Q18 The Government intends to handle notifications of e-cigarettes and refill containers electronically and make all information contained in notifications automatically available to the public unless this information can be considered truly commercially confidential. What information contained in the notifications should be considered commercially confidential?

Vigilance requirement on distributors

- 5.61. The TPD2 in article 20(9) puts an obligation on manufacturers, importers and distributors of electronic cigarettes and refill containers to establish and maintain a system for collecting information about all suspected adverse effect on human health of these products. The TPD2 does however not define distributors and no other obligations are put on distributors.

Q19 The Government is minded to put the obligation on ‘producers’ (which includes manufacturers, importers into the UK and those that rename a product) in the transposing regulations which will ensure that there will always be a person in the UK who collects information about suspected adverse effects in relation to e-cigarettes and refill containers. Do you agree?

Action to protect public health

5.62. The TPD2 gives Member States the power to take action to protect public health in the form of ‘appropriate provisional measures’ when products that comply with the TPD2 present a serious risk to public health. For example, if signals received by the competent authority, research, or surveys demonstrate a given combination of ingredients or hardware/component and liquid result in a hazardous emission in otherwise compliant products.

Q20 The Government is minded to give the Secretary of State for Health (SoS) the power to prohibit the supply of an e-cigarette or refill container or to require producers and suppliers to recall a product if he/she considers them a serious risk to public health. Do you think there are other options that should be provided to the SoS, for example the power to require modification of a product or to require enhanced monitoring and/or reporting of company data?

Choice of health warnings

5.63. The TPD2 provides two options on the wording prescribed in the health warnings 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’.

5.64. The Government is minded to adopt option b subject to the response to this consultation. To do so would further position e-cigarettes as an alternative to smoking and not a general consumer product, and complement messages already used by responsible manufacturers.

Q21 The Government is minded to require that e-cigarettes be labelled with the warning ‘This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers’. Do you agree?

Cross-cutting issues

Charging (TPD2 Articles 4-7, 19 and 20)

- 5.65. The Government can recover costs of meeting its obligations under EU legislation, including TPD2. The Government is minded to introduce proportionate charges. This will include charging for:
- 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 tobacco products including novel tobacco products (Article 5);
 - The peer review of scientific studies and additives undertaken by the tobacco industry (Article 6);
 - Assessing whether a tobacco product has a characterising flavour, whether prohibited additives or flavourings are used and whether a tobacco product contains additives in quantities that increase to a significant and measurable degree the toxic or addictive effect or the carcinogenic, mutagenic or reprotoxic (CMR) properties of the tobacco product concerned (Article 7);
 - If the UK chooses to implement an authorisation system for novel tobacco products then a fee can be charged for that authorisation (Article 19); and
 - The receiving, storing and handling and analysing information submitted to them on e-cigarettes (Article 20).
- 5.66. Following this consultation should we decide to charge fees, we will consult further on proposed fee levels.

Q22 Should the Government charge the industry proportionate fees to recover costs associated with the TPD2, including the following activities:

- a. The verification of the levels of tar, nicotine and carbon monoxide (TNCO) in cigarettes (Article 4);**
- b. The receiving, storage, handling, analysis and publishing information on ingredients and emissions of tobacco products including novel tobacco products (Article 5);**
- c. The peer review of scientific studies and additives undertaken by the tobacco industry (Article 6);**
- d. Assessing whether a tobacco product has a characterising flavour, whether prohibited additives or flavourings are used and whether a tobacco product contains additives in quantities that increase to a significant and measurable degree the toxic or addictive effect or the carcinogenic, mutagenic or reprotoxic (CMR) properties of the tobacco product concerned (Article 7);**
- e. If the UK chooses to implement an authorisation system for novel tobacco products then a fee can be charged for that authorisation (Article 19); and**
- f. The receiving, storing and handling and analysing information submitted to them on e-cigarettes (Article 20).**

Please provide further comment.

Transitional provisions for Tobacco Products, e-cigarettes and herbal products for smoking (TPD2 Article 30)

5.67. 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-cigarettes produced before November 2016. We intend to adopt this provision to minimise costs to business in changing their packaging to meet the new requirements and help retailers' switchover to new TPD2 compliant stock.

Date	Measure
20 May 2016	Deadline for Member States to bring into force measures requiring manufacturers, importers and other business operators to comply with new provisions
Nov 2016	Deadline for manufacturers and importers of tobacco products to submit data on ingredients and emissions for existing products; and manufacturers and importers of e-cigarettes to notify existing products on the market.
May 2017	Member States have the option to provide for a transitional period until May 2017 for retailers to "sell through" old products – this covers tobacco products, e-cigarettes and herbal products for smoking
May 2019	Member States required to apply 'Track and Trace' system and security features to cigarettes and roll your own tobacco
May 2020	Expiry of exemption for tobacco products with a characterising flavour whose Union-wide sales volumes represent 3% or more in a particular product category i.e. menthol cigarettes
May 2024	Track and trace system and security features extended to tobacco products other than cigarettes and roll your own tobacco e.g. cigars, pipe tobacco and waterpipe tobacco

Table 2. Summary of TPD2 key dates and transition periods

Q23 Should retailers and importers be given the proposed transition period until May 2017 to sell through old stock?

6. Impact Assessment (IA)

- 6.1. The Government has made a preliminary estimate of the expected costs and benefits of implementing the TPD2 in the UK. These early estimates of the overall policy are subject to considerable uncertainty. As such, we welcome views and request additional information on a number of areas from stakeholders. These areas are highlighted in the IA and questions summarised in Appendix B of this document. Further details are provided in the Impact Assessment published alongside this document.
- 6.2. An assessment of the impact on equality is published alongside this consultation document. We welcome additional information in relation to the potential impact on any group with a protected characteristic under the Equality Act 2010, or issues that should be considered under the public sector duties.²⁵

7. Territorial scope of this consultation

- 7.1. This consultation is being run by the Department of Health with the agreement of the Devolved Administrations across the United Kingdom. All consultation responses will be made available by the Department of Health for consideration by the Ministers responsible for public health in the three Devolved Administrations. We may also share some responses with other Government Departments who have competent authority roles under the Directive.

8. How to get involved in the consultation

- 8.1. The consultation questions set out in this and the accompanying documents are summarised at Appendix B. The consultation will run for 9 weeks, from 2 July 2015 to 23:45 on 3 September 2015. We welcome responses from any interested person, business or organisation.
- 8.2. Respondents are encouraged to provide their views online via our dedicated consultation portal, but responses can be made in any of the following ways:

- Completing the online survey at:
<http://consultations.dh.gov.uk/tobacco/tobacco-products-directive> or
- Filling in the response form by downloading it at:
www.gov.uk/government/consultations

and then emailing your response to: tobaccoproductsdirective@dh.gsi.gov.uk
or posting your response to:

Tobacco Products Directive Consultation
Department of Health
PO Box 311
HERNE BAY
CT6 9BU

- 8.3. The purpose of this consultation is to seek the views of interested people, businesses and organisations, with a focus on gaining new or additional information relevant to implementation of the TPD2.
- 8.4. We ask that you provide references to research or other evidence with your responses. If your response is lengthy please also provide a summary of no more than three sides of paper.
- 8.5. If you wish to get a copy of this consultation document in an alternative format, or need to respond in an alternative format for accessibility reasons, please contact us using the email or postal addresses given in section 8.2.
- 8.6. The Department of Health and Devolved Administrations will not be able to respond to individual consultation responses.

9. How to get involved in future stakeholder engagement on specific topics

- 9.1. In addition to the questions asked in this document, respondents are encouraged to indicate which of the following issues they would like to receive further targeted engagement on:

Reporting of ingredients

- Common reporting format for ingredients and emission data of tobacco products and e-cigarettes (Articles 5(5) and 20(13))

Priority list of additives

- Establish a list of priority additives for which enhanced reporting obligations shall apply (Article 6(1))

Characterising flavours

- Establish procedure for determining products with a characterising flavour (Article 7(3))

Labelling

- Determine precise position of the general health warning and information message on RYO tobacco marketed in pouches (Article 9(6))
- Determine technical specifications for combined health warnings, defining the layout, design and shape of the combined health warning. (Article 10(4))

Track and trace

- Determine technical standards for the operation of a track and trace system (Article 15(11))
- Determine key elements of the data storage contracts established under the track and trace system (Article 15(12))

Security features

- Determine technical standards for the security feature (Article 16(2))

E-cigarettes

- Establish the notification system (Article 20(2))
- Determine technical standards for refill mechanisms (Article 20(13))

Charging

- Determine proportionate fees should we decide to charge fees

Indication of your preference can be made in each of the methods of response as outlined in section 8.

10. Declaration of direct or indirect links to the tobacco industry by respondents

- 10.1. As a Party to the World Health Organisation's Framework Convention on Tobacco Control (FCTC), the United Kingdom has an obligation to protect the development of public health policy from the vested interests of the tobacco industry. To meet this obligation, we ask all respondents to disclose whether they have any direct or indirect links to, or receive funding from, the tobacco industry. We will still carefully consider all consultation responses from the tobacco industry and from those with links to the tobacco industry and include them in the published summary of consultation responses.

11. Next steps

- 11.1. All responses received by 23:45 on the closing date of 3 September will be carefully considered. A summary report of consultation responses will be published on the Department of Health website in due course, once the consultation has been completed.
- 11.2. The draft regulations will be finalised in due course, taking into account all relevant considerations.

12. Consultation process

- 12.1. If you have concerns or comments that you would like to make relating specifically to the consultation process itself, please contact:

Consultations Coordinator
Department of Health
2E26, Quarry House
Leeds
LS2 7UE

Email: consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

13. Confidentiality of information

- 13.1. We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter.
- 13.2. Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).
- 13.3. If you want the information that you provide to be treated as confidential, please be aware that under the FOIA there is a statutory Code of Practice with which public authorities must comply, dealing with obligations of confidentiality. In view of this, it would be helpful if you could clearly identify any confidential information in your response and explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.
- 13.4. The Department will process your personal data in accordance with the DPA and, in most circumstances, this will mean that it will not be disclosed to third parties.

¹ [Directive 2001/37/EC on the approximation and of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products](#). OJ. L194, 18.7.2001 p. 26

² World Health Organisation (WHO) Framework Convention on Tobacco Control (FCTC) www.who.int/fctc/en/ (accessed June 2015)

³ European Commission – Revision of the Tobacco Products Directive: http://ec.europa.eu/health/tobacco/products/revision/index_en.htm (accessed June 2015)

⁴ [Directive 2014/40/EU on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC](#). OJ. L 127, 29.4.2014, p. 1.

⁵ The Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 (2002 No. 3041) http://www.legislation.gov.uk/ukxi/2002/3041/pdfs/ukxi_20023041_en.pdf (accessed June 2015)

⁶ Department of Health (2014). Consultation on Standardised Packaging of Tobacco Products – draft regulations. <https://www.gov.uk/government/consultations/standardised-packaging-of-tobacco-products-draft-regulations> (accessed June 2015)

⁷ HM Revenue and Customs. Tobacco tax gap estimates 2013-14 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/364011/141016_Tobacco_Tax_Gap_2014.pdf (Accessed June 2015)

⁸ Action on Smoking and Health. Smoking Statistics – Illness and Death. (2014). www.ash.org.uk/files/documents/ASH_107.pdf (accessed June 2015)

⁹ 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.

¹⁰ Office of National Statistics. Integrated Household Survey January – December 2013. (2014). www.ons.gov.uk/ons/rel/integrated-household-survey/integrated-household-survey/january-to-december-2013/stb-integrated-household.html (accessed June 2015)

¹¹ Marmot, M. et al. (2010). *Fair Society, Healthy Lives: Strategic review of health inequalities in England post-2010*. Marmot review secretariat, London.

¹² Pasco JA, et al. Tobacco smoking as a risk factor for a major depressive disorder: a population-based study. The British Journal of Psychiatry. 2008 193: 322-326.

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- ¹³ Lawrence D et al. Smoking and mental illness: results from population surveys in Australia and the United States. BMC Public Health. 2009 9:285
- ¹⁴ Lasser K et al. Smoking and mental illness: a population-based prevalence study. JAMA. 2000 284 (20): 2606-2610
- ¹⁵ De Leon J et al. The association between high nicotine dependence and severe mental illness may be consistent across countries. The Journal of Clinical Psychiatry. 2002 63 (9): 812-816.
- ¹⁶ Office for National Statistics. General Lifestyle Survey Overview: A report on the 2011 General Lifestyle Survey. (2013). www.ons.gov.uk/ons/rel/ghs/general-lifestyle-survey/2011/index.html (accessed June 2015)
- ¹⁷ European Commission implementation plan (2014).
http://ec.europa.eu/health/tobacco/products/revision/implementation_en.htm (accessed June 2015)
- ¹⁸ European Commission Register of Commission Expert Groups
<http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3150&NewSearch=1&NewSearch=1> (accessed June 2015)
- ¹⁹ Permitted Additives to Tobacco Products in the United Kingdom, dated October 2003
http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digit_assets/@dh/@ab/documents/digitalasset/dh_095251.pdf (Accessed June 2015)
- ²⁰ European Commission Impact Assessment http://ec.europa.eu/health/tobacco/products/revision/index_en.htm (accessed June 2015)
- ²¹ Euromonitor International. July 2014. Cigarettes in the United Kingdom
- ²² Commission Directive 2012/39/EU amending Annex I to Directive 2001/37/EC. OJ. L69, 8.3.2012, p. 15
- ²³ Commission Delegated Directive 2014/109/EU amending Annex II to Directive 2014/40/EU of the European Parliament and of the Council by establishing the library of picture warnings to be used on tobacco products. OJ. L360, 17.12.2014, p. 22 <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1420551440300&uri=CELEX:32014L0109> (Accessed June 2015)
- ²⁴ Department of Health (2014). Consultation on Nicotine inhaling products: introducing a minimum age of sale. <https://www.gov.uk/government/consultations/nicotine-inhaling-products-introducing-a-minimum-age-of-sale> (accessed June 2015)
- ²⁵ Bodies subject to the equality duty must, when delivering their services and performing their functions, have due regard to the need to:
- eliminate unlawful discrimination, harassment, victimisation and any other conduct prohibited by the Equality Act 2010
 - advance equality of opportunity between people who share a particular protected characteristic and people who do not share it
 - foster good relations between people who share a particular protected characteristic and people who do not share it.

The public sector equality duty covers the “protected characteristics” of age, disability, gender reassignment, pregnancy and maternity, race (includes ethnic or national origins, colour or nationality), religion or belief (includes lack of belief), sex and sexual orientation. It also applies to marriage and civil partnership status, but only in respect of the requirement to have due regard to the need to eliminate discrimination.

Appendix A – TPD2 requirements – Tobacco Products

A quick reference table

'X' denotes requirements apply to product

'/' denotes subject to a decision on article 11 derogation

Requirement	Cigarettes	RYO	Waterpipe	Other TP (cigars, etc.)	Smokeless	Herbals
Reporting of ingredients (Article 5)	X	X	X	X	X	X
Reporting of emissions (A.5)	X	X	X	X	X	
Enhanced reporting of priority list of additives (A.6)	X	X				
Ban on characterising flavours (A.7(1))	X	X				
Restrictions on additives (A.7(6))	X	X	X	X	X	
General health warning (A.9)	X	X	X	X		
Information message (A.9)	X	X	X	/		
Modified health warning (A.12 and 21)					X	X
Combined text and picture warning (A.10)	X	X	X	/		
Cessation information (A. 10)	X	X	X	X		
Restrictions on presentation (A.13)	X	X	X	X	X	X
Restrictions on appearance and unit size (A.14)	X	X				
Track and Trace (A.15)	X	X	X	X	X	
Cross-border distance sales ban/registration (A.18)	X	X	X	X	X	

Appendix B – Summary of consultation questions

- Q1** Should the Government request peer review of any reports submitted by the industry in relation to certain additives contained in a priority list of additives?
- Q2** The Government intends to implement this provision of the Directive to mean images, targeted at consumers, that are used to promote the sale of products, such as retailer websites offering products for sale. Do you agree with this approach?
- Q3** The TPD2 stipulates where health warnings should appear on packs including that the general warning should appear on the lateral surface. The Government propose to transpose 'lateral' (Article 9) as 'secondary' (defined as the next two largest surfaces of the pack, after the front and the back surfaces) in our domestic legislation. Can you tell us of any packaging shapes where this interpretation would not be the most effective approach / would not work as intended?
- Q4** The TPD2 requires Member States to choose between the warnings 'Smoking kills' or 'Smoking kills – quit now'. The Government is minded to require that tobacco products be labelled with the warning 'Smoking kills – quit now' to align with UK smoking cessation messaging. Do you have any information/evidence that would inform this choice?
- Q5** Are there any other pack shapes for cigarettes, Roll Your Own (RYO) and waterpipe tobacco on the market, other than pouches and squat cylindrical tins/tubs, where there may be technical difficulties in applying any of the new health warnings under Articles 9 and 10?
- Q6** To ensure the combined health warnings are applied evenly across each brand of tobacco product, it is proposed that images should appear on between 1/24 (4.15%) and 1/12 (8.33%) of products and each set of images in the TPD2 picture library should be rotated on an annual basis. Are there any additional costs, above and beyond the current regime, imposed by this proposal?
- Q7** The draft regulations require producers to ensure the correct health warning is applied to tobacco products. We are minded to treat retailers who repackage tobacco products at the point of sale the same as producers. For example, loose tobacco packaged at point of sale, should comply with the full labelling provisions, including the rotation of the combined health warning. Do you agree with this approach?
- We also seek further details on the costs and practicalities of such businesses meeting these requirements.
- Q8** The Government is minded to derogate individually wrapped cigars and cigarillos from the full labelling regime, requiring only the general warning 'Smoking kills' or 'Smoking kills – quit now'; one of the text warnings from the combined warning list but no picture; and a reference to the smoking cessation information. Do you agree with this approach?
- Q9** The Government is seeking evidence and information on the supply chains currently used to distribute tobacco products in the UK, such as the number of links in the chain and the number of businesses affected.

- Q10** The Government would welcome initial views on how track and trace and security markings may impact on business, and what the key issues for business will be.
- Q11** If a registration scheme were introduced for cross border distance sales, the Government is minded to require the nomination of an individual to be responsible for verifying that the product complies with the provisions in the UK regulations, before the product is supplied to the consumer. Do you agree with this approach?
- Q12** Should cross-border distance sales of tobacco products to consumers be prohibited?
- Q13** Should cross-border distance sales of e-cigarettes and refills to consumers be prohibited?
- Q14** What systems to verify the age of customers are available to, or currently used by, businesses involved in distance sales to other EU Member States?
- Q15** Should novel tobacco products be subject to a notification scheme? If “No”, please explain why you think an authorisation scheme would be preferable?
- Q16** Under a notification scheme the Government is minded to include provision to require manufacturers or importers of novel tobacco products to provide, with any notification, information on:
- a. the toxicity of the product, its ingredients and emissions;
 - b. the addictiveness of the product, its ingredients and emissions;
 - c. the expected effects of the product on the cessation of tobacco consumption by existing users of tobacco products; and
 - d. the perception of the product by consumers or potential consumers (or predictions as to how the product will be perceived), including the attractiveness of the product.
- The Government believes that this information should and will be available to manufacturers and importers prior to launching all new products. Do you agree with this approach?
- Q17** The Government is minded to use the TPD2 definitions of an ‘electronic cigarette’ and ‘refill container’. Do you foresee any problems with inconsistency with the definitions in The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations?
- Q18** The Government intends to handle notifications of e-cigarettes and refill containers electronically and make all information contained in notifications automatically available to the public unless this information can be considered truly commercially confidential. What information contained in the notifications should be considered commercially confidential?
- Q19** The Government is minded to put the obligation on ‘producers’ (which includes manufacturers, importers into the UK and those that rename a product) in the transposing regulations which will ensure that there will always be a person in the UK who collects information about suspected adverse effects in relation to e-cigarettes and refill containers. Do you agree?

- Q20** The Government is minded to give the Secretary of State for Health (SoS) the power to prohibit the supply of an e-cigarette or refill container or to require producers and suppliers to recall a product if he/she considers them a serious risk to public health. Do you think there are other options that should be provided to the SoS, for example the power to require modification of a product or to require enhanced monitoring and/or reporting of company data?
- Q21** The Government is minded to require that e-cigarettes be labelled with the warning 'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'. Do you agree?
- Q22** Should the Government charge the industry proportionate fees to recover costs associated with the TPD2, including the following activities:
- a) The verification of the levels of tar, nicotine and carbon monoxide (TNCO) in cigarettes (Article 4);
 - b) The receiving, storage, handling, analysis and publishing information on ingredients and emissions of tobacco products including novel tobacco products (Article 5);
 - c) The peer review of scientific studies and additives undertaken by the tobacco industry (Article 6);
 - d) Assessing whether a tobacco product has a characterising flavour, whether prohibited additives or flavourings are used and whether a tobacco product contains additives in quantities that increase to a significant and measurable degree the toxic or addictive effect or the carcinogenic, mutagenic or reprotoxic (CMR) properties of the tobacco product concerned (Article 7);
 - e) If the UK chooses to implement an authorisation system for novel tobacco products then a fee can be charged for that authorisation (Article 19); and
 - f) The receiving, storing and handling and analysing information submitted to them on e-cigarettes (Article 20).

Please provide further comment.

- Q23** Should retailers and importers be given the proposed transition period until May 2017 to sell through old stock?

Question concerning the draft regulations

- Q24** Do you have any comments on the drafting of the regulations, including anything you want to draw to our attention on the practicalities of implementing the regulations, as drafted?

Questions concerning the draft Impact assessment

- Q25** 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:
- a) 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?

- b) What are the likely marginal impacts of implementing the TPD2 on e-cigarette manufacturers?**
- c) 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.**
- d) Do you have any further information that may inform the calculations in this IA, specifically in those areas outlined in Annex E?**
- e) Do you have any further comments on the approach taken in this IA?**

A full list of areas in which additional information is being sought is provided at annex E of the Impact Assessment