**Consultation on the implementation of the revised Tobacco Products Directive (2014/40/EU) – response form**

**How to get involved in the consultation**

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, organisation or business.

Respondents are encouraged to provide their views through the online survey at <http://consultations.dh.gov.uk/tobacco/tobacco-products-directive>

Alternatively, please fill in this form and:

Email your response to: [tobaccoproductsdirective@dh.gsi.gov.uk](mailto:tobaccoproductsdirective@dh.gsi.gov.uk)

Or post your response to: Tobacco Products Directive Consultation

Department of Health

PO Box 311

HERNE BAY

CT6 9BU

1. **Please provide your details and contact information:** (required)

Name of respondent (required)

     

Name of business or organisation (if applicable)

Address of respondent, business or organisation (required)

Email address (required)

(now go to question b)

1. **Are you responding:**

As a member of the public (go to question e)

As a health or social care professional (go to question c)

As a regulatory services professional (go to question c)

On behalf of a business or as a sole trader (go to question d)

On behalf of an organisation (go to question c)

1. **If you are responding on behalf of an organisation, as a health or social care professional, or as a regulatory services professional what type best describes you/your organisation?**

NHS Organisation

Non-Government Organisation – Health related

Non-Government Organisation – Children related

Non-Government Organisation – Other (please specify below)

Local Authority

Local Authority enforcement body (i.e. trading standards, environmental health)

Local tobacco control alliance

University or research organisation

Trade or representative body

Local smoking cessation service

Other (please specify below)

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| If “other”, please tell us the type of organisation |

**C1. Is this the official response of your organisation?** (required)

Yes

No

**C2. What is the name of your organisation?** (required)

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**C3. If applicable, what is the name of the person you are responding on behalf of?**

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| (now go to question e) |

1. **If you are responding on behalf of a business, what type is it? Please tick all that apply** (required)

E-cigarette manufacturer (tobacco industry owned)

E-cigarette manufacturer (non-tobacco industry owned)

E-cigarette importer (tobacco industry owned)

E-cigarette importer (non-tobacco industry owned)

E-cigarette wholesaler

Distributor of e-cigarette products

E-cigarette retailer (specialist store)

E-cigarette retailer (convenience store)

E-cigarette retailer (supermarket)

Other e-cigarette retailer

Pharmacy

Pharmaceutical industry

Tobacco manufacturer

Tobacco importer

Tobacco wholesaler

Tobacco retailer (specialist store)

Tobacco retailer (convenience store)

Tobacco retailer (supermarket)

Other tobacco retailer

Distributor of tobacco products

Other (please specify below)

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| If ‘Other’ please tell us the type of business |

**D1. Is this the official response of your business?** required)

Yes

No

**D2. What is the name of your business?** (required)

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**D3. If applicable, what is the name of the person you are responding on behalf of?**

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1. **Do you, or the business or organisation you represent, have any direct or indirect links to, or receive funding from, the tobacco industry?** (required)

No

Yes (please describe below)

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| If “yes”, please describe |

**E1. If you do not wish your response to be identified in the summary report of consultation responses, please tick this box**

Do not identify my response

All information in responses, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000, the Data Protection Act 1998 and the Environmental Information Regulations 2004). If you want your response to remain confidential, you should explain why confidentiality is necessary; your request will only be acceded to if it appropriate in all the circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

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| If you wish your response to remain confidential, please explain here why confidentiality is necessary |

(now go to question 1)

**Ingredients and Emissions**

1. **Should the Government request peer review of any reports submitted by the tobacco industry in relation to certain additives contained in a priority list of additives?**

Yes

No

Don’t know / unsure / have no view

Please provide any further comments below:

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**Labelling and Health Warnings**

1. **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?**

Please provide your response here:

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1. **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?**

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Please provide your response here.

1. **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?**

Yes

No

If you answered "Yes" above, please provide detail here.

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1. **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?**

Yes

No

If you answered "Yes" above, please provide detail here.

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1. **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?**

Yes

No

If you answered "Yes" above, please can you supply costs / evidence here.

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1. **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?**

Yes

No

Don’t know / unsure / have no view

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

Please provide detail here.

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1. **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?**

Yes

No

Don’t know / unsure / have no view

Please provide further detail here to explain your view.

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**Illicit Trade – Track and trace system and secutriy feature**

1. **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.**

Please provide any relevant information here.

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1. **We would welcome initial views on how track and trace and security markings may impact on business, and what the key issues for businesses will be.**

Please provide any relevant information here.

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**Cross-border distance sales of tobacco products and e-cigarettes**

1. **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?**

Yes

No

Don’t know / unsure / have no view

Please provide any further comments here.

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1. **Should cross-border distance sales of tobacco products to consumers be prohibited?**

Yes

No

Don’t know / unsure / have no view

Please provide any further comments here.

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1. **Should cross-border distance sales of e-cigarettes and refills to consumers be prohibited?**

Yes

No

Don’t know / unsure / have no view

Please provide any further comments here.

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1. **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?**

Please provide your response here.

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**Authorisation/notification of novel tobacco products**

1. **Should novel tobacco products be subject to a notification scheme?**

Yes

No

Don’t know / unsure / have no view

**If "No", please explain why you think an authorisation scheme would be preferable.**

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1. **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:**
2. **the toxicity of the product, its ingredients and emissions;**
3. **the addictiveness of the product, its ingredients and emissions;**
4. **the expected effects of the product on the cessation of tobacco consumption by existing users of tobacco products; and**
5. **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?**

Yes

No

Please provide any further comments here.

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**Electronic cigarettes**

1. **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?**

Yes

No

Don’t know / unsure / have no view

If you answered "Yes" or “unsure” above, please provide detail here.

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1. **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?**

Please provide relevant information here.

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1. **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?**

Yes

No

Don’t know / unsure / have no view

Please provide any further comments here.

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1. **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?**

Yes

No

Please provide any further comments here.

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1. **The TPD2 provides Member States with two options on the wording prescribed in the health warnings to appear on packs of e-cigarettes and refill containers. Member States must choose either 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’. 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?**

Yes

No

Don’t know / unsure / have no view

Please provide any further comments here.

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**Charging**

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

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|  | Yes | No | Don’t know / unsure / no view |
| 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, handling and analysing information submitted to them on e-cigarettes (Article 20). |  |  |  |

Please provide further comment here.

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**Transitional provisions for tobacco products, e-cigarettes and herbal products for smoking**

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

Yes

No

Don’t know / unsure / have no view

Please provide any further comments here.

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**Questions concerning the draft regulations**

1. **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?**

Please provide your response here.

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**Questions concerning the draft impact assessment**

1. **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:**
2. **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?**

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1. **What are the likely marginal impacts of implementing the TPD2 on e-cigarette manufacturers?**

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1. **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.**

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1. **Do you have any further information that may inform the calculations in this IA, specifically in those areas outlined in Annex E of the IA?**

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1. **Do you have any further comments on the approach taken in this IA?**

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**Future stakeholder engagement on specific topics**

**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. Please tick the box next to those that you would like to receive further engagement on:**

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| **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 |  |

Thank you for participating in this consultation.

The Department of Health will only contact you should we seek further information about your response.