



Department of Health

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>

We're doing it the following way though – when its finished, save the doc and email it to the address below (or print and post, whatever). Please don't use this document (or if you do, delete all the red bits lol). Click the link below!

Alternatively, please fill in this form:

[https://www.gov.uk/government/uploads/system/uploads/consultation_response_form_data/file/375/2015-07-01_TPD_-_Response_form_-_clickable FOR PUBLICATION.docx](https://www.gov.uk/government/uploads/system/uploads/consultation_response_form_data/file/375/2015-07-01_TPD_-_Response_form_-_clickable_FOR_PUBLICATION.docx) and:

Email your response to: tobaccoproductsdirective@dh.gsi.gov.uk

Or post your response to: Tobacco Products Directive Consultation
Department of Health
PO Box 311
HERNE BAY
CT6 9BU

OK, here we go. This will take some time, and it may leave you with feelings of frustration, rage and/or impotence – and in a mood for civil disobedience, but it needs to be done. A red asterisk means you have to complete that box. Write in the grey box, use as many or as few words as you like. The questions are all in the context of the consultation document:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/440991/TPD_Consultation_Doc.pdf

Links in the friendly, non-threatening font are for suggested info. Don't be worried about leaving questions blank, I did (a lot). Deep breath :)

A. 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)

B. 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)

My computer's not letting me write in these boxes (I'm not using Word so it may be that), I'm deleting the appropriate box and replacing it with a nice big "X". For the purposes of this walkthrough, I'm answering as a member of the public - there's nothing to trip you up in C or D if you're answering in another guise though, just go to the relevant question and we'll meet up again at E :) .

p.s. I'm not an expert by any means - your answers may well be far better than mine!

C. 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)

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)

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

(now go to question e)

D. 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)

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)

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

E. 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)

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

Tick this if you want, up to you.

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.

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

If I had more time I'd look all this up and tell you the permissible grounds for info remaining confidential. I don't, sorry. My advice - ignore, move on. If you're in witness protection or something then I guess you know how to fill this out. It's not the same as the box above (? might be actually ...) but lets not waste a whole load of time analysing that right now, lets ...

(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:

I don't care I'm afraid, I probably should, but I'm all about the ecig!

Labelling and Health Warnings

2. 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:

I'm basically leaving all the non-ecig boxes blank - if you have a view, please give it.

3. 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?

Please provide your response here.

4. 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.

WTF! Did they just actually say: This is our policy, can you think of a way to justify it? Sheesh! (I'm leaving this blank btw, just wanted to say that though. :)

5. 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.

6. 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.

7. 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.

8. 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.

Illicit Trade – Track and trace system and security feature

9. 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.

Well I know a bloke down the pub ... (and incidentally you'd think they'd have spell-checked this before publishing it wouldn't you?)

10. 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.

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

11. 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.

Right, we're into it now. 2 options with your responses from here on in. You can either be straightforward and comment about how it is ridiculous to be "harmonising" lit tobacco and ecigs, given their respective harm profiles - that would be a "no" because the whole idea of Drippa not being able to post to France or me not being able to buy direct from Inawera (say) is extremely absurd and has nothing to do with evidence and everything to do with protecting established businesses from disruptive products. And I'm happy with that, I really am - hopefully they'll get lots of straightforward responses. Or, you can be pragmatic. The choices the TPD gives them are to either ban cross-border sales, or if they allow them, to nominate an individual. Which would be a "Yes" backed up with comments about, well, we're back to absurdity again. So, rage against the machine or work with what we've got. I went for "yes" and said about how ridiculous it would be to ban cross border sales of ecigs. Totally up to you :) .

12. 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.

Your mileage may vary

13. 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.

Lots of options:

Lost consumer freedom, lost business opportunity, why prohibit something that helps people? If you are a vendor and have an idea of your overseas sales figures, it would be excellent to mention that here :) . This is the most direct question on ecigs in the whole exercise and it provides an opportunity to really go for it. Get personal, tell your story. Give the policy wonks something decent to read.!

14. 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.

? Isn't this what google is for, rather than an expensive consultation exercise? Anyway, help them out if you can - otherwise, move on (I did!).

Authorisation/notification of novel tobacco products

15. 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.

16. 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?

- Yes
- No

Please provide any further comments here.

Electronic cigarettes

17. 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.

'electronic cigarette' means a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges;

'refill container' means a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette;

They haven't heard of drippers then? Dunno about this question tbh, I left it blank but there's probably something to be said.

18. 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.

Proportions of flavouring used in juices is the obvious one, there's nothing in the notification regime (Part 6, no 30):

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/440989/SI_tobacco_products_acc.pdf (that's the proposed law btw :()
to suggest details of chip design for regulated mods - apart from 30.3.e "a description of the components of the product ..." Don't think they know about regulated mods!

Back to the 2 options - if you want to rage against the machine, I'd suggest ignoring chip design, let the buggers stew in their ignorance. If you want to be pragmatic maybe make explicit that chip design is "commercially confidential" info.

19. 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.

Seems sensible. The community's pretty good about sharing info about dodgy gear, we've done that informally anyway. I guess we'll give them that one. Think this is just about filling a loophole anyway. I didn't comment, just ticked "Yes". Up to you.

20. 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.

This is my bias - less law is best law, well I did join the Anarchists Society at Uni (I know :p). Not the bigger picture, up to you.

21. 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.

Another of the option ones. You can fill your boots with how nicotine really isn't that addictive alone - as implied by the NICE guidance on using NRT "Nicotine inhaled from smoking tobacco is highly addictive."
<https://www.nice.org.uk/guidance/PH45/chapter/Introduction-scope-and-purpose-of-this-guidance>, or more generally, <http://www.ecigarette-politics.com/is-nicotine-addictive.html>. Or you can accept that they have to either have that warning, or the marginally different "This product contains nicotine which is a highly addictive substance.". Not bothered myself, warnings are pointless if you are addicted and annoying if you're not, I took the opportunity to tell them it was a lie. And they shouldn't be doing that.

Charging

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

		Don't know / unsure / no view
Yes	No	

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.

Its a long shot, but if we got a massive "No" here, maybe loads of businesses who HELP PEOPLE STOP SMOKING won't be forced to go under by THIS STUPID LAW. Please, be passionate (at least tick "No").

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

23. 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.

You can be sensible and talk about how they should at least be allowed to sell things that STOP PEOPLE SMOKING for a little bit if you want, and if you've still got the patience at this point. Make a business case if you will, I'd given up, sorry.

Questions concerning the draft regulations

24. 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.

YES! The MHRA being the regulator for ecigs is a massive conflict of interest. They are funded by the direct competitors of ecigs. http://www.thecommentator.com/article/3801/big_pharma_more_conflicts_of_interest_for_instance. Stakeholders (i.e. users of ecigs) need to be involved with this. Nothing about us without us. There should be a consumer panel involved. I went on and on about this. Also the rules say ecigs should deliver a consistent dose of nicotine (para 36 (8)), this could wipe out ALL ecigs on the market.

Questions concerning the draft impact assessment

25. 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?

Impact assessment:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/440994/TPD_IA.pdf . The main thing here I guess is the redesigning of all atties to include the as yet unreleased leak-free refilling mechanism. Without that design available it could be a minor insert or a major revision.

It is likely that most products will just disappear.

(b) What are the likely marginal impacts of implementing the TPD2 on e-cigarette manufacturers?

As above plus unless the government pays for the reporting regime, they will go out of business, these aren't big companies in the main, they're SME's, with the emphasis on the "S". That means less people turn to vaping and smoking prevalence stays relatively high. Why pass a law that encourages people to keep smoking? Say stuff like that :)

(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.

This bit doesn't apply to ecigs - from the draft law: packaging not allowed if it " refers to taste, smell or other additives (except flavourings) or the absence of any such thing;" (38.3.c)

(d) 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?

Annex E is on page 59 of the impact assessment. Quite a few of the areas involve ecigs - I focussed on the advertising ban, I personally found out about them from the radio, that wouldn't have happened. If the whole point of the TPD is to reduce smoking, ecigs should be heavily advertised. It also unfairly prejudices them against NRT, which will continue to be allowed to be advertised.

(e) Do you have any further comments on the approach taken in this IA?

I made a general point about how the positioning of ecigs as similar to cigarettes (warnings in helvetica etc) is unlikely to help current smokers consider switching and will undermine the progress made by ecigs in reducing smoking prevalence.

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:

Tick as many of these as possible – I know its been onerous (but you're nearly done), ticking it doesn't mean you have to go through it all again but it does give you the chance. (I haven't got a clue what the references in brackets are to – its not the articles in the draft!)

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))

X

Determine technical standards for refill mechanisms (Article
20(13))

X

Charging

Determine proportionate fees should we decide to charge fees

X

Thank you for participating in this consultation.

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

Congratulations!

Now save and email or print and post as per page 1.

You have completed Level 1 :)