Lipstick on a pig: response to consultation on the Tobacco Products Directive

written by Clive Bates | 30 August 2015

I responded to the Department of Health consultation on implementing the EU Tobacco Products Directive [documents / consultation]. The on-line survey system accessible from the consultation page is *by far* the easiest way to respond. Closes 3rd September 2015.

To be candid, I find this consultation quite patronising. In the manner of putting lipstick on a pig, they are not consulting on the Directive itself – that is irrevocably fixed (albeit subject to legal action that could strike it down), but on implementation detail.

The part of the directive itself that deals with e-cigarettes (Article 20) *was never subject to consultation.*

Unsurprisingly it amounts to little more than pointless bureaucratic harassment – see why here. So this consultation deals only with options allowed *within* the fixed terms directive. I was thinking of not responding, but figured any opportunity to discourage the creation of an even bigger mess should be taken. The big mistakes were made in October 2013 – this consultation is a consequence.

My response below – questions not answered are greyed out. PS. if you respond, please give your own thoughts, in your own words, politely and constructively.

What I *really* think is at at Q.24 and 25.

Responses to questions start here:

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?

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 ensure this does not apply to e-cigarettes. The important differences between tobacco products and e-cigarettes are:*
>
> - *Tobacco brands have been in the market for years and have built huge brand equity through decades of advertising, promotion and sponsorship. E-cigarettesare a disruptive entrant that need to become established as an alternative to cigarettes.*
> - *Tobacco products kill about 100,000 UK and 700,000 EU citizens annually but e-cigarettes do not kill anyone – and will probably avoid thousands of deaths.There is no basis for treating them the same way.*

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?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?

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?

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?

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?

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?

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.

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.

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

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?

12 Should cross-border distance sales of tobacco products to consumers be prohibited?

No. This should not apply to smokeless tobacco.

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

No. There is no evidence that e-cigarettes and refills cause harm to the public and considerable evidence that they are a beneficial alternative to smoking. There is no case to restrict the trade in these products and no evidence exists to support an exception from the European Union principle of the free movement of goods.

The legal base for the directive is concerned with developing the internal market – given there is no basis for health concerns arising from e-cigarettes traded in the EU, even the option to for recipient countries to prevent cross border distance sales is an unlawful restriction of trade under the treaties and should never have been agreed in the directive.

14 What systems to verify the age of customers are available to, or currently used by, businesses involved in distance sales to other EU states

Given that e-cigarettes may help younger people quit smoking and there is no reason why 'harm reduction' should wait until 18, there is no need to go beyond the minimum age-verification regime for e-cigarettes. Any burden associated with age-verification should be proportionate to risk, and any risks of material harm are low.

Authorisation/notification of novel tobacco products (TPD2 Article 19)
15 Should novel tobacco products be subject to a notification scheme?

Yes. Only notification is necessary, not authorisation. It is unlikely that any manufacturer will bring products more dangerous than cigarettes on to the market. It is difficult therefore to see on what basis authorisation would be withheld, given that no authorisation is required for cigarettes. However, it will present ministers and officials with a choice to authorise or not authorise that is

bound to be politicised, create unnecessary conflict or lead to avoidable legal action. The directive Article 13.1(b) does not allow claims of differentiated risk and therefore does not require authorisation of risk-related claims. Given that smokeless tobacco and heat-not-burn tobacco products may have risks 1-3 orders of magnitude lower than cigarette smoking, this is a significant weaknesses in the directive. It has the effect of misleading consumers and preventing informed choice – and it should never have been agreed by British officials.

The right to intervene should be reserved for the unlikely event where notification suggests that a novel tobacco product will be more dangerous than conventional cigarettes. In that event, action should be taken under consumer protection legislation.

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?

No. The mandatory notification requirements for novel tobacco products should not exceed those for existing tobacco products such as cigarettes – this applies in part to (a) and fully to (b),(c) and (d). To impose greater burdens on manufacturers or importers of novel tobacco products than on cigarettes would breach the EU principle of non-discrimination ("equal treatment") and be unlawful under the the treaties and relevant EU jurisprudence. The requirements (c) and (d) are impossible to provide with any realistic basis in advance of release on to the market, and it is far from clear how these would be used in a regulatory determination to allow a product onto the market. It likely that this information would be used to greatly complicate the regulatory landscape and provide openings for politicisation of regulation of the type seen

in the United States.

It is worth recalling that snus was banned in the EU in 1992 because of unfounded ex ante concerns that it would have adverse population effects of the type suggested in these disclosure proposals. However, the population effects in Sweden have been highly positive. The fact that officials and ministers supported a continuation of the snus ban in the 2014 directive only serves to emphasise that the government cannot be trusted to make sound non-politicised judgements on these issues when it is given a choice. It would therefore be better to allow these products on to the market by default. Unless the notification regime gives the competent authority cause to believe a tobacco product might be more dangerous than cigarettes, the product should be allowed on to the market with no more difficulty than cigarettes. If there is a basis for concern that the product is more dangerous, action should be taken under consumer protection legislation.

Electronic Cigarettes (TPD2 Article 20)

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 2015?

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?

The continued development of vapour products as alternatives to cigarettes will depend on both consumer confidence and innovation. The principle for disclosure should be to disclose information about risks or benefits to consumers, but to protect the intellectual property of manufacturers and vendors to support innovation.

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?

> *No. There should be a named responsible person, but in an internal market directive this should be an individual identified at EU level, not member state level. This would mirror the responsibilities that cosmetics manufacturers have under the EU Cosmetics Regulation – a single EU responsible person.*

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?

> *No. This is unnecessary regulation. The General Product Safety Directive and related UK legislation provide the necessary powers and duties to keep consumers safe. If the government wishes to be more precise about what constitutes a safe product, it should support standards, not treat products on an ad hoc basis. It certainly is not the business of the Secretary of State to become involved in product design specifications. The right to remove unsafe products is all that is required, it is up to manufacturers to meet the general safety requirement and any safety standards.*

21 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?

> *No. The warning itself is inaccurate and misleading and should never have been accepted by British officials. Nicotine per se is not a "highly addictive substance". It's consumption through smoking causes dependency but that is*

largely a result of the pharmacokinetics of nicotine delivered through inhaled smoke. The PK data for e-cigarettes suggests a smaller and slower bolus effect and there is little evidence to support the health warning as described. E-cigarettes may be valuable as a relapse prevention strategy for ex-smokers or as an alternative to taking up smoking, so the shorter message is to be preferred. "should only be used as an alternative to smoking" would have been better. Sadly there was no opportunity to point out these arguments when the directive was agreed in secret without consultation.

Cross-cutting issues

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

The verification of the levels of tar, nicotine and carbon monoxide (TNCO) in cigarettes (Article 4); Yes

The receiving, storage, handling, analysis and publishing information on ingredients and emissions of tobacco products including novel tobacco products (Article 5); Yes

The peer review of scientific studies and additives undertaken by the tobacco industry (Article 6);Yes

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); Yes

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: Don't know / unsure / no view [I don't think there should be an authorisation regime under any circumstances].

The receiving, storing, handling and analysing information submitted to them on e-cigarettes (Article 20).:

No. The principle that firms should bear the cost of regulation is sound providing the regulation is well-founded. The making of article 20 of the TPD

violated all legal requirements and principles of good policy making. There was no consultation, no impact assessment, no scientific basis for the measures and negligible scrutiny. It is not fair to ask companies to assume burdens associated with such poor policy-making, over which they have had no say.

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

Yes, for e-cigarettes. The clumsy and inept terms of the directive will do needless harm to this emerging industry – the government should exploit to the full any flexibilities that the TPD allows to mitigate the damage.

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?

This consultation is an inherently patronising exercise focussed on the implementation details of badly designed but irrevocably fixed EU measures. These measures were agreed without any consultation, impact assessment, scrutiny or credible evidence base. My critique of the directive is here: What's wrong with the tobacco products directive for vapour products

When the government's preferred option of regulating these products as medicines was rejected by the European Parliament on 8 October 2013, the section of the directive dealing with e-cigarettes should have been withdrawn and cast into a new directive that would have been subject to the law-making disciplines of the EU's ordinary legislative procedure.

Instead, ministers and officials ploughed on regardless. The text was created in an secretive haggle during a handful of closed meetings in the triologue process between October and December 2013 with no public access to limité documents or other means of engagement. In the course of this, ~5,000 words of brand new legislation were created – not through any proper deliberative process but through the political horse-trading of politicians and politicised officials based on limited knowledge of the products they were

regulating.

The EU treaties require new legislation to be subject to consultation, impact assessment and parliamentary scrutiny, yet none of that was done. They require careful checking that the principles of proportionality and equal treatment are respected, yet these principles have been serially violated. The measures should be assessed for compatibility with their legal base, yet it is hard to see how TPD Article 20 helps to facilitate free movement of goods in the EU with a high regard for health protection. None of these obligations were met in the way Article 20 was formulated or by the finished text. It is unlikely that these measures would have been agreed had there been a more open policy-making process. (see detailed note on process failures)

There are several lessons from this:

- *These products need to be regulated with a view to maximising the opportunity, not with clumsy risk aversion and excessive caution about negligible or implausible risks. The recent Public Health England evidence review suggests that the health upside will be considerable but the directive approaches these products as a threat to be contained.*
- *It is far from clear what problem the TPD Article 20 is trying to solve that could not be addressed with a few technical standards and controls on marketing of the type defined by the Committee on Advertising Practice. There is no credible problem definition.*
- *The government should uphold the principles of good policymaking and the requirements of the EU treaties rather than regard reaching an agreement, no matter how poor, as the objective of its work in Brussels.*
- *The vaping public and manufacturers have been more right about vaping than the government from the 2010 MHRA consultation onwards. The habit of excluding those involved from deliberations should stop, and I recognise there are encouraging signs that it has stopped, albeit after the substantive measures were settled.*
- *While few will care much if excessive regulatory burdens are piled on to tobacco companies, it does matter for the large number of SMEs in the e-cigarette sector. The regulation appears to be designed as if there is no interest in meeting reasonable policy objectives with minimum burdens.*

Impact Assessment

25 (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?

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

25 (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.

25 (d) Do you have any further information that may inform the calculations in this IA, specifically in those areas outlined in Annex E?

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

The IA is one of the strangest government documents I have ever seen. While it diligently calculates minor administrative costs measured in a few thousands of pounds, it also includes: "Expected benefits are the health benefits that would accrue from improved smoking quit rates of life years valued at £13.7bn" and adds this multi-billion sum into the net calculation of other costs that are trivialised as a result.

There is nothing wrong in principle with including large benefits like this in an IA cost benefit analysis, but only if two conditions are met. The first is that there is some evidence to support the claimed change in prevalence – and this relies uncritically on guesswork by the Commission. The second is that this approach is adopted consistently. Most of the impacts of the regulation of e-cigarettes are likely to reduce sales of e-cigarettes and likely to reduce their effectiveness as replacements for smoking – increasing smoking prevalence. So these negative impacts need to be estimated in the impact assessment as it applies to article 20.

For example, questions not asked and effects not quantified in the IA include:

- *the negative impact of e-cigarette marketing restrictions on growth of the category at the expense of cigarettes. This is mentioned in passing*

in para 149 of the IA: "Regardless, the evidence implies that a ban on e-cigarette advertising may restrict future growth in the market and reduce consumption." But the implications of that statement are not developed into what could be a huge negative impact of the directive, if, say, it meant smoking prevalence was 1% higher.

- *the negative impact of excessive warnings in deterring consumers from switching from smoking to vaping*
- *the negative effect of the pointless bureaucratic restrictions on container size and nicotine strength on the convenience to consumers*
- *the negative effect of paperwork burdens beyond the cost of compliance – i.e. on the diversity of products on the market and resulting degradation of the incentive to switch.*
- *the negative impact on the pace and quality of innovation due to technical restrictions and burdens*
- *… and so on.*

For each of these, it only needs a few lost vapers and resulting additional smokers to swamp any other costs and purported benefits of the regulations in Article 20.

So the main issue with the IA is that it is estimating large benefits for tobacco regulation with reference to impacts on smoking prevalence, but it is ignoring the disbenefits arising from e-cigarette regulation with reference to smoking prevalence. Everything else in the IA is froth in comparison. These risks at least need to be articulated qualitatively and some estimate made of the range of possible impacts – not least so that there is a framework for assessing the damage that will be caused by TPD article 20 as it is implemented.

*Of course, the reason that policy-makers are supposed to do impact assessment is to inform the design of policy measures *before* they are settled. That this was not done for the directive Article 20 before it was settled was a policy-making failure and probably unlawful under the treaties*.*

** Article 5 of the Protocol on the Application of the Principle of Sustainability and Proportionality requires: "Any draft legislative act should contain a detailed statement making it possible to appraise compliance with the principles of subsidiarity and proportionality. This statement should contain some assessment of the proposal's financial impact and, in the case of a directive, of*

its implications for the rules to be put in place by Member States, including, where necessary, the regional legislation. The reasons for concluding that a Union objective can be better achieved at Union level shall be substantiated by qualitative and, wherever possible, quantitative indicators. Draft legislative acts shall take account of the need for any burden, whether financial or administrative, falling upon the Union, national governments, regional or local authorities, economic operators and citizens, to be minimised and commensurate with the objective to be achieved.".

I am unaware of any documentation that meets this requirement for Article 20.

Other interesting or provocative submissions

Dick Puddlecote's advice: Drafting a TPD2 consultation response.