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Comments on draft legislation on e-cigarettes and refill containers

I am writing as a former Director of Action on Smoking and Health (UK) and former UK civil servant, and now as a consultant in sustainability and public health. I have no conflicts I believe that e-cigarettes and other vaping products can play a major role in reducing the burden of disease and death caused by smoking. I would like to make brief comments on parts of the draft Icelandic legislation on electronic cigarettes and refill containers. My comments on the following pages are ordered under the main headings of the draft legislation.

Much of the proposed legislation approximates to the EU Tobacco Products Directive, 2014/40/EU Article 20. As such, it incorporates many of the weaknesses of that Directive. These flaws have been discussed extensively^{1 2} and should be considered carefully by the Parliament before they are adopted in Iceland. However, there are some positive aspects to the proposed legislation and some areas where a more moderate approach would be worthwhile.

I hope these comments are of value in the parliament as this important legislation receives consideration and scrutiny.

Yours sincerely,



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¹ Bates CD: What is wrong with the Tobacco Products Directive for vapour products? Counterfactual May 2015 [\[link\]](#)

² Snowdon CJ. E-cigarettes and Article 20 of the Tobacco Products Directive. European Policy Information Center (EPICENTER), September 2015. [\[link\]](#)

Section I: General provisions - Articles 1-3

Article 1: Aim

Article 1 suggests the aim is to set rules, which might be understood as a means rather than an end. A better description of the aim of policy in this area would be:

to govern the trade in e-cigarettes and refill containers with a high level of health and safety protection and to realise market-based opportunities to reduce the harms caused by smoking.

Article 2: Scope

The legislation should be limited only to nicotine-containing products. Other, non-nicotine, products would not be unregulated but covered by conventional consumer protection legislation – for example numerous EU directives provide a framework for consumer protection applicable in the EEA³. The rationale for special treatment of nicotine-based products is that nicotine is understood to be a dependence-forming substance and therefore may be consumed by people would otherwise make an informed choice not to use it.

Article 3: Definitions

For simplicity and to avoid confusion, the relevant definitions used in EU Tobacco Products Directive 2014/40/EU Article 2 should be used, for example:

(16) '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;

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

Section II Importation, sale and marketing - Articles 4-10

Article 4: Warnings on packaging

This Article does not state what health warnings would be included. Labelling generally performs several function:

- To communicate material health risks, if any
- To communicate safety risks and what to do if exposed to e-liquid
- To provide consumer information on ingredients so that it is clear what is being sold

³ For example: [1272/2008](#); REACH [1907/2006](#); Low Voltage [2006/95/EC](#); Electro-Magnetic [2004/108/EC](#); RoHS [2011/65/EU](#); WEEE [2012/19/EU](#); Batteries [2006/66/EC](#); Weights and measures [76/211/EEC](#) [2007/45/EC](#); Sale of goods [99/44/EC](#); Distance Selling [97/7/EC](#); Electronic Commerce [2000/31/EC](#); Misleading Advertising [2006/114/EC](#); Unfair Commercial Practices [2005/29/EC](#); Protection of Personal Data [95/46/EC](#)

- To provide information that helps consumers make informed choices.

So far, there is no credible evidence of a material health risk (though it should not be assumed that there are no risks), so it is unclear what a health warning should say.

The EU Directive Article 20(4)(b)iii specifies the following warning for use on e-cigarettes and refill containers.

(b) unit packets and any outside packaging of electronic cigarettes and refill containers: [...]

(iii) carry one of the following health warnings:

'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'. Or 'This product contains nicotine which is a highly addictive substance.' Member States shall determine which of these health warnings is to be used

But this warning would make no sense and would be improperly misleading in Iceland if the legislation also includes non-nicotine products within its scope, as specified in Article 2: *Scope* and Article 3: *Definitions*. The appropriate approach to informing consumers should be to communicate relative risk, for example with a warning that specifies:

"Exclusive use of this product may not be completely safe, but it is likely to be much less harmful than smoking cigarettes".

Article 5: Safety

This could refer to Iceland's general consumer protection regulation, for example the Iceland equivalent of the European Union General Products Safety Directive⁴. The requirement for child proof containers could refer to the relevant ISO standard⁵.

Article 6: Age restrictions

In a sparsely populated country, it is important to have internet sales so that users can access a wide range of products, not just those available in retail settings, which will tend to be those marketed by tobacco companies. Internet retailing meets this need. However, legislation should insist on age verification for internet sales.

Article 7: Maximum strength of and size of refill containers

The only advantage of Article 7 is compliance with the European Union Tobacco Products Directive. Every other aspect is a significant disadvantage. There are at least five reasons for having stronger liquids, for example up to 50-70ml/mg, rather than the EU standard of 20mg/ml.

1. Some users like stronger liquids and they relapse to smoking if these are no longer available in Iceland

⁴ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Text with EEA relevance) [\[link\]](#)

⁵ ISO 8317:2015 Child-resistant packaging -- Requirements and testing procedures for reclosable packages [\[link\]](#) and related standards, 55.020 - Packaging and distribution of goods in general [\[link\]](#)

2. Stronger liquids may be needed to help more heavily dependent smokers to switch. Blocking access to stronger liquids may prevent those most at risk from quitting smoking by switching to e-cigarettes.
3. Many smokers may need a stronger liquid while they make an initial conversion and as they get used to vaping.
4. Stronger liquids may be important in future designs or other innovations and so such a rule creates a barrier to innovation that may benefit consumers.
5. People using stronger liquids are likely to consume a lower volume of liquid and hence be exposed to lower levels of any harmful agents present in the liquid.

There is also no case for controlling tank size or the size of refill containers. This just adds to the inconvenience of using the products and increases the number of times per day that a user has to refill. In no other area of consumer safety (medicines, cleaning fluids, fuels) is the size of containers used to control risks. The well-established approach is to use three approaches together:

1. Use child resistant packaging
2. Warn of the dangers
3. Provide advice on what to do and contact information in the event of exposure

There is no reason to depart from this approach from e-cigarettes.

Senior European experts heavily criticised these aspects of the EU Tobacco Products Directive while the Directive was proceeding through the legislature in 2013⁶.

Article 8: Contents of refill containers

This provides compatibility with the European Union Tobacco Products Directive.

Article 9: Points of sale

There is no reason to prevent healthcare institutions or places where healthcare services are provided from selling e-cigarettes. In such settings these are only likely to be bought as alternatives to cigarettes, and as such they would be highly beneficial. In England, the main public health agency, Public Health England recently recommended that e-cigarettes are available in health care settings (Press release)⁷:

To become truly smokefree, Trusts should ensure

- *e-cigarettes, alongside nicotine replacement therapies are available for sale in hospital shops*
- *vaping policies support smokers to quit and stay smokefree*
- *smoking shelters be removed*
- *frontline staff take every opportunity to encourage and support patients to quit*

⁶ Etter JF et al, Scientific Errors in the Tobacco Products Directive A letter sent by scientists to the European Union, E-cigarette Research. (Letter from 15 experts to European Commission) 16 January 2014 [\[link\]](#)

⁷ McNeill A, Brose LS, Calder R, Bauld L & Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England. 6 February 2018 [\[link\]](#) [\[Press release\]](#)

Article 10: Advertisements and visibility at the point of sale

This is the weakest and most damaging part of the draft legislation. It is important to understand that e-cigarette advertising functions as anti-smoking advertising, trying to draw smokers into switching away from cigarettes. The reason that tobacco advertising is banned in many countries is the harm caused to human health (700,000 premature deaths per year in the European Union). But no deaths are caused by vaping and over time many will be avoided.

A ban on advertising constitutes a completely unjustified protection of the incumbent cigarette trade and holds back a much safer disruptive entrant technology from gaining market share.

The restrictions on advertising life-saving alternatives to smoking should be significantly scaled back in this legislation. If possible, the restrictions on advertising should focus on restricting overtly irresponsible or youth orientated advertising. The UK Codes of Advertising Practice⁸ provide a good model covering all advertising not banned by the European Union Tobacco Products Directive.

Article 10 goes considerably beyond the requirements of the EU Tobacco Product Directive by banning *all* advertising including point of sale display and fixed location advertising. The EU directive only prohibits advertising, sponsorship and promotion that crosses borders⁹. As a minimum, Article 9 should be recast to align only with the minimum requirements of the Tobacco Products Directive, if that is the purpose of this legislation.

Section III: restriction of the use of electronic cigarettes - Article 11:

It is reasonable to prohibit vaping in settings geared to the needs of children, or where children have no choice to be. But in adult settings (including in parts of the healthcare system), it is more appropriate to allow the directors, owners or managers of institutions to determine the policy approach to vaping – in many case such policies would be a ban, but that would have been determined locally and in the interest of such undertakings and their clientele. Article 11 would be improved by deleting sub-paragraph (a) and (c) and relying instead on the final paragraph as a general statement of policy:

The directors of undertakings and institutions not listed in the first paragraph shall be obliged to set rules on the use of electronic cigarettes in their premises, and such rules shall be visible in the areas in question

This is a strongly principled approach, recognizing that case for the government to override the directors, owners or managers of place can only be justified if there is material risk to bystanders, and there is no evidence of any material risk to bystanders exposed to vapour aerosol.

⁸ Committee on Advertising Practice (UK), UK Code of Broadcast Advertising: 33. E-cigarettes Broadcast [\[link\]](#); UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code): 22. E-cigarettes [\[link\]](#)

⁹ European Union Tobacco Products Directive, 2014/40/EU April 2014 – Article 20(5) [\[link\]](#)

Section IV: Market Monitoring - Articles 12-17

These section provide reasonable institutional governance and appropriate powers, with adequate scope for appeal and redress.

Section V: Article 18: Education and awareness-raising

While education is always important, it is essential that such education provides balance that allows for informed choice, rather than 'propaganda' designed to achieve a particular effect. For example, it is important to stress that the much lower risks of vaping can be a life-saving option for smokers, and not simply to try to make vaping seem as harmful as possible.

Section VI: Miscellaneous provisions - Articles 19-20

No comments

About the author

Clive Bates is director of Counterfactual, a consulting and advocacy practice focused on a pragmatic approach to sustainable development, energy policy and public health that he founded in 2013. From 1997 to 2003, he was the United Kingdom's director of Action on Smoking and Health, campaigning to reduce the harms caused by tobacco. From 2003 to 2013 he was a senior civil servant in the UK and for the UN in Sudan on unrelated business. Clive Bates and Counterfactual have no competing interests with respect to e-cigarette, tobacco or pharmaceutical industries.