

UK Product Safety Review: Call for Evidence

Response from Action on Smoking and Health and SPECTRUM

Closing date 17th June 2021

<https://www.gov.uk/government/consultations/uk-product-safety-review-call-for-evidence>

Respond to: productsafetyreview@beis.gov.uk

Action on Smoking and Health (ASH), is a public health charity set up by the Royal College of Physicians in 1971 to advocate for evidence-based policy measures to reduce the harm caused by tobacco. ASH receives funding for its full programme of work from the British Heart Foundation and Cancer Research UK. SPECTRUM is a public health research consortium of academics from 10 UK universities and partner organisations funded by the UK Prevention Research Partnership. The key focus of its research is unhealthy commodities which include tobacco.

Neither of the organisations have any direct or indirect links to, or receive funding from, the tobacco industry, except for nominal shareholdings in Imperial Brands and BAT for research purposes.

We are only responding to Q23 see below.

Question 23: Does the current framework adequately protect all people in society, including vulnerable groups and those with particular needs? And could it be improved?

1. No, we do not believe that the current framework adequately protect all people in society, including vulnerable groups and those with particular needs. In particular we are seriously concerned about the regulation of novel nicotine products other than e-cigarettes (such as nicotine pouches) which are currently only covered by the General Product Safety Regulations (GPSR). This is not the appropriate regulatory framework for nicotine products which are potentially highly addictive and under the GPSR are accessible to children.
2. Novel nicotine products (such as nicotine pouches) are not currently caught by other regulatory frameworks because:
 - E-cigarettes are regulated under the [Tobacco and Related Product Regulations](#) or [The Nicotine Inhaling Products \(Age of Sale and Proxy Purchasing\) Regulations 2015](#) (as amended in 2019 and 2020 following Great Britain's exit from the EU). However, although the TRPR includes a catch all category for novel tobacco products, there is no such category for novel nicotine products.
 - Only nicotine products marketed for cessation are regulated as medicines by the MHRA. Novel nicotine products are therefore not covered by medicines licensing because they are marketed as consumer products.
 - The Food Standards Agency has determined that because *"The primary purpose of these products is not as a food or nutrition related"* nicotine pouches *"should not be considered as food under Regulation (EC) 178/2002"* (letter from the FSA dated December 2020 URN: PLGEN20037).
3. That means that novel nicotine products (such as nicotine pouches) have:
 - **No limits on nicotine strength:** products available in the UK typically range from 4mg to 18 mg in strength (see <https://ukvaperstore.co.uk/nicotine-pouches.html>) with some products

advertised on sale online containing as much as 100 mg/g of nicotine (see [Candy Shop Cherry Cola - Nicotine Pouch - London Pods](#)). This is far higher than similar oral nicotine products such as 4mg NRT gum and lozenges licensed by the MHRA for smokers wanting to quit or access alternative sources of nicotine (see <https://bnf.nice.org.uk/drug/nicotine.html>). Although the actual amount of nicotine extracted by users will depend on a variety of factors including other product characteristics and user behaviour, these products contain significant levels of nicotine and need to be appropriately regulated.

- **No age of sale restrictions or limits on free samples:** novel nicotine products can be sold or handed out free to consumers of any age. This is because although the [Children and Families Act 2014](#) Part 5 section 92 and 93 allows the Secretary of State to “*make provision prohibiting the sale of nicotine products to persons aged under 18*”, the regulations as made were limited. [The Nicotine Inhaling Products \(Age of Sale and Proxy Purchasing\) Regulations 2015](#) (as amended in 2019 and 2020) following Great Britain’s exit from the EU) which brought the legislation into effect in England and Wales, limited the age of sale of 18 to nicotine inhaling products.
 - **No restrictions on advertising, promotion, and sponsorship:** these products are being promoted online via influencers, free samples, and competitions.
For examples see (accessed 16 March 2021)
<https://www.instagram.com/velo.unitedkingdom/>
https://www.instagram.com/nordicspirit_uk/b
4. The National Audit Office report on [Protecting consumers from unsafe products](#), published on 16th June, recommended that the Office for Product Safety and Standards (OPSS) should “*establish which consumers may be particularly vulnerable to unsafe products, and in what circumstances*”. Novel nicotine products such as pouches are a good example of products which cannot be considered safe for vulnerable consumers. The OPSS may not consider novel nicotine products should fall under their remit and certainly that is our opinion. Specialist regulation is needed to take account of the unique risks of these legal but addictive products, particularly to children and young people.
 5. The [Committee on Toxicity](#) has been requested by the Department for Health and Social Care (DHSC) and the Public Health England (PHE) Tobacco teams to consider the toxicological risks from tobacco-free oral nicotine pouches. COT has not yet reported, but the following [COT conclusion on e-cigarettes](#) is relevant, “*Non-users who have never been exposed to nicotine and who take up vaping would be at risk from effects of nicotine to which they would not otherwise be exposed. This also includes the risk of addiction.*”
 6. The lack of age of sale regulation and of restrictions on advertising should be addressed without delay, it does not need to wait for the COT to report. It is clearly inappropriate for these potentially highly addictive products to be available for sale and free distribution to children under 18, and for there to be no restrictions on advertising, promotion, and sponsorship.
 7. This is a serious public health issue, which could easily be addressed by revision of the [TRPR](#) and the [NIHPR](#). To that end, we urge the OPSS to refer regulation of these products to the DHSC. We

have copied our consultation response to the Chief Medical Officer, and to the officials responsible for tobacco control in the DHSC and within PHE.