

European Tobacco Harm Reduction Advocates (ETHRA) contribution to TRIS notification 2021/0434/LT - X00M

Introduction

Our contribution to TRIS notification 2021/0434/LT - X00M outlines why prohibiting all e-liquid flavours, apart from tobacco, will have a detrimental effect on public health in Lithuania.

European Tobacco Harm Reduction Advocates (ETHRA) is a group of 22 grassroots consumer associations in 16 European countries which support the public health approach of tobacco harm reduction, where people switch from high-risk products like cigarettes to low-risk products like e-cigarettes. We are mostly ex-smokers who have used safer nicotine products (vapes, snus, nicotine pouches, heated tobacco products) to quit smoking and remain smoke free. ETHRA represents approximately 27 million¹ consumers across Europe and is supported by experts in the field of tobacco control and nicotine research. ETHRA is a voluntary organisation with no industry conflicts of interest – see our Transparency Register entry: 354946837243-73.

The draft law aims to “*reduce the attractiveness and demand of electronic cigarettes and electronic cigarette fillers.*” If enacted, it will drastically restrict adult access to the products people use to quit smoking and remain smoke free, and cause harm by prolonging smoking.

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¹ Estimate of 27 million consumers provided by ECigIntelligence/TobaccoIntelligence. The actual figure is likely to be far higher because the data for smokeless tobacco is taken from research (Leon et al 2016) using data gathered in 2010 in only 17 countries

Switching from smoking to vaping provides substantial health gains

The harms from smoking are due to the inhalation of toxic products of combustion, not from nicotine use. So, the critical distinction from a public health perspective must be between combustible smoked products and non-combustible smokeless products. Significant public health gains can be made if smokers transition away from deadly combustible tobacco products to low-risk e-cigarettes.

The draft law disproportionately focuses on youth use of e-cigarettes, without due regard for the consequences for adult smokers. Special Eurobarometer 506 shows that smoking prevalence in Lithuania is 5% higher than the EU average, at 28%². This makes it clear that smokers in Lithuania need more help and options to quit smoking rather than fewer.

Some countries recognise the potential vaping products have to reduce death and disease from smoking. In the UK the Royal College of Physicians said in its 2016 report, *Nicotine Without Smoke*³: *“the available data suggest that they [e-cigarettes] are unlikely to exceed 5% of those [risks] associated with smoked tobacco products and may well be substantially lower than this figure”*.

Public Health England⁴ also concluded that vaping was at least 95% less harmful than smoking, and that smokers should be assured that switching to vaping is much less harmful than smoking. A study by Stephens WE⁵, suggested e-cigarette vapour has cancer potencies of just 0.4% of cigarette smoke. Public health endorsement of vaping has contributed to the UK experiencing the sharpest decline in smoking prevalence in the EU, falling 21pp since 2006². It should also be noted that vaping among never smoking youths in the UK is extremely low, Public Health England’s latest evidence update reports that *“between 0.8% and 1.3% of young people who had never smoked were current vapers”*⁶

The French Cancer Institute⁷ also recognises the huge harm reduction potential of vaping in their latest campaign, stating: *“Without tobacco, without smoke and without combustion, the*

² Comissão Europeia (2021) Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes.

³ Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*, April 2016

⁴ McNeill A, Brose LS, Calder R, Bauld L & Robson D (2018). Evidence review of ecigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England

⁵ Stephens, W. E. (2018) ‘Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke’, *Tobacco Control*, 27(1), pp. 10–17. doi: 10.1136/tobaccocontrol-2017-053808.

⁶ McNeill, A., Brose, L.S., Calder, R., Simonavicius, E. and Robson, D. (2021). Vaping in England: An evidence update including vaping for smoking cessation, February 2021: a report commissioned by Public Health England. London: Public Health England.

⁷ Institut National Du Cancer. (2021). Tabac et prévention des cancers. Available at: <https://www.e-cancer.fr/Acces-thematique/Tabac-et-prevention-des-cancers>

electronic cigarette represents an opportunity to reduce cancer mortality related to tobacco. It should be used with a view to quitting smoking for good.”

The latest call for a balanced approach towards the regulation of e-cigarettes comes from 15 past presidents of the Society for Research on Nicotine and Tobacco, the preeminent scientific professional society focused on nicotine and tobacco. This landmark paper⁸ states that the potential benefits of vaping for adult smokers are substantial. However, the past presidents regret that those benefits are not being fully realised in today’s environment of misinformation and a singular focus on the welfare of kids, to the detriment of the health of adults who smoke.

Vaping is an effective means of smoking cessation

Quitting smoking can be a long and arduous journey that can involve multiple relapses to smoking. Therefore, it is crucial that smokers have as many options available to them as possible. As a consumer product vaping can reach more smokers and is an effective and popular means of smoking cessation. Data from Belgium, France, Ireland and the UK⁹ attest to this efficacy.

Scientific reviews and studies provide solid evidence that vaping is an effective means of smoking cessation. An ongoing living review by the Cochrane Tobacco Addiction Group consistently finds that vaping is more effective than Nicotine Replacement Therapies (NRTs)¹⁰. Randomised Control Trials (RCT), considered the gold standard, also confirm that vaping is more effective than traditional smoking cessation methods like NRTs alone. Hajek et al¹¹ found vaping to be almost twice as effective as NRTs and Walker et al¹² found e-cigarettes combined with NRT’s to be 2.5 times more effective than patches alone.

A further RCT¹³ which aimed to assess the efficacy of e-cigarettes compared to NRTs for smokers who had previously been unable to quit, found that after six months 19% of the e-

⁸ Balfour, D. J. K. et al. (2019) ‘Balancing Consideration of the Risks and Benefits of E-Cigarettes’.

⁹ Interview on Tobacco Products Directive: notes by ETHRA, pps 8-9 Impact of e-cigarettes on smoking cessation. Available at: https://ethra.co/images/ETHRAS_notes_on_TPD_interview.pdf

¹⁰ Hartmann-Boyce J, McRobbie H, Butler AR, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2021, Issue 4. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub5.

¹¹ Hajek, P. et al. (2019) ‘A randomized trial of E-cigarettes versus nicotine-replacement therapy’, New England Journal of Medicine, 380(7), pp. 629–637. doi: 10.1056/NEJMoa1808779.

¹² Walker N, Parag V, Verbiest M, Laking G, Laugesen M, Bullen C. Nicotine patches used in combination with e-cigarettes (with and without nicotine) for smoking cessation: a pragmatic, randomised trial. Lancet Respir Med. 2020 Jan;8(1):54-64. doi: 10.1016/S2213-2600(19)30269-3

¹³ Myers Smith, K., Phillips-Waller, A., Pesola, F., McRobbie, H., Przulj, D., Orzol, M., and Hajek, P. (2021) E-cigarettes versus nicotine replacement treatment as harm reduction interventions for smokers who find quitting difficult: randomized controlled trial. Addiction, <https://doi.org/10.1111/add.15628>.

cigarette group had maintained smoking abstinence compared with only 3% of the NRT group.

Flavours are critical to the success of vaping

Attractive flavours are critical factors in the effectiveness of e-cigarettes for smoking cessation, this is also why NRTs come in a range of fruity and mint/menthol flavours. The TRIS notification detail even acknowledges that flavours in e-liquids are attractive to adults. A common misconception is that tobacco flavour is sufficient for adult smokers to transition away from smoking, when in reality it is common for vapers to migrate from tobacco flavour to fruits and sweet flavours¹⁴.

It shouldn't come as any surprise that adults enjoy things that taste good, this is certainly the case when it comes to smoking cessation aids. This was demonstrated by researchers in the Netherlands¹⁵ who concluded: *"Adults who have completely switched from smoking to e-cigarettes have often initiated e-cigarette use with fruity flavours rather than tobacco flavours, or switched from tobacco to non-tobacco e-liquid flavours over time."* The ability to disassociate from the flavour of tobacco, and enjoyment of the product being used, are important factors to avoid relapse to smoking.

A large-scale survey by Farsalinos et al¹⁶ examined the flavour preferences of adults who had completely switched from smoking to vaping and concluded that fruit and dessert/pastry/bakery flavours, were the most prevalent choices.

A study published in the Journal of the American Medical Association¹⁷ examined the association of flavoured e-cigarettes with subsequent smoking cessation and found that adults who vaped non-tobacco flavours were more likely to quit smoking than those who vaped tobacco flavours.

Given the important role flavours play in smoking cessation it is imperative that the unintended consequences of a flavour ban are considered. Such a ban would be disastrous for smoking cessation and public health as it would remove the products responsible for huge reductions in smoking prevalence from the market.

¹⁴ Russell C, McKegane N, Dickson T, Nides M. Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J.* 2018 Jun 28;15(1):33

¹⁵ Havermans, A. et al. (2019) 'Nearly 20 000 e-liquids and 250 unique flavour descriptions: an overview of the Dutch market based on information from manufacturers', *Tobacco Control*, p. tobaccocontrol-2019-055303. doi: 10.1136/tobaccocontrol-2019-055303.

¹⁶ Konstantinos Farsalinos, A. et al. (2018) 'Patterns of flavored e-cigarette use among adults' vapers in the United States: an internet survey. -N-6565 for "Regulation of Flavors in Tobacco'

¹⁷ Friedman, A. S. and Xu, S. Q. (2020) 'Associations of Flavored e-Cigarette Uptake with Subsequent Smoking Initiation and Cessation', *JAMA network open*, 3(6), p. e203826. doi:10.1001/jamanetworkopen.2020.3826.

Vape flavour bans encourage black markets

The added danger with limiting or banning flavours is that consumers are then forced to use the black market to obtain the product they need (or go back to smoking). This was the experience in Estonia where a flavour ban and high taxation led to an explosion of black-market products, reported to account for 62-80%¹⁸ of all sales. In response, Estonia recently amended its legislation to permit more flavours.

States in the USA that have banned flavours have also seen thriving black markets develop as ex-smokers seek out the only products that have successfully kept them smoke free. Black market sales of flavoured vaping products are reported to be a regular occurrence in car parks around Long Island New York¹⁹. Prohibition hasn't eliminated the product; it has simply driven it underground and criminalised those whose only crime is wanting to remain, or become, free from cigarette smoking.

ETHRA recently conducted a survey²⁰ of nicotine consumers in Europe, which attracted over 35,000 EU responses. We found that 94.6% of current vapers used a flavour other than tobacco. When asked about reactions towards the possibility of a flavour ban, 28% said they would be likely to restart smoking, and 71% would consider using the black market or other alternative sources.

Consumers turning to an unregulated black market, with no manufacturing standards, could pose significant health risks. Oil based flavourings, which are unsuitable for vaping, could easily be added to liquids by those unaware of the inherent danger of inhaling oil-based flavours.

Smoking increases where flavour bans are enacted

A recent study by Friedman A²¹ examined the effects of a flavour ban in San Francisco relative to other districts without a flavour ban. The study concluded that *“San Francisco’s flavor ban was associated with more than doubled odds of recent smoking among underage high school students relative to concurrent changes in other districts.”*

Youth vaping has not led to an increase in smoking

Although youth vaping in Lithuania is relatively high, this hasn't translated into an increase in smoking. The TRIS notification detail cites youth vaping figures from the European School Survey Project on Alcohol and Other Drugs (ESPAD), as part of the rationale for the

¹⁸ Baltic Times, Estonian FinMin looking into prospect of lowering excise duty for e-cigarettes 25 Nov 2019

¹⁹ Filter, Vape Bans Are Creating a Thriving Illicit Market 8 July 2020

²⁰ European Tobacco Harm Reduction Advocates. EU Nicotine Users Survey report. June 2021. Available at: <https://ethra.co/news/80-ethra-eu-nicotine-users-survey-report>

²¹ Friedman AS. A Difference-in-Differences Analysis of Youth Smoking and a Ban on Sales of Flavored Tobacco Products in San Francisco, California. *JAMA Pediatr.* 2021;175(8):863–865. doi:10.1001/jamapediatrics.2021.0922

proposal to prohibit e-liquid flavours. However, the same ESPAD²² survey shows that youth smoking rates are low. Past 30-day smoking, 1-5 cigarettes per day, is only 4.2%, this falls further to 2.2% for those smoking 6-10 cigarettes. It could be argued that youth use of vapour products has diverted them away from the most harmful method of nicotine consumption, which is smoking.

Conclusions

We are dismayed that the Government of the Republic of Lithuania wishes to limit the appeal of e-cigarettes when adult smoking prevalence remains stubbornly high at 28%. This 28% represents approximately 784,000 Lithuanian smokers who could greatly benefit from switching to a less harmful alternative to smoking. Vaping is proven to help smokers quit, and flavours are an essential part of this.

Removing flavours will keep more people smoking by making vaping less attractive. The Royal College of Physicians (London) explained this in 2016²³: *“if [a risk-averse and precautionary] approach also makes e-cigarettes less easily accessible, less palatable, or acceptable, more expensive, less consumer-friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult.”*

We suggest that robust age of sale legislation is a much better way of tackling the issue of youth use. The current proposal to restrict flavoured e-liquid will have an extremely negative effect on adult smokers by removing the products that have helped millions of EU citizens quit smoking for good.

²² Molinaro, S. et al. (2019) ESPAD Report. Additional Tables. Table 3a. Available at: http://www.espad.org/sites/espad.org/files/20203880_TD0320532ENN_PDF.pdf

²³ Royal College of Physicians (London), Nicotine without smoke: tobacco harm reduction, April 2016. Section 12.10 page 187