European Tobacco Harm Reduction Advocates Interview on Tobacco Products Directive: note by ETHRA

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Who we are

European Tobacco Harm Reduction Advocates (ETHRA) is a group of 21 consumer associations in 16 European countries, representing approximately 27 million consumers[1] across Europe and supported by scientific experts in the field of tobacco control or nicotine research. We are mostly ex-smokers who have used safer nicotine products, such as vapes and snus, to quit smoking and to remain smoke free. ETHRA is not funded by the tobacco or vaping industry, in fact we are not funded at all as our grouping is a voice for our partners who arrange their own revenue and who give their time to ETHRA for free. Our mission is to give consumers of safer nicotine products a voice and to ensure that the full harm reduction potential of safer nicotine products is not hindered by inappropriate regulation. Damian Sweeney, who represented ETHRA in the phone interview, is the chair of the New Nicotine Alliance Ireland. ETHRA is listed in the EU Transparency Register at: 354946837243-73.

Key areas where the TPD fails to ensure a high level of health protection

Failure to consider the effect of TPD e-cigarette measures on *smoking*

It is impossible to evaluate European Union policy on vaping and other low-risk products without reference to the effect these policies have on smoking, the far riskier behaviour. Regulations for safer products should be based on risk in relation to combustible cigarettes, not according to whether products contain nicotine or tobacco.

Inappropriate regulations that make safer nicotine products (SNPs) less desirable to adults, more inconvenient or expensive to use, and increase misperceptions of harm can themselves cause harm by deterring smokers from switching – and so prolonging smoking. We have seen little sign that the Commission and the most vocal public health activists and academics have understood the likely unintended consequences of excessively restrictive policies on vaping or other low risk products and how these can cause extra harm by deterring switching and prolonging smoking.

In our experience there are several key areas where the TPD is prolonging smoking through inappropriate regulation of safer alternatives to smoking and is therefore failing to ensure a high level of health protection for EU citizens. We would like to highlight the following:

20mg/ml limit on nicotine concentration in e liquids

Article 20(3)(b) of the TPD requires that the nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml (about 2% nicotine). This limit is far too low and has no scientific basis. There are very successful and effective products on the market outside the European Union with nicotine strengths approaching 60mg/ml. The EU's nicotine limit is a

[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.

contentious issue: when TPD2 was drafted the scientists whose research had been cited wrote to the Commission to complain that their findings had been misrepresented[2].

The 20mg/ml limit is too low to satisfy many dependent smokers. These smokers are the people who vaping could help, yet they are being deprived of the level of nicotine that many of us consumers found to be critical in initially moving us away from smoking. Restricting nicotine limits to 20mg/ml takes away the 'hook' for many smokers in deciding to switch. Nicotine obtained via vaping has a different delivery profile to that obtained by smoking so it can take some getting used to and using e-liquids with a reasonable nicotine concentration can help with that.

In our own extensive experience, the inadequate nicotine concentration limit is forcing consumers to buy e-liquids from outside the EU, from countries which do not have the same quality standards as the EU. As with the mandatory warning labels, discussed below, the 20mg/ml nicotine limit sends a false message to consumers that there is an inherent danger to using nicotine, when in fact the risk profile for vaping nicotine in e-liquids is similar to that of drinking coffee.[3]

In relation to the 20mg/ml limit, the key recital to the TPD (38) shows the legislators had a sound policy intention for a single market directive:

> *This concentration allows for a delivery of nicotine that is comparable to the permitted dose of nicotine derived from a standard cigarette during the time needed to smoke such a cigarette.*

Allowing comparable nicotine delivery to cigarettes is a reasonable and fair basis for a single market directive like the TPD and clearly the intention of the legislators. However, the 20mg/ml limit does not achieve this because it is measuring the wrong quantity and places limits on the design of more compact devices that are more likely to suit novice vapers. The Directive is based on a misunderstanding – *stronger e-liquids do not mean higher nicotine exposure*. Users control their exposure to nicotine by modifying how deeply and how often they puff on the device – a well understood process known as 'self-titration'.[4] But if the nicotine concentration is too low it becomes harder for users to achieve a satisfactory nicotine dose[5] without taking in a larger quantity of liquid, which requires a more powerful

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[2] At least three communications were made by scientists to the Commission to point out the flawed reasoning underpinning the 20mg/ml limit.

(1) Farsalinos K. The European Commission has misinterpreted my scientific research on nicotine in e-cigarettes, 10 Jan 2014 [access]

(2) Etter, JF and 14 others, Scientific Errors in the Tobacco Products Directive, A letter sent by scientists to the European Union. 17 January 2014. [access]

(3) Dawkins L. Please Do Not Distort My Words To Justify Your Policy, 13 January 2014. [access]

[3] Britton J. E-cigarettes and the precautionary principle, BMJ Opinion, 20 Sept 2019 [access]

[4] Dawkins LE, Kimber CF, Doig M, Feyerabend C, Corcoran O. Self-titration by experienced e-cigarette users: blood nicotine delivery and subjective effects. Psychopharmacology (Berl). 2016 Aug 1;233(15–16):2933–41. [access]

[5] Dawkins LE, Cox S, Goniewicz M, McRobbie H, Kimber C, Doig M, et al. 'Real-world' compensatory behaviour with low nicotine concentration e-liquid: subjective effects and nicotine, acrolein and formaldehyde exposure. Addiction. 2018 Oct 1;113(10):1874–82. [access]

battery, larger devices and potentially a greater exposure to toxicants.[6] There are three main consequences of the limit, and none are positive.

First, the 20mg/ml limit works against more compact devices that use low volumes of liquid at higher strength to deliver the same amount of nicotine as larger devices using higher power and larger volumes of weaker liquids. It makes it impossible to make more compact and convenient devices with sufficient nicotine delivery to appeal to many of those making the first steps away from smoking.

Second, it will mean some users are forced to consume greater quantities of weaker liquids with potentially greater toxicant exposure. While these elevated risks remain very low compared to smoking, there is no justification to *increase* them using EU regulation.

Third, it provides an unjustified regulatory advantage to cigarettes, the more harmful product. The nicotine delivery of cigarette *to the user* is not significantly limited by the nicotine yield limits imposed by Article 3 of the Directive, as most smokers can compensate and self-titrate to achieve the nicotine dose they want. This effect has been well understood for several decades.[7] [8] The 20mg/ml limit is, however, a significant constraint for the e-cigarette category.

This is an internal market failure that has the effect of protecting cigarettes from competition from easy-to-use e-cigarettes that would provide comparable nicotine delivery if this limit was not in place. For this reason, it does not achieve the internal market goal of a level-playing field for competition and innovation and is strongly biased in favour of the more harmful products, cigarettes. It does the opposite of providing a high level of health protection. In our view this limit should be removed or replaced with a limit that is much higher, for example, allowing liquids up to seven percent nicotine strength.

Mandatory health warnings on vaping products

The excessive mandatory health warnings overstate the risks of vaping and are deterring smokers from trying vaping. The prominence (size, placement, colour and typeface) and the alarming wording suggest far greater risk than there is. The warnings are similar in style to those used on cigarettes, yet the risk, if any, is a small fraction of the risk of smoking. This tilts perceptions in favour of the more dangerous products. The warnings about nicotine have the effect of reinforcing the widespread misunderstanding that it is nicotine, not smoke, that is the most significant cause of harm. E-cigarettes only represent a fraction of the risk of combustible tobacco products and the warning labels should reflect this difference in risk.

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[6] Kosmider L, Cox S, Zaciera M, Kurek J, Goniewicz ML, McRobbie H, et al. Daily exposure to formaldehyde and acetaldehyde and potential health risk associated with use of high and low nicotine e-liquid concentrations. Sci Rep. 2020 Dec 1;10(1). [access]

[7] Benowttz NL, Hall SM, Herning RI, Jacob P, Jones RT, Osman AL. Smokers of Low-Yield Cigarettes Do Not Consume Less Nicotine. *N Engl J Med*. 1983 Jul 21;309(3):139–42. [access]

[8] Russell MAH, Jarvis M, Iyer R, Feyerabend C. Relation of nicotine yield of cigarettes to blood nicotine concentrations in smokers. Br Med J. 1980 Apr 5;280(6219):972–6. [access]

A note on the risk profile of vaping in relation to combustible cigarettes: The Royal College of Physicians stated in its 2016 report Nicotine Without Smoke[9] that:

> *"the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure". (Section 5.5 page 87).*

Public Health England's 2018 evidence review[10] found that

> *"vaping is a fraction of the risk of smoking, at least 95% less harmful, and of negligible risk to bystanders. Yet over half of smokers either falsely believe that vaping is as harmful as smoking or just don't know".*

The warning labels do not reflect this huge difference in risk and scare people away from vaping. This is a missed opportunity: instead of labels which deter smokers from trying the far safer alternative, labelling could be used instead to encourage smokers to switch and to inform about relative risk. In a recent study into consumers' reaction to the TPD[11], lead researcher Dr Emma Ward, suggested that "*harm reduction messages on packaging, comparing e-cigarettes to tobacco could also nudge smokers to switch to less harmful vaping*".

In a survey for Action on Smoking and Health (UK)[12], smokers were asked to give reasons why they would not switch to e-cigarettes. The most common response was "*I do not want to substitute one addiction for another*", a damaging and distracting risk perception nurtured and reinforced by the EU warnings.

Lastly, the warning labels nonsensically require a nicotine warning on products intended for vaping, whether or not they contain nicotine. This leads smokers to falsely believe that nicotine must be very hazardous, as warnings even appear on hardware such as batteries.[13]

The ban on advertising e-cigarettes and other low risk products

Article 20(5) prohibits advertising of vaping products in most forms not in a fixed location. This is a form of regulatory protection to the market incumbent, the cigarettes. Advertising is essential for entrants and innovators to gain a hold on a market dominated by a more harmful rival. We are concerned that bans on advertising mean fewer smokers will be aware

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[9] Royal College of Physicians (London), Nicotine without smoke: tobacco harm reduction, April 2016 [access]

[10] Public Health England, Evidence review of e-cigarettes and heated tobacco products 2018 A report commissioned by Public Health England, February 2018 [access]

[11] Ward E, Anholt C, Gentry S, Dawkins L, Holland R, Notley C. A qualitative exploration of vapers' perceived impacts, behavioural reactions, and future reflections of the EU Tobacco Products Directive (2017) as applied to electronic cigarettes. Vol. 13, *Tobacco Use Insights*.; 19 June 2020 [access] [press notice]

[12] Action on Smoking and Health / YouGov. Use of e-cigarette (vaporisers) among adults in Great Britain in 2019. [access]

[13] Article 2 of the TPD defines 'electronic cigarettes' to include "any component of that product". Article 20(4)(b) specifies warnings that must be applied to electronic cigarettes [access]

of the products and attracted to trying to switch to the lower risk products. There is emerging evidence that bans on e-cigarette advertising cause increases in smoking.[14] [15]

We believe that e-cigarette manufacturers and vendors should be subject to controls on content and placement of advertising, sponsorship and promotion, but not an outright ban.

10 ml refill bottle limit and 2ml tank size limit

This regulation again favours cigarette smoking by making life more inconvenient for e-cigarette users for no purpose whatsoever. This regulation also makes vaping more expensive for consumers and the little bottles are difficult to open for those with dexterity issues. In no other consumer product is control of poison risk done by limiting container size. The conventional approach is to have child resistant packaging, warnings and instructions on what to do if exposed. With child proof caps now the industry standard, even the flawed justification for the 10ml limit has gone. The 2ml tank limit means that consumers have to refill more frequently, contributing to making vaping fiddly, and deterring older smokers and others with dexterity issues from switching. The restriction on refill bottle capacity to 10ml increases plastic waste, going against EU environmental commitments on single use plastics.

Flavours

Given the purpose of the TPD is to harmonise regulation with a high level of health protection, it allows member states too much room for manoeuvre with regards to regulation of safer products. Several member states have already implemented flavour bans for e-liquids and there are more in the pipeline. These flavour bans destroy the appeal of vaping products to smokers, so favour the combustible cigarette trade and thereby prolong smoking and undermine both the internal market and health objectives of the TPD.

Having a wide variety of flavours is intrinsic to the success of vaping products: the ability to tailor the product to each individual's tastes plays a very important role in the effectiveness of vaping. The evidence in this area is very clear and shows that whilst many vapers start with a tobacco flavour, over time they gravitate towards fruit, dessert and sweet flavours.[16]

A survey into the flavour preferences of 69,000 adult vapers who had quit smoking found that over 95% of those surveyed most commonly used flavours other than tobacco or menthol.[17] Public Health England's 2020 Evidence Update also found that fruit flavours are

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[14] Dave D, Dench D, Grossman M, Kenkel DS, Saffer H. Does e-cigarette advertising encourage adult smokers to quit? *J Health Econ*. 2019 Feb;68:102227. [link]

[15] Tuchman AE. Advertising and demand for addictive goods: The effects of e-cigarette advertising. Mark Sci. 2019;38(6):994–1022. [access]

[16] Russell C, McKeganey 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 [access]

[17] Farsalinos K., Patterns of flavored e-cigarette use among adults vapers in the United States: an internet survey, August 2018 (figure 7 & 8) [access][summary]

the most popular flavours for adult vapers[18]. A recent study published in JAMA[19] concluded that:

> "*adults who began vaping non-tobacco flavored e-cigarettes were more likely to quit smoking than those who vaped tobacco flavors*."
>
> *Relative to vaping tobacco flavors, vaping nontobacco-flavored e-cigarettes was not associated with increased youth smoking initiation but was associated with an increase in the odds of adult smoking cessation.*

Banning or restricting flavours will have a disastrous effect on smoking cessation, effectively removing the products responsible for huge reductions in smoking prevalence from the market. 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. 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% of all sales[20].

Snus

The TPD prohibits the sale of snus throughout the EU, except in Sweden, which obtained an exemption when joining. Lifting the snus ban represents a huge opportunity to reduce the burden on health from smoking. Snus is a pasteurised smokeless tobacco product that has been used in Scandinavia for centuries. Snus has replaced smoking at such an extraordinary rate in Sweden, Norway and Iceland that these countries are now close to the point of being smokefree (smoking prevalence of 5% or lower).

It's been known for decades that people smoke for the nicotine but die from the tar, it is the release of toxic and carcinogenic gases from the combustion of tobacco that causes harm.

Swedish snus is far less risky to health than smoking. The Global Burden of Disease Study summarises the health risks of snus as follows:[21]

> *Based on available evidence, for chewing tobacco Risk Ratios were significantly higher than one for oral cancer and oesophageal cancer, while for snus or snuff we did not find sufficient evidence of a Risk Ratio greater than one for any health outcome.*"

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[18] Public Health England. Vaping in England: an evidence update including mental health and pregnancy, March 2020 [access]

[19] Friedman AS, Xu SQ. Associations of Flavored e-Cigarette Uptake With Subsequent Smoking Initiation and Cessation. JAMA Netw open. 2020 Jun 1;3(6):e203826. [access]

[20] Baltic Times, Estonian FinMin looking into prospect of lowering excise duty for e-cigarettes 25 Nov 2019 [access]

[21] Gakidou E, Afshin A, Abajobir AA, Abate KH, Abbafati C, Abbas KM, et al. A systematic analysis for the Global Burden of Disease Study 2016. Lancet. 2017 Sep 16;390(10100):1345–422. [access]

There is clear evidence that snus not only lowers the smoking prevalence[22], but that this translates to a lower burden of disease.[23]

This has been recognized in the USA where the FDA granted Swedish Snus the first ever modified risk order in 2019. The FDA stated that[24]

> *"the modified risk products, as actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole."*

By ignoring the scientific evidence on smokeless tobacco, and upholding the ban on snus, the EU is falling behind other countries in not taking advantage of the health benefits which Swedish snus could bring to smokers. In June 2017, eighteen international tobacco control experts wrote to the European Commission highlighting the multiple absurdities in the EU snus ban and setting out the public health and policy case to lift the ban.[25]

The evidence on snus should be reassessed and the ban overturned.

Impact of e-cigarettes on smoking cessation

We were asked during the interview for evidence that e-cigarettes have contributed to declines in smoking prevalence. The most directly applicable study draws on the EU's Eurobarometer survey.[26] [27]

> *An estimated 6.1 and 9.2 million EU citizens had quit and reduced smoking with the use of ecigarettes respectively.*

This relates to 2014 survey data, so we would expect far more by now. However, this cannot tell us whether the TPD has increased or decreased smoking cessation compared to not having the TPD. Our view is that the TPD will have depressed this figure compared to the regulatory environment in place in 2014 (i.e. before the TPD came into effect).

Here we give some information from a number of countries:

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[22] Ramström L, Borland R, Wikmans T. Patterns of Smoking and Snus Use in Sweden: Implications for Public Health. Int J Environ Res Public Health. Multidisciplinary Digital Publishing Institute (MDPI); 2016 Nov 9;13(11). [access]

[23] Ramström L, Wikmans T. Mortality attributable to tobacco among men in Sweden and other European countries: an analysis of data in a WHO report. *Tob Induc Dis*. 2014 Jan;12(1):14. [access]

[24] Food and Drug Administration (United States). FDA grants first-ever modified risk orders to eight smokeless tobacco products, 22 October 2019 [access]

[25] Letter to Commissioner Timmermans from 18 experts in tobacco science and policy regarding the European Union snus prohibition, June 2017 [access]

[26] Farsalinos KE, Poulas K, Voudris V, Le Houezec J. Electronic cigarette use in the European Union: analysis of a representative sample of 27 460 Europeans from 28 countries. *Addiction*. 2016 Jun 24; [access]

[27] Farsalinos KE, Poulas K, Voudris V, Le Houezec J. E-cigarette use in the European Union: millions of smokers claim e-cigarettes helped them quit. *Addiction*. 2017 Mar;112(3):545–6. [access]

Ireland: The Healthy Ireland Survey commissioned by HSE (public health) shows that the smoking rate in 2015 and 2016 was 23%. This is about the time that vaping products were becoming popular. From 2017 until last year smoking rates plummeted to 17%. The survey shows that over those years 39% of successful quit attempts were made by people using e-cigarettes. Vaping prevalence in Ireland was 3% in 2015 and rose to 5% last year.[28]

France: In the French Baromètre de santé public France[29] vapers aged 18 to 75 have almost all used tobacco, as current or former smokers. Between 2014 and 2017, the proportion of daily smokers decreased among vapers (from 64.5% to 39.7%), while that of ex-smokers increased (from 23.5% to 49.5%). The number of daily ex-smokers who have quit smoking for more than six months and who think that vaping helped them quit is estimated at around 700,000 since the availability of e-cigarettes on the French market.

UK: Public Health England's 2020 review[30] found that smoking among adults in England has continued to decline over the past ten years and in 2019 was around 15%. The same review found that "Vaping remains most common among smokers and former smokers, with less than 1% of people who have never smoked currently vaping", and that "data from stop smoking services in England suggests that when a vaping product is used in a quit attempt, either alone or with licensed medication, success rates are comparable to, if not higher than, licensed medication alone."

ASH's Use of e-cigarettes (vaporisers) among adults in Great Britain: [31]

> *"However, the Smoking Toolkit Study (an ongoing series of monthly surveys of the adult population of England) has shown a clear association between changes in population rates of quitting smoking and prevalence of e-cigarette use after adjusting statistically for a range of potential confounding factors. If the association is causal, e-cigarettes were responsible for an estimated 69,930 additional ex-smokers in England in 2017. Furthermore, recent evidence from a randomised controlled trial showed that vaping was nearly twice as effective as NRT in helping smokers quit in a Stop Smoking Service setting in England."*

Initiation of consumption by young people

Article 28 states that initiation of consumption by young people is to be examined in the report, so we provide some information about that here.

Belgium: The 2018 Health Survey[32] on the use of electronic cigarettes concludes that the majority of experimenting with electronic cigarettes by youth (15 to 24 years old) does not

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[28] Healthy Ireland Summary Report 2019. Section 3: Smoking. November 2019.[access]

[29] Baromètre de Santé publique France 2017. Usage de la cigarette électronique, tabagisme et opinions des 18-75 ans [access]

[30] Public Health England. Vaping in England: an evidence update including mental health and pregnancy, March 2020 [access][summary]

[31] Action on Smoking and Health / YouGov. Use of e-cigarette (vaporisers) among adults in Great Britain in 2019. [access]

[32] Sciencsano (Belgium), 2018 Health Interview Survey on the use of electronic cigarettes [access][PDF]

seem to lead to regular use and that daily use is relatively low (0,6%). In the overall population 90% of vapers used to smoke cigarettes.

France: The OFDT monitoring of high school students[33] shows that daily smoking dropped from 23.2% in 2015 to 17.5% in 2018, while almost daily vaping reached 2.8% in 2018. Using this data a study examined specifically if vaping among adolescents is associated with subsequent smoking initiation: "Among ever-smokers, adolescents who declared having ever used e-cigarettes were less likely than those who did not to transition to daily smoking at 17. We found similar results for those who experimented with e-cigarettes before initiating smoking", concluded the researchers.

UK: Data from the 2019 ASH YouGov Smokefree youth GB survey[34] suggest that while some young people, particularly those who have tried smoking, experiment with e-cigarettes, regular use remains low. Regular use of e-cigarettes remains largely confined to current or ex-smokers. Not a single never smoker reported vaping daily and only 0.1% vaped more than once a week.

Ireland: Youth smoking in Ireland has fallen to 5.9%.[35] There is no official data for youth vaping rates in Ireland but the Healthy Ireland survey participants are from 15 years up. Healthy Ireland 2019 data finds that never smokers that vape is 1% and has been consistently <1% since the survey started in 2015.

The safer products remain less available than the dangerous ones

It is a failure of TPD2 that combustible cigarettes remain so easy to buy yet safer nicotine products do not. The new COVID-19 restrictions have made this very evident, consumers in Austria and Belgium could not buy vaping products when shops closed, because those countries have a ban on online sales. A new survey from Belgium[36] examines the effects of this, one effect was that previously ex-smokers had to return to smoking.

Throughout Europe the COVID-19 restrictions affected access to safer products but we are not aware that there were any difficulties with obtaining combustible products.

More generally, in Estonia, Finland and other member states with strict measures, some products are now illegal in those countries but remain available in other EU countries. As a result of such differences in the level of regulation there are now sizeable black markets in some member states.

Specific products not covered by the TPD

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[33] *Sandra Chyderiotis et al.,Does e-cigarette experimentation increase the transition to daily smoking among young ever-smokers in France?, Drug and Alcohol Dependence (vol. 208), 2020. https://doi.org/10.1016/j.drugalcdep.2020.107853

[34] Action on Smoking and Health (UK) Use of e-cigarettes among young people in Great Britain, 2019 [access]

[35] Health Service Executive (Ireland) Youth Smoking in Ireland: A special analysis of the Health Behaviour in School-aged Children (HBSC) study, 2018 [access]

[36] Adriaens K, Van Gucht D, Van Lommel S, Baeyens F. Vaping during the COVID-19 lockdown period in Belgium. Qeios. 2020 Jul 2; [access]

In the interview you asked us to elaborate on specific products not covered by the TPD. We would like to draw your attention to non-tobacco nicotine pouches and non-nicotine containing e-liquids.

Non-tobacco nicotine pouches

Having these low risk products appropriately regulated and widely available to smokers would be of great benefit to public health, by giving smokers another harm reduction option to switch away from deadly combustible tobacco. These products are generally very safe. However, some nicotine pouches manufactured and sold in Russia with extremely high nicotine levels were also introduced on the EU market, which is putting consumers at risk. Regulating to limit the nicotine concentration would be appropriate and the limits should be set to benefit consumers, allowing them to benefit from the nicotine but without the potentially harmful effects.

Non nicotine containing e-liquids – "short fills"

The 10ml limit led to the creation of short fills to both allow consumers to purchase larger volumes that they had previously been used to – which did not create the waste that 10ml bottle sizes do and were more cost effective for consumers - and also to minimise notification costs to industry. If costs of notification were kept to an affordable level and the bottle size limit abandoned, short fills would not be necessary in the market and would disappear.

Is the TPD future proof?

New products are being developed all the time, in response to the high consumer demand for safer alternatives to smoking. When TPD2 was drawn up, less than 10 years ago, the only safer nicotine consumer products in common use at that time were snus and e-cigarettes. Non-tobacco containing nicotine pouches have become popular since then but the TPD has not been sufficiently flexible to accommodate them. So, as the TPD has not adapted to recent developments it seems highly unlikely that in its current form it will adapt to future ones.

The TPD definitions for e-cigarettes need updating and some are no longer relevant. We strongly recommend that expert consumers are invited to give input into reworking those.

The definition for tobacco for oral use is convoluted and absurd. This, together with the ban itself, has led to legal challenges. It is morally indefensible for EU citizens' money to be used in defending the ban on the sale of snus, a product which could have a huge benefit to public health if the ban was lifted.

Should different categories of products be regulated differently?

Yes, safer products should be regulated differently to combustible tobacco products. If safer nicotine products have to coexist with combustible products within the same directive there should be two categories: one for products which are combustible, and therefore likely to cause significant harm to the user, and one for all non-combustible products, which are far less harmful to the user. The difference in risk between combustible and non-combustible

products is significant. However, the difference in risk between the various non-combustible products is negligible in relation to that of smoking, and so for the purposes of the TPD only one distinction should be made.

Conclusion

It is vital that consumers are recognised as essential stakeholders in discussions of policy. We are the people with greatest knowledge about these products and the group most affected by the regulations. We reaffirm here our belief that all consumers should have been given the opportunity to take part in the review process.

We regret that the focus for the TPD evaluation is largely on compliance and there is no examination of whether the regulations themselves are maximising the potential benefit to public health. Do the health warnings, advertising restrictions and nicotine limit deter smokers from switching to safer products? A failure to regulate safer products well is a win for the combustible cigarette trade - is the TPD prolonging smoking by not regulating safer products appropriately? Neither the questionnaire sent out to member states nor the stakeholder questionnaire addressed the issue of unintended consequences and we feel that is a missed opportunity.

We are acutely aware that there are many current smokers who have not yet found a way out of combustible tobacco, who could benefit greatly if appropriate regulation was applied. Perceptions of risk are going in the wrong direction, with many smokers falsely believing that e-cigarettes are as harmful to health as combustible tobacco products. Unfortunately, some of the TPD regulations are contributing to these misperceptions and keeping people smoking. In order to fulfil its purpose of ensuring a high level of health protection for EU citizens the TPD must regulate safer nicotine products appropriately.