Regulation of e-cigarette flavours
Submission by Clive Bates
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I am a former Director of Action on Smoking and Health (UK), a former civil servant and now a consultant in sustainability and public health. I have no relevant conflicts of interest concerning the tobacco, e-cigarette, or nicotine industries. I support the concept of tobacco harm reduction as a policy and practice to reduce the severe harms associated with smoking and the harmful impacts induced by policies to control smoking (such as economic burdens, stigma, and social isolation). Vaping products can play an essential and growing role, providing smokers find them appealing. The current proposal will reduce the appeal and protect the cigarette trade.

The proposed "whitelist" approach to ingredients will amount to an almost complete ban on commercially viable vaping products. It will assist the continued dominance of the cigarette.

The impact on public health depends on how current users and future potential users will respond to the measure. The government cannot just assume they will become abstinent. Simply removing one appealing aspect of one product category does not address the deeper drivers of nicotine, tobacco or substance use. So, the likely responses will be to switch to other forms of nicotine use, including smoking, or other forms of substance use. Alternatively, users may try to secure the same vaping experience by other means. They can do this by using food or aromatherapy flavours, buying illicitly manufactured flavoured products, importing flavoured products from outside the Netherlands, or creating homemade flavours for personal use or selling to family and friends. Each of these options is worse than the status quo. There is no credible assessment of how these pathways will play out. If there were, it would show that even minor increases in smoking would destroy any conceivable health justification for this intervention.

The proposal is unworkable and should not proceed. As an annexe, I have provided a more detailed analysis submitted to an earlier consultation by twenty-four experts in nicotine science and policy. Nothing has changed to invalidate this analysis, and its findings remain relevant to the consideration of this measure.

Yours sincerely

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Annexe

Regulation of e-cigarette flavours – a response

Submission from twenty-four tobacco and nicotine experts

January 2021

Regulation of e-cigarette flavours – a response

This document responds to the proposed Decree of the State Secretary for Health, Welfare and Sport on the regulation of e-cigarette flavours in the Netherlands.[1] We provide a summary followed by a detailed discussion of each of the twelve sections in the summary.

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[1] Government of the Netherlands, Consultation: regulation of e-cigarette flavours (translation), 19 December 2020. [link]

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We confirm that signatories report no conflicts with respect to FCTC Article 5.3 and no financial conflicts of interest with respect to tobacco or e-cigarette companies under the International Committee of Medical Journal Editors (ICJME) reporting standard. We regret that we do not have the resources to provide a submission in Dutch. We hope our views are of value as the government makes its decisions on this important and sensitive area of public health.

Part I: Summary

The case for the ban on vaping flavours described in the memorandum supporting the measure is wholly inadequate, and the measure should not proceed on this basis. The critical weaknesses in the rationale described in the memorandum are as follows:

1. **Sets conflicting objectives and takes a "war on drugs" approach to nicotine.** The proposed measure is supposed to support a "smoke-free Netherlands" objective for 2040 as part of the Prevention Agreement. As stated, this is a sensible goal and should be widely supported – it recognises that *smoke*, not nicotine, is the overwhelming cause of disease. It is practical and achievable if smoke-free alternatives to smoking, such as vaping products, are available. However, the proposal introduces a significant expansion of scope by extending "smoke-free" to mean all tobacco, even if not smoked and then to tobacco-free nicotine products like e-cigarettes. It will make it impossible to use harm-reduction approaches, despite the enormous potential to reduce disease and death. It misunderstands the nature of youth risk behaviours. It amounts to extending the war on drugs to nicotine, but at a time when failures of prohibition are widely recognised. It would be better to stick to a smoke-free goal and use smoke-free alternatives to achieve it rather than pursue nicotine prohibition. The Netherlands is rightly world-famous for its pragmatic approach to soft drugs — that pragmatism should be leveraged to accelerate the end of smoking in the Netherlands by embracing harm reduction for those who smoke.
   [Go to detailed discussion]

2. **Adopts false and misleading claims about the risks of e-cigarettes.** The justification fails to adequately characterise the overwhelming evidence showing e-cigarette use is much less harmful than smoking. Suppose policymakers believe e-cigarettes are just as harmful as cigarettes. In that case, their policies will be detrimental to public health by hindering substitution as smokers move from high-risk to low-risk products. It is clear from toxicology and exposure studies that e-cigarettes are, beyond any reasonable doubt, far less harmful than cigarettes. It is simplistic to apply the precautionary principle to use long-term uncertainties to justify excessive regulation. This ignores the substantial body of science suggesting much lower risk and neglects the problem that excessive regulation can cause harm by protecting the cigarette trade, which is known to be highly harmful.
   [Go to detailed discussion]

3. **Draws on irrelevant information about an outbreak of lung injuries in North America.** Without a credible case for harm arising from e-cigarette use, the justification includes distracting and irrelevant references to "EVALI", an outbreak of severe lung injuries in the United States in 2019. EVALI was caused by the addition of a cutting agent, Vitamin E Acetate, to illicit *cannabinoid* (THC) vape pens. This substance cannot be added to nicotine liquids and would serve no purpose if it could. There is no other credible evidence of material risks of severe lung injury.
   [Go to detailed discussion]

4. **Misunderstands "dual-use".** Concurrent use of e-cigarettes and cigarettes ("dual-use") should be understood as progress towards reducing smoking or smoking abstinence in most cases. Unless a smoking cessation method is 100% and immediately effective, it will mean some continued smoking on the pathway to smokefree status *whatever method is used*. It is true that some 'dual users' do not see significant reductions in toxicant exposure, but that is likely caused by higher dependence for which dual use is a marker. It is likely that public hostility to e-cigarettes, including from the government, agencies and academics, contributes to users not appreciating the benefits of switching completely. A cause of dual-use-related harm could, in part, be negative statements of tobacco control activists, academics and politicians.
   [Go to detailed discussion]

5. **Asserts a "gateway effect" but there is more likely to be a diversion away from smoking.** The memorandum claims there is a gateway effect from vaping to smoking. At an individual level, some adolescents will be likely to take up e-cigarette use, but there is also growing evidence that other adolescents who would otherwise have smoked are diverted away from starting to smoke. This diversionary effect is consistent with observed declines in youth smoking prevalence despite the recent increases in e-cigarette use as the technology has emerged. The strong correlations between smoking and vaping commonly reported in the literature are likely partly caused by 'common liabilities'. These are characteristics such as genetics, mental health status, home environment, community, school etc. that incline a young person both to smoking and to vaping. *The vaping cannot be assumed to cause the smoking.* Regulating based on assumptions of a gateway effect where none exists is not responsible or 'precautionary'. Over-regulation of e-cigarettes, the far safer product, could prevent e-cigarettes functioning as a diversion from smoking for young people.
   [Go to detailed discussion]

6. **Takes a simplistic approach to youth risk behaviours and fails to demonstrate benefits to adolescent public health.** The rationale offered is grounded in a naïve account of youth risk behaviours, which do not stop simply because adults in authority disapprove of them or pass laws to prevent them. There is a long and complicated chain of causation from a ban on e-cigarette flavours to improved health, with many possible diversions into perverse and harmful consequences. Legislating to ban something does not make it go away or necessarily cause its existing users to become abstinent – it provokes a variety of responses on the part of consumers. Illicit drugs are subject to prohibitions and strong sanctions yet are still widely used and supplied by criminal enterprise. The proposal lacks justification of the measure as a successful youth-orientated public health intervention. Without realistic insights into youth risk behaviours, the government is likely to regulate in a way that *increases* harm to young people – for example, by tacitly encouraging young people to revert to smoking.
   [Go to detailed discussion]

7. **Ignores perverse consequences of prohibition, even though these are foreseeable.** The case provides little analysis of a range of harmful perverse consequences that could arise from a

prohibition of vaping flavours. These are foreseeable, yet not foreseen in the justification as presented. They include but are not limited to:

- Fewer smokers switching to vaping
- More vapers relapsing to smoking
- Teenagers smoking instead of vaping
- More teenagers switching to vaping cannabinoids such as THC
- Cross-border sales of flavoured e-liquids
- More home mixing of flavoured liquids (with additional risks)
- Black market trade in flavoured liquids and flavoured e-cigarettes
- Workarounds like selling flavours separately or use of food flavours
- Loss of legitimate retail and online businesses replaced by criminal networks or exporters from outside the Netherlands or European Union.

[Go to detailed discussion]:

8. **Fails to show benefits for adolescents or address concerns it may cause harm to young people.** The justification fails to articulate the benefit for youth. It does not show that:
    - Flavours play an important causal role in adolescent vaping
    - A ban on flavours would reduce adolescent vaping, rather than just stimulate workarounds
    - If reductions in adolescent vaping were achieved as intended, this would translate to a benefit to health and not trigger an uptick in other risk behaviours.

    [Go to detailed discussion]

9. **Ignores the harmful effects of a vaping flavour ban on adults.** Where vaping displaces smoking – both in adults and adolescents – there are health, welfare, and economic gains for the users and for society. These benefits have been largely ignored in the reasoning presented to support the ban. The government's own target is to be smoke-free by 2040 – the substitution of smoke-free alternatives in place of cigarettes will be critical in meeting that target.
    [Go to detailed discussion]

10. **Creates regulatory protection for the cigarette trade.** The case does not recognise that vaping is an alternative to smoking and a pathway for smoking cessation and that flavours are an important part of the experience for adults. In obstructing this pathway and making it practically harder and less attractive for smokers to switch or risking that vapers will relapse to smoking, the proposals amount to a regulatory defence of the cigarette trade. While this is unlikely to be the government's intention, it may well be the perverse effect of this proposed intervention. It is quite possible that

the e-cigarette flavour ban will protect the cigarette trade and increase smoking, resulting in more disease and death. Nothing in the memorandum provides an adequate counter to these concerns. The government should adopt "risk-proportionate regulation", which encourages producers and consumers to migrate from high-risk to low-risk products — rather than unjustified regulation that will inhibit switching away from smoking.
[Go to detailed discussion]

11. **Violates important regulatory principles, including those underpinning the European Union internal market.** The proposed measure is disproportionate, discriminatory, anti-competitive, and counter to the aims of the European Union internal market. A key competitive advantage of e-cigarettes over cigarettes is the availability of diverse flavours (other than tobacco flavour). The availability is important because most adult users prefer these non-tobacco flavours. The proposed measure is indiscriminate in banning all but one flavour and does not adequately show that all non-tobacco flavours or descriptors have particular appeal to youth.
[Go to detailed discussion]

12. **Proposes an illiberal policy and fails to recognise a major global public health opportunity**. Though it is a political judgment, the measure appears to be excessively illiberal in its intrusion in adults' rights to protect their own health, on their own initiative, and at their own expense – or simply to use nicotine in a much safer way, if they choose to. It sets a precedent for governments to use potential risks to youth to curtail reasonable adult free choices. The aim should be to use targeted measures to control youth risks, not general measures that target all users. The policy overreacts to relatively minor and manageable risks but denies or ignores a significant opportunity to help millions of smokers radically reduce their health risks. In its role as Chair of the WHO Framework Convention on Tobacco Control Conference of the Parties in 2021, the Netherlands should be leading a positive approach to tobacco harm reduction.
[Go to detailed discussion]

The remainder of this submission discusses each of these twelve points in turn, providing an outline of supporting evidence.

Part II: Detailed discussion

1. Sets conflicting objectives and takes a "war on drugs" approach to nicotine

According to the memorandum justifying the flavour ban (*1 Rationale*):[1]

> In the National Prevention Agreement […] measures have been agreed with civil society organisations to achieve a smoke-free generation by 2040. To achieve these objectives, it has been decided that by 2020 (sic) more children must grow up in a smoke-free and tobacco-free environment. According to the signatories of the Prevention Agreement, a smoke-free and tobacco-free environment also means that children will not come into contact with novel tobacco products and electronic cigarettes (hereinafter referred to as e-cigarettes), with and without nicotine.

The overwhelming cause of disease and premature death associated with tobacco use arises from *smoke inhalation*.[2] A smoke-free objective makes sound public health sense. It can be more easily justified and is more likely to be achieved without recourse to coercive and punitive measures when nicotine is available in alternative smoke-free options. However, the text above greatly expands the objective beyond the public health imperative to tackle serious disease. There are three problems with establishing what amounts to a 'nicotine-free' goal.

- First, the goal of eliminating nicotine conflicts with the more important goal of eliminating harm.[3] This is because it is possible to provide nicotine with low or negligible harms to the user. By banning or over-regulating these products, the government would prevent people who want to use nicotine or are dependent on it from switching to low-risk options – leaving the high-risk options (cigarettes) to dominate. This is a "quit or die" philosophy, and it will mean reaching a smoke-free status will take longer, encounter more resistance, and cause more death and disease on the way.
- Second, policymakers should be wary of advice that departs from the reality of teenage lives and imagines utopian "abstinence-only" outcomes, rather than dealing with the world as it is.[4]
- Third, the history of drug prohibition does not suggest that laws banning a product cause it to disappear. It is simply supplied and consumed differently, often at great cost and harm to society.[5]

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1 Decree of the State Secretary for Health, Welfare and Sport of regulating e-cigarette flavors. Explanatory Memorandum English translation. [link]

2 U.S. Department of Health and Human Services. How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease. Centers for Disease Control and Prevention (US); 2010. [link]

3 See letter from 32 experts in nicotine science and policy to Mrs Helma Lodders, Committee Chair, Committee for Health, Welfare and Sports, House of Representatives (Netherlands), *Tobacco Harm Reduction and the Dutch National Prevention Agreement:* 4 March 2019 [link]

4 Kozlowski LT, *Prevention and Protection Polices for Youth Use of E-Cigarettes and Tobacco Products*. U.S. E-cigarette Summit 2018, Washington DC, 30 April 2018 [slide deck][video]

5 Open Society Foundation, Alternative World Drug Report: Counting the Costs of the War on Drugs [2016 2nd Edition]

2. Adopts false and misleading claims about the harmfulness of e-cigarettes

There is no serious doubt that vaping is much less harmful than smoking. There is no real doubt that e-cigarettes are much less harmful than cigarettes.[6] The main reason is that most of the harm from smoking arises from products of combustion of tobacco leaf. E-cigarettes eliminate both combustion and tobacco leaf. In this sense, they are completely different products from a toxicity perspective. The US National Academies of Science, Engineering and Medicine concluded its extensive review: [7]

> While e-cigarettes are not without health risks, they are likely to be far less harmful than combustible tobacco cigarettes. E-cigarettes contain fewer numbers and lower levels of toxic substances than conventional cigarettes. The long-term health effects of e-cigarettes are not yet clear.

Compared to smoking, the exact level of risk reduction is inevitably uncertain as vaping products have not been on the market for the decades needed to establish definitive mortality risk differential from cigarettes through long-term epidemiology. However, in its 2016 assessment, the Royal College of Physicians of London used carefully chosen language to characterise the likely level of risk reduction: [8]

> Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, 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.

Studies of biomarkers of exposure show greatly reduced risk. To have a sense of relative risk, we can draw on studies of biomarkers of exposure (toxicants in blood, saliva, and urine). These studies tend to show greatly reduced exposures – either close to background levels or comparable to smokers who stop smoking and use nicotine replacement therapy (NRT). In 2018, Public Health England experts reviewed the available studies of biomarkers of exposure. [9] Based on its assessment of the evidence, PHE concluded in 2018:

> Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping. It should be noted that this does not mean e-cigarettes are safe (Executive summary)

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6 Abrams DB, Glasser AM, Villanti AC, Pearson JL, Rose S, Niaura RS. Managing nicotine without smoke to save lives now: Evidence for harm minimization. P*rev Med (Baltim)*. Academic Press; 2018 Jun 23; [link]

7 National Academies of Science, Engineering and Medicine (US). *The Public Health Consequences of E-cigarettes. Washington DC*. January 2018. [link]

8 Royal College of Physicians. Nicotine without smoke: tobacco harm reduction. London: RCP; 2016. [link]

9 ` 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 [Internet]. London: 2018 [[link] For biomarker studies see page 163 in the main report [PDF]

To take one example, Shahab et al. 2017 compare smoking, vaping and NRT (our annotations in red):[10]

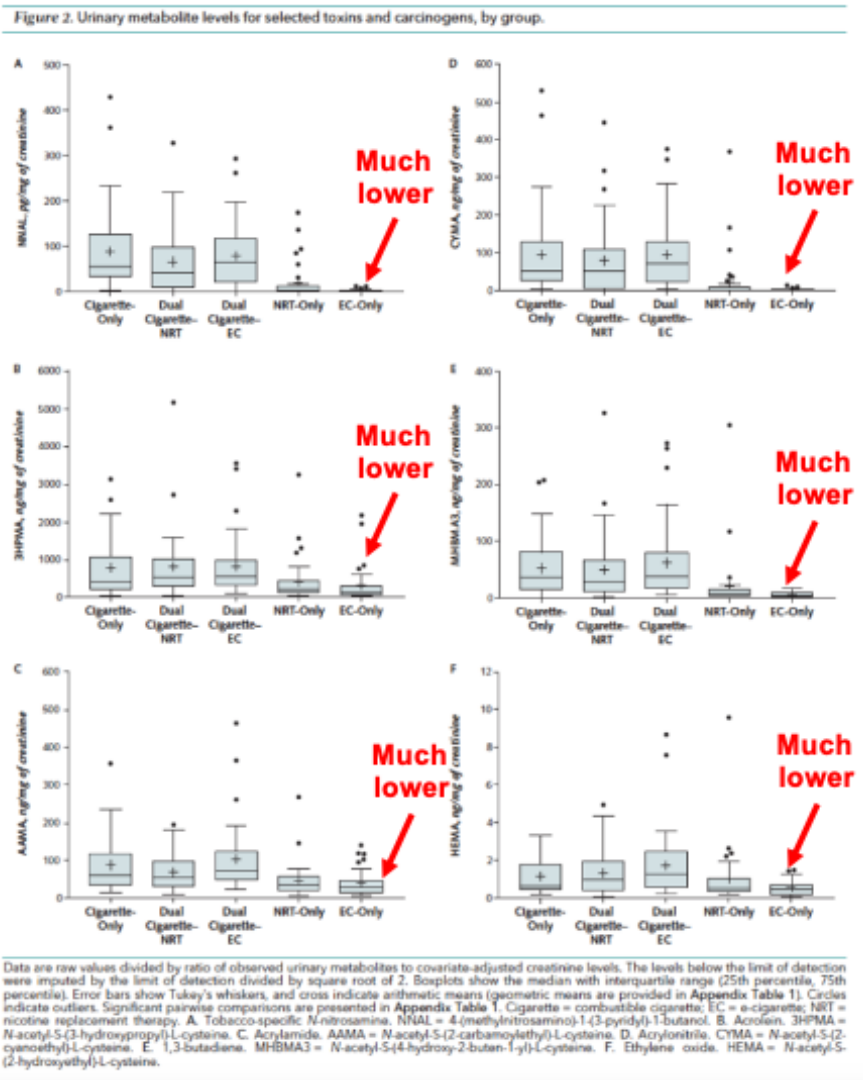

Figure 2. Urinary metabolite levels for selected toxins and carcinogens, by group.

Data are raw values divided by ratio of observed urinary metabolites to covariate-adjusted creatinine levels. The levels below the limit of detection were imputed by the limit of detection divided by square root of 2. Boxplots show the median with interquartile range (25th percentile, 75th percentile). Error bars show Tukey's whiskers, and cross indicate arithmetic means (geometric means are provided in Appendix Table 1). Circles indicate outliers. Significant pairwise comparisons are presented in Appendix Table 1. Cigarette = combustible cigarette; EC = e-cigarette; NRT = nicotine replacement therapy. A. Tobacco-specific *N*-nitrosamine. NNAL = 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol. B. Acrolein. 3HPMA = *N*-acetyl-S-(3-hydroxypropyl)-L-cysteine. C. Acrylamide. AAMA = *N*-acetyl-S-(2-carbamoylethyl)-L-cysteine. D. Acrylonitrile. CYMA = *N*-acetyl-S-(2-cyanoethyl)-L-cysteine. E. 1,3-butadiene. MHBMA3 = *N*-acetyl-S-(4-hydroxy-2-buten-1-yl)-L-cysteine. F. Ethylene oxide. HEMA = *N*-acetyl-S-(2-hydroxyethyl)-L-cysteine.

With a new product, long term impacts are inevitably uncertain, but we know *enough* to encourage smokers to switch. Anti-vaping arguments often refer to long term uncertainty about risks, implicitly suggesting they may be greater than we realise today – though, in fact, they may equally prove to be negligible. We cannot know the long-term effects of any relatively new product. However, we can use established benchmarks to gauge the health risk arising from the reduced exposures to toxicants. For example, there is extensive data from occupational health science (exposure to chemicals in the workplace). When these benchmarks are used to assess risk from e-cigarettes, the risks appear to be trivial compared to continued smoking.[11] Some activists point to the fact that it took decades to discover

[10] Shahab L, Goniewicz ML, Blount BC, et al. Nicotine, carcinogen, and toxin exposure in long-Term e-cigarette and nicotine replacement therapy users. *Ann Intern Med* 2017;166(6):390–400. [link]

[11] Burstyn I. Peering through the mist: Systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks [Internet]. BMC Public Health. 2014 [cited 2020 Dec 5];14(1):18. [link]

the health impacts of smoking and try to draw a parallel with e-cigarettes. That argument overlooks decades of progress in science since the 1950s. If cigarettes were introduced today, we would know immediately that these products are very harmful.

So-called precautionary action can do harm. Long term health impacts remain the subject of speculation, but no material adverse health effects have so far been detected at a significant scale. Projections based on greatly reduced toxicity suggest much lower risk.[12] However, the justification rests on a precautionary approach:

> The Trimbos Institute has concluded, based on the precautionary principle, that Dutch public health would benefit most from discouraging the use of e-cigarettes

When evidence is inevitably incomplete, the question arises how much is enough?[13] Despite the opinion of Trimbos, we do now know *enough* to treat e-cigarettes as though we are confident that they are much less harmful than smoking. Treating them as if there is no difference or a small difference in risk will cause policymakers to implicitly erect regulatory barriers to switching from smoking to vaping, with a public health cost. Taking so-called precautionary action and being wrong in the precautionary assumption is not cost-free and will cause harm. The cost of inaction is continued smoking, from which half of continuing smokers will die prematurely, and many more suffer needlessly. That is the case with using uncertainty about risks to justify the e-cigarette flavour ban.

If vaping substitutes for smoking there is a public health benefit, but this is not acknowledged in the justification for the flavour ban. When flavoured e-cigarettes contribute to smoking cessation, when they substitute for smoking or reduce smoking to low levels, and when they prevent initiation on combustible products there is a potential health benefit from harm reduction that must be acknowledged[14]. These effects can apply to both adults and to youth. The harm reduction benefits arise because non-combustible products are much less risky than smoking products.

3. Draws on irrelevant information about an outbreak of lung injuries in North America.

The EVALI lung injury outbreak is irrelevant. Rather than accept overwhelming evidence for greatly reduced risk, the justification draws on the 2019 outbreak of "EVALI" (E-cigarette and Vaping product Associated Lung Injury) in the United States, though notes that there have been no cases in the Netherlands. This section is a distraction. EVALI is a misnomer and relates to the contamination of the

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12 Abrams DB, Glasser AM, Pearson JL, Villanti AC, Collins LK, Niaura RS. Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives. *Annu Rev Public Health*; 2018. [link]

13 Fairchild AL. Is Good Enough Good Enough? E-Cigarettes, Evidence, and Policy. *Am J Public Health* 2021 ;111(2):221–223. [link]

14 Kozlowski LT, Warner KE. Adolescents and e-cigarettes: Objects of concern may appear larger than they are. *Drug Alcohol Depend.* 2017 May;174(1 May 2017):209–14. [link][PDF]

supply of illicit cannabinoid (THC) vape pens in the United States with a cutting agent, Vitamin E Acetate. This agent is added to the viscous oily excipient used for THC liquids.[15] This agent cannot be added to nicotine e-liquids and would serve no economic purpose because nicotine e-liquids can be diluted easily and cheaply with standard diluents, propylene glycol and glycerol. The EVALI outbreak was largely contained within North America, and it emerged in mid-2019 and had largely disappeared by February 2020.[16] The pattern is consistent with an episode of supply chain adulteration. Once Vitamin E Acetate was identified as a cause, there is a vanishingly small chance of any other independent cause arising in the same limited geography, causing the same symptoms, and appearing and disappearing at the same time.

Vague references to severe lung conditions in vapers do not form a basis for regulation. Having failed to show EVALI is relevant to the Netherlands or to nicotine vaping, the justification pivots to assertions from a Trimbos fact sheet[17] claiming Dutch pulmonologists have seen other lung injuries, which in turn references a news article about some pulmonologists calling for a ban on e-cigarette, claiming lung cases had risen from three to eight.[18] This is a poor articulation of evidence for policymaking purposes. It may be true that some vapers experience lung problems, but whether these can be attributed to vaping is doubtful. Adverse events do occur across the population, and some will afflict people who vape, but not necessarily because of their vaping – this is common in adverse event reporting for medicines. It is also possible that adverse events would arise from prior or ongoing smoking. Even if there were adverse respiratory events caused by vaping, and this is far from established, they would be exceedingly rare – like severe allergic reactions to commonplace foods or substances. They do not form a reliable basis for regulation, especially the proposed flavour ban.

4. Misunderstands dual-use

Dual-use is not a reason for scepticism about e-cigarettes. The justification inappropriately highlights dual use as part of the justification for banning e-cigarette flavours.

> However, in the Netherlands, 72% of e-cigarette users had not switched completely by 2018. These were dual users who also used tobacco cigarettes in addition to e-cigarettes. This results in little or no health gain and there are even signs that dual use could be potentially more harmful than using only tobacco cigarettes or e-cigarettes.

Almost all pathways to smoking cessation involve continued smoking. Unless a smoking cessation method is 100% effective immediately, there will be continued smoking in the period between

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15 Blount BC, Karwowski MP, Shields PG, et al. Vitamin E Acetate in Bronchoalveolar-Lavage Fluid Associated with EVALI. *N Engl J Med* [Internet] 2020 [cited 2020 Dec 3];382(8):697–705. [link]

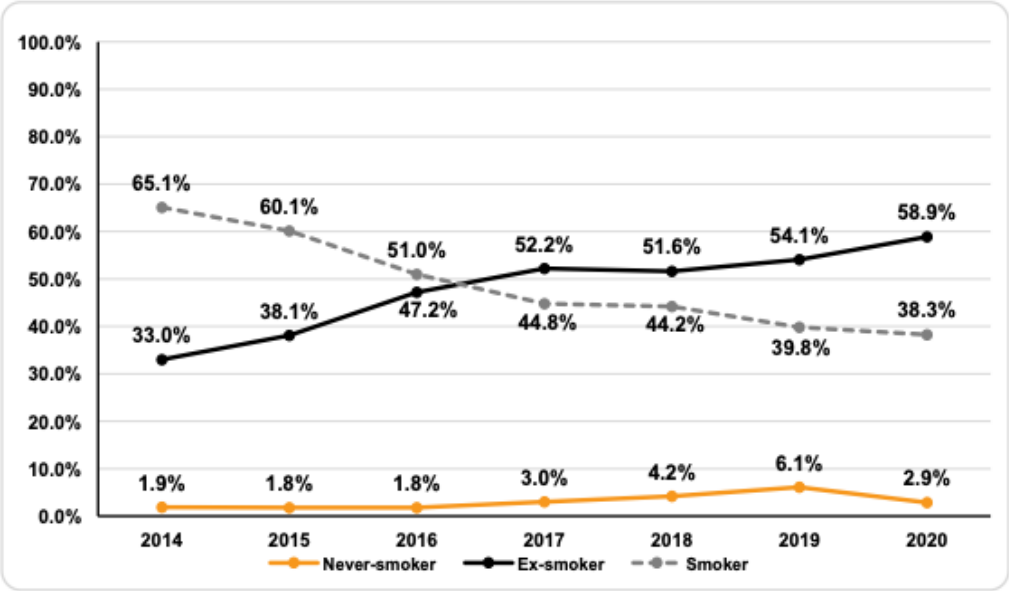
16 Centers for Disease Control and Prevention (CDC). Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products. 2020 ; [link]

17 Trimbos Institute. Factsheet Elektronsische Sigaretten (E-sigaretten) April 2020 [link] See Reference 11. Translation [link]

18 Geels M. Pulmonologists want a total ban on e-cigarettes in the Netherlands. NRC [Internet]. 2019; [link].

attempting to quit and successfully quitting smoking, if this is achieved at all. Given the very poor efficacy of NRT and prescriptions medicines, most smokers using these approaches will need to make multiple attempts with successive relapses to smoking. What matters is the effectiveness of the pathway to smoking cessation – how quickly it is achieved, how well it is sustained, and how many smokers find that route appealing. On those measures, e-cigarettes score highly.

Dual-use is part of a positive transition from smoking to vaping Dual-use is common in the Netherlands, but less so in the United Kingdom, where there is a more positive government and healthcare system attitude to vaping as an alternative to smoking. In Britain, dual-use is well below 50% of vapers and has decreased over time.[19] The figure below shows the smoking status of current e-cigarette users:



Unweighted base: GB adult vapers 2014, n=498; 2015, n=614; 2016, n=667; 2017, n=669; 2018, n=738; 2019, n= 854; 2020, n=787).

Quitting smoking can be incredibly hard. For many smokers, dual-use should be understood as a transitional phase in the migration from smoking to vaping. It is often a marker for more dependent smokers trying to quit smoking or cut down – it represents important progress over exclusive smoking.[20]

Some dual users have higher exposures than exclusive cigarette users, but this is likely due to higher dependence. The justification inappropriately cites a cross-sectional analysis of dual users in a biomarker study[21] to claim: "*there are even signs that dual use could be potentially more harmful than*

[19] Action on Smoking and Health / YouGov. Use of e-cigarettes among adults in Great Britain, 2020. October 2020. [link]

[20] Simonavicius E, McNeill A, Arnott D, Brose LS. What factors are associated with current smokers using or stopping e-cigarette use? *Drug Alcohol Depend* [Internet] 2017;173:139–143. [link]

[21] Goniewicz ML, Smith DM, Edwards KC, et al. Comparison of Nicotine and Toxicant Exposure in Users of Electronic Cigarettes and Combustible Cigarettes. *JAMA Netw Open* [Internet] 2018 [cited 2021 Jan 9];1(8):e185937. [link]

using only tobacco cigarettes or e-cigarettes". However, this is not what this study does conclude. Because of its cross-sectional nature, the study does not consider the smokers' baseline cigarette consumption before they became dual users. It is also likely that dual users are more dependent on average and, therefore smoke more frequently and intensely.[22] Rather than misinterpret the findings of this biomarker study, the government should encourage dual users to switch completely away from smoking as soon as they can, while recognising such behavioural changes are difficult and can take time.

Transition from dual-use to exclusive vaping is held back by anti-vaping activism. If the government, agencies, academics and activists are constantly scaring vapers and smokers about vaping, it is understandable that fewer will find the motivation to move from dual-use to exclusive vaping. Smokers who better understand the vast differences in risk between smoking and switching to vaping are more likely to switch completely.[23] Dual-use is, in part, caused by anti-vaping activism and those activists and politicians who confuse users about risks (see discussion of EVALI above). By overemphasising the potential risks of vaping and dual-use, the government will mislead and confuse the public. This is likely to result in dual-use persisting longer and fewer smokers trying vaping as an alternative. Sustaining dual-use through anti-vaping communications and rhetoric is one more way in which activists, academics and politicians may prolong smoking – even if unintentionally.

5. Asserts a 'gateway effect' but there is more likely to be a diversion away from smoking

The justification draws falsely on an unproven gateway effect. The justification for the flavour ban suggests, albeit tentatively, that e-cigarettes may provide a gateway to smoking. In doing so, it implicitly attributes the risk of smoking to the much safer vaping products. There is no basis for this.

> In addition to the fact that young people may become addicted to nicotine and exposed to harmful substances through the use of e-cigarettes, young people who use e-cigarettes are more likely to smoke tobacco cigarettes and vice versa. It is difficult to determine whether young people started smoking because of e-cigarettes or whether common underlying factors increase the risk of vaping and smoking. However, recent insights increasingly suggest that e-cigarettes may be a stepping-stone to tobacco smoking

No support for a gateway effect, and common liability is more likely. There is so far no compelling evidence of a gateway effect.[24] Detailed examination of the studies claiming to have found a gateway

[22] Shiffman S, Sembower MA, Kim M. Comparisons of dependence on cigarettes and e-cigarettes: Data from the PATH study [Poster for SRNT 2018]. [link]

[23] Persoskie A, O'Brien EK, Poonai K. Perceived relative harm of using e-cigarettes predicts future product switching among US adult cigarette and e-cigarette dual users. *Addiction* [Internet] 2019;114(12):2197–2205. [link]

[24] Etter J-F. Gateway effects and electronic cigarettes. *Addiction* [Internet] 2017. [link]

effect showed that all had fundamental weaknesses, primarily uncorrected confounding.[25] [26] Confounding is probably an insurmountable challenge for any standard observational study.

The alternative explanation for the observed associations between e-cigarette use and smoking relates to characteristics of the individual and their circumstances that incline them to both vaping and smoking. Given the similarities between the two habits (albeit with radically different risk to health), it is not at all surprising that whatever reasons people have to smoke are also reasons to vape. These common characteristics – genetics, mental health, family, community, delinquency, etc.) are sometimes known as common liabilities, common risk factors or confounders. These provide a more credible explanation for at least part of the observed associations between smoking and vaping.[27] [28]

The common liability explanation is backed up by population trends. There has been a sharp rise in adolescent vaping in the United States since 2014, but it has not generated a surge in smoking. There has also been an *accelerated* decline in youth smoking coinciding with the rise in youth vaping. [29]

> There was a substantial increase in youth vaping prevalence beginning in about 2014. Time trend analyses showed that the decline in past 30-day smoking prevalence accelerated by two to four times after 2014.

Recent time-series analysis has found that a diversion effect (i.e. a gateway out of smoking) was more likely to be the explanation.[30]

> A simulation model shows that a substantial diversion effect is needed to explain observed nicotine use trends among US adolescents, and it must be larger than any possible opposing catalyst effect, if present.

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[25] Chan GCK, Stjepanović D, Lim C, et al. Gateway or common liability? A systematic review and meta-analysis of studies of adolescent e-cigarette use and future smoking initiation [Internet]. Addiction. 2020 [cited 2020 Dec 4];add.15246. [link]

[26] Lee PN, Coombs KJ, Afolalu EF. Considerations related to vaping as a possible gateway into cigarette smoking: An analytical review. *F1000Research* 2019; [link]

[27] Vanyukov MM, Tarter RE, Kirillova GP, et al. Common liability to addiction and "gateway hypothesis": Theoretical, empirical and evolutionary perspective. *Drug Alcohol Depend* [Internet] 2012;123:S3–S17. [link]

[28] Phillips C V. Gateway effects: Why the cited evidence does not support their existence for low-risk tobacco products (and what evidence would). *Int J Environ Res Public Health* 2015; [link]

[29] Levy DT, Warner KE, Michael Cummings K, et al. Examining the relationship of vaping to smoking initiation among US youth and young adults: A reality check. *Tob Control* 2019; [link]

[30] Selya AS, Foxon F. Trends in Electronic Cigarette Use and Conventional Smoking: Quantifying a Possible "Diversion" Effect among U.S. Adolescents. *Addiction* [Internet] 2021 Jan 11;add.15385. [link]

Likewise, an analysis of US data using propensity score matching found that initial e-cigarette users were *less* likely than others with similar propensity to initiate smoking.[31] The study concluded:

> Less than 1% of US adolescents who use e-cigarettes first were established cigarette smokers. They were less likely to be smokers than adolescents who tried other combustible or non-combustible tobacco products first and propensity score matched adolescents without initial e-cigarette use.

These studies are all consistent with vaping being a gateway 'exit' and that the strong associations between vaping and smoking are more likely to arise from common liabilities. As no individual study design can establish causality definitively, and while we wait for triangulation of methodological approaches to provide a more complete picture, it would be premature to assume strong effects in either direction. Nonetheless, recent data at the population-level are more consistent with the prospect that the observed associations between smoking and vaping benefit adolescent health rather than cause harm. Reassuringly, even if there were a strong gateway effect into smoking, this is mostly of theoretical concern as regular use of e-cigarettes among tobacco-naïve adolescents is exceedingly rare.[32] [33]

Weak assumptions about gateway effects are not somehow "precautionary" but cause harm. The problem is that perverse consequences arise from assuming a gateway effect when there is not. If, on the contrary, there is a diversion effect, it not cost-free or somehow 'precautionary' to block this pathway to smoking cessation with excessive regulation. For this reason, the following statement in the memorandum provides an inappropriate foundation for policy:

> However, recent insights increasingly suggest that e-cigarettes may be a stepping stone to tobacco smoking. […] It was therefore decided in the Prevention Agreement that a smoke-free and tobacco-free environment also means that children must not come into contact with novel types of tobacco products and e-cigarettes, with and without nicotine

There are harmful consequences for being wrong about gateway effects, given there is no doubt about the risk of smoking. It would mean that policies built on this assumption will cause harm if they work as intended. If e-cigarettes are an alternative to smoking and much less harmful, then basing policy on an assumption of a gateway effect, such as banning flavours, will degrade a beneficial pathway out of smoking and support the cigarette trade prolong smoking, and cause harm. This is exactly the position in the Prevention Agreement, and it does not withstand scrutiny.

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[31] Shahab L, Beard E, Brown J. Association of initial e-cigarette and other tobacco product use with subsequent cigarette smoking in adolescents: a cross-sectional, matched control study. *Tob Control* 2020 0:tobaccocontrol-2019-055283. [link]

[32] Action on Smoking and Health (UK) and YouGov. Use of e-cigarettes among young people in Great Britain,. June 2019. [link]

[33] Jarvis M, Jackson S, West R, Brown J. Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey 2017-2019 reveal about high school e-cigarette use in the USA? *Qeios* [745076.5] 2020 [link]

6. Takes a simplistic approach to youth risk behaviours and fails to demonstrate benefits to adolescent public health

Policy should be made using appropriate data. The memorandum does not present politicians and policymakers with the appropriate context for the youth data. The justification for the measure draws on 'ever use' statistics – trying an e-cigarette just once or more in a lifetime – rather than more meaningful current and frequent use, and without the data for other risk behaviours for context. This has the effect of suggesting the issue is of greater significance in the Netherlands than it really is. The government should have included an objective presentation of the data in its justification, such as the table below.

The Netherlands Substance use - Class 4 (age 15-16)	Per cent
Alcohol (ever) whole glass or more	48.5
Alcohol (ever) sips or whole glass	64.5
Fig. One or more glasses of alcohol for 4 weeks	40.5
5 / more drinks one gel. 4 wks.	29.4
Ever drunk or tipsy	38.2
Drunk or tipsy last 4 wks.	22.4
Smoking (ever) a whole cigarette or more	15.0
Smoking (ever) few puffs / whole cigarette	23.5
Smoking daily	4.1
Smoking weekly	6.4
E-cigarette (ever)	29.1
E-cigarette daily	0.8
E-cigarette weekly	2.1
Weed / hash ever used	14.1
Used weed / hash in the last 4 weeks	6.9

Source: Health Monitor Youth 2019, GGDs and RIVM[34]

Some observations follow from this data:

- **Quoting "ever-use" statistics raises unwarranted concern**. *Potentially* problematic e-cigarette use accounts for a small fraction of those who ever tried vaping. Prevalence of ever-use at age 15-16 is 29.1%, but daily use is a tiny fraction of this at just 0.8%. The prevalence of vaping at least once a week is just 2.1%. The use of 'ever-use' statistics in the justification for this measure is misleading – and may simply be a marker for youthful experimentation or rebellion. This indicator signifies the

[34] National Institute for Health and Environment (RIVM), Ministry of Health, wellbeing and sports, Health Monitor Youth 2019; region. Updated 15 October 2020. Accessed 15 January 2021 [link]

characteristics of the individual rather than a harm pattern of substance use. It is not surprising that during the emergence of a new technology, many young people will try it. What matters is whether they develop a sustained habit. Frequent vaping is 'potentially' problematic if it represents additional new nicotine users who would not have otherwise used nicotine in a more harmful way, such as smoking (see below).

- **The problem remains youth smoking - and vaping may help.** Daily smoking prevalence (4.1%) is five times higher than daily vaping prevalence (0.8%). It is also quite possible that the more frequent users (daily vaping) are doing this *instead* of smoking or as part of an effort to stop smoking. *The youth nicotine problem is a smoking problem*, and youth vaping may help to mitigate this.
- **In other countries vaping may be suppressing smoking in youth**. We have been unable to find data on the proportion of Dutch adolescents who vape and have also smoked or would likely to be smokers in the absence of vaping. However, data from the United States shows that most (two-thirds) frequent teenage vapers are prior smokers[35] , and only a small fraction of never-users become frequent vapers[36]. A survey of youth e-cigarette use in Britain found that "*Regular use of e-cigarettes remains largely confined to current or ex-smokers*"[37]. At present, the government does not know if youth vaping is helping Dutch youth migrate away from smoking – and so no-one can know whether this proposal will do more harm than good even if it works as intended.
- **Ignoring relative risk in youth risk behaviours**. Any view of youth risk behaviours should consider whether one behaviour (for example, vaping) may be a substitute for another and how much harm may arise from these behaviours. If the vaping is a small fraction of the risk of smoking (less than 5%), then the impact of a policy (such as a vaping flavour ban) that may conceivably lead to extra youth smoking *is dominated by its effect on smoking*. No analysis or research is presented on the possible increases in youth smoking. This perverse effect is in addition to any detriments to adults.
- **The approach ignores the most serious risks and is inconsistent with alcohol**. To avoid confronting the possible negative consequences of a vape flavour ban on youth smoking, the justification simply ignores the smoking-vaping interaction. But a further issue is inconsistency with the management of other youth risk behaviours. Alcohol presents a much greater immediate risk to young people than vaping: notably through road accidents, other accidents, violence, sexual vulnerability and assault, and incapacitation. 24.2% of teenagers reporting being "drunk or tipsy" in the past four weeks, yet there are no proposals to remove a broad category of alcoholic beverages from the market to "protect youth". Why not? The most compelling explanation is that the government harbours misconceptions about nicotine (believing nicotine is responsible for the harms caused by smoking

[35] Jarvis M, Jackson S, West R, Brown J. Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey 2017-2019 reveal about high school e-cigarette use in the USA? *Qeios* [745076.5] 2020 [link]

[36] Villanti AC, Pearson JL, Glasser AM, Johnson AL, Collins LK, Niaura RS, et al. Frequency of youth e-cigarette and tobacco use patterns in the U.S.: Measurement precision is critical to inform public health. *Nicotine Tob Res*. December 2016 [link]

[37] Action on Smoking and Health (UK) and YouGov. Use of e-cigarettes among young people in Great Britain,. June 2019. [link]

when the evidence is clear that it does not) and that nicotine use is increasingly concentrated in disadvantaged groups who find it harder to resist arbitrary and capricious policies that harm them.

- **The policy analysis is unrealistic about drug use and substance markets**. Though teenage use of cannabis is illegal and access restricted, the numbers using it are relatively high. 6.9% used 'hash / weed' in the last four weeks (there is no comparable figure for vaping, but e-cigarette use in the last week was 2.1%). Is it possible that some teenagers would switch from vaping nicotine flavours to vaping cannabinoids (THC) rather than tobacco? The justification does not consider this, yet it is a foreseeable negative consequence of banning flavoured e-cigarettes.

The fallacy of prohibition. The persistence of illicit drug use (in the Netherlands and nearly all other countries) is a reminder that banning something by law does not make it go away; it mainly changes how it is supplied. The justification includes no evaluation of the likely supply-side response to a vaping flavour ban – but it could include a significant black market supply chain developing. It is possible that existing illicit suppliers and informal social supply networks may add vaping products to their range of drugs and increase their contact with young people, introducing them to a wider range of illicit substances and behaviours – a variant of the gateway effect, mediated by blending supply chains.[38]

7. Ignores the consequences of prohibition even though these are foreseeable

Banning a product by law does not make it disappear. A ban cannot stop current or future users replacing the banned substance with some other risky substance or behaviour. There are many possible responses to a ban on vaping flavours, including:

- The intended outcome - abstinence from nicotine and not adopting any other risk behaviour
- Using tobacco flavoured vape products instead of other flavoured products
- Accessing flavoured vapes via an illicit supply chain (a black market)
- Buying from foreign suppliers in person or via the internet and importing for personal use
- Buying from foreign suppliers to resell to others through informal networks
- Making and mixing their own flavours at home or buying or selling home-mixed flavours
- Using vapes that are made to look tobacco flavoured but have other flavours
- Using flavour agents for food, drink or aromatherapy for adding to unflavoured nicotine liquids
- Using flavours made for vaping but ostensibly marketed for another purpose
- Switching to cannabinoid (THC or CBD) vapes
- Relapsing back from vaping to smoking – both teenagers and adults

[38] Coomber R, Moyle L, South N. The normalisation of drug supply: The social supply of drugs as the "other side" of the history of normalisation. *Drugs Educ Prev Policy* [Internet] 2016 [cited 2021 Jan 22];23(3):255–263. [link]

- Not switching from smoking to vaping and continuing to smoke
- Initiating smoking instead of initiating vaping
- Continuing to smoke or to start smoking as an adolescent because parents or adult role models smoke instead of vaping
- Using other tobacco or nicotine products – hand-rolling tobacco, smokeless tobacco, heated tobacco, or new nicotine pouches
- Adopting another risk behaviour that may be worse

Most responses are either harmful or make no difference. Only the first of the list above meets the policy aims for adolescents. Several of the options increase the risks to both adults and adolescents. Yet the justification provides no real insight into these likely and foreseeable responses.

Evidence suggests e-cigarettes and cigarettes are substitutes. There is evidence that making e-cigarettes less attractive to adolescents has the effect of increasing cigarette use. For example, a study of the effect of e-cigarette tax increases on adolescents showed harmful substitution behaviour.[39]

> We find that higher e-cigarette cartridge prices reduce e-cigarette use and increase current cigarette consumption, especially for males and for older teenagers

Studies of the impact of strengthened access restrictions also showed that measures designed to reduce e-cigarette use through access restrictions also had the effect of increasing smoking.[40]

> This effect is both consistent with e-cigarette access reducing smoking among minors, and large: banning electronic cigarette sales to minors counteracts 70 percent of the downward pre-trend in teen cigarette smoking for a given two-year period.

Again, changes in age restrictions are not flavour bans. But they do help to illustrate the effect of suppressing teenage e-cigarette use through deliberate policy measures, and therefore what may happen if the government's policy works as intended.

No attempt has been made to examine the impact of flavour bans introduced elsewhere. Initial data, albeit from a small sample, on the impact of the flavour ban in San Francisco suggests a statistically significant increase in cigarette smoking among young adults from 27.5% to 37.1%.[41] A more detailed evaluation is not yet available, but this study is grounds for caution.

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[39] Pesko MF, Warman C. The Effect of Prices on Youth Cigarette and E-Cigarette Use: Economic Substitutes or Complements? *SSRN Electron J* [Internet] 2017 [link]

[40] Friedman AS. How does electronic cigarette access affect adolescent smoking? *J Health Econ* [Internet] 2015 [cited 2021 Jan 23];44:300–308. [link]

[41] Yang Y, Lindblom EN, Salloum RG, Ward KD. The impact of a comprehensive tobacco product flavor ban in San Francisco among young adults. *Addict Behav Reports* [Internet] 2020;11:100273. [link]

8. Fails to show benefits for adolescents and address concerns it may cause harm to young people

Flawed justification for banning flavours to protect youth. The justification rests largely on the idea that banning vaping flavours will have a protective effect for Dutch youth. However, the justification for benefits for youth is very weak and the challenges substantial. It does not establish flavours as a causal factor in youth vaping – though banning *nearly all* flavours will make the products less attractive to *everyone*, including adults and smokers. In its assessment of the reasons for adolescent e-cigarette use, the US Centers for Disease Control and Prevention identified several factors more important than flavours, notably curiosity.[42] The table below is a simplified version of Table 6 in the CDC report: *Reasons for e-cigarette use among middle and high school students who reported using e-cigarettes and other tobacco products during the past 30 days — National Youth Tobacco Survey, United States, 2019*

Reason given (top 5 only)	E-cig only users	E-cig and other tobacco users
I was curious about them	56.1%	38.4%
Friend or family used them	23.9%	22.2%
They are available in flavors, such as mint, candy, fruit, or chocolate	22.3%	26.6%
I can use them to do tricks	22.0%	29.0%
They are less harmful than other forms of tobacco, such as cigarettes	17.0%	19.1%

Will anti-vaping controversy stimulate youth vaping? If the government proceeds with this measure, it should brace for increased adolescent curiosity in vaping flavours. The proposed measure may attract young users to the controversy and make matters worse – at least this cannot be ruled out. It is notable that the United States, the country with the highest intensity of 'moral panic' about adolescent vaping, also has the among the highest measured youth vaping prevalence.

Flavours do not seem important to <u>non-users</u>. To the extent there is evidence, it suggests that flavours are not an important motivation to *non-users*. In one study, when teenage subjects were asked to rate their interest in using e-cigarettes on a scale of 0-10 when offered in a list of flavours, they reported minimal interest, reaching an average interest score of only 0.41 out of 10.[43] Where studies report the

[42] Wang TW, Gentzke AS, Creamer MLR, et al. Tobacco product use and associated factors among middle and high school students-United States, 2019. *MMWR Surveill Summ* [Internet] 2019 [cited 2021 Jan 17];68(12):1–22. [link]

[43] Shiffman S, Sembower MA, Pillitteri JL, Gerlach KK, Gitchell JG. The impact of flavor descriptors on nonsmoking teens' and adult smokers' interest in electronic cigarettes. *Nicotine Tob Res* 2015; published online Jan 7 [link][release].

motivation of teenage users, *harm reduction* is an important reason for young people vaping.[44] [45] It is not surprising that anyone who already vapes says they like the flavours, but that does not mean they started because of flavours (few young people start smoking or drinking because the flavours appeal to them). It would be more concerning if they continued to vape while not liking the flavours.

Look for deeper explanations. The causes of adolescent vaping and smoking are probably lodged deep in psychological motivations. One US study analysed youth smoking and vaping data and found:[46]

> While e-cigarette use rises, understanding the underlying reasons why youth and adults use e-cigarettes is important for policy efforts. This study found two overarching factors, "alternative to cigarettes" and "larger social environment", which combine sub-categories to explain main motivators of e-cigarette use.

The study then listed sub-factors in order of strength. In this 'factor analysis' of PATH data, "It comes in flavors I like" was merely the sixth most prominent factor in the "alternative to cigarettes" category:

1. They don't smell
2. They might be less harmful to me than cigarettes
3. They might be less harmful to people around me than cigarettes
4. Using them help people to quit smoking
5. They are more acceptable to non-tobacco users
6. It comes in flavors I like/liked
7. […] several other factors of lower prominence

Banning flavours will not make the demand go away. These analyses do not suggest that flavours are irrelevant, but that other factors may maintain the appeal and demand for vaping. These factors make it more likely that adolescent users will either just use the tobacco flavour or seek supply-side options to access banned flavoured products (black market, cross-border, home mixing etc.). See section 7 on the perverse consequences of regulation above.

Suppressing demand for adolescent e-cigarette use may be harmful. Even if the policy works as intended and teenage vaping decreases, there is a further link in the chain of reasoning to establish whether this is public health measure for youth. That is the effect on youth behaviours of the intervention, including relapse to smoking or reduced displacement of smoking by vaping, as discussed in Section 5 on the gateway effect.

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[44] Shiffman S. Sembower MA. PATH Data: Harm Reduction is Teens' Top Reason for Using e-cigarettes, Poster SRNT, Florence March 2017 [link]

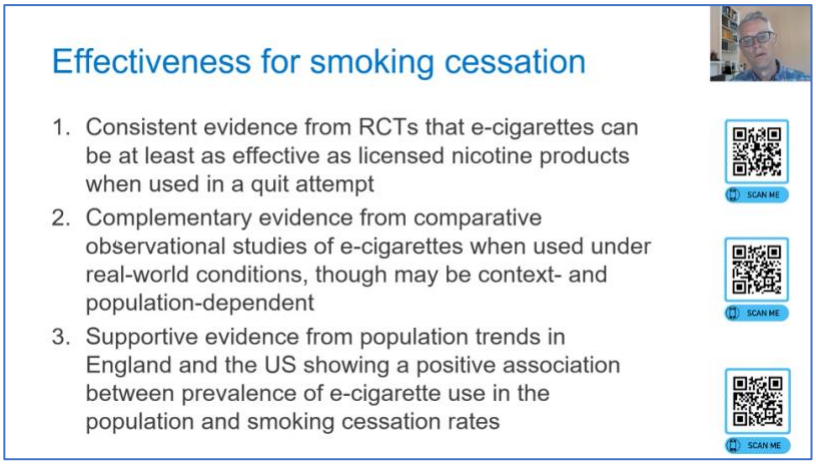
[45] Ambrose BK, Day HR, Rostron B, Conway KP, Borek N, Hyland A, et al. Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014. *JAMA*. American Medical Association; 2015 Nov 3;314(17):1871. [link]

[46] Nicksic NE, Snell LM, Barnes AJ. Reasons to use e-cigarettes among adults and youth in the Population Assessment of Tobacco and Health (PATH) study. *Addict Behav* [Internet] 2019;93:93–99. [link]

9. Ignores the harmful effects of a vaping flavour ban on adults

The Netherlands still has a real adult smoking problem. Adult smoking prevalence is 22.4% (3 million adults age 18 and over), peaking at 32% in the 18-24 young adult age group. Smoking rates are significantly higher among people with lower or middle levels of education than those with higher education.[47] In contrast, 3.1% of Dutch adults sometimes used e-cigarettes.[48] By contrast, in the United States, cigarette use in the 18-24 age group is 8%, and any combustible tobacco use is 11.2%, about one-third the level of the Netherlands. However, e-cigarette use in this age group is 9.3%.[49] However, the government appears determined to discourage switching from smoking to vaping even though this is an effective strategy to reduce smoking.

The evidence strongly supports vaping as a pathway to quitting smoking. The evidence comes from multiple sources, each with its own strengths and weaknesses, but taken together make a strong case – and stronger than the conventional smoking cessation treatments. British smoking cessation expert, Professor Robert West, summarised the state of evidence in a 2019 presentation.[50] The slide from Professor West's presentation above summarises his view of the evidence, and a link to the full presentation is provided at the footnote.



The following provides an overview of studies that support the evidence framework articulated in Professor West's presentation.

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47 Netherlands Expertise Centre for Tobacco Control. Smoking in the Netherlands: key statistics for 2018, Trimbos-instituut, Utrecht, 2019 (English translation) [link]

48 Netherlands Expertise Centre for Tobacco Control. Elektronische sigaretten (e-sigaretten). Trimbos-instituut 2020 [link] Translation [link

49 Cornelius ME, Wang TW, Jamal A, Loretan CG, Neff LJ. Tobacco Product Use Among Adults — United States, 2019. *MMWR Morb Mortal Wkly Rep* [Internet] 2020 [cited 2021 Jan 22];69(46):1736–1742. [link]

50 Robert West, Should health professionals recommend smokers to switch to e-cigarettes? A reprise of a keynote lecture at the Society for Research in Nicotine and Tobacco European conference in Oslo September 2019 Vimeo video [ink]

- *Randomised controlled trials.* Several recent trials show positive results.[51] [52] The most substantial clinical trial to date showed e-cigarettes with approximately twice the smoking cessation efficacy of NRT.[53]. There is an accumulating evidence base: the Cochrane Review now recognises evidence of efficacy, albeit somewhat qualified by the small number of studies.[54]
- *Observational data*. There is evidence that smokers who use e-cigarettes are more likely to quit smoking than those who do not.[55] [56]
- *Population trends*. There is evidence that as the prevalence of e-cigarette use increases in a population, smoking cessation activity also increases.[57] [58] [59] [60]
- *Modelling studies*. Modelling studies based on the experience so far show very substantial public health potential even when parameterised with sceptical assumptions.[61] [62]

The testimony of users really matters. Millions of former smokers will testify that e-cigarettes – especially in non-tobacco flavours – were important in assisting their efforts to stop. Collections of testimonials provide compelling evidence of smoking cessation success stories.[63] Though this type of

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[51] Eisenberg MJ, Hébert-Losier A, Windle SB, et al. Effect of e-Cigarettes plus Counseling vs Counseling Alone on Smoking Cessation: A Randomized Clinical Trial. *JAMA - J Am Med Assoc* 2020;324(18):1844–1854. [link]

[52] Pulvers K, Nollen NL, Rice M, et al. Effect of Pod e-Cigarettes vs Cigarettes on Carcinogen Exposure Among African American and Latinx Smokers: A Randomized Clinical Trial. *JAMA Netw open* [Internet] 2020 [cited 2021 Jan 18];3(11):e2026324. [link]

[53] Hajek P, Phillips-Waller A, Przulj D, et al. A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy. *N Engl J Med* 2019;380(7):629–637. [link]

[54] Hartmann-Boyce J, McRobbie H, Lindson N, et al. Electronic cigarettes for smoking cessation. *Cochrane database Syst Rev* 2020 10(10):CD010216. [link]

[55] Jackson SE, Kotz D, West R, Brown J. Moderators of real-world effectiveness of smoking cessation aids: a population study. *Addiction* [Internet] 2019 [cited 2020 Dec 3];114(9):1627–1638. [link]

[56] Kotz D, Brown J, West R. "Real-world" effectiveness of smoking cessation treatments: A population study. *Addiction* 2014;109(3):491–499. [link]

[57] Beard E, West R, Michie S, Brown J. Association of prevalence of electronic cigarette use with smoking cessation and cigarette consumption in England: a time–series analysis between 2006 and 2017. *Addiction* 2020];115(5):961–974. [link]

[58] Zhu S-H, Zhuang Y-L, Wong S, Cummins SE, Tedeschi GJ. E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. *BMJ*. 2017;358:j3262. [link]

[59] Levy DT, Yuan Z, Luo Y, Abrams DB. The relationship of e-cigarette use to cigarette quit attempts and cessation: Insights from a large, nationally representative U.S. Survey. *Nicotine Tob Res* 2018; [link]

[60] Beard E, West R, Michie S, Brown J. Association between electronic cigarette use and changes in quit attempts, success of quit attempts, use of smoking cessation pharmacotherapy, and use of stop smoking services in England: time series analysis of population trends. *BMJ* [Internet] 2016 [cited 2020 Dec 3];354:i4645. [link]

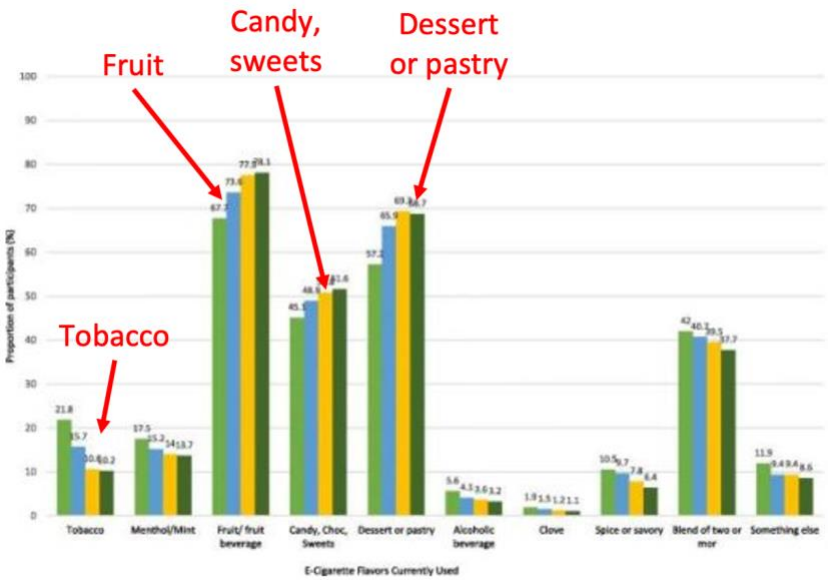
[61] Levy DT, Borland R, Lindblom EN, et al. Potential deaths averted in USA by replacing cigarettes with e-cigarettes. *Tob Control* [Internet] 2018 [cited 2020 Dec 5];27(1):18–25. [link]

[62] Mendez D, Warner KE. A Magic Bullet? The Potential Impact of E-Cigarettes on the Toll of Cigarette Smoking. *Nicotine Tob Res* 2020; [link]

[63] For example, see CASSA (US) testimonials, [link]

evidence is often dismissed as 'anecdote', no-one trying to understand the impact of vaping on health would ignore user experience.[64] A detective would not ignore witnesses' testimony but include it in building a case drawing on multiple strands of evidence (forensic, phone records, identification, financial records, witnesses, etc.)

Strong evidence that flavours play an important role in adult smoking cessation. Further, it is clear that adults make extensive use of non-tobacco flavours, including fruit and candy, even though these may be considered childish, or even 'kid-appealing'. One study found 68% of American adult e-cigarette users had used non-tobacco flavours in the past 30 days. Of these, 45% had used fruit, 44% menthol or mint, and 26 per cent candy, chocolate or other sweet flavour.[65] Russell and colleagues conducted a large survey of US users:[66] The data show extensive and increasing use of non-tobacco flavours in the United States. See the chart showing high preferences for flavours among adults (authors' annotations in red):



The adult behavioural and supply-side response to a flavour ban is difficult to predict. Still, the government did not attempt to estimate these effects in the justification for the flavour ban. There is some evidence suggesting that the availability of non-tobacco flavours helps some adult smokers transition completely away from smoking.[67] In Section 7 above, we set out a range of possible behavioural responses to a flavour ban, some of which increase harm. However, given that smoking is

64 See Carl V Phillips, Science lesson 3: Anecdotes ARE scientific data, Patreon, 14 April 2019 [link]

65 Bonhomme MG, Holder-Hayes E, Ambrose BK, Tworek C, Feirman SP, King BA, et al. Flavoured non-cigarette tobacco product use among US adults: 2013-2014. *Tob Control*. BMJ Publishing Group Ltd; 2016 Nov;25(Suppl 2):ii4-ii13. [link]

66 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* [Internet] 2018 [cited 2018 Jul 17];15(1):33. [link]

67 Farsalinos KE, Romagna G, Tsiapras D, Kyrzopoulos S, Spyrou A, Voudris V. Impact of flavour variability on electronic cigarette use experience: an internet survey. *Int J Environ Res Public Health* 2013; 10: 7272–82.[link]

far more harmful than vaping, the impact of only a small uptick in smoking would overwhelm any conceivable benefits from reductions in vaping.

Dutch vapers are trying to use vaping for harm reduction, but the government seems determined to obstruct them. In 2018, the Supplementary module of the Lifestyle Monitor asked about the user motives of Dutch e-cigarette users (multiple answers were possible):[68]

- 44.2% wanted to quit smoking tobacco cigarettes.
- 29.3% wanted to smoke fewer tobacco cigarettes.
- 21.3% cited the lower cost of e-cigarettes as a motive.
- 16.6% cited convenience, no ashes or less fire hazard.
- 14.4% said they liked e-cigarettes better than regular tobacco products

All of these are good reasons to use e-cigarettes. The government should not be putting itself in the way by obstructing the uptake and continuation of vaping as an alternative to smoking.

There is economic evidence that e-cigarettes function as an *alternative* to cigarettes, not as a complement. Economic data suggest that when policies are used to make e-cigarettes less attractive, then smoking increases. For example, studies of the effects of e-cigarette tax increases suggest tax increases cause e-cigarette consumption to fall and cigarette consumption to rise for adults[69]

> We find that higher e-cigarette tax rates increase traditional cigarette use and reduce e-cigarette use. Cross-tax effects imply that the products are economic substitutes.

Though a flavour ban is not the same as a tax increase, both have the effect of making e-cigarettes less attractive to the user—both taxes and a flavour ban risk triggering a substitution effect, causing an increase in cigarette use. Policy analysis in this field suggests that the welfare costs of activating such substitution pathways via misguided policies could be high.[70]

It is beyond reasonable doubt that e-cigarettes effectively help people stop smoking, and the reason is obvious. As well as all the evidence discussed above, there is also a case grounded in common sense. Vaping replaces more of the experience of smoking (effective delivery of nicotine in a similar way to smoking, throat sensation, flavour, hand-to-mouth movement, behavioural ritual and cultural or identity aspects) – but at a much lower risk to health. The underlying public health model is different from conventional smoking cessation treatments. With nicotine replacement therapy or prescription

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68 Trimbos Institute in collaboration with CBS and RIVM. LSM-A Resources / Lifestyle Monitor. 2018. Cited at reference 17 in Netherlands Expertise Centre for Tobacco Control. Elektronische sigaretten (e-sigaretten). Trimbos-instituut 2020 [link]

69 Pesko MF, Courtemanche CJ, Maclean JC. The effects of traditional cigarette and e-cigarette tax rates on adult tobacco product use. *J Risk Uncertain* 2020;60(3):229–258. [link]

70 Kenkel DS, Peng S, Pesko MF, Wang H. Mostly harmless regulation? Electronic cigarettes, public policy, and consumer welfare. *Health Econ* [Internet] 2020 [cited 2021 Jan 23];29(11):1364–1377. [link]

medications like Varenicline or Bupropion, the aim is to manage withdrawal and craving on the pathway from smoking to abstinence. In contrast, vaping is a rival consumer proposition available to smokers, for those who want it, replacing one pleasure with another

10. Creates regulatory protection for the cigarette trade

Protecting the cigarette trade. Given the known harms of smoking, it is unclear why a government or public health authorities would wish to intervene to regulate e-cigarettes in a way that degrades the competitive advantage e-cigarettes relative to cigarettes. The Royal College of Physicians explained this issue with great clarity:[71]

> A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, e.g. exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks. However, if this 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. (Section 12.10 page 187)

The likely effect of the flavour ban is to perpetuate smoking. The justification fails because there is no evidence to support risk-averse, precautionary action based on avoidable harm arising from e-cigarette use. On the contrary, it is more likely there would be perverse consequences for youth from limiting the appeal to adolescents, such as more smoking. So there is nothing to put on the precautionary side of the balance set out by the Royal College of Physicians. On the other hand, there are already numerous ways in which the Netherlands and European Union regulation supported by the Netherlands "causes harm by perpetuating smoking". These include Netherlands measures mentioned in the justification:

- Bans on vaping in public places equivalent to smoking bans
- Plain packaging
- Display bans.

This unjustified assistance to the cigarette trade builds on several counterproductive EU measures:

- Limits on e-cigarette nicotine strength give cigarettes a major advantage by ensuring e-cigarettes are less able to pull smokers away from cigarettes
- Excessively large, bold and misleading mandatory warnings
- Bans on most forms of advertising of vaping products
- Restrictions on e-commerce (optional)
- Multiple petty impositions (limits on tank and refill container size, leaflets).

[71] Royal College of Physicians. Nicotine without smoke: tobacco harm reduction [Internet]. London: RCP; 2016. [link]

The issue is not that there should be a "level playing field" for cigarettes and e-cigarettes or that they should be treated equally. E-cigarettes are different and should be treated *proportionately*, considering the health consequences. See the discussion of regulatory principles in the following section.

Rational regulation of tobacco and nicotine products would be 'risk-proportionate'. It is unclear what regulatory philosophy the government has adopted. The appropriate approach is to be 'risk-proportionate'. This approach applies fiscal and regulatory measures in proportion to risks. It aims to encourage smokers' migration to low-risk products by creating incentives for both consumers and producers to transition. The following table provides an overview of risk-proportionate regulation:

Measure	Smoking products	Smokefree products
Taxation	Relatively high taxes	Low or zero tax (VAT or sales tax only)
Illicit trade	Track and trace (FCTC protocol)	Complaint-driven
Advertising	Prohibit other than within trade	Control themes and placement
Warnings	Graphic warnings depicting disease	Messages encouraging switching
Public places	Legally mandated controls	Up to the discretion of the owner
Plain packaging	Yes	No
Ingredients	Control reward-enhancing additives	Blacklist material health hazards
Flavours	Prohibit	Allow, restrict ingredients that could be hazardous for inhalation
Flavour descriptors	Not applicable if flavours banned	Control appeal to youth/trademarks
Age restrictions	No sales to under-21s	No sales to under-18s
Internet sales	Banned	Permitted with age controls
Product standards	Control risks and reduce the appeal	Control risks

11. Violates important regulatory principles

The proposed flavour ban violates key European Union regulatory principles. Though the justification for the vaping flavour ban argues that its proposed approach is consistent with European Union regulation and regulatory principles, it does not provide a convincing case. The measure violates four important principles of good regulation generally and as applied in the European Union.

I. Violates the principle of proportionality. Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.[72] There is no justification for prohibiting *all non-tobacco flavours.* The government has provided no evidence to suggest that any specific flavours are targeted at adolescents or disproportionately successful in attracting youth that would not otherwise vape. It is disproportionate to ban an entire category of

[72] Treaty on European Union Article 5.4. [link]

products widely enjoyed by adults with a view to protecting youth rather than devise measures targeted at achieving the desired outcome. The ban on flavours represents a disproportionate barrier to competition and innovation and protects a much more harmful product from much safer novel products. It will damage multiple businesses (notably vape shops) that sell their products to adults as alternatives to smoking and provide a valuable support network. This sweeping measure is likely to cause net detriment to both adolescents and adults health by perpetuating smoking.

II. Violates the principle of non-discrimination or 'equal treatment'. European Union policymaking is supposed to follow the principle of non-discrimination. The European Court of Justice has articulated this principle as follows:[73]

> … the principle of equal treatment or non-discrimination requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified.

There is a major difference between cigarettes and e-cigarettes in their respective risk to health. They should be treated differently for this reason. Though the European Union bans flavoured cigarettes, there is no justification for extending that ban to e-cigarettes simply because they sounds the same. This is because flavour additives are intrinsic to the design of e-cigarettes and almost all final consumer vaping products, including tobacco flavoured products, are artificially flavoured. By contrast, cigarettes are flavoured by the products of combustion of tobacco, and these aromatic agents in cigarette smoke are not subject to any meaningful controls. The proportion of the cigarette market that has ever had an artificial characterising flavour is far lower than the e-cigarette market, so a ban on characterising flavours has a much greater impact on the e-cigarette market than on the cigarette market. There is no justification for imposing greater and discriminatory impediments on the far less dangerous category.

III. Violates the precautionary principle. The precautionary principle is widely misapplied and misunderstood. It requires careful consideration of "the benefits and costs of action or lack of action" and, therefore, an assessment of likely perverse consequences of regulatory intervention.[74] In this case, that would mean careful regulation of safer alternatives that potentially leads to more smoking. The case for the ban on flavours has a completely inadequate assessment of the likely and plausible perverse consequences that may arise from the proposed measures. Even a small increase in smoking – whether by adults or adolescents – would completely overwhelm any benefits arising from reduced vaping. Other harmful effects arising from black markets, home mixing and cross border trade have not been incorporated into the justification for precautionary action.

IV. Violates a foundational concept of the internal market. The underlying principle of the European Union internal market is to develop competition but qualified with regard for broader objectives:

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[73] Case 304/01 Sept 2004 *Spain v European Commission* para 31 [link]

[74] European Union, Communication (COM(2000) 1final) on the precautionary principle, 2000 – summary [link]

> *Article 114 TFEU*. [Proposals for development of the internal market] concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. [75]

In proposing a ban on all non-tobacco e-cigarette flavours, the government is taking an anti-competitive action against a much less dangerous product than the dominant nicotine product in both the European Union and the Netherlands. The likely effect is to strengthen the cigarette oligopoly or to delay its decline. It is likely to weaken health protection by preventing three million Dutch citizens from taking measures to protect their own health, on their own initiative and at their own expense. It fails to recognise the importance of the internal market's innovating functioning in developing alternatives to the most dangerous products.

12. Proposes an illiberal policy and fails to recognise a major global public health opportunity

A simplistic prohibitionist agenda. The proposed measure appears to be riding a wave of prohibitionist motivation pushed heavily from the United States. The billionaire financier, Michael Bloomberg, is on the record favouring prohibition of vaping. [76] As part of his campaign, he has provided at least $160 million for campaigns to ban flavoured e-cigarettes.[77] This sort of money has persuaded many agencies, including several in Europe, to campaign against flavoured vaping products to "protect youth from vaping". However, as argued throughout this submission, this is grounded in simplistic ideas of cause and effect:

> flavours are popular with adolescent vapers > ban flavours > adolescents will stop vaping.

Departs from traditional Dutch pragmatism. It takes no account of reality-based insights into youth risk behaviours, adolescent and adult smoking, and substance use generally. It does not consider how users and suppliers respond if the demand remains. It is notably inconsistent with relatively tolerant alcohol policies worldwide, despite significantly greater risks to young people arising from alcohol. The Netherlands has been widely and rightly respected for its pragmatic approach to cannabis, in which it has successfully reconciled the demands of adult society for a recreational drug with proportionate protection of youth.[78]

Sets unrealistic and counterproductive goals. The calls for a nicotine-free society set out in the rationale for the flavour ban are, in contrast, not pragmatic. Tobacco has been in use for several millennia[79] and

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75 Treaty on the Functioning of the European Union Article 114 [link]

76 New York Times, Candidates Up Close: Should vaping products be legal? Michael Bloomberg, 25 January 2020. [link]

77 Washington Post, Bloomberg to spend $160 million to ban flavored e-cigarettes, 10 September 2019 [link]

78 Kuper S. What the What the Dutch can teach the world about cannabis, Financial Times, 26 October 2018. [link]

79 Tobacco Use in ancient cultures, Wikipedia [link]

nicotine is a mild recreational drug with some positive effects[80], with very little risk when decoupled from tobacco smoke. There are several dangers of imposing anti-vaping policies based on an extreme aversion to youth vaping and poor policy analysis.

- Firstly, measures such as broad flavour bans will fail in their own terms and do more harm than good to adolescents by blocking an important diversion from smoking for adolescents.
- Secondly, it will do more harm than good to adults who are using vaping to quit or reduce their smoking. Given the risks of smoking far outweigh those of vaping, this will increase harm to society.
- Thirdly, it represents an infantilisation of adult society. In this approach, adults cannot make informed decisions about their health because of excessive and misguided reaction to youth risk behaviours.
- Fourthly, it overlooks the connection between adolescents and adults – they are not living in separate societies. Young people will grow to be adults, have parents or role models who smoke, and face negative personal, economic and health impacts from adult smoking.
- Finally, it is inconsistent with risk tolerance in other areas of life and appears to be driven by activists who find the idea of vaping objectionable. They are free to hold that view, but it should not become the law for everyone.

A better way. The appropriate approach is to adopt a risk-proportionate regulatory framework for tobacco and nicotine products. If the government believes it should control youth vaping, then it should use measures targeted specifically at adolescents, not affecting at all users indiscriminately. That means focussing on communications, on access and on controlling marketing or branding targeted at youth.

Embracing the opportunity and assuming leadership through the FCTC. Above all, the Netherlands government should now re-evaluate its governing philosophy for tobacco and nicotine. The idea of smoke-free society is possible and desirable. It can be achieved quickly without prohibition or strongly coercive measures through the use of low-risk alternatives. Realising a smoke-free society means defining vaping and other low-risk smoke-free products as part of the solution, not part of the problem.[81] This approach commands widespread support in the expert community, and it deserves more careful appraisal by legislators, policymakers and the public health community.[82] We hope that the government of the Netherlands recognises the opportunity and shows leadership as it takes on the Chair of the WHO Framework Convention on Tobacco Control Conference of the Parties later in 2021.

28 January 2021

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80 Harvard Medical School. Nicotine: it may have a good side, March 2014. [link]

81 Beaglehole R, Bates C, Youdan B, Bonita R. Nicotine without smoke: fighting the tobacco epidemic with harm reduction *Lancet*. 394(10200):718–720. [link]

82 Letter from 72 experts in tobacco and nicotine policy to WHO Director General. *Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction*. 1 October 2018. [link]