

Chapter	Consultation Response (max. 3800 characters) - namely around 500 words	COMMENTS AND LINK TO STUDIES USED
ABSTRACT	<p>Page2, lines 42 - 47: “Regarding the role of electronic cigarettes as a gateway to smoking/the initiation of smoking, particularly for young people, the SCHEER concludes that there is strong evidence that electronic cigarettes are a gateway to smoking for young people. There is also strong evidence that nicotine in e-liquids is implicated in the development of addiction and that flavours have a relevant contribution for attractiveness of use of electronic cigarette and initiation.”</p> <p>Page 2, Lines 49 - 52: “Regarding the role of electronic cigarettes in cessation of traditional tobacco smoking, the 50 SCHEER concludes that there is weak evidence for the support of electronic cigarettes' 51 effectiveness in helping smokers to quit while the evidence on smoking reduction is 52 assessed as weak to moderate.”</p>	<p>Page2, lines 42 - 47: When it comes to vaping policies, it is important to keep in mind that vaping was invented as a safer alternative to conventional smoking, and therefore its main target audience are tobacco consumers. There are many variables that contribute to smoking rates among young people, and many recent studies that have concluded that vaping is a gateway to smoking have failed to take those into account. For example, one study found that adolescents who were less satisfied with their life, in general, were more likely to seek risky experiences and have a higher tendency to use illicit substances regularly. Lawmakers should therefore focus on solving issues such as illicit trade and mental health and ensure age restrictions are enforced.</p> <p>Page 2, Lines 49 - 52: Vaping has helped millions of smokers switch thereby lowering their health-associated risks. A study conducted by the University College London in 2019 analysed data from over 50,000 smokers from 2006 to 2017 and found that using e-cigarettes in order to quit was positively associated with the quit success rates, with every 1 per cent rise in use of e-cigs associated with a 0.06% increase in the quit success rate. The 2018 U.S. National Academies of Sciences, Engineering, and Medicine Report found that the smoking rate has decreased overall more rapidly since vaping became more prominent in the United States.</p>
SUMMARY	<p>Page 7, LINE 16 - 19: “Overall, there is moderate, but growing level of evidence from human data 17 suggesting that electronic cigarette use has harmful health effects, especially but not 18 limited to the cardiovascular system. However, more studies, in particular on long19 term health effects, are needed. “</p>	<p>Page 7, LINE 16 - 19: The U.K.'s top health body, Public Health England, has repeatedly said that vaping and e-cigarettes are 95 percent less harmful than smoking. The same conclusion has been drawn by the New Zealand Ministry of Health and Health Canada, which have both launched public initiatives imploring smokers to turn to vaping.</p>

	<p>Page 7, LINE 38-42: “It has to be noted, that many of the studies published on this topic are dealing with 39 data from the US. Products on the US market may differ considerably from those 40 sold in the EU and conclusions drawn for the US may not be directly transferable to 41 the EU. Nevertheless, trends may also spill over and developments outside the EU 42 should not be disregarded. “</p> <p>Page 7, LINE 44-50: “Regarding flavours, consistent evidence was found that flavours attract both youth 45 and adults to use electronic cigarettes. Flavours decrease harm perceptions and 46 increase willingness to try and initiate use of electronic cigarettes. Adolescents 47 consider flavour the most important factor trying electronic cigarettes and were 48 more likely to initiate using through flavoured electronic cigarettes. Among adults, 49 electronic cigarette flavours increase product appeal and are a primary reason for 50 many adults to use the product. “</p> <p>Page 8, Line 28 - 32: “Overall, the SCHEER is of the opinion that there is strong evidence that electronic 29 cigarettes are a gateway to smoking for young people. There is also strong evidence 30 that nicotine in e-liquids is implicated in the development of addiction and that 31 flavours have a relevant contribution for attractiveness of use of electronic cigarette 32 and initiation.”</p>	<p>Page 7, LINE 38-42: Many ingredients in liquids in the US are banned in the EU. Therefore, many of the following arguments in the report seem to be irrelevant.</p> <p>Page 7, LINE 44-50: Flavours play a key role in helping smokers quit. Legislation on vaping flavors must take this fact into account. A study published in the New England Journal of Medicine in 2019 assigned participants into e-cigarettes and nicotine replacement groups and found that vaping was twice as effective as nicotine-replacement products in helping smokers quit. Crucially, participants in the e-cigarette group were encouraged to experiment with e-liquids of different strengths and flavours. Among participants in the study who didn't fully stop smoking, those in the e-cigarette group were more likely to reduce their smoke intake than those in the nicotine-replacement group. Survey results from the longitudinal survey study from Yale School of Public Health found that “relative to vaping tobacco flavors, vaping non tobacco-flavored e-cigarettes was not associated with increased youth smoking initiation but was associated with an increase in the odds of adult smoking cessation”.</p> <p>Page 8, Line 28 - 32: Nicotine, also found in e-cigarettes and used in conventional nicotine replacement therapy, doesn't increase the risk of serious illnesses (heart attack, stroke) or mortality. The British National Health Service sticks to the following view: “While nicotine is the addictive substance in cigarettes, it's relatively harmless. Almost all of the harm from smoking comes from the thousands of other chemicals in tobacco smoke, many of which are toxic.</p>
--	--	---

	<p>Page 8, Line 48-53: “From recent reviews, there is evidence that electronic cigarettes help smokers to 49 stop smoking in the long term compared with placebo electronic cigarettes. 50 However, the small number of trials, low event rates and wide confidence intervals 51 around the estimates result in weak evidence by GRADE standards regarding the 52 support of electronic cigarettes' effectiveness in helping smokers to quit while the 53 evidence on smoking reduction is assessed as weak to moderate.”</p>	<p>A closer look at the outcome of the survey shows that only 2.1% of non-smoking individuals surveyed frequently used e-cigarettes. The Action on Smoking and Health (ASH) UK reports similar findings and states that youth smoking rates are at an all-time low and youth use of e-cigarettes is rare, and most users are current or former smokers.</p> <p>Page 8, Line 48-53: The effectiveness of e-cigarettes as a smoking cessation tool is undeniable, keeping in mind that it targets smokers as opposed to non-smokers. Vaping is twice as effective as nicotine replacement therapies.</p>
<p>SCIENTIFIC OPINION</p>	<p>PAGE 13, LINES 5-9: “The health impacts of electronic cigarette’s use are still difficult to establish due to the lack 6 of long-term data from epidemiological studies or clinical trials. However, since 2016, the World Health Organization (WHO)6 7 has already noted that, while electronic cigarettes might 8 be “less harmful” than conventional cigarettes, electronic cigarettes still “are harmful to 9 health and are not safe”. “</p> <p>PAGE 13, LINES 36-38: “Although electronic cigarettes are relatively new in terms of exposure to humans, and more 37 research is needed over a longer period of time, there is</p>	<p>PAGE 13, LINES 5-9: Public Health England established already in 2015 that vaping is 95% less harmful - and confirmed in 2020 that vaping has a small fraction of the risks of smoking. The same conclusion has been drawn by the New Zealand Ministry of Health and Health Canada, which have both launched public initiatives imploring smokers to turn to vaping. Vaping was endorsed by Joachim Schüz, head of environment and radiation at the WHO’s cancer research agency, the International Agency for Research on Cancer during his speech at the The Committee on the Environment, Public Health and Food Safety of the European Parliament in February 2020. In his opinion, e-cigarettes are in “no way as harmful” as tobacco cigarettes and could help heavy smokers to quit.</p> <p>PAGE 13, LINES 36-38: No one argues that there are no health risks at all. However, the risks associated with vaping have to be compared with those related to conventional smoking. Also it is established that the risk of cancer from e-cigarettes compared to that from</p>

	<p>large scientific body of studies 38 indicating that electronic cigarette use can pose various health risks to the user. “</p> <p>PAGE 18, LINES 35-39: “Overall, the SCHEER is of the opinion that there is strong evidence that electronic 36 cigarettes are a gateway to smoking for young people. In addition, there is strong evidence 37 that nicotine in e-liquids is implicated in the development of addiction. There is also strong 38 evidence that flavours have a relevant contribution for attractiveness of use of electronic 39 cigarette and initiation too.”</p> <p>Page 19, Lines 1-7: “Taking into account data from cohort studies and randomised control trials, the weight of 2 evidence for smoking cessation is weak and for smoking reduction it is weak to moderate. 3 There is evidence that nicotine containing electronic cigarettes help smokers to stop 4 smoking in the long term compared with placebo electronic cigarettes (nicotine free). 5 However, the small number of trials, low event rates and wide confidence intervals around 6 the estimates result in low evidence by GRADE standards regarding the support of 7 electronic cigarettes' effectiveness in helping smokers to quit. “</p>	<p>smoking is less than half a percent. Therefore, vaping is an important tool to improve public health.</p> <p>PAGE 18, LINES 35-39: The main drive behind proposed flavour bans is protecting minors, who are allegedly drawn to the myriad of vape flavors. But considering all minors who use these products are acquiring them outside the legal market, it is clear that the most immediate impact will be on responsible adult vapers who prefer these flavors. The latest CDC in the US figures show that 20.8% of high schoolers have vaped at least once in the last 30 days. But nearly half of those 7 were vaping cannabis rather than nicotine, usually products that were procured illegally.</p> <p>As already mentioned, only 2.1% of non-smoking individuals surveyed frequently used e-cigarettes. The data from Action on Smoking and Health (ASH) UK reports similar findings and states that youth smoking rates are at an all-time low and youth use of e-cigarettes is rare and most users are current or former smokers.</p> <p>Page 19, Lines 1-7: Adults who use vaping and e-cigarettes as a means to quit smoking are vastly improving their chances of living long, healthy, and productive lives because by choosing vaping they get an opportunity to switch One study found that the increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level. Another study, led by Queen Mary University of London Professor Peter Hajek found that vapour products are almost twice as effective for smoking cessation than nicotine-replacement therapy.</p>
<p>METHODOLOGY</p>	<p>Page 20, Lines 24 - 42: “To address the terms of reference of</p>	<p>Page 20, Lines 24 - 42:</p>

	<p>this Opinion, the Commission library service performed 25 a literature search until April 2019. The search terms used are listed in Annex 4. This search 26 resulted in 3 715 articles published. To cope with this amount of scientific publications, the 27 members of the working group agreed to use for the Opinion firstly review articles 28 published between 01.01.2015 and April 2019. If necessary, the primary sources were also 29 used, as well as further articles of importance published after April 2019. In addition, the 30 SCHEER made use of reports by other organisations on this topic, as well as on information 31 provided by the Commission. 32 33 Many publications used by the SCHEER reflect the situation on the US market. Although, 34 the products as well as the liquids used differ frequently between Europe and the US (e.g. 35 with US allowing higher nicotine concentrations with respect to the limit of 20mg/ml 36 nicotine set by TPD in Europe), the SCHEER uses data describing the US market if 37 necessary and tries to draw conclusions for Europe wherever possible. The SCHEER is 38 aware, that this Opinion is related to a fast-developing market with new product types 39 brought to the market within short time periods. In the view of the SCHEER it is important, 40 not to disregard the development in non-European regions, as trends may also spill over to 41 the EU, even if new products have to be adapted to the requirements of the EU legislation 42 (i.e. regarding maximum nicotine content).”</p>	<p>In order to develop a coherent vaping framework, it is not enough to look at one side of the coin. As was mentioned, there’s an overwhelming scientific evidence proving that [1] “E-cigarettes were more effective for smoking cessation than nicotine-replacement therapy”, and [2], that “The substantial increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level.”</p> <p>Moreover, a recent Cochrane Systematic Review of more than 50 studies and more than 12,000 participants, found that e-cigarettes with nicotine can help more people to quit smoking than traditional nicotine replacement therapy (such as gums or patches) or e-cigarettes without nicotine.</p> <p>[1] - https://onlinelibrary.wiley.com/doi/10.1111/add.14656 [2] - https://www.bmj.com/content/358/bmj.j3262</p>
6.5.5 Risk Assessment	PAGES 60 - 62: “6.5.5.6 Conclusions 36 37 On risks for electronic cigarette users 38 In its report on "Electronic Nicotine	PAGES 60 - 62: We absolutely agree that e-cigarettes are not risk free. However, we see as a main missing feature of this preliminary opinion a comparison in terms of the level of

	<p>Delivery Systems and Electronic Non-Nicotine Delivery 39 Systems (ENDS/ENNDS)" published in August 2016 the WHO (WHO, 2016) stated: "Based 40 mostly on the levels and number of toxicants produced during the typical use of 41 unadulterated ENDS/ENNDS made with pharmaceutical-grade ingredients, it is very likely 42 that ENDS/ENNDS are less toxic than cigarette smoke. However, ENDS/ENNDS are unlikely 43 to be harmless, and long-term use is expected to increase the risk of chronic obstructive 44 pulmonary disease, lung cancer, and possibly cardiovascular disease as well as some other 45 diseases also associated with smoking. The magnitude of these risks is likely to be smaller 46 than from tobacco smoke although there is not enough research to quantify the relative risk 47 of ENDS/ENNDS over combustible products". 48 49 Based on the exposure assessment (Section 6.5.2), the hazard identification (Section 50 6.5.3), the human health impacts (Section 6.5.4) and the risk assessment (Section 6.5.5), 51 and taking into account the moderate to strong weight of evidence for the exposure 52 assessment for users of electronic cigarettes, the SCHEER concludes for exposure of 53 electronic cigarette users that: 54 55 - The overall weight of evidence is moderate for risk of local irritative damage to the 56 respiratory tract of electronic cigarette users due to the cumulative exposure to 57 polyols, aldehydes and nicotine. The lines of evidence are the following SCHEER Preliminary Opinion on electronic cigarettes</p>	<p>harm exhibited by e-cigarettes as opposed to traditional cigarettes. There is strong evidence from a number of studies that e-cigarettes are less harmful by a large degree than traditional cigarettes.</p>
<p>6.6 Role in the initiation of smoking</p>	<p>PAGE 64, Line 34: "Flavours" -</p>	<p>PAGE 64 - Flavours play a key role in helping smokers quit. Legislation on vaping flavors must take this fact into account. Survey results</p>

<p>(particularly focusing on young people)</p>	<p>Page 65-66, lines 52-57, 1-2: “According to the EHN, the fact that people, and particularly young people who have never 53 smoked, are increasingly taking up electronic cigarette use deserves much attention as they 54 are at substantial risk of becoming regular cigarette smokers. Moreover, it was 55 recommended (1) that flavours should be prohibited, mainly because they are likely to 56 attract children and young people (2) the same regulations as for conventional cigarettes 57 should be set for electronic cigarettes (i.e. regarding marketing, advertising, labelling and 1 packaging, buying restrictions, age limits and the use of electronic cigarettes in public 2 places, which should be prohibited).”</p> <p>Page 67, LINES 11-24: “Role as a gateway product or renormalisation of traditional tobacco smoking 12 One of the four core purposes of this scientific opinion is to assist the Commission in 13 assessing the most recent scientific and technical information on electronic cigarettes with 14 regards to their role as a gateway to smoking and with respect to the initiation of smoking 15 particularly focusing</p>	<p>from the longitudinal survey study from Yale School of Public Health found that “relative to vaping tobacco flavors, vaping non tobacco-flavored e-cigarettes was not associated with increased youth smoking initiation but was associated with an increase in the odds of adult smoking cessation”.</p> <p>A study from Yale School of Public Health discovered that fruity and sweet flavours are over twice as likely to help smokers quit cigarettes.</p> <p>Page 65, lines 55-57, Page 66, Lines 1-2 We agree with the report that age limits and buying restrictions for adolescents are necessary. Minors should not be allowed to purchase vaping products, and so it is important to create and sustain the conditions under which there is no incentive for them to look for e-cigarettes elsewhere. Vaping regulations should be smart and ensure the necessary age restrictions are put in place. Reducing black market activities and illicit trade are vital to reducing underage vaping. However, the recommendation to ban flavours will create more harm than doing any good whatsoever. Banning flavours would have a profoundly negative effect on society, pushing smokers back to cigarettes or to the black market, which has happened in, for example, some states in the United States who have implemented such bans, as shown in this report.</p> <p>Gateway hypothesis: see comments above.</p> <p>Page 67, LINES 11-24: Renormalization hypothesis: the statement seems to overlook the true essence of addiction. In the average dosage in vaping or smoking, nicotine mimics some of the effects of an endogenous substance (acetylcholine) and thereby activates nerve cells in the brain and in the autonomic nervous system. Professor Bernd Mayer (toxicologist at the University of Graz) explains that “the effect as a nerve poison, the blockage of the function of nerve cells, only occurs in the event of a massive overdose, which is not achieved with inhalation. The addiction to</p>
--	--	--

	<p>on young people. Within this context there are two hypotheses that 16 need to be tested, the gateway hypothesis (in which the use of electronic cigarettes lead 17 never tobacco users to begin using other tobacco products) (Bunnell et al., 2014; Kandel 18 and Kandel 2014) and the renormalisation hypothesis (in which the public acceptance of 19 electronic cigarette use may lead to a renormalization of tobacco use. (Fairchild et al., 20 2014)). Indeed, with adult and adolescent smoking rates decreasing due to tobacco control 21 efforts, there remains concern if the expansion of electronic cigarettes may hinder tobacco 22 control efforts and impact smoking rates as adolescents and young adults who were likely 23 to never use any form of nicotine products start experimenting with electronic cigarettes 24 and other forms of nicotine delivery. “</p>	<p>smokers is based on a combination of nicotine and other ingredients of tobacco smoke together with conditioned behaviour [the so-called ‘smoking ritual’].” In the absence of tobacco smoke, the potential for addiction to nicotine is very low, so that most vapers feel much less addictive pressure than smokers.</p> <p>Moreover, The 2018 U.S. National Academies of Sciences, Engineering, and Medicine Report found that the smoking rate has decreased overall more rapidly since vaping became more prominent in the United States. The researchers concluded: “The inverse relationship between vaping and smoking was robust across different data sets for both youth and young adults and for current and more established smoking.</p>
<p>6.7 Role of electronic cigarettes in the cessation of traditional tobacco smoke and dual use</p>	<p>PAGE 71, LINES 19-27: “Taking the above RCTs into account and the information available through systematic 20 reviews that have synthesized the observational literature on the impact of electronic 21 cigarette use the most recent 2020 Surgeon general’s report on Smoking Cessation 22 (Surgeon General 2020) concluded that “The evidence is inadequate to infer that e23 cigarettes, in general, increase smoking cessation”. Moreover the report also concluded that 24 “the evidence is suggestive but not sufficient to infer that the use of e-cigarettes containing 25 nicotine is associated with increased smoking cessation compared with the use of e26 cigarettes not containing nicotine, and the evidence is suggestive but not sufficient to infer 27 that more frequent use of e-cigarettes is</p>	<p>PAGE 71, LINES 19-27: The claim that non-smokers would get introduced en masse to smoking due to vaping seems not to be supported by data from the newest Action on Smoking and Health (ASH) UK report. It states that “only 0.3% of never-smokers are current vapers (amounting to 2.9% of vapers), down from 0.8% in 2019”.</p> <p>A study conducted by the University College London in 2019 analysed data from over 50,000 smokers from 2006 to 2017 and found that using e-cigarettes in order to quit was positively associated with the quit success rates, with every 1 per cent rise in use of e-cigs associated with a 0.06% increase in the quit success rate.</p> <p>An evidence review from Public Health England found that “e-cigarettes could be contributing to at least 20,000 successful new quits per year and possibly many more, e-cigarette use is associated with improved quit success rates over the last year and an accelerated drop in smoking rates across the country, many thousands of smokers incorrectly believe that vaping is as harmful as smoking; around 40% of smokers have not even tried an e-cigarette.</p>

	<p>associated with increased smoking cessation 28 compared with less frequent use of e-cigarettes.”</p> <p>PAGE 71: LINES 30-34: “In addition, the European Heart Network reported that there is not sufficient evidence until 31 now that electronic cigarettes’ use is an effective mean for smoking cessation. 32 33 There is a lack of robust longitudinal data on the effect of electronic cigarettes on smoking 34 cessation.”</p>	<p>Also, the French Federation on Addiction (FFA) published an official report recognising that e-cigarettes are “a complementary tool in reducing risks which has enabled a large number of smokers to significantly reduce the negative effects of tobacco”.</p> <p>Another systematic review and meta-analyses assessed the findings of six studies, involving 7,551 participants, which reported smoking cessation after using e-cigarettes found that the use of e-cigarettes is associated with smoking cessation and reduction.</p> <p>To add to this point, a Cancer Research UK-funded study by University College London, UK found that vapour products users are 95% more likely to be successful at quitting smoking than those who do not use vapour products.</p> <p>On robust longitudinal data on cessation, there are studies to that effect, that the European Heart Network has not taken into account. According to a longitudinal study assessing the behaviour of 844 e-cigarette users over 12 months, the conclusion was that “E-cigarettes may contribute to relapse prevention in former smokers and smoking cessation in current smokers.”</p> <p>PAGE 71: LINES 30-34: See previous sections for evidence on why e-cigarettes an effective cessation tool method for smokers.</p>
--	--	---