Impact assessment

1. Introduction

Tobacco use is the main preventable source of disease and mortality in Norway, and also the main single cause of social health inequalities. The Norwegian Tobacco Control Act has as its objective to contribute to a tobacco-free society.

As an EFTA State, Norway has not yet implemented the Tobacco Products Directive 2014/40/EU (hereafter the TPD), but the Decision of the EEA Joint Committee no. 6/2022 of 4 February 2022, which will make the TPD part of the EEA Agreement, is expected to enter into force in the near future.[1]

In 1989, Norway introduced a general ban on the import and sale of novel tobacco and nicotine products, which also covers electronic cigarettes (e-cigarettes) and refill containers with nicotine. In connection with the ongoing implementation in Norway of the TPD, the general ban was lifted in July 2021 and replaced by an authorisation scheme, largely based on the TPD Article 19. However, as a transitional arrangement, the ban was continued for e-cigarettes and refill containers with nicotine and for waterpipe tobacco. There is however an opening for private import of e-cigarettes and refill containers under certain conditions.

The Norwegian Tobacco Control Act includes a long-term goal for a tobacco-free society. It is also a clear political goal that young people should not use e-cigarettes. A WHO report from 2019 recommends that countries introduce measures to hinder the uptake of e-cigarettes among young people, including regulations such as flavour ban and standardised packaging.[2]

In 2022, only 2 % among young people aged 16–24 years smoke daily. However, the use of tobacco for oral use (hereafter snus) has been increasing since the early 2000s, especially among young people. In 2022, 22 % aged 16–24 years used snus daily.

Due to the current ban on the sale of e-cigarettes and refill containers with nicotine in Norway, only 1 % of the population used e-cigarettes daily in 2019, while 2,5 % used it occasionally. Use among never-smokers was nearly non-existent.

In Denmark, about one in twenty among 15–29 year olds (3.9 %) used e-cigarettes (daily or occasionally) in 2020, and more than one in three (31,6 %) had tried e-cigarettes.[3]

In England, current use of e-cigarettes among 11–18 year olds was 8,6 % in 2022, compared with 4 % in 2021. In comparison, adult prevalence of e-cigarettes use was around 7. [4]

---

[1] Decision of the EEA Joint Committee No 6/2022: https://www.efta.int/sites/default/files/documents/legal-texts/eea/other-legal-documents/adopted-joint-committee-decisions/2022%20-%20English/006-2022.pdf

[2] WHO Report on the Global Tobacco Epidemic, 2019: https://www.who.int/publications/i/item/9789241516204

[3] Bast LS et al, *Use of Tobacco and Nicotine Products among Young People in Denmark-Status in Single and Dual Use.* Int J Environ Res Public Health. 2022 May 5;19(9):5623. https://pubmed.ncbi.nlm.nih.gov/35565011/

[4] Nicotine vaping in England: 2022 evidence update main findings: https://www.gov.uk/government/publications/nicotine-vaping-in-england-2022-evidence-update/nicotine-vaping-in-england-2022-evidence-update-main-findings

The Norwegian government is currently working on a new national tobacco control strategy, where the protection of children and young people from the harms of tobacco and nicotine addiction will be a priority. As part of this work, the Norwegian Ministry of Health is proposing to introduce standardised packaging and a flavour ban for e-cigarettes and refill containers, in order to make them less attractive for children and young people. In addition, a minimum size and weight limit for snus is proposed, based on similar legislation in Sweden. This regulation is meant to make snus less accessible for children and young people.

2. Health risks from the use of e-cigarettes and snus

In 2022, the Norwegian Institute of Public Health published a report on the health effects of e-cigarette use.[5] The conclusions of the report are:

> "*Constituents and exposure of e-cigarette aerosols*
>
> *Several harmful chemicals as well as various metals/trace elements have been identified in e-cigarette aerosols. The large variation in e-cigarette devices and liquids used as well as in vaping patterns make human exposure highly variable and complex. Thus, it is difficult to precisely know or predict the exposure levels of potentially harmful substances.*
>
> *Non-malignant respiratory diseases*
>
> *Systematic reviews indicate that use of e-cigarettes is associated with local irritation of the respiratory tract, increased coughing as well as asthma. Human, animal, and in vitro studies, indicate that e-cigarettes with nicotine may affect biomarkers such as: i) bronchoconstriction, ii) impairing cough reflexes, iii) reducing mucociliary transport, iv) inflammation and v) decreased resistance to bacterial, viral infection. A sustained impact of such parameters on the respiratory system is linked not only to asthma but also chronic obstructive pulmonary disease (COPD). Thus, use of e-cigarettes may represent a risk for development of respiratory disease and increase exacerbation of respiratory diseases.*
>
> *The recent outbreak of serious lung injuries (EVALI), mainly in USA, was mostly associated with use of tetrahydrocannabinol (THC)-containing e-cigarette liquid from informal sources. Cases of EVALI were reported mainly during a period of two years. The presence of vitamin E acetate in the e-liquid has been strongly linked to the EVALI outbreak. Evidence is not sufficient to rule out the contribution of other chemicals of concern. The EVALI outbreak shows how use of new products may confer unpredicted health hazards, and that the device may result in adverse health outcomes as it may be used for inhaling other substances than those originally intended.*
>
> *Cardiovascular diseases*
>
> *The umbrella review shows that human use of e-cigarette and animal exposure to e-cigarette aerosol have reported effects linked to central nerve system (CNS, brain), more specifically activation of the sympathetic nerve axis, as well as effects on oxidative stress and inflammation, endothelial dysfunction, and platelet activation, all representing central pathways associated with increased cardiovascular disease risk. For the naïve tobacco users, use of e-cigarettes may represent an increased risk for development of CVD, and it may contribute to an enhanced risk for more severe adverse outcomes following acute*

[5] Valen, Rune et al. *Adverse health effects of electronic cigarette use: an umbrella review and toxicological evaluation.* Norwegian Institute of Public Health, Oslo, Norway, 2022: https://www.fhi.no/contentassets/5ddc2c84f7d04995bd419344cbc55628/final8-adverse-health-effects-of-electronic-cigarette-use_110522.pdf

cardiovascular events. Our overall evaluation that uses of e-cigarettes may a represent an enhanced risk for CVD is supported by findings related to the use of snus, recent literature, and the current mechanistic understanding of the effects of cigarette constituents on CVD.

Mental disorders

Several studies have shown an association between mental health and increased user prevalence of nicotine containing products. The causal factors underlying the association are unknown. It is possible that common vulnerability (genetic and environmental) is involved. Adolescents with mental problems have been reported to be more likely to start with e-cigarettes, supporting the "self-medication" hypothesis rather than a causal association. On the other hand, the currently reported studies that found e-cigarette use associated with depressive symptoms, indicate that use of e-cigarettes may also affect mental health. Both studies in humans and animal experiments indicate an increased risk of development of addiction and long-term cognitive impairments in adolescence upon nicotine exposure. Effects of nicotine on the developing brain supports that nicotine may affect development of mental problems, such as ADHD, depression, and anxiety. However, it is too early to conclude on causal inference of e-cigarettes and mental disorders.

Adverse pregnancy outcomes and effects on early life health

The information from the systematic review on use of e-cigarettes for pregnancy and early life health outcomes was restricted to uncertain effects on birthweight and being small for gestational age. However, the combined evidence of: i) increased risk of adverse pregnancy outcomes associated with cigarettes as well as smokeless tobacco use ii) in vivo studies showing deleterious effects of nicotine and nicotine containing products on fetal and early life development iii) mechanistic insights substantiating toxic effects of nicotine on the placenta, fetus and early life development, all indicate that use of nicotine containing e-cigarettes constitutes a potential threat to the mother and child.

Non-malignant oral diseases

The umbrella review show that use of e-cigarettes may cause symptoms of oral discomfort and oral mucosal lesions. Although there is scarce evidence from longitudinal studies on the use of e-cigarettes regarding periodontal and peri-implant disease, overall data indicate that there may be an association.

Cancer

The results obtained from the umbrella review alone were insufficient for a conclusion whether use of e-cigarettes constitute a cancer hazard. However, recently important new information relevant for evaluation of potential carcinogenic effects associated with e-cigarette use has been published. E-cigarette aerosol was reported to induce lung adenocarcinomas and bladder urothelial hyperplasia in mice. The authors suggested a role of nicotine in cancer formation by decreased DNA repair activity and increased DNA adduct formation by endogenously formed NNK from nicotine.

Based on results from our umbrella review, the NASEM report and the new information summarized above we conclude: i) There is no available evidence that e-cigarette use is associated with intermediate cancer endpoints in humans from human studies; ii) There are adequate long-term animal bioassays of e-cigarette aerosol exposures to inform cancer risk; there is evidence from in vivo animal studies using intermediate biomarkers of cancer to support the hypothesis that long-term e-cigarette use could increase the risk of cancer; iii) There is evidence that e-cigarette aerosol can be mutagenic or cause DNA damage in humans,

animal models, and human cells in culture, iv) There is substantial evidence that some chemicals present in e-cigarette aerosols (e.g., formaldehyde, acrolein) are capable of causing DNA damage and mutagenesis.

Based on a toxicological evaluation of current literature, we conclude that regularly, long-term use of e-cigarette is likely to represent an enhanced risk for developing cancer. However, the impact on the prevalence of cancer in the general population is unknown.

Poisonings and injuries

E-cigarettes are associated with accidental poisonings, intentional poisonings and traumatic injuries caused by explosions, thermal and chemical injuries due to overheating of lithium batteries. We have no information regarding the frequency of such accidents.

Relevance of exposure levels following e-cigarette use and association to disease

The presence of hazardous constituents in e-cigarette aerosols does not necessarily confer an elevated risk for disease development and/or exacerbations. The outcome will depend on factors such as the level of hazardous constituents, age of initiation and quantity of exposure (frequency, duration, and years of exposure) as well as individual variations in susceptibility. The results from the present umbrella-review as well as information from international reports and recent literature on e-cigarettes and other nicotine products, implies that it is likely that the levels of inhaled nicotine and other components from e-cigarette use may enhance the risk for adverse health effects.

Conclusion

The main health concern linked to use of e-cigarettes arises from inhalation of harmful constituents in e-cigarette aerosol produced from the e-liquid. The composition of the aerosol varies due to device characteristics, e.g., temperature during aerosolization of e-liquid, substances released from the device/heating element as well as variation in e-liquid contents. E-cigarettes should not be considered a homogeneous product group.

E-cigarettes were introduced to the market without adequate animal and in vitro studies to clarify the harmful effects that use of e-cigarettes could cause.

There are few high-quality human studies of e-cigarettes and disease, with longitudinal design, long-term exposure, and sufficient exposure characterization and follow-up time.

Based on our umbrella review and toxicological evaluation, we conclude that use of e-cigarettes leads to an increased risk for adverse health effects. The relative risks for these adverse health effects are still uncertain."

A 2021 report from the Scientific Committee on Health and Environmental Risks (SCHEER) concludes as follows:

"The SCHEER concludes that on health effects

a) For users of electronic cigarettes
1. The overall weight of evidence is moderate for risks of local irritative damage to the respiratory tract of users of electronic cigarette due to the cumulative exposure to polyols, aldehydes and nicotine. However, the overall reported incidence is low.
2. The overall weight of evidence for risks of long-term systemic effects on the cardiovascular system is moderate.

3. The overall weight of evidence for risks of carcinogenicity of the respiratory tract due to long-term, cumulative exposure to nitrosamines and due to exposure to acetaldehyde and formaldehyde is weak to moderate. The weight of evidence for risks of adverse effects, specifically carcinogenicity, due to metals in aerosols is weak.
4. The overall weight of evidence for risks of other long-term adverse health effects, such as pulmonary disease CNS and reprotoxic effects based on the hazard identification and human evidence, is weak, and further consistent data are needed.
5. To date, there is no specific data that specific flavourings used in the EU pose health risks for electronic cigarette users following repeated exposure.
6. The overall weight of evidence for risks of poisoning and injuries due to burns and explosion, is strong. However, the incidence is low.

b) For second-hand exposed persons
1. The overall weight of evidence is moderate for risks of local irritative damage to the respiratory tract mainly due to exposure to glycols.
2. The overall weight of evidence for risks of systemic cardiovascular effects in second-hand exposed persons due to exposure to nicotine is weak to moderate.
3. The overall weight of evidence for carcinogenic risk due to cumulative exposure to nitrosamines is weak to moderate.

Electronic cigarettes are relatively new in terms of exposure to humans. More research is needed, in particular on long-term health effects.

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 moderate evidence that electronic cigarettes are a gateway to smoking for young people. There is 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.

Regarding the role of electronic cigarettes in cessation of traditional tobacco smoking, the SCHEER concludes that there is weak evidence for the support of electronic cigarettes' effectiveness in helping smokers to quit while the evidence on smoking reduction is assessed as weak to moderate." [6]

As for the role of e-cigarettes in smoking cessation, the US Surgeon General in 2020 concludes:

"E-cigarettes, a continually changing and heterogeneous group of products, are used in a variety of ways. Consequently, it is difficult to make generalizations about efficacy for cessation based on clinical trials involving a particular e-cigarette, and there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation." [7]

WHO concludes as follows on the health risks of e-cigarettes:

"Electronic cigarettes (or e-cigarettes) are the most common form of electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS) but there are

---

[6] Scientific Committee on Health, Environmental and Emerging Risks, *Opinion on electronic cigarettes*, 2021: https://ec.europa.eu/health/sites/default/files/scientific_committees/scheer/docs/scheer_o_017.pdf
[7] U.S. Department of Health and Human Services, *Smoking cessation: a report of the Surgeon General*, 2020: https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf

others, such as e-cigars and e-pipes. ENDS contain varying amounts of nicotine and harmful emissions.

E-cigarette emissions typically contain nicotine and other toxic substances that are harmful to both users, and non-users who are exposed to the aerosols second-hand. Some products claiming to be nicotine-free have been found to contain nicotine.

The consumption of nicotine in children and adolescents has deleterious impacts on brain development, leading to long-term consequences for brain development and potentially leading to learning and anxiety disorders.

Nicotine is highly addictive and some evidence suggest that never-smoker minors who use ENDS can double their chance of starting to smoke tobacco cigarettes later in life.

Evidence reveals that these products are harmful to health and are not safe. However, it is too early to provide a clear answer on the long-term impact of using them or being exposed to them. Some recent studies suggest that ENDS use can increase the risk of heart disease and lung disorders. Nicotine exposure in pregnant women can have similar consequences for the brain development of the fetus.

ENDS use can also expose non-smokers and bystanders to nicotine and other harmful chemicals.

Electronic delivery systems have also been linked to a number of physical injuries, including burns from explosions or malfunctions, when the products are not of the expected standard or are tampered with by users.

Accidental exposure of children to ENDS e-liquids pose serious risks as devices may leak, or children may swallow the poisonous e-liquid." [8]

On the effect of e-cigarettes in smoking cessation, WHO states:

"To date, evidence on the use of ENDS as a cessation aid is inconclusive. In part due to the diversity of ENDS products and the low certainty surrounding many studies, the potential for ENDS to play a role as a population-level tobacco cessation intervention is unclear.

To truly help tobacco users quit and to strengthen global tobacco control, governments need to scale up policies and interventions that we know work. Tried and tested interventions, such as brief advice from health professionals, national toll-free quit lines and cessation interventions delivered via mobile text messaging are recommended. Where economically feasible, governments should also consider promoting nicotine replacement therapies and non-nicotine pharmacotherapies for cessation."

In a report from 2021 on the application of the TPD, the European Commission states:

"The industry presents e-cigarettes as reduced-risk products and claims that they help smokers to quit. However, worrying trends of popularity exist among youths. There is strong evidence that flavours in e-liquids are attractive to youths and adults. Significantly, young people use non-traditional flavours in particular, such as candy and fruit. These flavours strongly influence young people by decreasing harm perception and increasing the will to try. Member States are increasingly banning flavours for e-cigarettes. Views on the actual health effects of e-cigarettes are divided, ranging from harmful to harm-reducing for the individual, compared

[8] WHO, *Tobacco: E-cigarettes*, 2022: https://www.who.int/news-room/questions-and-answers/item/tobacco-e-cigarettes

to conventional tobacco products for smoking. As scientific consensus has yet to be reached, the precautionary principle prevails and the TPD takes a careful approach in regulating these products.

The WHO further concluded that no firm evidence exists on the safety of e-cigarettes, but there is increasing evidence of harm. Also, there is concern over increased indoor use and potential related harm.

To better understand the health effects and the public health dimension of e-cigarettes, the Commission has tasked the Scientific Committee on Health and Environmental Risks (SCHEER) to study the health effects of e-cigarette use, and their role in encouraging people to start or quit smoking. For users of electronic cigarettes, they found moderate weight of evidence for risks of local irritative damage to the respiratory tract and moderate, but a growing level of evidence from human data suggesting that electronic cigarettes have harmful health effects, especially but not limited to the cardiovascular system. More so, they found weak to moderate weight of evidence for risks of carcinogenicity of the respiratory tract due to long-term, cumulative exposure to nitrosamines and due to exposure to acetaldehyde and formaldehyde and concluded that weight of evidence for risk of poisoning and injuries due to burns and explosion is strong. They also found weak to moderate weight of evidence for several risks related to second-hand exposure. Overall, there is moderate evidence that electronic cigarettes are a gateway to smoking for young people and strong evidence that flavours have a relevant contribution for attractiveness of use of electronic cigarette and initiation. On the other hand, there is weak evidence for the support of electronic cigarettes' effectiveness in helping smokers to quit while the evidence on smoking reduction is assessed as weak to moderate.

Conclusions on e-cigarettes and refill containers

E-cigarettes contain nicotine, a toxic substance. The Commission will base its risk management decisions on e-cigarettes on the SCHEER scientific opinion. The SCHEER opinion underlined their health consequences and the important role they play in smoking initiation. This opinion supports the careful and precautionary approach taken so far. However, it should be explored whether some provisions could be further developed or clarified, such as tank size or labelling requirements; use of flavours; use of nicotine-free liquids; and advertising provisions. Insofar as e-cigarettes are smoking cessation aids, their regulation should follow the pharmaceutical legislation." [9]

3. Standardised packaging for e-cigarettes and refill containers

3.1. Current regulations

The WHO Framework Convention on Tobacco Control regulate tobacco packaging and labelling in Article 11 and tobacco advertising in Article 13. The guidelines to these articles both recommend introducing standardised tobacco packs, as such a measure will eliminate the effects of advertising on packaging, increase the effect of health warnings and remove the elements on the pack that give the impression that some products are less harmful than others.

[9] *Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the application of Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products*, 2021, COM(2021) 249; https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021DC0249&from=EN

The TPD contains provisions on, inter alia, the manufacture, presentation, and sale of tobacco products and e-cigarettes. Under the TPD, Member States may choose to set standardisation requirements for tobacco products and thereby go beyond the Directive without violating the principles of the free movement of goods. Reference is made to the TPD preamble recital points 53 and 55 and Article 24(2).

The packaging of e-cigarettes and refill containers mainly falls outside the scope of the TPD, with the exception of ingredients list, health warning and product presentation regulated in Article 20(4)(b).

Norway introduced standardised packaging for cigarettes, snus and RYO tobacco in 2017, cf. previous notification 2015/9009/N and the Norwegian Tobacco Control Act § 30. At that time, the Ministry of Health was given statutory authority to expand the regulation to also cover tobacco accessories and tobacco surrogates (including e-cigarettes and refill containers). This authority has so far not been utilised.

When the TPD enters into force in Norway, the Tobacco Control Act § 34a will regulate the notification scheme for e-cigarettes and refill containers based on TPD Article 20. This will also apply to e-cigarettes and refill containers without nicotine. In § 34a, fourth paragraph, the Ministry is granted statutory authority to adopt regulations on i.a. product quality, safety and design.

The Norwegian Tobacco Control Act § 30a, second paragraph, stipulates that packages for e-cigarettes and refill containers may not include elements or features referred to in TPD Article 13, with the exception of reference to taste or smell. In § 30a third paragraph, e-cigarettes and refill containers without nicotine are exempted from the second paragraph. The provision has not yet entered into force in Norway.

3.2. Main points of the proposal

The Ministry proposes to introduce standardised packaging for e-cigarettes and refill containers, and for the sake of clarity it is proposed to insert an explicit regulation in the Tobacco Control Act, cf. the new sentence in the Tobacco Control Act § 30 first paragraph. It is proposed that the regulation should apply to e-cigarettes and refill containers regardless of nicotine content. This is to ensure that children and young people are not attracted to the product group e-cigarettes as such.

The proposed standardisation means that the products may not have logos or other forms of branding elements on unit packets and any outside packaging, rather they may only have stipulated information such as brand name, product name, manufacturer name, and other statutory elements, including health warnings. Thus, all products will have to have the same colours and the same standard font.

The Tobacco Control Act § 30 first paragraph states that the Ministry of Health lays down detailed rules on the design of the standardisation. Detailed regulations for e-cigarettes and refill containers will be notified at a later stage. The Ministry of Health will be able to lay down rules on, inter alia, colours, shape, appearance, text, material, and labelling as well as potentially

permissible additional product information on the pack. The future regulations will as far as possible be based on the existing Norwegian standardisation rules for tobacco products and the existing regulation of standardisation of e-cigarettes in Denmark and the Netherlands.

Furthermore, the Ministry proposes to amend the Tobacco Control Act § 30a, third paragraph, so that also e-cigarettes and refill containers without nicotine must adhere to the product presentation rules in § 30a, second paragraph.

For e-cigarettes and refill containers without nicotine, which are the only legal products on the Norwegian market today, importers and retailers will be given a transitional period to sell out their inventories.

3.3. Considerations of the Ministry of Health

E-cigarettes and refill containers with nicotine will shortly be entering the Norwegian market. The Ministry is concerned by new knowledge about the health risks connected with the use of e-cigarettes as well as experiences from several countries of increased use of e-cigarettes among children and young people. The Ministry is therefore of the view that it is necessary to make these products less attractive to children and young people, in order to avoid a similar trend for e-cigarettes as we have seen among young people in Norway when it comes to the use of snus.

With the proposal to introduce a standardised format for e-cigarettes and refill containers, regardless of nicotine content, the manufacturers' ability to use the products as branding and advertising will be limited. Standardisation means, inter alia, that the goods do not have logos or other forms of branding elements and have the same colours and the same standard font. The introduction of standardisation is particularly targeted at children and young people, who are more receptible towards advertising through branding elements, characteristics, etc.

Several countries, European as well as globally, have introduced or are introducing standardised tobacco packs, such as Australia, France, Great Britain, New Zealand, Norway, Ireland, Hungary, Slovenia, Uruguay, Canada, Belgium, Georgia, Romania, and Thailand.
A growing body of evidence supports that the measure will have a long-term effect, especially towards children and young people.

A few countries have also started to introduce standardised packs for e-cigarettes, such as Denmark, the Netherlands and Israel.

Denmark adopted standardised packaging for both tobacco products and e-cigarettes in 2020, cf. Act no. 2071 of 21 December 2020 and Bill 61.[10] The Danish Ministry of Health justifies the regulation by saying that children and young people are more sensitive to branding, logos etc. and that standardisation will limit the packaging's advertising effect. The purpose of the standardisation is to avoid that the various brand logos, colours and symbols on the packs are given special characteristics, which could promote their appeal to children and young people or give the wrong impression of the product.

The Netherlands introduced standardised packaging for tobacco products in 2020, and for e-cigarettes in 2022. In the public consultation regarding standardisation of e-cigarettes, the Dutch

[10] Act no. 2071 of 21 December 2020, Denmark: https://www.retsinformation.dk/eli/lta/2020/2071

government argues that standardised packaging will reduce the products' appeal towards young people and increase the awareness of the products' health risks.[11] The measure is meant to protect both young people and adults from nicotine addiction. The Dutch government also states that the use of e-cigarettes among young people is significant and that it is important to hinder young people from addiction to a product which is both harmful to health in itself and also a gateway to tobacco smoking. They also argue that e-cigarette packaging is often designed with attractive bright colours, glitter, embossments and catching slogans. Refill containers are available in all tropical flavours and cheerful colours and packaging designs. These elements make them especially attractive for young people.

As for e-cigarettes' role in smoking cessation, Dutch authorities point out that a substantial proportion of e-cigarette users continue to smoke tobacco products in addition and therefore do not get any harm-reducing effect from e-cigarette use. They state that there is increasing evidence that the use of e-cigarettes in itself is harmful to health and that the dual use of cigarettes and e-cigarettes could be more harmful than the use of only cigarettes or e-cigarettes. They also point to countries such as Australia, Uruguay and Brazil banning the sale of e-cigarettes, on the grounds that the products have no documented effect on smoking cessation. Based on the precautionary principle, the Dutch authorities therefore believe that public health benefits most from limiting the use of e-cigarettes to the group of smokers who really cannot stop smoking with recommended smoking cessation aids.

The Norwegian Ministry of Health is concerned that e-cigarettes should not appeal to children and young people. In the same way that the packaging of tobacco products is not assumed to be of significant importance for adult users' preferences, the Ministry assumes that the packaging and appearance of e-cigarettes are also not of importance for adult smokers' transition to e-cigarettes for harm reduction, cf. Oslo District Court's ruling on petition from Swedish Match for temporary injunction on the standardised packaging legislation relating to snus.[12]

The Norwegian Institute of Public Health in 2018 reviewed the literature on product regulation of tobacco products and e-cigarettes.[13] They concluded that it seems that different designs of the tobacco products themselves and their packaging contribute to erroneous perceptions about how harmful the products are. When it comes to e-cigarettes, there is great variation in design and packaging. Some e-cigarettes are designed with glitter, diamonds, cartoon characters, etc., which can be particularly attractive to young people.

The Danish Health Authority reports that research on standardised packs shows an effect on smokers' thoughts and attempts of smoking cessation as well as the appeal of the cigarette packs, the users' experience of smoking, etc. Standardised tobacco packs, which limit manufacturers' ability to use cigarette packs as advertising, are deemed by the Danish Health Authority to be particularly targeted at young people.[14]

The Danish Health Authority cites a Cochrane Review from 2017, which concludes that standardised cigarette packs affect (especially young people's) attitudes toward cigarettes and that such packs are perceived as less attractive.[15] Based on existing behavioural research, it is

[11] Dutch public consultation, August 2020: https://www.internetconsultatie.nl/standaardverpakkingen
[12] Oslo District Court ruling, 6 November 2017 on temporary injunction, page 32.
[13] Folkehelseinstituttet, *Gjennomgang av forskningslitteratur om tobakksproduktregulering*, 2018.
[14] Danish TRIS notification 2020/228/DK, Bill to amend the Act banning tobacco advertising, etc. the Act on tobacco products, etc. the Act on electronic cigarettes, etc. and various other Acts (Implementation of national action plan against smoking by children and young people), Impact assessment
[15] Cochrane: McNeill et al. *Tobacco packaging design for reducing tobacco use (Review)*. 2017.

expected to lead to a reduction in the proportion that starts smoking, and an increase in the proportion that quits smoking. The Cochrane Review also describes several studies that examine the effect of standardised cigarette packs on smoking prevalence or attempts at smoking cessation. Among others, there is a central study from Australia which estimates that standardised cigarette packs have led to a reduction in smoking prevalence of 0.55 percentage points from December 2012 to September 2015.

The Danish Health Authority also bases its knowledge on a review by Drovandi et al. from 2019, which focuses on young people's experience of standardised cigarette packs and pictorial warnings and concludes that graphic health warnings and standardised tobacco packs appear to increase young people's awareness of the dangers of tobacco use and that standardised packs contribute to an increased awareness among young people as to the health risks from smoking and to reducing the appeal, popularity, and coolness of the packs and smoking.[16] According to the review, it is also well-documented that the tobacco industry's marketing strategies target teenagers and young adults because attracting the next 'generation' of smokers is essential to industry's survival.

The Danish Health Authority also points to the fact that the age of first attempting to smoke a whole cigarette has risen in Australia during the period in which standardised tobacco packs were introduced there, and that young people are extremely sensitive to branding and advertising.

The Ministry is of the opinion that the findings on the effects of standardised cigarette packs are transferable to packaging for e-cigarettes etc. The elements of advertising and branding are the same and the objective of the regulations both for tobacco products and for e-cigarettes is to reduce the attractiveness of the products and thus hinder uptake among young people.

Since Norway is now proposing a ban on flavourings in e-cigarettes etc., regardless of their nicotine content, the same labelling provisions regarding reference to flavourings should apply to e-cigarettes as applies to tobacco products. Furthermore, the Ministry finds it important to as far as possible regulate e-cigarettes and refill containers with and without nicotine in the same way. The Ministry cannot see any reason why e-cigarettes without nicotine should be allowed to have misleading elements or features on their package. The same goes for the other elements regulated by TPD Article 13. Therefore, the Ministry proposes to remove the current exemptions for e-cigarettes and refill containers in the Tobacco Control Act § 30a, cf. TPD Article 13, cf. Article 20 (4)(b)(ii). As a result, all e-cigarettes and refill containers should be subject to the ban in the Tobacco Control Act § 30a, second paragraph, cf. proposed amendments to § 30a, third paragraph, with the exception of reference to nicotine content, cf. § 30a, second paragraph, litra b.

4. Ban on characterising flavours in e-cigarettes etc.

4.1. Current regulations

[16] Drovandi A, Teague PA, Glass B, Malau-Aduli B. *A systematic review of the perceptions of adolescents on graphic health warnings and plain packaging of cigarettes.* Syst Rev. 2019: https://www.ncbi.nlm.nih.gov/pubmed/30654833

The TPD requires a ban on characterizing flavours in cigarettes and RYO tobacco, cf. Article 7(1), cf. Article 7(12). This ban has been implemented in the Norwegian Tobacco Control Act § 32 first paragraph (not yet in force). Characterising flavour is defined in TPD Article 2(25). The TPD also requires a ban on flavourings in any components to cigarettes and RYO tobacco, cf. TPD Article 7(7).

In the TPD preamble point 47, it is stated:

> *"This Directive does not harmonise all aspects of electronic cigarettes or refill containers. For example, the responsibility for adopting rules on flavours remains with the Member States. It could be useful for Member States to consider allowing the placing on the market of flavoured products. In doing so, they should be mindful of the potential attractiveness of such products for young people and non smokers. Any prohibition of such flavoured products would need to be justified and notification thereof submitted in accordance with Directive 98/34/EC of the European Parliament and of the Council."*

The regulation of flavourings in e-cigarettes and refill containers is thus left to the discretion of the Member States. As far as the Ministry is aware, Denmark, Estonia, Finland, Hungary and the Netherlands have introduced total or partial bans on characterising flavours in e-cigarettes and refill containers.

The Finnish ban applies to all flavourings in e-cigarettes and refill containers regardless of nicotine content, except for tobacco flavour. The Finnish ban was introduced in connection with the implementation of the TPD in 2016.

In Denmark, the ban applies to all flavours except tobacco and menthol, and all e-cigarettes and refill containers – with and without nicotine. The ban also applies to separate containers of flavourings intended to be used with e-cigarettes. Also, equipment that is used in connection with e-cigarettes, which makes it possible to alter its taste or smell, is covered by the ban.

The Netherlands has adopted a ban on e-cigarettes and refill containers with flavours except tobacco flavours, with and without nicotine, from 2023.[17] The Dutch regulation is different from the ones in Finland and Denmark as it lists what flavour additives are allowed to be added to the products. The reasoning is that the assessment of whether an aroma is characteristic or not is complicated, unpredictable for the industry and resource intensive for the government. A positive list is however easy to supervise and cases of doubt will be decided by chemical analyses of the fluid.[18] The Dutch flavour ban also applies to components to e-cigarettes. This is to prevent the addition of unauthorised flavouring additives by means of cartridges, separate mouthpieces or other e-cigarette components.

In addition to the flavour ban, the Netherlands has introduced a ban on any reference to flavour on the packaging. Several e-cigarettes have brand names which appeal to young people, such as «OMgin», «have anise day», «unicorn milk» and «bad boy fuel», or names involving the words «party» or «happy».

The United States of America introduced a new regulation in 2020 which in practice bans e-cigarettes with flavourings, except tobacco and menthol. The industry may apply to the US Food and Drug Administration (FDA) for authorisation to market such products if they can document that the product contributes to the protection of public health and does not appeal to young people.

---

[17] Tabaks- en rookwarenregeling: https://wetten.overheid.nl/BWBR0037958/2023-01-01

[18] Dutch public consultation, 2020: https://www.internetconsultatie.nl/smaakjes

According to the FDA, the regulation came as a response to the fact that the use of e-cigarettes among young people has increased substantially in recent years (more than doubled from 2017 to 2019) and is considered an epidemic by the FDA.[19]

4.2. Main points of the proposal

The Ministry proposes a new provision in the Tobacco Control Act § 32a, first paragraph, banning characterising flavours in e-cigarettes and refill containers, with or without nicotine. This means that the products may only have the smell and taste of tobacco.

It is also proposed that the ban should extend to separate containers intended for use with e-cigarettes and refill containers. Flavourings that are not explicitly marketed for use in e-cigarettes, as the case may be, may fall under the ban. Such may be the case where e.g. a flavouring is marketed at a point of sale that sells e-cigarettes, particularly a speciality shop, and where it is deemed that buyers in this context have an understanding that the flavouring can be used in e-cigarettes.

Furthermore, it is proposed that the ban should also apply to equipment and components meant for use in connection with e-cigarettes to alter its taste or smell, cf. § 32a, second paragraph. The proposed provision shall ensure that there are no attempts to circumvent the ban on characterising flavours by means of adding the flavourings to the equipment utilised in conjunction with the e-cigarettes rather than directly into the products or their components. The term 'equipment' shall be understood in a broad sense and may thus include, for example, sachets and the like with a flavour for the products, while 'components' are for instance cartridges, separate mouthpieces etc.

In § 32a, third paragraph, it is proposed that the Ministry is given statutory authority to make exceptions from the ban and set further rules in regulations on limit values for additives or combinations of additives that provide a characterising flavour and a list of permitted flavour additives. The Ministry will at a later stage assess whether the Dutch model of a positive list is more suitable than an assessment of characterising flavour. If so, the Ministry will notify regulations concerning such a regulatory system.

For e-cigarettes and refill containers without nicotine, which are the only legal products on the Norwegian market today, importers and retailers will be given a transitional period to sell out their inventories.

4.3. Considerations of the Ministry of Health

According to the Norwegian Institute of Public Health, flavours are one of the factors which increase young people's interest in e-cigarettes, and that a ban may contribute to less use among youngsters.[20] Other factors are the name and the design of the product.

According to the Danish Health Authority flavours are a leading cause of e-cigarette use among youngsters.[21] Studies show that youngsters perceive e-cigarettes with fruit flavour as less harmful than e-cigarettes with tobacco flavour. They refer to research that shows that young people perceive e-cigarettes with the taste of e.g. fruit, less harmful to health than tobacco

---

[19] FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization*, 2020: https://www.fda.gov/media/133880/download

[20] Folkehelseinstituttet, *Gjennomgang av forskningslitteratur om tobakksproduktregulering*, 2018.

[21] Danish public consultation, 2020: https://hoeringsportalen.dk/Hearing/Details/63671

flavoured e-cigarettes. They derive from this that flavours may affect the initiation of e-cigarette use as they make the products more attractive and easier to use.

National Academies of Sciences, Engineering, and Medicine (NASEM) conclude that the use of e-cigarettes increases the risk of smoking tobacco later in life. One of the studies shows that the risk of taking up smoking tobacco is 3.5 times higher for persons who have tried e-cigarettes than for those who have not.[22]

In its 'Report on the Global Tobacco Epidemic 2019', WHO states that children and young people who have never smoked, but who use e-cigarettes, appear to at least double their risk of starting to smoke cigarettes later in life.

A 2018 Canadian study found that young people who had used e-cigarettes within the last 30 days had an increased risk of having tried to smoke cigarettes, as compared to those who had not used e-cigarettes within the last 30 days.[23]

A 2019 cohort study among approximately 6 000 children and young people in the United States also found an association between the use of e-cigarettes and an increased risk for starting to use cigarettes.[24]

Public Health England states in their 2018 report that non-smokers in the UK who try e-cigarettes are more likely to subsequently try smoking cigarettes than those who have not tried e-cigarettes. However, the report deems it to not be causal and that e-cigarettes do not appear to have a bearing on the decline in tobacco use among young people in the UK.[25]

A systematic review from 2018 looked at e-cigarette users' preferences for, inter alia, different flavourings in different age groups. It appears that flavourings are an important factor for teens in relation to trying e-cigarettes and that teens start their consumption of e-cigarettes with flavoured e-cigarettes, especially sweet flavourings. The study also found that users perceived sweet and fruity flavours as less harmful, while tobacco flavours were perceived as more harmful.[26]

A 2019 report from the Nordic Welfare Centre concludes that flavouring additives are a leading reason behind children and young people trying e-cigarettes. New users particularly prefer sweet flavours such as candy, fruits, chewing gum, and soft drinks. Furthermore, fruit-flavoured e-cigarettes, for example, are perceived as less harmful than tobacco-flavoured e-cigarettes.[27]

Based on experience from other countries where e-cigarettes have been on the market for several years and the use among young people has increased, the Ministry is of the opinion that it is necessary to introduce further restrictions on e-cigarettes and refill containers to make them less attractive for youngsters, before they enter the Norwegian market.

---

[22] National Academies of Sciences, Engineering, and Medicine. *Public health consequences of e-cigarettes.* 2018. Washington DC: The National Academies Press.
[23] S. Aleyan et al. *Risky business: a longitudinal study examining cigarette smoking initiation among susceptible and non-susceptible e-cigarette users in Canada*. BMJ Open 2018.
[24] K.M. Berry et al. *Association of electronic cigarette use with subsequent initiation of tobacco cigarettes in US youths.* JAMA Network Open. 2019.
[25] A. McNeill et al. *Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England.* London: Public Health England.
[26] S. Zare, M. Nemati, Y. Zheng. *A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine, strength, and type.* 2018.
[27] Nordic Welfare Centre. *The significance of flavour additives in the use of moist snuff and e-cigarettes — with a focus on young people and the Nordic region.* 2019.

The Ministry puts special emphasis on the SCHEER report, which concludes that e-cigarettes seem to be a gateway to tobacco smoking and that flavours increase the attractiveness of e-cigarettes for youngsters.

A ban on flavours may also contribute to less risks of nicotine poisoning among toddlers, as tobacco flavoured e-liquids will be less attractive for them to swallow than for instance a strawberry flavoured liquid.

Furthermore, the Ministry takes notice of a report from the Norwegian Institute of Public Health, which states that flavour additives may pose health risks in themselves. Such risks are the same also for e-cigarettes without nicotine.[28]

In summary, the Ministry believes that there is a need to strengthen the regulation of e-cigarettes in order to protect children and young people from future nicotine addiction. This proposal of a flavour ban, in addition to the proposal for standardised e-cigarette packaging, will together ensure that e-cigarettes become far less attractive to children and young people. At the same time, tobacco flavoured e-cigarettes will still be available to adult smokers who wish to switch to e-cigarettes for harm-reduction reasons. The regulation will also, to a greater extent, treat e-cigarettes and tobacco cigarettes equally, as the latter will also be subject to a ban on characterising flavour when the TPD is implemented in Norway.

The Ministry is of the opinion that adult smokers' access to e-cigarettes must be balanced against the need to protect children and young people from these products. In the Ministry's view, the experiences from other countries have shown that e-cigarettes can have great appeal among youth and that there is a need for measures to prevent such a development in Norway. The Ministry emphasizes that the proportion of smokers is decreasing and that e-cigarettes are not a recommended aid for smoking cessation. The Ministry also emphasizes that, according to the Danish Health Authority, flavourings are a leading reason why young people try e-cigarettes, and that young people perceive e-cigarettes with sweet flavours to be less harmful to their health than e-cigarettes with a tobacco flavour. E-cigarettes with a characterising flavour can thus influence consumption patterns and the number of people who start using them. Characterising flavours contribute to making the use of e-cigarettes more attractive. Against this background, the Ministry is particularly concerned that more young people in Norway will start using e-cigarettes and become addicted to nicotine.

The Ministry proposes that e-cigarettes and refill containers without nicotine should be subject to the same flavour ban as e-cigarettes and refill containers with nicotine. As mentioned above, harmful effects from flavourings in themselves will occur regardless of whether the liquid contains nicotine. It is also important to avoid that e-cigarettes without nicotine attract young users and become a gateway to later use of e-cigarettes with nicotine. Such a solution will also ensure the most uniform regulation possible and simplify supervision of the ban.

5. Minimum size for snus

In line with the Tobacco Products Directive 2014/40/EU Article 14, Norway has already introduced legislation requiring that packs of cigarettes must contain no less than 20 cigarettes and packs of RYO tobacco must contain no less than 30 grams, cf. Regulations no. 141 of 6 February 2003 on the contents, labelling and design of tobacco products etc. (hereafter 'Regulations on labelling') § 31. There is no similar regulation for snus.

[28] Folkehelseinstituttet, *Helserisiko ved bruk av e-sigaretter*, 2015: https://www.fhi.no/globalassets/dokumenterfiler/rapporter/2015/helserisiko-ved-bruk-av-e-sigaretter-pdf.pdf

Only Norway and Sweden have an exemption from the EU/EEA wide ban on the sale of snus in TPD Article 17. As a result of this, the regulation of content and design of snus is left to these countries, with the exception of the TPD regulations on health warnings in Article 12 and product presentation in Article 13.

The use of snus has increased dramatically in Norway since the turn of the century, especially among young people. The prevalence of snus use among young people in Norway is high: In 2022, 29 % in the age group 16–24 years used snus daily or occasionally. The Ministry is especially concerned by the high prevalence among young women, which increased from 12 % daily snus use in 2021 to 16 % in 2022 among women 16–24 years old. Among women aged 25–34 years, the prevalence of daily snus use increased from 17 % to 22 %. As we know that many women are not able to quit using snus during pregnancy, and the negative health risks nicotine pose to the foetus, this increase is particularly alarming.

As part of the government's strategy to reduce the snus prevalence among young people, the Ministry proposes to introduce a minimum size for snus boxes, to either 20 portions or 30 grams of loose snus. This proposal complements other measures to curb the use of snus among young people, and young women in particular, such as the upcoming new health warning on the snus package relating to the health risks of snus use during pregnancy.

The tobacco industry has launched smaller snus packs, commonly called "beginner's snus", as these are cheaper and thus more accessible for young people. According to a report from the Norwegian Directorate of Health from 2016, there were 183 different products of snus on the Norwegian market. Among these, 25 were loose snus, while the rest were different types of portion snus; regular, slim, mini etc. Most loose snus products were around 40 grams per pack, while portion snus were around 16 to 22 grams and mini-snus less than 10 grams per pack.

In the Swedish Tobacco Control Act (2018:2088) chapter 5 § 14, there is already a requirement for portion snus to contain at least 20 portions. According to the Swedish bill 2017/18:156, there are sufficient studies and literature reviews from recent years demonstrating health risks connected with snus use, to warn against use of the product.

Norway is aiming for a tobacco free generation and in order to achieve this, it is necessary to hinder the uptake of snus use among young people. The regulation of a minimum size for snus packs is expected to make the product less attractive and accessible for young people.

A pack of snus usually contains 20 portions, but there are packs with as few as 5 portions. The Ministry has based its proposal for a minimum size of 20 portions on the fact that this is already the most common size on the market and that this is already a requirement in Sweden.

The Ministry additionally proposes a minimum weight limit for snus at 15 grams. The Ministry is of the opinion that there are good reasons for reducing the availability of the smallest mini-snus packs. The proposed limit will not affect the most common portion snus packs on the market.

As far as the Ministry is aware, there are no loose snus products on the market with less than 30 grams. The proposal will thus not have any effect in practice today, but the Ministry considers it important to set a minimum limit in case the product development may change in the future.

Based on the above, the Ministry proposes that the proposed minimum limits are inserted into § 31 first paragraph of Regulations on labelling.

6. Economic impact on the public sector and trade and industry

The proposals are expected to contribute to a reduction in children and young people use of e-cigarettes and snus. It is impossible to estimate the impact of the proposal on overall tobacco consumption or sales. The proposals will in the Ministry's view have limited financial and administrative consequences, except for the tobacco and nicotine industry.

In a report from 2010 the Norwegian Directorate of Health calculated that smoking costs society between NOK 8 and 20 billion per year in direct costs, and NOK 80 billion per year if one includes indirect costs (economic valuation of welfare effects).[29] The positive value of a further reduction in smoking was estimated at NOK 2–3 billion per percentage point. Although these sums are based on the smoking prevalence up to the year 2000, and thus must be assumed to decrease as the prevalence of smoking decreases, they give a picture of the enormous socio-economic costs smoking entails.

As e-cigarettes with nicotine are currently prohibited in Norway, the ban on characterising flavours and regulation on standardised packaging will only have practical and financial short-term consequences for today's importers and retailers of e-cigarettes without nicotine. In the long term, there will also be consequences for foreign manufacturers and importers of e-cigarettes to Norway. However, the Ministry believes that the consideration of protecting public health must outweigh the consideration of this industry's earnings.

With regard to the proposal to introduce a minimum size and weight for snus, the Ministry considers that the proposal will not have major consequences for tobacco producers. As the requirement of 20 portions is already in force in Sweden, it must be assumed that most manufacturers have already adapted to such regulation. The minimum weight requirement for portioned snus will mean that a few types of snus, so-called mini-snus, must increase their packaging content by approximately 5 grams. A transitional period will be granted to ensure that producers have time to adjust their production accordingly.

7. Assessment of the proposals' relation to the Tobacco Products Directive

The TPD contains provisions on i.a. the manufacture, presentation and sale of tobacco products and e-cigarettes. The TPD Article 24(1) stipulates that the Member States, as regards matters regulated by the directive, cannot prohibit or restrict tobacco products and related products that meet the directive's requirements. Exceptions to this are included in art. 24(2) for standardisation of tobacco packages and art. 24(3) for prohibition of certain product categories.

The current proposals put forward by the Ministry concern regulations that in the Ministry's view go beyond the scope of the TPD. In the TPD recital point 55, it is stated:

[29] Helsedirektoratet, *Samfunnsøkonomiske kostnader av røyking – En vurdering av metodikk og kostnadenes størrelsesorden*, 2010: https://www.helsebiblioteket.no/samfunnsmedisin-og-folkehelse/helsefremmende-og-forebyggende-tiltak/rapporter/samfunnsokonomiske-konsekvenser-av-royking?lenkedetaljer=vis

"A Member State should remain free to maintain or introduce national laws applying to all products placed on its national market for aspects not regulated by this Directive, provided they are compatible with the TFEU and do not jeopardise the full application of this Directive.(…)"

With regard to the proposed ban on characterising flavours in e-cigarettes, the Ministry points out that the TPD does not contain any regulations on flavourings in e-cigarettes, only for tobacco products, cf. Article 7(1) and Article 20. Furthermore, the TPD recital point 47 states that the Member States are responsible for the regulation of flavourings in e-cigarettes:

"This Directive does not harmonise all aspects of electronic cigarettes or refill containers. For example, the responsibility for adopting rules on flavours remains with the Member States. It could be useful for Member States to consider allowing the placing on the market of flavoured products. In doing so, they should be mindful of the potential attractiveness of such products for young people and non smokers. Any prohibition of such flavoured products would need to be justified and notification thereof submitted in accordance with Directive 98/34/EC of the European Parliament and of the Council."

As far as the Ministry is aware, both Finland, Denmark, Estonia, Hungary and the Netherlands have (partially and fully) introduced bans on characteristic flavours in e-cigarettes and refill containers (both with and without nicotine).

When Denmark notified its proposal for a ban on characteristic flavours in e-cigarettes etc., the European Commission pointed out that Denmark proposed to exempt menthol flavour in addition to tobacco flavour from the ban, and asked Denmark to justify the exception, particularly in light of the fact that the TPD prohibits menthol flavour in tobacco cigarettes and rolling tobacco from 20 May 2020. The Danish authorities replied that this solution is the result of a political agreement and that among young people who use e-cigarettes, the use of menthol flavours is less widespread than the use of candy, soda and fruit flavours.

The Norwegian proposal does not contain any exception for menthol flavouring, and the Commission's comment is thus not relevant to our proposal. However, it is worth noting that in its comment the Commission questioned whether the Danish regulation went far enough, and not the introduction of the flavour ban as such.

In addition, the Ministry would like to emphasize that it appears from the above-mentioned report on the application of the TPD that an increasing number of EU countries are banning characteristic flavours in e-cigarettes, and that the Commission believes that it should be investigated whether this in the future also should be regulated by the TPD.

With regard to the proposal for standardisation of e-cigarette packaging, the Ministry points out that the TPD sets out a number of product requirements for e-cigarettes with nicotine in terms of ingredients, function, ingredient labelling and health warnings, cf. Article 20. The TPD does not apply to e-cigarettes without nicotine. In addition, TPD Art. 13 on product presentation applies to e-cigarettes, with the exception of nicotine labelling and reference to taste. However, there is no regulation of the appearance or design of e-cigarettes, in the same way that there is no such regulation for tobacco products. The TPD Article 24(2) states that the directive does not prevent the Member States from introducing standardised tobacco packaging, as long as it is justified in the interests of public health. There is no corresponding provision for e-cigarette packaging. The Ministry notes that both Denmark and the Netherlands have adopted standardised packaging for e-cigarettes.

As regards the proposal for a minimum size for snus, the Ministry considers that this falls completely outside the scope of the TPD. The Directive stipulates in Article 14 requirements for

shape and minimum sizes for cigarettes and rolling tobacco, but this has not been done for snus. This is probably because the sale of snus is prohibited in the EU, with the exception of Sweden, cf. Article 17.

Finally, the Ministry refers to the TPD recital point 53, where it is made clear that the directive does not fully harmonize the regulation of tobacco products and related products:

> *"Tobacco and related products which comply with this Directive should benefit from the free movement of goods. However, in light of the different degrees of harmonisation achieved by this Directive, the Member States should, under certain conditions, retain the power to impose further requirements in certain respects in order to protect public health. This is the case in relation to the presentation and the packaging, including colours, of tobacco products other than health warnings, for which this Directive provides a first set of basic common rules. Accordingly, Member States could, for example, introduce provisions providing for further standardisation of the packaging of tobacco products, provided that those provisions are compatible with the TFEU, with WTO obligations and do not affect the full application of this Directive."*

The proposed regulations on flavourings in e-cigarettes etc., standardised packaging for e-cigarettes etc. and the minimum size of snus are all matters which the TPD does not harmonize, and where the Member States have the right to introduce national rules. On this basis, the Ministry is of the opinion that the legislative proposals are not in breach of the TPD, but rather must be assessed in accordance with the EEA Agreement Article 11 on restrictions on the free movement of goods and Article 13 which mandates the introduction of restrictions on the free movement of goods provided they are suitable and necessary for public health reasons.

8. Assessment of the proposals' relation to the EEA Agreement Articles 11 and 13

The EEA Agreement in Article 11 sets out a ban on quantitative import restrictions and other measures with equivalent effect. The three proposals constitute product requirements and the Ministry assumes that they are all in principle contrary to the EEA Agreement Article 11. The question is whether the measures are nevertheless legal according to the EEA Agreement Article 13.

Tobacco use and the use of e-cigarettes can lead to serious health risks. The proposals aim to prevent tobacco use and the use of e-cigarettes among children and young people by making the products less attractive and less accessible to them, and the measures are thus justified in the interest of public health. This is a legal consideration according to Article 13.

Although the use of snus and e-cigarettes is less harmful to health than smoking, this does not mean that the health risk is unimportant. This applies in particular to vulnerable groups such as children and young people, people with heart disease and pregnant women. Norway has chosen a very high level of protection for public health, particularly in the tobacco area, and in § 1 of the Tobacco Control Act, a long-term goal is set that Norway will become tobacco-free.

In light of the strong increase in snus use among young people in recent years, and the risk of a similar development when e-cigarettes enter the Norwegian market, the Ministry considers it particularly important to introduce measures to make snus and e-cigarettes less attractive to children and young people.

It is clear case law that it is up to the Member States to determine the level of protection of public health and how this protection is to be achieved.[30] This means that the Member States

[30] C-151/17 *Swedish Match*, para. 54, C-221/10 *Artegodan v. Commission*, para. 99

have a certain margin of discretion, but nevertheless such that this margin of discretion must be safeguarded within the framework of the principle of proportionality. The proportionality test consists of two main elements: Suitability and necessity. In the closer assessment, account must be taken of the fact that the isolated effect of various tobacco control measures is difficult to measure, that the effect will often occur over some time and that the measures are part of a comprehensive package of measures which underpin and reinforce each other.

Assessment of suitability

The Ministry is of the opinion that the proposed measures are suitable for reducing health damage caused by tobacco use and the use of e-cigarettes, particularly by contributing to reduced uptake among young people. The purpose of the proposals is to make tobacco products and e-cigarettes less attractive and accessible to children and young people.

With a ban on characteristic flavours in e-cigarettes and refill containers etc., e-cigarettes will become less attractive to children and young people, and the products will thus not become a gateway to nicotine addiction or later tobacco use. In contrast, adult established smokers who wish to replace tobacco cigarettes with e-cigarettes can still do so. The Ministry is aware that some smokers will also find e-cigarettes less attractive if they only come with a tobacco flavour. However, the Ministry believes that it is more important to protect children and young people from nicotine addiction. The flavour ban could also help to avoid nicotine poisoning in smaller children. As mentioned, the need to protect children and young people is more important than facilitating the transition from tobacco products to e-cigarettes for adult smokers. The Ministry underlines that the use of e-cigarettes also involves health risks, that e-cigarettes are not a recommended aid for quitting smoking and that there are other well-documented methods for quitting smoking that do not have negative health effects.

With the regulation of standardised e-cigarette packs, the advertising effect of these packs will be reduced. Furthermore, the risk that the package design may provide misleading information about health risk will be minimised.

The regulation of the minimum size for snus will make snus less accessible to children and young people. This is particularly important in light of the large proportion of young people who use snus in Norway, particularly with regard to the health risks associated with snus use, especially during pregnancy.

The Ministry assumes that the measures taken together will help to reduce and denormalize tobacco use and the use of e-cigarettes in society, especially when it comes to young people.

The requirement for suitability means that it must be "reasonable to believe that the measure would be able to contribute to protecting human health", cf. case E-16/10 *Philip Morris* para. 83. This applies even if there is some scientific uncertainty about the suitability and necessity of the measure.

The proposed measures are a natural extension of other tobacco prevention measures, such as the display ban, the advertising ban and standardised tobacco packaging, and the current Norwegian ban on e-cigarettes and refill containers with nicotine. The measures are part of a coherent and consistent tobacco policy since the early 1970s. On this basis, the Ministry is of the opinion that the measures meet the suitability requirement according to the EEA Agreement Article 13.

The Ministry has also considered in particular whether the proposals unlawfully discriminate between different product groups, especially when it comes to e-cigarettes. The Ministry proposes that the flavour ban should only apply to e-cigarettes, not to snus. It follows from

established case law from the European Court of Justice (ECJ) that equal conditions should not be treated differently and that different conditions should not be treated equally, unless such differential treatment is objectively justified. In case C-477/14 *Pillbox 38*, the ECJ found that, objectively speaking, e-cigarettes have different characteristics than tobacco products, especially tobacco cigarettes, and that different treatment of these products does not therefore conflict with the principle of equal treatment, cf. para. 35–43. In the Ministry's view, the same assessment applies to snus, so that differential treatment of e-cigarettes in relation to snus does not constitute a breach of the principle of equal treatment.[31]

The Ministry also believes that the fact that a product group is new to the market can in certain cases justify that the product group is treated differently from established products on the market. In case C-210/03 *Swedish Match*, the ECJ found that the EU ban on the sale of snus was not contrary to the principle of equal treatment. The Court justified this by the fact that snus was a new product on the market, and that the product was therefore in a special position that opened up the possibility of treating this product differently from established tobacco products, without this constituting a breach of the principle of equal treatment. [32] Also, in case C-151/17 *Swedish Match*, the ECJ dealt with the EU ban on the sale of snus and concluded that as the sale of snus is still illegal in the EU, snus must still be considered a new product on the EU market. The ECJ considered that the ban is suitable and necessary to achieve the objective of protecting public health.[33] In the Ministry's view, these cases also have transfer value to the special regulation of e-cigarettes, as e-cigarettes with nicotine are currently prohibited from being sold in Norway, and will thus be a completely new product category when the tobacco directive enters into force here. The Ministry considers that the differential treatment of this product category compared to established tobacco products does not conflict with the principle of equal treatment.

As for e-cigarettes and refill containers without nicotine, it is important to as far as possible regulate this product group similarly to e-cigarettes and refill containers with nicotine, to facilitate enforcement, hinder gateway issues and also because flavourings in themselves may be harmful to health.

Assessment of necessity
The next question is whether the measures are necessary to achieve the objectives, or whether they can be achieved just as effectively with less intrusive measures. The decisive factor is whether all the objectives can be reached equally effectively with alternative means.

The Ministry is aware that the proposed measures are particularly intrusive towards manufacturers of e-cigarettes. Such measures will only be necessary to achieve the objectives up to the chosen level of protection. In the assessment, emphasis must be placed on the fact that for several decades Norway has chosen a particularly high level of protection in the tobacco area with extensive tobacco control legislation and other measures. This approach is now being applied to e-cigarettes, which are expected to be on the Norwegian market in the near future. The Ministry is concerned that e-cigarettes may become widespread among young people and become a gateway to nicotine addiction and possibly later tobacco use. It is indicated in the objective of the Tobacco Control Act that the long-term goal of Norwegian tobacco policy is to

[31] Oslo District Court ruling 6 November 2017, page 35.
[32] C-210/03 *Swedish Match*, para. 71. C-434/02 *Arnold André*, para. 69.
[33] C-151/17 *Swedish Match*, para. 26 and 35–63.

achieve a tobacco-free society. The Ministry assumes that the proposals for a ban on characteristic flavours in e-cigarettes, regulation of standardised e-cigarette packaging and a minimum size for snus are important elements in a larger package of measures aimed at reducing and preventing the harmful effects of tobacco use and the use of e-cigarettes. The measures work together and over time and take us one step closer to the goal of a tobacco-free society.

The Ministry is of the opinion that there are no other measures that will have an equivalent effect in relation to all the objectives that justify the proposed measures. Certain countries have introduced less far-reaching flavour bans for e-cigarettes, e.g. excluding menthol flavour. The Ministry notes that the European Commission has been critical of such a less complete ban, as exceptions can make the ban less effective and the regulation less consistent.

When it comes to the regulation of e-cigarettes' packaging, the Ministry has considered less intrusive measures, such as only regulating certain specific elements that must be considered particularly appealing to young people. Based on the public consultation statements received, the Ministry has concluded that only full standardisation will be able to remove the advertising effects of the packaging designs and achieve the objective of making e-cigarettes etc. less attractive to young people.

With regard to the proposal for a minimum size for snus, the Ministry cannot see that there are any alternative measures that would be able to achieve the same objective. The Ministry also points out that parts of this regulation have already been introduced in Sweden, where most of the snus sold in Norway is produced. The measure will thus have limited practical consequences for the industry.

Conclusion

The Ministry concludes that the proposals are not in breach of EEA law. The Ministry believes that these initiatives together will contribute to prevent children and young people from using e-cigarettes and snus.