ROYAL NORWEGIAN MINISTRY
OF HEALTH AND CARE SERVICES

Impact assessment - Prohibition on E-cigarettes and Refill Containers

1 Introduction

In 1989, Norway introduced a general ban on the import, manufacture and sale of novel tobacco and nicotine products. This ban thus automatically applied to nicotine-containing e-cigarettes and refill containers when those came on the European market. In connection with the ongoing implementation in Norway of Tobacco Products Directive 2014/40/EU (hereafter 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 nicotine-containing e-cigarettes and refill containers and for waterpipe tobacco.

The Norwegian Ministry of Health and Care Services now proposes to permanently continue the Norwegian ban on nicotine-containing e-cigarettes and refill containers in Regulations no. 2131 of 17 June 2021 (hereafter Regulations 2021/2131). In the on-going national consultation, the Ministry has invited stakeholders to express their views on whether the prohibition also should include e-cigarettes and refill containers without nicotine. The notification thus includes such an extended prohibition.

As an EFTA State, Norway has not yet implemented the TPD, but the Decision of the EEA Joint Committee no. 6/2022 of 4 February 2022, which makes the TPD part of the EEA Agreement, is expected to enter into force in the near future.

As the TPD is not yet in force in Norway, the ban cannot be notified according to the TPD Article 24(3). However, as we are currently in a transitional period, the assessment below is based on the same assessment criteria as in Article 24(3).

In the following, the Norwegian Ministry of Health and Care Services notifies a continued national prohibition on the import, manufacture and placing on the market of nicotine-containing e-cigarettes and refill containers, and an extension of the ban to also include e-cigarettes and refill containers without nicotine.

In the following, the term “e-cigarettes etc.” is meant to include both e-cigarettes and refill containers.

2 EEA Law

The TPD regulates the manufacture, presentation and sale of tobacco and related products placed on, or intended to be placed on, the internal market.

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An “electronic cigarette” is defined in the TPD Article 2(16) as “a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges”.

A “refill container” is defined as “a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette”. E-cigarettes and refill containers are regulated in the TPD Article 20.

At the outset, Article 24(1) of the TPD stipulates that Member States, with regard to matters regulated by the Directive, may not prohibit or restrict tobacco products and related products that meet the requirements of the Directive. However, Article 24(3) of the TPD permits national provisions prohibiting certain categories of tobacco or related products on the grounds of the “specific situation” in a Member State, provided that such prohibitions are justified, necessary and proportionate to their objective. Furthermore, the national provisions must not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. The reasoning behind this can be found in recital 54 of the Directive:

> *"Moreover, in order to take into account possible future market developments, Member States should also be allowed to prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in the Member State concerned and provided the provisions are justified by the need to protect public health, taking into account the high level of protection achieved through this Directive. Member States should notify such stricter national provisions to the Commission."*

In case C-547/14 *Philip Morris Brands and Others* the Court of Justice clarified how the TPD Article 24 is to be interpreted. The Court held that the TPD is not intended to interfere with the policies of the Member States concerning the lawfulness of tobacco products as such. Furthermore, the Court stated that Article 24(3) concerns an aspect of tobacco regulation that is not covered by the harmonisation measures in the Directive and the Court ruled that 24(3), in conjunction with Article 24(1), should be understood as delimiting the scope of the TPD. Thus, the Directive requires that all tobacco products and related products meeting the requirements set out in the legal act may be freely marketed in the internal market in all cases where the product category is *legal* in the relevant Member State. This entails that the question of whether a product should be categorized as legal or not is not subject to harmonization, and Member States can prohibit product categories under "specific conditions" in accordance with Article 24(3).

In line with this case-law, the Ministry's proposal to prohibit e-cigarettes etc. concerns an aspect not harmonised by the TPD.

As mentioned above, the TPD has not yet come into force in Norway. Nevertheless, the proposed measures have been assessed based on the criteria set out in Article 24 of the Directive. This must be viewed in light of the fact that the Directive is highly likely to come into force soon, and that an assessment under Articles 11 and 13 of the EEA Agreement anyhow to a great extent aligns with the conditions outlined in Article 24 of the Directive.

3 Health risks, prevalence and Norway's level of health protection

3.1 Health risks associated with the use of e-cigarettes

In 2022, the Norwegian Institute of Public Health summarised the health risks associated with the use of e-cigarettes and concluded that such use may increase the risk of respiratory diseases (such as COPD), cardiovascular diseases, oral diseases, birth defects, poisonings and injuries, and possibly cancer and mental disorders.[1] The Institute elaborated on the adverse health effects as follows:

> *"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*

[1] Norwegian Institute of Public Health, *Adverse health effects of electronic cigarette use: an umbrella review and toxicological evaluation*, 2022.

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 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."

In a report from the EU Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) concerning the health risks associated with e-cigarette use, the following conclusion was presented:[2]

«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] SCHEER (Scientific Committee on Health, Environmental and Emerging Risks), *Scientific Opinion on electronic cigarettes*, 16 April 2021

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.»

With regard to the role of e-cigarettes in smoking cessation, the Ministry also refers to the 2020 report on smoking cessation by the U.S. Surgeon General, which concludes as follows:

«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.»[3]

In 2023, the WHO issued a 'Call for action' on e-cigarettes, where they state:[4]

"E-cigarettes with nicotine are highly addictive and are harmful to health. Globally, the market is growing rapidly, with a large diversity of products and attractive flavours, aggressively marketed targeting children and young people. This has driven widespread use of these products among younger children and adolescents with rates exceeding adult use in many countries.

E-cigarettes are often promoted as a less harmful alternative to conventional cigarettes; however, to date, the commercialization (sale, importation, distribution, or manufacture) of e-cigarettes as consumer products has not been proven to have had a net benefit for public health. Instead, alarming evidence on their adverse population health effects is mounting."

Regarding e-cigarettes for smoking cessation, the WHO states:

[3] U.S. Department of Health and Human Services. *Smoking Cessation. A Report of the Surgeon General*. 2020.
[4] WHO, *Electronic cigarettes – Call to action*, 2023

"Cessation strategies should be based on the best available evidence of efficacy, synergistic with other tobacco control measures and subject to monitoring and evaluation. Based on the current evidence, it is not recommended that governments permit sale of e-cigarettes as consumer products in pursuit of a cessation objective. Any government pursuing a smoking cessation strategy utilizing e-cigarettes should control the conditions under which the products are accessed to ensure appropriate clinical conditions and regulate the products as medicines (including requiring marketing authorization as medicines). The decision to pursue a smoking cessation objective, even in such a controlled form, should be made only after considering national circumstances, along with the risk of uptake and after exhausting other proven cessation strategies."

In May 2021, the European Commission presented a report on the application of the Tobacco Products Directive, based on the five years that had passed since the Directive entered into force in the EU.[5] Referring to the above-mentioned SCHEER report, the Commission highlighted the health risks associated with the use of e-cigarettes and the important role e-cigarettes play in smoking initiation. Furthermore, the Commission noted that the SCHEER report supports the precautionary approach that has underpinned the regulation of e-cigarettes. Finally, the Commission emphasised that to the extent e-cigarettes are used as a means of smoking cessation, they should fall under the pharmaceutical legislation.

In a report by the Institute of Medicine (now the National Academy of Medicine) from 2015, it is emphasised that adolescents are particularly vulnerable to the harmful effects of nicotine:

«The parts of the brain most responsible for decision making, impulse control, sensation seeking, and susceptibility to peer pressure continue to develop and change through young adulthood, and adolescent brains are uniquely vulnerable to the effects of nicotine and nicotine addiction.»[6]

Furthermore, the National Academies of Sciences, Engineering, and Medicine documented in a 2018 report that repeated nicotine exposure during adolescence alters brain regions involved in addiction, attention, learning, and memory.[7]

In its 2014 report on the health consequences of smoking, the U.S. Surgeon General stated that the potential long-term cognitive effects of nicotine exposure in this age group are a matter of serious concern.[8] As adolescence and young adulthood constitute a critical period for growth and development, nicotine exposure may have lasting negative effects on brain development. The report emphasises that brain development is not complete until approximately 25 years of age. Furthermore, young people are more susceptible to addiction, and early initiation of tobacco use may lead to more severe health consequences later in life.

[5] 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, COM(2021) 249 final, 2021.
[6] Institute of Medicine, P*ublic Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products*. 2015.
[7] National Academies of Sciences, Engineering, and Medicine. *Public health consequences of e-cigarettes*. 2018.
[8] National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health. *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. 2014.

In recent years, e-cigarette use among young people in the United States has increased drastically and is now the most commonly used tobacco-related product among youth. On its website *Know the Risks*, the U.S. Surgeon General states that this is a matter of concern:

> *«E-cigarette use poses a significant – and avoidable – health risk to young people in the United States. Besides increasing the possibility of addiction and long-term harm to brain development and respiratory health, e-cigarette use is associated with the use of other tobacco products that can do even more damage to the body.»*

In its 2016 report to the Conference of the Parties to the WHO Framework Convention on Tobacco Control, the WHO stated that the aerosol from both nicotine-containing and nicotine-free e-cigarettes typically contains a range of toxic substances that may be harmful to health.[9] These include glycols, aldehydes, volatile organic compounds (VOCs), polycyclic aromatic hydrocarbons (PAHs), tobacco-specific nitrosamines (TSNAs), metals, silicate particles and other elements. Dicarbonyl compounds (glyoxal, methylglyoxal, diacetyl) and hydroxycarbonyl compounds (such as acetol) are also considered to be important constituents of the aerosol.

The levels of toxicants can vary significantly between products, and in some cases exceed those found in tobacco smoke. Several metals – including lead, chromium and nickel – as well as formaldehyde have been detected in the aerosol from certain e-cigarettes at concentrations equal to or higher than those found in conventional cigarette smoke under normal conditions of use.

WHO also refers to a systematic review of the health risks associated with passive exposure to aerosol from both nicotine-containing and nicotine-free e-cigarettes. The review concluded that “the absolute impact of passive exposure to e-cigarette aerosol has the potential to lead to adverse health effects.” Levels of certain metals, such as nickel and chromium, are higher with passive exposure to e-cigarette aerosol than with passive exposure to tobacco smoke. As of today, the extent of the health risks associated with such passive exposure remains empirically unknown.

Regarding nicotine-containing aerosol, WHO notes that although nicotine itself is not classified as a carcinogen, it may act as a “tumour promoter” and appears to be involved in the development of malignant diseases as well as in neurodegeneration.

Children and adolescents are particularly vulnerable to the harmful effects of nicotine. According to a Danish report from 2022 by the Danish Council for Prevention, nicotine affects the brains of children and adolescents to a greater extent than previously assumed.[10] The brain does not fully develop until the age of 25–30, and nicotine use during adolescence negatively impacts brain development in several domains.
In addition to causing addiction, nicotine increases the risk of developing dependence on cigarettes and other substances. Nicotine thus appears to have a so-called “gateway” effect. According to the report, nicotine may also impair cognitive functions such as attention and motivation, the development of self-regulation (e.g. emotional control and

[9] WHO, *Electronic nicotine delivery systems and electronic non-nicotine delivery systems (ENDS/ENNDS),* Appendices to WHO report (FCTC/COP/7/11), 2016.
[10] Vidensråd for Forebyggelse, *Børn og unges nikotinbrug – konsekvenser og forebyggelse*, 2022.

impulsivity), mental health (including anxiety and depression), increase sensitivity to stress, and induce an inflammation-like state in the brain that may interfere with normal brain maturation.

In addition to the negative effects on brain development, the report points out that nicotine use during pregnancy may increase the risk of low birth weight and impaired lung function in the child, as well as preterm birth and stillbirth. The report also concludes that nicotine has harmful effects on the cardiovascular system, and that in the long term, this increases the risk of high blood pressure, heart disease and blood clots. It concludes that childhood and adolescence constitute periods of heightened vulnerability to nicotine addiction, and that these are particularly sensitive periods for lasting damage to brain development.

In a new report from the Nordic Welfare Centre, the health risks associated with the use of tobacco and nicotine products are summarised as follows:[11]

> *«First and foremost, nicotine crosses the blood and brain barrier easily, causing neurological and cognitive impairments to the developing brain. This results in negative effects on the maturation of the brain and thus the development of attention, motivation, self-control, and emotional regulation. Additionally, reverse associations between nicotine and mental health have been found, indicating that nicotine might induce symptoms of anxiety and depression. Nicotine use in adolescence also increases the risk of damage to the oral mucosa and cardiovascular diseases later in life.*
>
> *The addiction to nicotine itself also has a negative impact on the everyday life of adolescents, i.e., feeling stuck in their addiction or experiencing that the joy of everyday activities is conditioned by nicotine use. Also, the use of nicotine at a young age increases the risk of lifelong addiction and experimentation with other, potentially more harmful, substances. This is the so-called gateway effect of nicotine use.*
>
> *Generally, tobacco and nicotine use in youth has a very experimental character, and occasional smoking may turn into daily smoking over time. The use of more than one tobacco or nicotine product or a shift between products is also quite common. Further, experimental use at a young age may predict daily use later in life. Therefore, when it comes to youth, occasional tobacco and nicotine product use gives cause for great concern from a public health preventive perspective.»*

3.2 Prevalence in the use of e-cigarettes in Norway

In 2024, 6% of the population used e-cigarettes, of whom 2% reported daily use, according to Statistics Norway (SSB). E-cigarette use is most prevalent among young people, especially young women aged 16–24 years. In this age group, 17% of women reported regular use, compared to 7% among young men. For young women, this represents almost a doubling in use in just one year, from 9% in 2023.

The survey *Ung i Oslo* from 2023 showed that the use of e-cigarettes among lower and upper secondary school students in Oslo has increased significantly since the previous

[11] Nordic Welfare Centre, *Use of nicotine products among youth in the Nordic and Baltic countries*, 2025.

survey in 2021.[12] While 15% had tried e-cigarettes in 2021, the figure had more than doubled to 31% in 2023. In 2021, 2% of adolescents reported occasional use, whereas in 2023, this figure had risen to 14%. There was also a clear majority of girls reporting occasional use of e-cigarettes.

The *Ungdata* survey from 2024 shows that 30% of lower and upper secondary school students nationwide have tried e-cigarettes – an increase from 16% in 2021.[13] Among these, approximately half report having stopped. Around 6% reported daily or weekly use in 2024, compared to only 2% in 2021. In 2024, 8% reported using e-cigarettes less than weekly, compared to 3% in 2021. The figures show that more girls than boys report regular use. The prevalence increases through lower secondary school, is highest among girls in the first year of upper secondary (Vg1), and declines in older age groups.

Overall, more young people (aged 16–24) use tobacco and nicotine products today than ten years ago, according to Statistics Norway (SSB). As many as 26% of young men smoked daily or occasionally in 2024, compared to 20% in 2014. Among young women (16–24 years), the smoking rate remains at 14% – the same level as in 2014. Regular e-cigarette use among young women has literally skyrocketed – from 1% to 17% over the past nine years. From last year to this year alone, the share nearly doubled.

According to the Norwegian Directorate of Health, recent research shows that changes in the tobacco market over the past decades have led to an increase in dual and multiple use of cigarettes, snus and e-cigarettes among Norwegian youth. Based on data from 2023 there is clear overlap in the use of these products. Three out of four daily smokers also use snus and/or e-cigarettes. Among those who have never smoked, 3% use snus and 5% use e-cigarettes. Multiple use is most common among those who smoke or use e-cigarettes daily, but there is also a certain correlation between the use of snus and e-cigarettes. Studies have further linked multiple product use to increased mental health problems and behavioural issues among adolescents.

In the above-mentioned report by the Nordic Welfare Centre, the use of tobacco and nicotine products among young people in the Nordic region is compared. The Ministry would like to highlight the following figures and analyses from the report:

[12] Bakken, A. *Ung i Oslo 2023. Ungdomsskolen og videregående skole*. NOVA Rapport 6/23. OsloMet. 2023.
[13] Bakken, A. *Ungdata 2024. Nasjonale resultater.* NOVA Rapport 6/24. OsloMet. 2024.

Figure 1. Smoking among youth in the Nordic countries

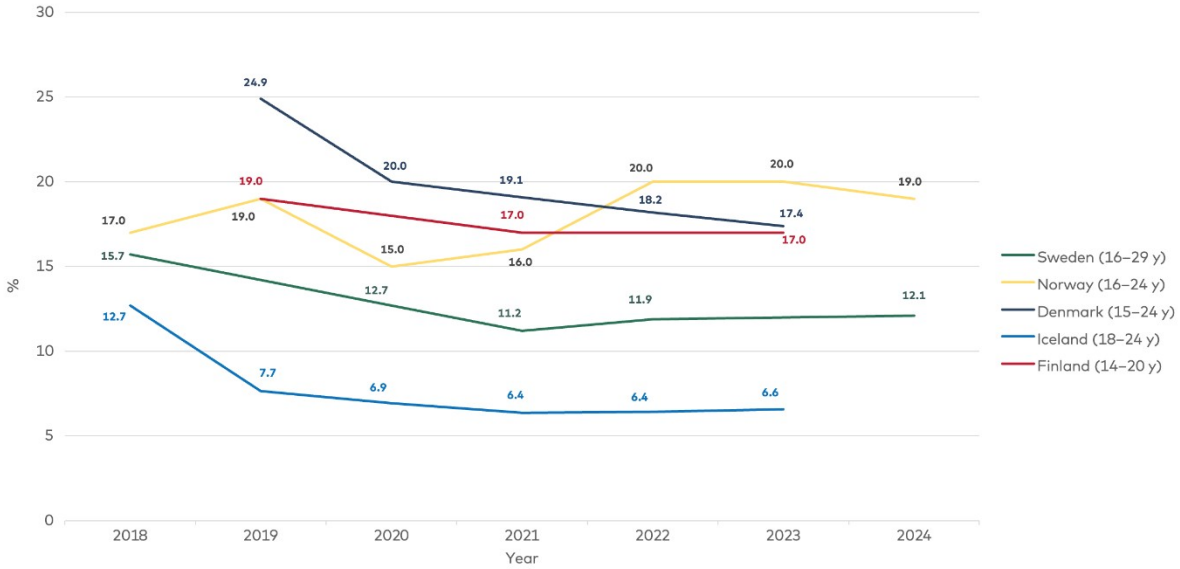

Figure 1 shows the trend in tobacco smoking among youth in the Nordic countries since 2018. With the exception of Norway, all countries experienced a decline in smoking. The most recent figures show that Norway has the highest smoking prevalence among youth, at 19% in 2024, while Iceland has the lowest, at 6.6% in 2023.

Figure 2. Use of e-cigarettes among youth in the Nordic countries

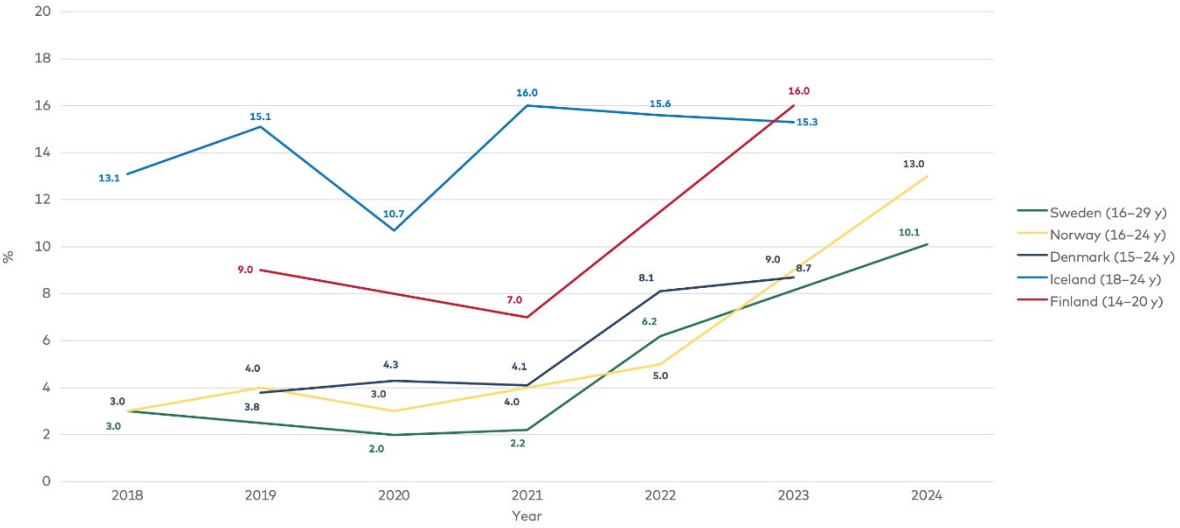

Figure 2 shows the trend in e-cigarette use among youth in the Nordic countries. All countries have seen an increase, particularly since 2021. Iceland stands out with a consistently high level of use throughout the period. The most recent figures (from 2023 and 2024) show that e-cigarette use among youth is highest in Finland at 16% in 2023, and lowest in Denmark at 8.7% in 2023.

Figure 3. Use of e-cigarettes among youth in the Nordic countries, by gender

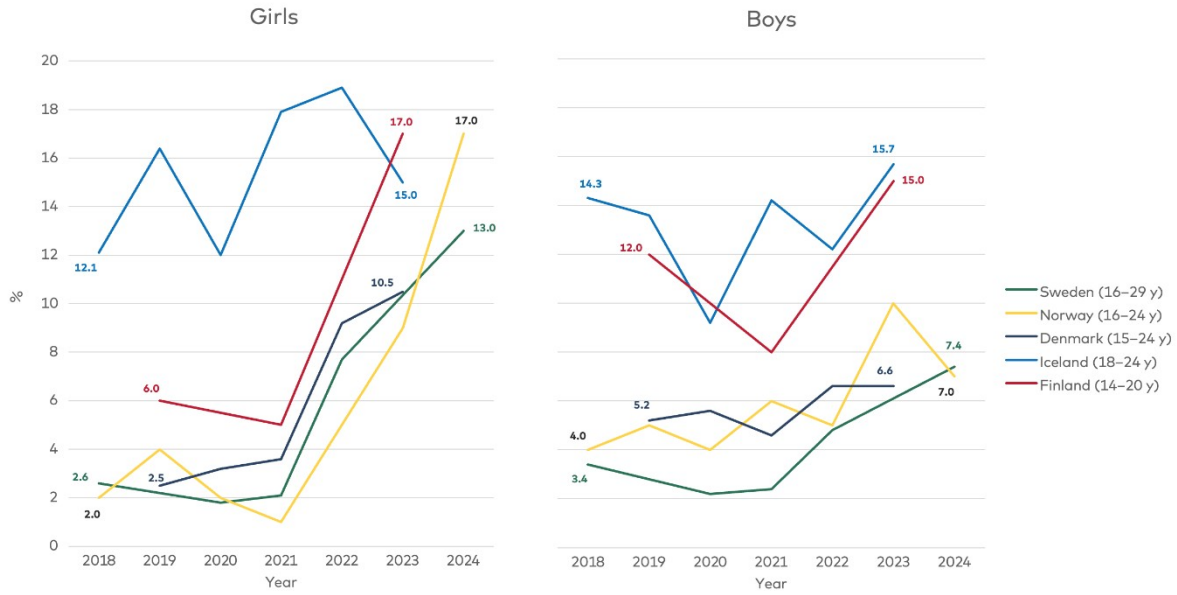

Figure 3 shows the prevalence trends among young girls and boys in the Nordic countries. The increase is significantly greater among girls than boys. In all countries except Iceland, the prevalence is higher among girls – particularly in Norway, with a prevalence of 17% among girls and 7% among boys.

3.3 Norway's level of health protection

As stated by the EFTA Court in Case E-16/10 *Philip Morris* para. 77, the protection of public health is one of the most important interests protected by EEA Law, and it is for the EEA States to decide what degree of protection they wish to assure. Norway has a long history of aiming for a particularly high degree of protection when it comes to tobacco control and has a long-term goal of a tobacco-free society, as outlined in the Tobacco Control Act Section 1.

Furthermore, a main goal of the Government's tobacco control strategy from 2023 is to achieve a tobacco- and nicotine-free generation for those born in 2010 and later, as stated in the White paper on Public Health from 2023.[14]

On this basis, the Ministry considers that it is important to prevent children and young people from being attracted to novel harmful and addictive products. The proposed prohibition aims to reduce the use of tobacco products and related products, especially among young people, and in this way attain the objective of protecting public health at the particularly high level Norway has chosen. The measure is part of a coherent and consistent tobacco policy since the early 1970s.

[14] Meld. St. 15 (2022–2023) *Folkehelsemeldinga – Nasjonal strategi for utjamning av sosiale helseforskjellar*

4 Assessment of Article 24(3) – Nicotine-containing e-cigarettes etc.

4.1 Introduction

Norway initially had a prohibition on the import, manufacture and sale of all novel tobacco and nicotine products from 1989 to 2021.[15] In anticipation of the implementation of the TPD, the general prohibition was in 2021 replaced by an authorization scheme for novel tobacco and nicotine products.[16] The latter is largely based on the TPD Article 19. When the authorization scheme entered into force, the long-standing prohibition was continued for both waterpipe tobacco and nicotine-containing e-cigarettes etc. through a transitional provision in Section 7 of Regulation 2021/2130. The statutory authority for this provision is Section 42 of the Tobacco Control Act, which allows for the introduction of prohibitions on certain product categories, and Section 45, which authorises the Ministry to adopt transitional provisions. This was done as a temporary solution awaiting the entry into force of the TPD Article 20.

The temporary provision has lasted longer than expected due to the delay in the process of the TPD implementation. Due to new knowledge about heath risks of e-cigarettes and the increasing uptake among children and young people, the Ministry now proposes to continue the Norwegian ban on e-cigarettes etc. with nicotine and to extend it to also cover e-cigarettes etc. without nicotine.

4.2 Specific situation in Norway

The first question related to the Article 24(3) assessment is whether there is a "specific situation" that justifies a continued prohibition on e-cigarettes etc. with nicotine in Norway.

The Ministry considers that the current Norwegian prohibition on nicotine-containing e-cigarettes etc., which has in reality existed since 1989, constitutes such a "specific situation". This long-lasting prohibition entails that there has never been any e-cigarettes or refill containers with nicotine available on the Norwegian market.

The Norwegian Tobacco Control Act Section 1 sets out a long-term objective for Norway to become a tobacco-free society, and one of the Government’s main goals in its national tobacco control strategy from 2023 is to achieve a tobacco and nicotine free generation. If the Norwegian ban on nicotine-containing e-cigarettes etc. is not continued, this regulatory change would constitute a liberalisation of the rules governing tobacco and nicotine products in Norway and would directly conflict with the national tobacco control strategy. The Ministry considers that it would be damaging to public health to liberalise the national policy by permitting a product category that has been banned for more than three decades. This would be especially unfortunate today since the use of e-cigarettes among young people are on the rise, in addition to a rise in smoking and snus use among young people.

[15] Repealed Regulation no. 1044 of 13 October 1989 concerning the prohibition against novel tobacco and nicotine products (Regulation 1989/1044).
[16] Regulation no. 2130 of 17 June 2021 concerning the authorization scheme for novel tobacco and nicotine products (Regulation 2021/2130).

Based on the above, the Ministry is of the view that the proposed continued prohibition on nicotine-containing e-cigarettes etc. is based on grounds that relate to the "specific situation" of Norway.

4.3 Justified measure

The next question is whether the proposed continuation of the prohibition on nicotine-containing e-cigarettes etc. is a justified measure to attain the objective of protecting public health, more specifically whether the measure is suitable for reducing or hindering increase in the use of e-cigarettes among children and young people and thus protect them from addiction and the health risks the use of this product poses. This criterion in Article 24(3) corresponds to the suitability test that forms part of the proportionality assessment under Article 13 of the EEA Agreement. The requirement of suitability implies that it must be “reasonable to assume that the measure would be able to contribute to the protection of human health”, cf. Case E-16/10 *Philip Morris*, paragraph 83. This applies even in the presence of some scientific uncertainty regarding the suitability and necessity of the measure. Furthermore, the measure must in fact pursue the objective of protecting public health in a consistent and systematic manner. This means that “...the national legislation as a whole and the various relevant rules are appropriate for ensuring attainment of the objective relied upon only if they genuinely reflect a concern to attain that objective in a consistent and systematic manner...”, as required under the case-law of the Court of Justice, cf. Case C-539/11 Ottica New Line, para. 47.

It is beyond doubt that the use of e-cigarettes with nicotine is addictive and highly harmful to health, particularly for children and young people, cf. Chapter 3 above.

The Ministry is of the opinion that if nicotine-containing e-cigarettes etc. are permitted in Norway, we will likely see a further increase in the use of this product, especially among young people. Continuing the prohibition on nicotine-containing e-cigarettes etc. will, in the Ministry's view, likely reduce or at least prevent an increase in the use of this product among young people in Norway.

The Ministry considers that a continued prohibition is suitable to support the government’s objective of achieving a tobacco and nicotine free generation. Moreover, a continued prohibition will limit access to this product, and in that way reduce the risk of nicotine addiction and dependence, especially among children and youth.

From the Ministry's perspective, a continued ban on nicotine-containing e-cigarettes etc. is especially important in Norway, as illegal nicotine-containing e-cigarettes have become increasingly popular among young people. The Norwegian experience with the oral tobacco “snus” has shown that creative product development from the industry has led to record high prevalence among young people, despite the government’s attempts at hindering this through measures such as high taxes, a strict advertising ban, standardised packaging, health warnings, school campaigns etc.

On this basis, the Ministry is concerned that e-cigarettes with nicotine could easily take further hold on young people in Norway if legalized. In order to prevent nicotine-containing e-cigarettes etc. from gaining further foothold in Norway, the Ministry believes that prohibiting this product category is a suitable measure for preventing such a development.

In conclusion, the Ministry considers that continuing the prohibition on nicotine-containing e-cigarettes etc. is a justified measure to attain the objective of protecting public health, especially for children and young people. The measure will protect these groups by limiting access to the products, thereby reducing the risk of addiction and related health consequences, and dependence and will hinder e-cigarettes with nicotine from becoming an established product in Norway. Furthermore, the measure is part of a consistent and coherent national tobacco and nicotine policy.

4.4 Necessity

The next question is whether the proposed prohibition is *necessary* in order to achieve the objective of protecting public health at the particularly high level of protection chosen by Norway. More specifically, whether the measure is necessary for reducing or hindering increase in the use of tobacco and related products among children and young people and thus protect them from addiction and the health risks the use of these products pose. The necessity test requires an assessment of whether the measure goes beyond what is necessary to attain the legitimate objectives pursued, or if it could be attained by an alternative measure that is equally useful but less restrictive to the fundamental freedoms guaranteed by the EEA Agreement, cf. case E-2/24 *Bygg og Industri AS*, para. 132. This criterion in Article 24(3) corresponds to the same assessment as the necessity test that forms part of the proportionality assessment under Article 13 of the EEA Agreement.

The EFTA Court has ruled that the requirement of necessity entails an assessment of whether the chosen measure is "… functionally needed in order to achieve the legitimate objectives of the legislation at the level of protection chosen by the Contracting Party …".[17] Thus, there cannot exist other, less trade restrictive measures having the effect of fully achieving the objectives at the level of protection chosen.

The health risks associated with the use of nicotine-containing e-cigarettes, as well as the products' appeal to children, are discussed in Chapter 3 above. In continuation of this, the Ministry refers to the following statement from the European Commission in its Implementing Decision of 26 July 2016 concerning national provisions notified by Finland prohibition the placing on the market of certain categories of smokeless tobacco products:

> *"…Moreover, as regards the objective to prevent the formation of addiction and dependence on products that are novel to the Finnish market, it is recalled that nicotine is a particularly addictive toxic substance. Any measure that is less than a preventive measure, such as the proposed prohibition which operates at a stage before dependence*

[17] Case E-3/06 *Ladbrokes*, para. 58.

on such products is established, would be less effective since it is manifestly much more difficult to diminish or cease addiction after dependence has been formed. The addictive nature of tobacco products underscores the entitlement to take timely preventive action in a context where, having regard to the particular predisposition of the population to particular categories of tobacco products, the risk for future widespread use and dependence is particularly acute."

The Ministry considers that the European Commission's view applies correspondingly to the proposed continuation of the Norwegian prohibition on nicotine-containing e-cigarettes etc. This is a measure meant to act *before* dependence develops and is therefore more effective than compensatory measures that may be introduced after the prohibition is lifted.

The Ministry also agrees with the European Commission's emphasis on the fact that the addictive nature of tobacco products justifies early preventive measures. This, of course, also applies to nicotine products, as nicotine is the substance responsible for dependence. Given the significant increase in the use of nicotine-containing e-cigarettes among young people in Norway, the Ministry is of the opinion that there is a real risk of widespread use and increased nicotine dependence in this group if the national prohibition is not upheld. The Ministry further underlines that there is a genuine concern that nicotine-containing e-cigarettes could gain a stronger foothold in the Norwegian market if the product category is permitted, particularly among children and adolescents.

The Ministry has considered whether there are alternative measures that could achieve the objective of protecting public health – particularly children and adolescents – from addiction and health consequences to the same extent as a prohibition. Norway has already introduced or adopted strict measures for e-cigarettes such as a flavour ban, standardised packaging, excise duties, health warnings, point of sale display ban, advertising restrictions and age restrictions. However, this has not been enough to hinder the use of e-cigarettes without nicotine (which are legally sold) among youth in Norway, nor the use of illegal e-cigarettes with nicotine. Experience from other countries with similar measures has shown that such measures are not sufficient to protect children and adolescents once the product is on the market. The Ministry again refers to the European Commission's statement that the most effective measure is a prohibition before addiction occurs. In the Ministry's view, there are thus no less restrictive measures that are equally useful in attaining the objective of protecting children and adolescents under the particularly high level of protection chosen by Norway.

In the view of the Ministry, the proposed continuation of the prohibition on nicotine-containing e-cigarettes etc. is necessary in order to achieve the objective of protecting public health. More specifically, the measure is necessary to reduce or prevent an increase in the use of tobacco and nicotine products among children and young people, thereby protecting them from addiction and the associated health risks. This must be seen in light of the fact that a prohibition on this product category has already been in place for several decades. Accordingly, the Ministry considers that the objective cannot be achieved by means of a less restrictive measure.

The Ministry is in parallell planning to strengthen the enforcement of the current prohibition on e-cigarettes etc. with nicotine, and has already proposed higher penalty levels and more tools for the police. We are also looking into possible ways of strengthening customs controls.

4.5 Arbitrary discrimination or disguised restriction on trade between the Member States

Finally, the proposed prohibition must not be a means of arbitrary discrimination or constitute a disguised restriction on trade between the Member States. The Ministry submits that the continued prohibition will apply to potential domestic and imported products alike. Currently there is no manufacture of e-cigarettes etc. in Norway, and the proposed ban will also include a prohibition on the manufacture of such products.

The Ministry also refers to the fact that EU/EEA law allows Member States to treat new/novel product categories differently from those already placed on the market, without violating the principle of equal treatment – a distinction that is also reflected in Article 19 of the TPD. In Case C-210/03 *Swedish Match*, the Court of Justice found that the specific EU prohibition on the placing on the market of tobacco for oral use was not in breach of the principle of equal treatment. The Court justified this by stating that oral tobacco was a new product on the market and thus in a special position that allowed it to be treated differently from established tobacco products – without this constituting a breach of the principle of equal treatment, cf. Case C-210/03 *Swedish Match*, paragraph 71, and Case C-434/02 *Arnold André*, paragraph 69. The Court also addressed the prohibition on the placing on the market of tobacco for oral use in Case C-151/17, *Swedish Match*, and found that such products, having never been lawfully placed on the market in the Member States concerned, must still be regarded as novel in comparison with other tobacco products. The Court held that the prohibition was both suitable and necessary for achieving the objective of ensuring a high level of public health protection, in particular due to the potential appeal of such products to young people and the associated public health risks, cf. Case C-151/17, *Swedish Matc*h, paragraphs 26 and 35–63. In the Ministry's view, these cases are relevant by analogy to the present matter.

In the Ministry's view, these cases are relevant by analogy to the present matter. As nicotine-containing e-cigarettes etc. has been prohibited in Norway for several decades, this product category – if placed on the market – must be regarded as new to Norwegian consumers, even though it is not "novel" within the meaning of Article 2(14) of the Directive. Accordingly, the Ministry considers that treating this product category differently from established tobacco products does not constitute arbitrary discrimination, and that the continuation of the prohibition on nicotine-containing e-cigarettes etc. is not in breach of the principle of equal treatment. The Ministry further maintains that the proposed continued prohibition does not constitute a disguised restriction on trade between the Member States. To the Ministry's knowledge, there is no domestic production of this product category in Norway, nor will this be allowed in the future.

Based on the above, the Ministry concludes that the proposed continuation of the prohibition of nicotine-containing e-cigarettes etc. does not constitute a means of arbitrary discrimination or a disguised restriction on trade between the Member States.

4.6 Conclusion

The Ministry is of the view that the proposed national provision on continuing the prohibition on nicotine-containing e-cigarettes etc. is based on grounds that relate to the "specific situation" of Norway, and that the measure is justified, necessary and proportionate in order to achieve the objective of protecting public health at the particularly high level of protection chosen by Norway. Furthermore, the Ministry is of the opinion that the proposed measure does not constitute a means of arbitrary discrimination or a disguised restriction on trade between the Member States. On the basis of the considerations set out above and taking account of the objective of ensuring a high level of public health that the TPD is intended to achieve, the national prohibition on nicotine-containing e-cigarettes and refill containers, cf. Articles 2(16) and 2(17), comply with the requirements laid down in Article 24(3) of the Directive.

In summary, the proposed continuation of the prohibition of nicotine-containing e-cigarettes will entail that the use of this product category likely will be maintained on a relatively low level in Norway. The Ministry is particularly concerned with halting the worrying trend of increased use of e-cigarettes among children and young people in Norway. Thus, the Ministry considers that it is crucial to continue the current Norwegian prohibition. The proposed prohibition also aligns with Norway's long history of aiming for a particularly high level of protection when it comes to tobacco control, its long-term goal of a tobacco-free society, cf. the Tobacco Control Act Section 1, and the government’s goal in the national tobacco control strategy of a tobacco- and nicotine-free generation for those born in 2010 and later.

5 Prohibition on e-cigarettes and refill containers without nicotine

5.1 Introduction

In the on-going national consultation, stakeholders are invited to express their views on whether the current prohibition should be extended to also include e-cigarettes without nicotine. There are strong arguments for extending the prohibition to such products.

Since e-cigarettes and refill containers without nicotine are not regulated by the TPD, the assessment must be carried out solely under the general provisions of the EEA Agreement concerning the free movement of goods. As a general rule, the proposed prohibition must be regarded as restriction under Article 11 of the EEA Agreement. The question is whether the restriction may be justified under Article 13 of the EEA Agreement.

5.2 Suitability

The Ministry has considered whether a similar prohibition on e-cigarettes etc. without nicotine as for e-cigarettes etc. containing nicotine, is a suitable measure for achieving the objective of protecting public health.

The Ministry notes that according to the WHO, e-cigarettes without nicotine may also contain several of the same harmful substances as nicotine-containing e-cigarettes, cf. Chapter 3.1 above. Thus, prohibiting this product category would help prevent children and adolescents from being exposed to harmful substances, and thus protect their health. There is also reason to believe that e-cigarettes without nicotine may serve as a gateway to e-cigarettes containing nicotine, and potentially also to other tobacco products, cf. *inter alia* the SCHEER report mentioned in section 3.1 above.

A complete prohibition on e-cigarettes etc, would also result in significantly more effective enforcement by supervisory authorities, particularly the Norwegian Customs, which oversees the import of products into Norway. Experience shows that e-cigarettes are often incorrectly labelled as nicotine-free, despite containing nicotine.

On this basis, the Ministry considers that a potential prohibition on e-cigarettes etc. without nicotine would constitute a suitable measure for achieving the objective of protecting public health, particularly the health of children and adolescents.

5.3 Necessity

The next question is whether a prohibition on e-cigarettes etc. without nicotine is *necessary* in order to achieve the objective of protecting public health at the particularly high level of protection chosen by Norway.

Reference is made to the knowledge base concerning the health risks associated with the use of e-cigarettes both with and without nicotine, as well as the appeal of these products to children and adolescents, cf. Chapter 3 above.

The Ministry has not identified any alternative measures that would be capable of achieving the same objective. As mentioned above, Norway has already introduced a number of measures to prevent the use of e-cigarettes without nicotine among young people, including an age limit, a ban on advertising, a display ban, a flavour ban, etc. In addition, requirements for standardised packaging of e-cigarettes are currently being introduced. In all of these regulations, Norway has chosen to treat e-cigarettes etc. with and without nicotine equally. As explained by the Ministry in the bill *Prop. 125 L (2022–2023)* on stricter regulation of e-cigarettes (i.e. flavour ban and standardised packaging):

> *"The Ministry also seeks to prevent e-cigarettes not containing nicotine from attracting young users and thereby serving as a gateway to later use of e-cigarettes containing nicotine or tobacco products, as also highlighted by the Norwegian Directorate of Health in its submission. By including e-cigarettes without nicotine in the scope of the prohibition,*

the regulation of e-cigarettes becomes as consistent as possible, and enforcement of the rules is simplified."

In its consultation response to the aforementioned proposal, the Norwegian Institute of Public Health stated:

"It appears appropriate that the regulation should apply to e-cigarettes and refill containers both with and without nicotine, based on the aim of preventing children and adolescents from being attracted to the product category of e-cigarettes as such."

A final step in protecting the health of children and adolescents from these products appears to be a prohibition. The Ministry also refers to the European Commission's statement that a prohibition is the most effective preventive measure vis-à-vis new user groups such as children and adolescents, cf. chapter 4.2 above. On this basis, the Ministry considers that a prohibition on e-cigarettes etc. without nicotine is necessary to achieve the objective of protecting public health at the particularly high level of protection pursued by Norway.

5.4 Conclusion

The Ministry concludes that a prohibition on e-cigarettes etc. without nicotine is compatible with the rules on the free movement of goods, cf. Article 11 in conjunction with Article 13 of the EEA Agreement.