

Impact assessment

1 Introduction

Tobacco smoking is the leading single cause of illness and premature death in Norway. The use of e-cigarettes also poses risks for serious health damage. Children and young people are particularly vulnerable to the harmful effects of tobacco products and other nicotine products. With this proposal of new regulations on standardised electronic cigarettes and refill containers, the Ministry aims to reduce children's access to e-cigarettes and refill containers.

The Norwegian Tobacco Control Act includes a long-term goal for a tobacco-free society. It is also a goal in the government's tobacco control strategy to achieve a tobacco and nicotine free generation. 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.

In 1989, Norway introduced a general ban on the import and sale of novel tobacco and nicotine products, which also covered 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 on e-cigarettes and refill containers with nicotine was continued. As an EFTA State, Norway has not yet implemented the Tobacco Products Directive 2014/40/EU (hereafter the TPD), but the Directive is expected to enter into force in Norway in the near future.

2 Background

2.1 The National Tobacco Control Strategy

The government's tobacco control strategy, as mentioned above, was included in the White Paper on Public Health presented in March 2023. Based on the long-term goal of a tobacco-free society, the government set the following main objectives in the strategy:

- The percentage of daily smokers and snus users should be under 5% in all age and education groups.
- Children born in 2010 and later shall not use tobacco or nicotine products.
- Everyone who wishes to quit smoking shall be offered free help to do so.
- Access to tobacco and nicotine products shall be significantly reduced to protect children and young people.
- No one shall be affected by passive smoking.
- In line with our international obligations, the tobacco industry shall not be able to influence tobacco policy.

The inclusion of nicotine products is new and a consequence of product development. Nicotine products refer to non-medical nicotine products.

2.2 Health risks from e-cigarette use

In 2021, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) delivered an opinion on electronic cigarettes, with the following conclusion:

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.¹

In 2022, the Norwegian Institute of Public Health published a report where they found that using e-cigarettes may increase the risk of respiratory diseases (such as COPD), cardiovascular diseases, oral diseases, birth defects, poisoning and injuries, as well as possibly cancer and mental health disorders.²

Also in 2022, the Danish Council on Health and Disease Prevention published a report, stating that children and young people are particularly vulnerable to the negative effects of nicotine.³ New studies have shown that nicotine affects the brains of children and young people much more than previously thought. The brain is not fully developed until the age of 25–30, and using nicotine during adolescence negatively affects the development of the brain in several areas. In addition to creating addiction, nicotine increases the risk of becoming dependent on cigarettes and other substances in general. As a consequence, nicotine appears to have a so-called “gateway” effect. Furthermore, nicotine can have harmful effects on cognitive functions such as attention and motivation, self-control development, mental health, increased stress sensitivity, and an

¹ SCHEER (Scientific Committee on Health, Environmental and Emerging Risks), *Scientific Opinion on electronic cigarettes*, 16 April 2021.

https://health.ec.europa.eu/document/download/50b3adac-5451-47c1-8427-ea67e874c970_en

² Norwegian Institute of Public Health. *Adverse health effects of electronic cigarette use: an umbrella review and toxicological evaluation*. Oslo, 2022.

https://www.fhi.no/contentassets/5ddc2c84f7d04995bd419344cbc55628/final8-adverse-health-effects-of-electronic-cigarette-use_110522.pdf

³ The Council on Health and Disease Prevention. *Nicotine use among children and young people – consequences and prevention*, Copenhagen, 2022: 1-96.

https://vidensraad.dk/sites/default/files/node/field_downloads/vff_nicotine_rapport_DIGI_sp_read_01.pdf

inflammatory-like condition in the brain, which may disrupt the brain's maturation process.

2.2 The use of tobacco products and e-cigarettes in Norway

According to Statistics Norway's (SSB) survey on tobacco use in the population (ages 16–74) in 2023, 7% smoked daily and 9% smoked occasionally. Among young people (ages 16–24), only 3% smoked daily, but 17% smoked occasionally. The percentage of daily smokers has been more than halved over the past ten years, but in recent years, there has been a slight increase in the proportion of daily smokers in the younger age groups.

Regarding snus, 20% of the population used snus, of which 16% used it daily. Among adult men, 26% used snus (21% daily), and among adult women, 15% used snus (11% daily). Among young people (ages 16–24), 30% used snus (20% daily). In the 16–24 age group, 30% of young men used snus (22% daily), while among young women, 26% used snus (17% daily). In the 25–34 age group, 38% of men used snus (34% daily), and 27% of women used snus (23% daily).

Despite the Norwegian ban on the sale of nicotine-containing e-cigarettes, data from SSB/Norwegian Institute of Public Health show that the proportion of regular users of e-cigarettes is highest among the youngest (16–24 years) at about 4%, and lowest among the oldest (65–74 years) at about 2%.

In the European School Survey Project on Alcohol and Other Drugs (ESPAD), 10% of Norwegian youth aged 15–16 reported using e-cigarettes in the past 30 days in 2019. This is below the European average (14%), but higher than in, for example, Sweden (6%).

The 2023 Ungdata survey among youth in the capital city, aged 12–19 years, showed that the use of e-cigarettes among pupils in lower and upper secondary schools in Oslo had increased significantly since the previous survey in 2021.⁴ While 15% had tried e-cigarettes in 2021, the number more than doubled to 31% in 2023. In 2021, 2% of the youth reported using e-cigarettes occasionally, while in 2023, 14% reported such use. There was also a clear majority of girls who used e-cigarettes occasionally.

The national youth survey from 2024, showed a similar increase in the use of e-cigarettes; in 2021, 5% among youth used e-cigarettes daily or occasionally, in 2024 the corresponding number was 14%.⁵

⁴ NOVA/OsloMet, *Ung i Oslo 2023*:
<https://oda.oslomet.no/oda-xmlui/bitstream/handle/11250/3065089/NOVA-Rapport-6-2023.pdf?sequence=7&isAllowed=y>

⁵ NOVA/OsloMet, *Ungdata 2024 - Nasjonale resultater*:
https://oda.oslomet.no/oda-xmlui/bitstream/handle/11250/3145138/Ungdata2024_NasjonaleResultater_UU.pdf?sequence=1&isAllowed=y

4 Regulations on standardised e-cigarettes etc.

4.1 Introduction

The Ministry of Health and Care Services presented a bill proposing statutory authority for introducing standardised e-cigarettes and refill containers in 2023, cf. previous notification 2023/9003/N. The bill was adopted by the Parliament in November 2023.

The current proposal includes new regulations on standardised packaging for e-cigarettes and refill containers, both with and without nicotine. Standardised packaging refers to uniform design and labelling of all packages. Standardisation means that the packages will be a single colour, and the application of brand and variant names, as well as producer information, should follow standardised colour, placement, font, and size. Thus, the use of manufacturers' own logos, trademarks, symbols, images, colours, or other forms of package advertising will not be allowed.

The proposal also includes regulations on the colour of e-cigarettes, the design of refill containers, the colour of e-liquid and certain other elements, such as barcodes and packaging material.

4.2 Background

One of the goals of the Norwegian tobacco control policy is to prevent children and young people from using e-cigarettes. Several reports in recent years have highlighted the health risks associated with e-cigarette use, cf. Chapter 2.1 above. Despite the current Norwegian prohibition on nicotine-containing e-cigarettes, there is increasing use of e-cigarettes in Norway among young people, cf. Chapter 2.2 above.

In WHO's 2019 tobacco report, countries are recommended to implement measures to prevent e-cigarette use among young people, including requirements for standardised packaging. The Norwegian Institute of Public Health reviewed the research literature on product regulation of tobacco products and e-cigarettes in 2018. They concluded that variations in the design of tobacco products and their packaging contribute to misconceptions about the harm of these products. Regarding e-cigarettes, there is significant variation in design and packaging. Some e-cigarettes are designed with glitter, diamonds, cartoon characters etc., or as toys – elements that are particularly appealing to young people.

In a "call to action" from 2023, WHO urged national authorities to swiftly implement effective measures to protect children and young people from the health harms of e-cigarettes.⁶ WHO highlights that e-cigarette use among young people has increased, that e-cigarettes do not provide net benefits to public

⁶ WHO, news release 14 December 2023: <https://www.who.int/news/item/14-12-2023-urgent-action-needed-to-protect-children-and-prevent-the-uptake-of-e-cigarettes>

health, and that e-cigarettes are not an effective smoking cessation aid. WHO recommends that countries with a ban on e-cigarettes strengthen monitoring and enforcement of the ban, and that countries that allow e-cigarettes as a consumer product ensure strong regulations to reduce the appeal and health risks of these products, including flavour bans, nicotine content limits, and specific taxes.

4.3 Legal basis

The TPD contains provisions regarding, among other things, the manufacture, presentation, and sale of e-cigarettes and refill containers. However, it does not regulate the appearance or design of e-cigarettes or refill containers.

Furthermore, the Directive does not apply to nicotine-free e-cigarettes. TPD Article 24(1) states that Member States may not, for considerations relating to aspects regulated by the Directive, prohibit or restrict the placing on the market of tobacco or related products which comply with the Directive. Exceptions to this are outlined in Article 24(2) for the standardisation of tobacco packaging, provided that such measures are justified by public health considerations.

Norway currently has a national prohibition on the import and sale of nicotine-containing e-cigarettes and refill containers. This prohibition will be replaced by a new registration scheme when the TPD enters into force in Norway, cf. Section 34a of the Norwegian Tobacco Control Act and Article 20 of the TPD. The registration scheme in Norway will also include nicotine-free e-cigarettes.

Under the Norwegian Tobacco Control Act Section 30, first paragraph, it is currently prohibited to introduce or sell tobacco packaging and tobacco products that do not have a standardised design. The standardisation may apply to colour, shape, appearance, material, and labelling. Detailed provisions on standardisation are set out in Regulations of 6 February 2003 no. 141 on the content, labelling, and design of tobacco products, which specifies that these requirements apply only to cigarettes, roll-your-own tobacco and snus, cf. Section 17 of the regulation.⁷

4.4 Regulations in other countries

Denmark

In 2020, Denmark adopted legislation requiring e-cigarettes and refill containers with and without nicotine to have standardised packaging. The requirement came into force on 1 October 2022. The Danish Ministry of Health justified this regulation by stating that children and young people are more sensitive to branding, logos etc., and that standardisation reduces the advertising effect of packaging.

⁷ Regulations of 6 February 2003 no. 141 on the content, labelling, and design of tobacco products: <https://lovdata.no/dokument/SF/forskrift/2003-02-06-141?q=tobakk>

Under Act No. 426 of 18 May 2016 on electronic cigarettes, Section 9a, sellers in Denmark must ensure that all individual packaging and any outer packaging have a standardised design.⁸

Detailed requirements for standardisation are outlined in the regulations on standardisation of e-cigarettes. These include specifications for colour, packaging elements, and surface design of inner and outer packaging materials for e-cigarettes and refill containers. Additionally, the regulations mandate labelling on packaging, such as health warnings, brand and variant names, barcodes, and batch numbers.

Finland

Finland implemented standardised packaging for tobacco products, e-cigarettes, and refill containers on 1 May 2023. The requirement applies to both nicotine-containing and nicotine-free e-cigarettes.

The Finnish regulations differ from the Danish model by including provisions on the refill containers themselves, such as their shape, colour, and surface design.⁹ Refill containers must be cylindrical with a funnel-shaped nozzle, transparent, colourless, and have a smooth surface. The cap must be transparent, white, or black, with any labels adhering to a standardised colour. Furthermore, Finnish regulations specify that e-liquids must be yellowish or colourless and not stand out in appearance from other e-liquids. This requirement applies only to nicotine-containing e-liquids and aims to prevent the use of colour as a sales-promoting feature.

The Netherlands

The Netherlands introduced standardised tobacco packaging in 2020 and extended the requirement to e-cigarettes and refill containers in 2022. A consultation paper from 2020 justified standardised packaging for e-cigarettes and refill containers by stating that it reduces their appeal to young people and increases awareness of health risks. The measure aims to protect both young people and adults from nicotine addiction.

Dutch authorities highlighted that e-cigarette use is significant among young people and that it is crucial to prevent them from becoming addicted to a product that is harmful and could serve as a gateway to smoking tobacco products. They noted that e-cigarette packaging often features attractive colours, glitter, embossing, and appealing slogans, making these products particularly enticing to young people.

⁸ BEK nr 699 af 19/04/2021 (*Bekendtgørelse om standardisering af elektroniske cigaretter og genopfyldningsbeholdere med og uden nikotin*): <https://www.retsinformation.dk/eli/lta/2021/699>

⁹ Social- och hälsovårdsministeriets förordning om märkning och utformningen i övrigt av tobaksprodukter och relaterade produkter och av deras detaljhandelsförpackningar (591/2016); <https://valvira.fi/sv/tobak/detaljhandelsforpackningar-for-elektroniska-cigaretter>

4.5 The Ministry's assessments and proposals

Section 30 of the Norwegian Tobacco Control Act regarding standardised packaging currently applies only to tobacco products. Parliament has approved extending this provision to include e-cigarettes and refill containers.

The standardisation requirement will apply to e-cigarettes and refill containers with or without nicotine, aiming to prevent children and young people from being attracted to these products. Uniform regulation will also simplify product oversight.

Like the requirement for standardised tobacco product design, the standardisation will apply to imported products and points of sale, including duty-free sales and specialty shops.

According to Section 30, first paragraph, the standardisation may apply to colour, shape, appearance, material, and labelling, including the use of trademarks, logos, and other elements related to brand building. This is not an exhaustive list, meaning that other elements may also be standardised.

The current draft regulations for the standardised design of e-cigarettes and refill containers are based on the existing Norwegian regulations on standardisation for tobacco products, as well as the Danish and Finnish regulations on standardisation of e-cigarettes and refill containers.

4.5.1 Definitions

The draft regulations Section 1 contain several definitions relevant to the standardisation provisions, including definitions of single packaging, brand name, packaging material, outer surfaces, etc.

4.5.2 General Provision on Trademark Requirements and Exceptions

For tobacco products, there is an exemption from the standardisation requirements for the quota of goods that travellers to Norway may legally import duty- and tax-free or in small quantities for personal use as travel goods. The Ministry proposes a similar exemption for e-cigarettes and refill containers, cf. the draft regulations Section 2.

4.5.3 Colour of e-cigarettes and ban on child-attractive design

The Danish and Finnish regulations do not have provisions regulating the colour of the e-cigarette itself. In comparison, tobacco cigarettes must be white, with a possibility of a cork colour on the filter tube.

The Ministry considers it important to regulate the e-cigarette itself. Unlike tobacco products, e-cigarette users rarely keep and carry the packaging in which the product is sold, unlike a cigarette pack or snus box. This particularly applies to refillable e-cigarettes. The Ministry points out that there is considerable variation in the design of e-cigarettes, with many having bright and shiny colours

that are very eye-catching. Some e-cigarettes are also decorated with glitter, diamonds, cartoon characters, and similar elements. For disposable e-cigarettes, the colour often indicates the flavour, e.g., a red colour indicating strawberry flavour. The Ministry considers that the colour of e-cigarettes should be standardised as much as possible. With such regulation, e-cigarettes will appear less appealing to children and young people.

Thus, the Ministry proposes that e-cigarettes should be designed in neutral colours, such as black, silver-gray, white, or matte Pantone 448 C, cf. the draft regulations Section 3.

There is a significant product variation on the global market at present, including e-cigarettes designed as toy figures. There are strong grounds to prohibit such child-friendly designs. Thus, a ban on such design is proposed in the draft regulations Section 3, second sentence. The Ministry invites feedback on whether further requirements should be made for the design of e-cigarettes or associated elements, and what these should be.

4.5.4 Colour and gloss of outer packaging

In connection with the introduction of standardised tobacco products and packaging in Norway, reference was made to consumer surveys from Australia regarding colour choice. The Ministry found it well-documented that the colour Pantone 448 C would help achieve the regulations' objective.

The Ministry believes that the same colour should be used for packaging of e-cigarettes and refill containers, as proposed in the draft regulations Section 4, first paragraph. This will ensure uniform regulation of tobacco and nicotine products. The colour Pantone 448 C will be associated with tobacco products, and in extension, signal that using e-cigarettes also has harmful health effects. Additionally, a uniform regulation of tobacco and nicotine products will simplify the supervision for the authorities. The same colour has also been chosen in Denmark and Finland.

Regarding the inner surfaces of packaging, it is regulated that these should be matte white or matte Pantone 448 C for cigarettes and roll-your-own tobacco. In the Danish regulations, silver-gray is also allowed. The Ministry has, on this basis, included silver-gray in the draft regulations Section 4, second paragraph, for the packaging of e-cigarettes and refill containers.

4.5.5 Colour and shape of refill containers and e-liquid

The Ministry refers to the Finnish regulations on the design and colour of refill containers, including requirements for the colour of e-liquid, and considers that similar requirements should be included in the Norwegian draft regulations.

The Ministry notes that, like the packaging it comes in, the refill container should not attract attention or appear exciting to children and young people. In this

regard, it is noted that there have been cases of nicotine poisoning among small children. With a neutral design of the refill container, young children are less likely to be tempted to drink the contents of the container. By standardising the shape of the refill container, the possibility is also removed for it to stand out among other products. Thus, The Ministry proposes that refill containers should be cylindrical, transparent, and colourless, cf. the draft regulations Section 5. Furthermore, it is proposed that the surface should be smooth and without embossing, and that the lid should be transparent, white, or black. Any labels should be the same colour as the product's packaging.

The Ministry finds that the e-liquid should also be regulated, so that it cannot be artificially coloured, in order to reduce the attractiveness towards children and young people. In the Finnish regulation it is specified that e-liquid can be yellowish or colourless. The Ministry also considers that colour additives or other elements that may alter the e-liquid's character, such as glitter, should be prohibited. See draft regulations Section 6.

4.5.6 Packaging surfaces, packaging material and barcode

Regarding the surfaces of the packages, the regulation proposed is similar to the current regulations for tobacco products, i.e. that both outer and inner packaging surfaces must be flat and smooth without irregular elements, cf. the draft regulations Section 7. However, a corresponding exception is included, as in the Danish regulation, for elements necessary to fold the material.

Regarding packaging material, the proposed regulation is similar to the current regulations for tobacco products and also the Danish e-cigarette regulations, cf. the draft regulations Section 8. The Ministry also proposes similar regulation of tear-off strips as in the Danish regulations, cf. the draft regulations Section 8, second paragraph.

As for the barcode, the Danish regulations require that the code be placed at the bottom or on the side of the package if the package is cube shaped. The Ministry considers it sufficient to regulate that the barcode cannot be placed on the front, as is already regulated for tobacco products, cf. the draft regulations Section 9.

4.5.7 Product ID

Furthermore, it is proposed that outer packages and individual packages containing e-cigarettes and refill containers should bear a product ID (EC-ID), similarly to the Danish regulations, which specifies requirements for font size, font, colour etc, cf. the draft regulations Section 10.

4.5.8 Inserts

The Ministry proposes a similar ban for inserts into the packaging of e-cigarettes and refill containers, as is already regulated for tobacco products, with an exemption for the user manual, cf. the draft regulations Section 11.

4.5.9 Ban on certain packaging elements

Tobacco products are prohibited from using packaging elements that emit sound or smell, and from using packaging elements that change after the sale. A similar ban for e-cigarettes and refill containers is proposed, cf. the draft regulations Section 12.

4.5.10 Material and shape of individual and outer packaging

In the Finnish regulations, it is specified that individual packages for e-cigarettes and refill containers must be cube-shaped and made of cardboard. The Ministry considers that similar requirements should be applied to e-cigarettes and refill containers for the Norwegian market, cf. the draft regulations Section 13. This will ensure uniform design of individual and outer packages.

4.5.11 Labelling of e-cigarettes and packaging

The Norwegian regulations for tobacco products when it comes to brand name and variant name on the packaging, are very similar to the Danish regulations for e-cigarettes. The Ministry proposes similar regulation in the draft regulations Section 14.

The Ministry notes that the Danish regulations specifies that only the letters “a” to “å” and the numbers “0” to “9” can be used. The Ministry proposes using phrasing similar to the Danish regulation to make it clear which characters/symbols can be used for labelling the packaging.

Additionally, the Danish regulation also includes the use of hyphen, apostrophe, and acute accent (accent aigu) symbols. This is not included in the current regulation of standardised tobacco packaging, and the Ministry does not see the need to include these for e-cigarettes and refill containers.

4.5.12 Producer information

Producer information is allowed on tobacco product packaging. A similar provision is proposed in the draft regulations Section 15.

4.5.13 Transition period

Currently, only nicotine-free e-cigarettes and refill containers are allowed for sale in Norway. The Ministry considers that a transition period of one year from the entry into force of the proposed standardisation provisions will give the industry sufficient time to adjust to the new labelling rules, to rework production, and to sell out inventories of products that do not meet the new requirements. The Ministry notes that when the requirements for standardised tobacco products were introduced in Norway on in 2017, a one-year transition period was also set.

As for nicotine-containing e-cigarettes and refill containers, these products are currently illegal to sell in Norway and are thus not on the market. The Ministry therefore see no need for a transition period for these products, cf. the draft regulations Section 16.

4.5.14 Supervision and sanctions

The Norwegian Directorate of Health is responsible for supervising compliance with the Tobacco Control Act and its regulations. Furthermore, the municipalities are responsible for conducting on-site inspections at points of sale.

Regarding sanctions, the supervisory authorities can require corrections and impose coercive fines for violations of the regulations, as stated in the Norwegian Tobacco Control Act Section 36. Furthermore, the municipalities and the Directorate of Health may impose a sales ban on retailers and wholesalers if they find that provisions of the Act have been violated, cf. the Tobacco Control Act Section 36 b. A sales ban may also be imposed on specific products or product batches, as per the second paragraph of the same provision. A provision for imposing violation fees is set out in the Act Section 36 a. This provision has not yet entered into force.

According to the Act Section 43, tobacco substitutes and tobacco equipment that are imported, exported, or produced in violation of the provisions of the Tobacco Control Act or related regulations may be withheld, confiscated, and destroyed. E-cigarettes and refill containers are covered by this provision. Upon importation, it will be the Customs Authority that controls the products.

5 Economic impacts of the of the proposal

From the Ministry's perspective, the proposal regarding standardised design for e-cigarettes and refill containers will have modest economic and administrative consequences. As e-cigarettes with nicotine are currently banned from being imported and sold in Norway, the new standardisation requirements will only have practical significance for current retailers of nicotine-free e-cigarettes. The Ministry has proposed provisions for transition periods to allow businesses time to sell out their stock.

6 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:

“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.”

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 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 Denmark, Finland and the Netherlands have adopted standardised packaging for e-cigarettes.

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 standardised packaging for e-cigarettes etc. is a matter 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 proposal is not in breach of the TPD, but rather must be assessed in accordance with the EEA Agreement Article 11 and Article 13.

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

The EEA Agreement Article 11 sets out a ban on quantitative import restrictions and other measures with equivalent effect. The current proposal constitutes product requirements and the Ministry assumes that it is in principle contrary to the EEA Agreement Article 11. The question is whether the measure is nevertheless legal according to the EEA Agreement Article 13.

The use of e-cigarettes can lead to serious health risks. 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 the government is working towards a goal of a nicotine free generation. The current proposal aims to prevent the use of e-cigarettes among children and young people by making the products less attractive, and the measures are thus justified in the interest of public health. This is a legal consideration according to Article 13.

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 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.¹⁰ This means that the Member States 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 measure is suitable for reducing health damage caused by the use of e-cigarettes, particularly by contributing to

¹⁰ C-151/17 *Swedish Match*, para. 54, C-221/10 *Artogodan v. Commission*, para. 99

reduced uptake among young people. The purpose of the proposal is to make e-cigarettes less attractive to children and young people.

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 Ministry assumes that the measure will help to reduce and denormalize e-cigarette use 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 measure is 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 measure is part of a coherent and consistent tobacco policy since the early 1970s. On this basis, the Ministry is of the opinion that the measure meets the suitability requirement according to the EEA Agreement Article 13.

Assessment of necessity

The next question is whether the measure is 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 measure is 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 achieve a tobacco-free society, and in the government's tobacco control strategy there is a goal of a nicotine-free generation. The Ministry assumes that the

proposed regulations on standardised e-cigarette packaging is an important element 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.

Ministry has considered less intrusive measures, such as only regulating certain specific packaging and product 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 and refill containers less attractive to young people.

Conclusion

The Ministry concludes that the proposal is not in breach of EEA law. The Ministry believes that this initiative will contribute to preventing children and young people from using e-cigarettes.