ROYAL NORWEGIAN MINISTRY
OF HEALTH AND CARE SERVICES

Impact assessment concerning a prohibition on a certain category of tobacco for oral use

1. Introduction

Tobacco products are regulated by the Tobacco Products Directive 2014/40/EU (hereafter the TPD). 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.

Similar to the previous Tobacco Products Directive 2001/37/EC, the TPD Article 17 contains a prohibition on the placing on the market of tobacco for oral use. Sweden and Norway have exemptions from this ban.

In the following, the Norwegian Ministry of Health and Care Services notifies a proposal for a national prohibition on the import, manufacture and placing on the market of a type of smokeless tobacco. The product category at issue is tobacco for oral use other than traditional snus. ‘Snus’ is a term often used to describe tobacco for oral use originating from Sweden, which has been in traditional use in Sweden and Norway since the 19th century. Snus is a smokeless tobacco product in pouches or in loose form to be shaped by the fingers, in which nicotine is absorbed into the bloodstream by placing it under the lip.

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).

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

2.1 Health risks associated with the use of tobacco for oral use

The health risks associated with the use of tobacco products are well known and documented. This applies not only to smoking, but also to smokeless tobacco products. The use of smokeless tobacco products increases the risk of serious health issues, including cancer, type 2 diabetes, the risk of death after a heart attack or stroke, birth defects, and possibly an increased risk of psychosis, weight gain, and obesity.

In 2019, the Norwegian Institute of Public Health published a report on the health risks of snus use.[1] The conclusions were:

[1] Folkehelseinstituttet, *Helserisiko ved snusbruk*, Oslo, 2019.

Postal address	Office address	Telephone	Department	Reference
Postboks 8011 Dep	Teatergt. 9	+47 22 24 90 90	Department of Public Health	Anne Lodding Gabrielsen
0030 Oslo		Org. nr.		
postmottak@hod.dep.no	www.hod.dep.no	983 887 406		+47 22 24 87 94

“There has been an increase in the use of Swedish snus in Norway in recent decades, especially among young adults, and especially among young women during the last decade. The majority of snus users are former smokers, but in the past 15 years there has been an increase in the proportion of snus users without prior smoking experience.

In the period 2016-2018, 33% of men and 40% of women had not smoked before starting snus use. This is an increase from the period 2004-2006, when 23% of men and 12% of women who had used snus had never smoked.

Studies in animals and cells have shown that tobacco-specific nitrosamines are carcinogenic. Nicotine cause a variety of effects that may have adverse health consequences of varying severity.

Research on the health risks associated with use of Swedish snus in humans mainly comes from observational studies. Even with the inherent limitations of such studies, we conclude that systematically summarized research shows that the use of Swedish snus:

• probably increases the risk of cancer of the esophagus and pancreas, and possibly increases the risk of cancer of the stomach and rectum

• possibly increases mortality after a cancer diagnosis (all types of cancer combined, and for prostata cancer specifically), both when the cause of death is considered cancer-related and for all causes

• probably increases the risk of high blood pressure

• probably increases lethality during the weeks after a heart attack or stroke, and may increase the long-term risk of dying after stroke

• may halve the risk of dying among those who stop using snus after a heart attack.

• may increase the risk of non-affective psychosis, weight gain and obesity

• high consumption of Swedish snus probably increases the risk of type 2 diabetes and metabolic syndrome

Women who use Swedish snus during pregnancy have:

• probably increased risk of premature births

• possible increased risk of stillbirths, being small for gestational age, reduced birth weight, cesarean section, neonatal apnea and oral cleft malformations, and levels of nicotine degradation products (cotinine) in the child's urine.

One study found that use of Swedish snus reduced the risk of getting Parkinson's disease. For many other health outcomes, there was too little information to conclude whether snus affects the risk of adverse health outcomes or in which direction.

The new studies have strengthened the conclusions of the report from the Norwegian Institute of Public health 2014 that use of snus increases the risks of some serious adverse health outcomes and some less serious adverse health outcomes."

In an article from 2023, based on a systematic review by the Norwegian Institute of Public Health, the Cancer Registry of Norway and the National Institute of Occupational Health (STAMI), the evidence for cancer risk from snus use was summarized as follows:[2]

"Some of the studies retrieved in this systematic review, reported an increased risk of cancer of the esophagus, pancreas, stomach and rectum as well as cancer-specific death associated with the use of Swedish snus. Our confidence in the various risk estimates varied from moderate to very low. However, precise risk estimates for rare cancers with a moderate risk, are challenging to achieve. Swedish snus contains carcinogenic constituents such as TSNAs, although in lower levels compared with some other smokeless tobacco products. We conclude that use of snus entails a cancer hazard where the magnitude of cancer risk may be affected by user history and the susceptibility of the host."

According to the review, the risk of squamous cell carcinoma of the esophagus is likely more than three times higher in people who regularly use Swedish snus. Squamous cell carcinoma of the esophagus is a relatively rare but serious form of cancer. The risk of pancreatic cancer, which is more common and very serious, is likely twice as high in people who regularly use Swedish snus. The confidence in these two risk estimates was moderate.

The risk of squamous cell carcinoma of the esophagus increased from 16 per 100,000 (among non-users of snus) to 55 per 100,000 (among snus users) in an observational study published in 2008 with 142,891 participants. The risk of pancreatic cancer increased from 72 per 100,000 (non-users) to 151 per 100,000 (users) in an observational study published in 2007 with 122,639 participants. The risk of cancer-related mortality increased from 2,141 per 100,000 (non-users) to 2,395 per 100,000 (users).

Some of the studies included in this systematic review also reported an increased cancer risk in the main part of the stomach and the rectum. The confidence in the risk estimates for these two cancer locations was low.

Based on existing knowledge about the substances in snus, their effects on cells and laboratory animals, and the reviewed human studies in the systematic review, it can be summarized that Swedish snus poses a cancer risk. The magnitude of this risk likely depends on user history (type of snus used, how much and how long it has been used), and susceptibility to cancer development may vary.

Children and adolescents are particularly vulnerable to the harmful effects of nicotine. According to a report from 2022 by the Danish Council for Prevention, nicotine affects the

[2] Valen H, Becher R, Vist GE, et al. *A systematic review of cancer risk among users of smokeless tobacco (Swedish snus) exclusively, compared with no use of tobacco*. Int J Cancer. 2023; 153(12): 1942-1953.

brains of children and adolescents to a greater extent than previously assumed.[3] 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 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:[4]

> *“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] Vidensråd for Forebyggelse, *Børn og unges nikotinbrug – konsekvenser og forebyggelse*, 2022.
[4] Nordic Welfare Centre, *Use of nicotine products among youth in the Nordic and Baltic countries*, 2025.

2.2 Prevalence of snus use in Norway

The use of snus has become increasingly widespread in Norway, particularly among young people. While smoking rates have significantly declined over the years, the use of snus has increased rapidly, reflecting a shift in tobacco consumption habits. According to Statistics Norway, 20% of the population used snus in 2024, 15% daily. While the percentage of smokers has been halved in the last ten years, the proportion of snus users has nearly doubled. Snus use is most prevalent among young men, but the percentage of young women using snus has increased the most over the past decade. Around the year 2000, snus use in Norway was significantly lower, with only about 5 % of the adult population using it daily.

Among men aged 25–34, 37% reported daily use of snus, while 8 % used it occasionally. This means that nearly half (45%) of men in this age group use snus regularly. Among women in the same age group, 22% used snus daily and 8% occasionally.

In the 16–24 age group, 30% used snus, of whom 21% used it daily. Among men in this group, 33% used snus, including 25% daily. Among women, the corresponding figures were 26% using snus, with 16% daily. The statistics indicate an increasing trend in snus use among young people.

Furthermore, the *Ungdata* survey shows that the proportion of students in lower and upper secondary schools who use snus daily or weekly increased from 8 % to 10 % between 2021 and 2024. Snus is more common among boys than girls, and use increases with age. While only 1–2 % of students in 8th grade use snus regularly, this rises to 22 % among boys and 16 % among girls by the end of upper secondary school. After a period of decline in snus use in the 2010s, recent figures suggest that the trend is now reversing.

According to the above-mentioned 2019-report from the Norwegian Institute of Public Health, the snus sold on the Norwegian market in 2015 contained on average more nicotine per gram than the one sold in 2005. At the same time, there is an ever greater variation in portion sizes. This means that the degree of nicotine exposure depends on the type of snus used. Of those who had ever used snus in the period 2016–2018, 33% of men and 40% of women had no previous experience with smoking. This is an increase from the period 2004-2006; then 23% of men and 12% of women who had used snus had not smoked before.

In the above-mentioned 2025-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:

> *“Oral nicotine products*
>
> *The use of oral nicotine products among youth has increased in most Nordic countries since 2018. Oral nicotine products cover both snus and nicotine pouches and, in some cases, also chewing tobacco. Only Norway and Sweden had available data for 2024 by mid-December 2024.”*

Figure 3.1. Oral nicotine product use in the Nordic countries

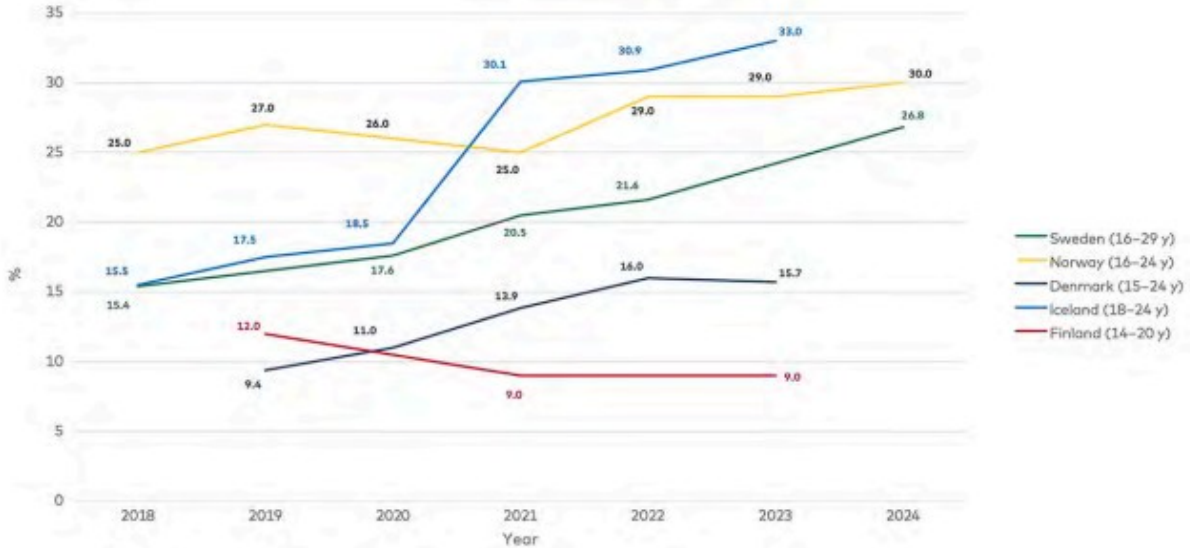

Figure 3.1. presents the development in the use of oral nicotine products among youth in the Nordic countries. All countries, except Finland, experienced an increase in reent years. The most recent prevalences (2023/2024) indicate that the use of oral nicotine products is most prevalent among Icelandic and Norwegian youth (respectively 33% and 30%).

2.3 Norway's level of protection of public health

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 goal of a tobacco-free society in the long term, 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.[5]

On this basis, the Ministry considers that is important to prevent children and young people from being attracted to new harmful and addictive products. The proposed prohibition aims to reduce the use of smokeless tobacco 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.

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

3. EEA Law

3.1 Relevant provisions

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

The TPD Article 17 states:

> *“Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.”*

A ‘smokeless tobacco product’ is defined in the TPD Article 2(5) as a “tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use”.

Furthermore, ‘tobacco for oral use’ is defined in the TPD Article 2(8) as “all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets”.

A ’novel tobacco product’ is defined in Article 2(14) as a tobacco product that has been placed on the market after 19 May 2014, and that does not fall within the categories of "cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use." Thus, these product categories are exempt from the Directive's registration/authorisation requirements.

At the outset, the TPD Article 24(1) stipulates that the 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, the TPD Article 24(3) 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 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 the import, manufacture and placing on the market of tobacco for oral use, except traditional snus, concerns an aspect not harmonised by the TPD.

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

3.2 Norway’s derogation from Article 17 of the TPD

As mentioned above, the TPD Article 17 prohibits the placing on the market of "tobacco for oral use". Such a prohibition had initially been established in 1992 following an amendment introduced by Council Directive 92/41/EEC to Council Directive 89/622/EEC. The prohibition was subsequently re-enacted in Directive 2001/37/EC of the European Parliament and of the Council.

However, Norway and Sweden were granted a derogation from the prohibition, making them the only two EU/EEA Member States in which the placing on the market of this product category is permitted. The derogation was given because a type of tobacco for oral use, “Swedish snus”, was regarded as a tradition-bound product in both Norway and Sweden. Historically, the snus traditionally used in Norway has been produced in Sweden. As far as the Ministry has been able to ascertain, most traditional snus is produced in Sweden. In addition, there is some minor production of traditional snus in Norway. Furthermore, a similar product, so-called “American snus”, is produced in the United States. The Ministry emphasises that even though the term “Swedish snus” is often used to indicate the type of product which is traditionally used in Norway, the proposed prohibition is not intended to grant products from Sweden any special treatment.

Concerning the EU ban on “tobacco for oral use”, the recitals of the TPD state:

> *“(20) Given the general prohibition of the sale of tobacco for oral use in the Union, the responsibility for regulating the ingredients of tobacco for oral use, which requires in-depth knowledge of the specific characteristics of this product and of its patterns of consumption, should, in accordance with the principle of subsidiarity, remain with*

Sweden, where the sale of this product is permitted pursuant to Article 151 of the Act of Accession of Austria, Finland and Sweden."

"(32) Council Directive 89/622/EEC (1) prohibited the sale in the Member States of certain types of tobacco for oral use. Directive 2001/37/EC reaffirmed that prohibition. Article 151 of the Act of Accession of Austria, Finland and Sweden grants Sweden a derogation from the prohibition. The prohibition of the sale of tobacco for oral use should be maintained in order to prevent the introduction in the Union (apart from Sweden) of a product that is addictive and has adverse health effects. For other smokeless tobacco products that are not produced for the mass market, strict provisions on labelling and certain provisions relating to their ingredients are considered sufficient to contain their expansion in the market beyond their traditional use."

The legal definition of tobacco for oral use in the TPD is broad. This has particular implications for the regulation of novel tobacco products under Article 19 of the Directive. That provision requires that novel tobacco products be subject to either a notification scheme or an authorisation scheme. Certain product categories with traditional use in the Member States, including tobacco for oral use, are exempted from this requirement, cf. the definition of novel tobacco products in Article 2(14):

"[For the purposes of this Directive, the following definitions shall apply]:

14) 'novel tobacco product' means a tobacco product which:

(a) does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use; and
(b) is placed on the market after 19 May 2014;"

Norway initially had a prohibition on all novel tobacco and nicotine products (Regulation 1044/1989)[6] from 1989 to 2021, which, in connection with the preparations for the implementation of the TPD, was replaced by an authorisation scheme for novel tobacco and nicotine products (Regulation 2130/2021).[7] The latter implements Article 19 of the TPD, with certain national additions, and entered into force on 1 July 2021. All tobacco for oral use was exempted from the authorisation requirement in Norway, due to the definition of novel products in the TPD.

It was the use of traditional Swedish snus that formed the basis for the derogations granted to Sweden and Norway from the TPD Article 17. The relatively large discrepancy between the definition of "tobacco for oral use" in the TPD Article 2(8) and the long-standing understanding of traditional Swedish snus, has not been addressed earlier. An illustrative

[6] Regulation no. 1044 of 13 October 1989 concerning the prohibition against novel tobacco and nicotine products (Regulation 1044/1989).
[7] Regulation no. 2130 of 17 June 2021 concerning the authorization scheme for new tobacco and nicotine products (Regulation 2130/2021). This regulation implements Article 19 of the Tobacco Products Directive and came into effect on an independent basis before the directive as such has entered into force.

example is how the distinction between the terms “tobacco for oral use” and “snus” is not addressed in a 2010 report from the Commission to the Council on the implementation by Sweden of the measures necessary to ensure that tobacco for oral use is not placed on the market in other Member States.[8]

Following a complaint case from 2024, in which the Norwegian Directorate of Health argued that a new type of snus, a pill-like product, should be considered a novel tobacco product pursuant to TPD Article 19, cf. Article 2(8), the Ministry became aware of how the definition of tobacco for oral use in the TPD results in certain new product types falling outside the scope of the authorisation scheme for novel products. The definition in Article 2(8) means that, in principle, all smokeless tobacco products for oral use fall within the exemption from the authorisation scheme – unless they are intended to be inhaled or chewed. As a consequence, tobacco products that are, in reality, *novel* to the Norwegian market are not subject to the control and oversight envisaged by the authorisation scheme. Thus, the transition from a prohibition on novel tobacco products to an authorisation scheme is problematic in light of the goals of the Norwegian tobacco control strategy.

As a consequence, Norway now seeks to prohibit all "tobacco for oral use" that does not constitute what we consider traditional snus – undoubtedly the only form of tobacco for oral use with traditional use in Norway.

4. The definition of "tobacco for oral use" compared to "snus"

The legal definition of tobacco for oral snus in the TPD Article 2(8), by its wording, encompasses all tobacco products intended for oral use, except those intended for inhalation or chewing. Furthermore, the definition specifies that "tobacco for oral use" is wholly or partly made of tobacco, in “powder or in particulate form” or in any combination of those forms. It is clear what the terms "tobacco products for oral use, except those intended to be inhaled or chewed" and "made wholly or partly of tobacco" mean. The condition "powder form" is also unambiguous, namely a substance that has been ground, crushed, or finely divided into small, dry, and loose particles, typically characterized by its ability to spread easily and conform to the shape of the container in which it is stored.

As regards “particulate form”, this in English refers to a substance composed of small, separate particles, but it does not necessarily specify whether they are fine or coarse. This means it can include both fine, powder-like particles and larger granules. The term used in the French and Spanish versions of the TPD, "particules fines" and "partículas finas" both meaning "fine particles” indicate something slightly different, as they explicitly mention "fine particles". The German version of the TPD uses the term "Granulatform". This term refers to larger particles or granules and does not necessarily mean "fine particles". Thus, the term used in the German version is narrower than in the English, French and Spanish version of

[8] REPORT FROM THE COMMISSION TO THE COUNCIL on the implementation by the Kingdom of Sweden of the measures necessary to ensure that oral tobacco is not placed on the market in other Member States, COM/2010/0399; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52010DC0399&qid=1732190669821

the TPD. The Danish version of the TPD uses the term “fine partikler”. Thus, this definition emphasizes explicitly "fine particles", like the French and Spanish versions.

One can argue that the English term "particulate form" has a broader scope than the French, Spanish and Danish versions. While the latter explicitly refer to fine particles, "particulate form" in the English version may also include larger particles or granules. Thus, the English wording allows for a broader interpretation than the versions in French, Spanish and Danish. The German text is even more restrictive and may, in practice, exclude the finest particles. The Ministry is of the opinion that it can be argued that both fine particles and larger granules should be included in the definition based on the above-mentioned versions of the Directive.

In the Ministry’s view, the TPD provides for a broad definition of what is to be considered tobacco for oral use – all tobacco intended for use in the mouth must be regarded as tobacco for oral use under Article 2(8), unless the product is intended to be inhaled or chewed.

The broad definition in the TPD goes beyond what has traditionally been regarded as “snus” in the countries with a long-standing use of the product – Norway and Sweden. The type of snus most commonly used in Norway and Sweden today is snus in sachet portions placed under the lip, as also reflected in the wording of the TPD definition, which refers to “particularly those presented in sachet portions or porous sachets;” However, the definition in Article 2(8) also encompasses other types of tobacco for oral use. So-called loose snus – a product regarded as the original form of snus, consisting of finely or coarsely ground tobacco shaped to the desired size and form before being placed under the lip – is also clearly included in the Directive's legal definition.

Both Norwegian and Swedish sources show that there is a relatively significant discrepancy between the definition of “tobacco for oral use” in the TPD and the way “snus” has traditionally been understood in countries with a long-standing and traditional use of the product. In the Ministry’s view, snus must be regarded as a subcategory of the broader product category of tobacco for oral use.

In the encyclopedia *Store Norske Leksikon*, snus is described as a tobacco product consisting of finely ground tobacco mixed with water, salt, flavourings, and humectants and acidity regulators, and presented either in pre-portioned sachets or as a moist or semi-moist powder that is shaped and placed under the upper or lower lip.

In the dictionary *Svenska Akademiens Ordbok*, snus is described as tobacco that is ground and treated, inter alia with solutions of mineral salts, colourants and essences, into a brownish-black powder that is placed between the gums and the upper or lower lip. In the Swedish government inquiry *SOU 2021:22*, snus is defined as follows: *“Snus is used by placing the product in the mouth, inside the lips but outside the teeth. The components of the product are mainly absorbed in the mouth, although some end up in the gastrointestinal tract.”*

In the Ministry's view, these definitions are consistent with the general understanding among the public in Norway and Sweden of what snus is.

Thus, traditional Swedish snus is a product consisting of moist or semi-moist powder presented either in sachet portions or as loose moist or semi-moist powder that is shaped to the desired size (loose snus) and placed under the upper or lower lip.

The Court of Justice of the European Union has also referred to a similar definition of "snus" In Case C-468/14 *Commission v Denmark*, para.10, the Court stated: *"Snus is a finely ground or cut tobacco product, sold loose or in small sachet portions, and intended to be consumed by placing it in the oral cavity between the gums and the lip"*.[9]

Thus, in the Ministry's view, traditional Swedish snus must be considered a subcategory of the broader category of tobacco for oral use.

5. The definition in the TPD Article 2(8) – implications for the authorisation scheme

The TPD Article 19 stipulates that Member States may establish a registration or authorisation scheme for "novel tobacco products". The Directive thus establishes a clear regulatory distinction between traditional and novel product types. The rationale for this is that tobacco products deemed "novel" should be subject to monitoring/control, while still allowing for the marketing of traditional tobacco products without such registration/ authorisation. Such a distinction is, in the Ministry's opinion, useful for preventing creative product development from ensnaring new generations in tobacco and nicotine addiction.

The legal definitions of the various product categories exempt from the registration/ authorisation requirements under the TPD Article 19 are formulated in significantly different ways. By comparison, the legal definitions of *inter alia* "pipe tobacco" and "chewing tobacco" are significantly less broad. Thus, when it comes to these products, the tobacco industry has a more limited scope for using creative product development and for creating novel tobacco products that can be placed on the market without being subject to the monitoring and pre-market control required by Article 19. The definition of "tobacco for oral use" is – unlike the other product categories that are exempt – formulated in a particularly broad manner. This affects the scope of the exemption in Article 19.

The fact that "tobacco for oral use" is defined in such a broad manner means that virtually all tobacco products not intended for inhalation or chewing is exempt from the authorisation requirements – as tobacco is primarily intended for use or consumption orally. This may include products that contain tobacco but are fundamentally different in nature from what has traditionally been regarded as snus in countries with a tradition of use, such as tobacco strips.

[9] Our own translation from Danish into English.

Another example is the previously mentioned pill-like product, which is not intended to be swallowed and does not dissolve. Since the product, in the Ministry's assessment, falls within the TPD's definition of tobacco for oral use, the product is not considered a novel tobacco product. Thus, this new and innovative product is exempted from the requirements of the authorisation scheme.

As a consequence, the tobacco industry has – regarding "tobacco for oral use" – a wide scope for creative product development when it comes to tobacco for oral use, and such products can be placed on the market without any form of authorisation. This means that such innovative tobacco products can be placed on the market without any form of pre-market assessment.

In the Ministry's view, this undermines parts of the authorisation scheme – whose entire existence is based on the objective of monitoring the development of novel tobacco products, because "[a]ll tobacco products ... may potentially cause death, disease, and disability," as stated in recital 34 of the Directive. The Ministry is particularly concerned about how such a lack of pre-market control will hinder Norwegian authorities' efforts to protect children and young people from tobacco and nicotine addiction and the associated health risks.

When the Norwegian derogation for tobacco for oral use was negotiated in 1992, Norway had a national ban on all novel tobacco and nicotine products. At that time, it was not foreseen how new tobacco products for oral use could develop and challenge the traditional understanding of tobacco for oral use, i.e. traditional Swedish snus.

In summary, the current situation in Norway entails that innovative and new types of tobacco products for oral use are exempted from the pre-market control requirements that are laid down in Article 19. In order to prevent such products from gaining a foothold in Norway, the Ministry seeks to prohibit all tobacco for oral use that does not constitute traditional snus – the only tradition-bound type of tobacco for oral use in Norway.

6. The Ministry's assessment

6.1 Introduction

A prohibition on tobacco for oral use other than traditional snus, constitutes, in principle, an unlawful restriction under Article 11 of the EEA Agreement, unless the prohibition is justified by legitimate considerations in accordance with Article 13, including the protection of public health.

Article 24(3) of the TPD allows Member States to prohibit certain product categories due to a "specific situation" in the respective country, provided that the prohibition is justified by the need to protect public health. The prohibition must be justified, necessary and proportionate to the objective, and must not constitute arbitrary discrimination or a disguised restriction on trade between Member States.

Below, the Ministry will assess the notified proposal in light of Article 24(3) of the TPD. This must be seen in the context of the fact that the TPD is likely to enter into force in the near future, and that an assessment under EEA Articles 11 and 13 would in any event largely coincide with the criteria set out in the TPD Article 24(3).

As mentioned in section 2.3 above, extensive case law from the EFTA Court and the Court of Justice of the European Union establishes that the protection of public health is one of the most important interests safeguarded by EEA law, and that it is for the EEA States themselves to determine the level of protection they wish to maintain.

6.2 Specific situation

The first question related to the Article 24(3) assessment is whether there is a "specific situation" that justify a prohibition on tobacco for oral use other than traditional snus, in Norway. The Ministry is of the opinion that there are two closely linked "specific situations" that justify the prohibition.

Firstly, the Ministry considers that the Norwegian prohibition on all novel tobacco and nicotine products from 1989 to 2021 constitutes such a “specific situation”, cf. the repealed Regulation of 1989. This long-standing prohibition has led to that there is no tradition for using tobacco for oral use in Norway beyond traditional snus.

Secondly, another “specific situation” is the fact that the sale of “tobacco for oral use” is permitted in Norway – unlike in the rest of the EEA. The fact that this product category is allowed in our country, combined with the relatively broad definition in Article 2(8) compared to the snus products that were envisaged when Norway’s derogation from the EU snus prohibition was introduced, makes Norway particularly vulnerable to the tobacco industry’s innovative and creative product development. New and potentially appealing products targeting children and young people could in future be placed on the Norwegian market without being subject to the prior approval required by Article 19 – as long as they fall within the broad definition in Article 2(8). Norway is thus facing a challenge that other EEA countries do not. The broad definition of “tobacco for oral use” means that the EU’s prohibition of this product group has a wide scope. At the same time, this also means that Norway’s derogation has a wide scope.

In the Ministry’s view, this places Norway in a particularly vulnerable position which justifies measures to prevent children and young people from being recruited into tobacco addiction through creative product development. Since the consequences of the Directive’s definition of “tobacco for oral use” for the approval scheme for novel products have only recently become clear to the Norwegian authorities, there is urgency in closing this loophole in the regulatory framework before new and creative products for oral use find their way onto the Norwegian market.

As mentioned, the Tobacco Control Act sets out the long-term objective that Norway is to become a tobacco-free society, and one of the Government’s main goals in its tobacco

strategy is to achieve a tobacco- and nicotine-free generation. Against this background, the Ministry considers that it would be highly unfortunate if tobacco products that have effectively been prohibited in Norway for more than three decades were now to be permitted.

Furthermore, the recently repealed prohibition on novel tobacco products means that other types of "tobacco for oral use" than snus – with the exception of one product (the pill-like product referred to above) – are currently not available on the Norwegian market.
On the basis of the above, the Ministry is of the view that the proposed prohibition is justified by the "specific situation" in Norway.

6.3 Justified measure

The next question under Article 24(3) of the TPD is whether the proposed prohibition is a "justified measure" to achieve the objective of protecting public health. This entails assessing whether the measure is suitable for reducing the use of tobacco for oral use among children and young people, and thereby protecting them from the addiction and health risks associated with the use of such products, cf. above.

This criterion in Article 24(3) corresponds to the same assessment as 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, cf. Case C-539/11 *Ottica New Line*, paragraph 47.

It is beyond any doubt that the use of tobacco and nicotine products is harmful to health, particularly for children and young people, as discussed in Chapter 2.

The Ministry is of the view that if no measures are implemented, it is likely that new types of tobacco for oral use will be placed on the Norwegian market without being subject to any form of pre-market control, cf. the discussion above. In the Ministry's assessment, a prohibition on such products would likely prevent an increase in the use of such products among children and young people in Norway. Prohibiting most of the products covered by the broad definition in Article 2(8) will reduce, potentially in large numbers, the number of novel products placed on the market without the pre-market control required by Article 19. In the Ministry's view, this is likely to reduce or at least prevent an increase in the use of tobacco and nicotine products among young people in Norway.

There is currently widespread use of traditional snus among children and young people in Norway. The Ministry is concerned that new, innovative products could easily gain a foothold in this user group. In the Ministry's view, this makes a prohibition on other "tobacco for oral use" than snus particularly important in this context. The Ministry refers in this regard to Recital 54 of the Directive, which states that Member States "in order to take into account

possible future market developments" should be able to prohibit a certain category of tobacco products.

The Ministry considers it particularly important to prevent children and young people from being attracted to new harmful and addictive products. The proposed prohibition on tobacco for oral use other than traditional snus aims to reduce the use of tobacco products, particularly among children and young people, in order to achieve the objective of protecting public health at the particularly high level chosen by Norway.

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 The Ministry's proposal to prohibit tobacco for oral use other than traditional snus is an important measure to protect children and young people from the tobacco industry's creative product development and, ultimately, from addiction and health risks.

On this basis, the Ministry considers that a prohibition on other types of "tobacco for oral use" than traditional snus is a justified measure to achieve the objective of protecting public health, particularly the health of children and young people. The measure will protect these groups by limiting access to the products, thereby reducing the risk of addiction and health risks. Furthermore, the measure forms part of a consistent and comprehensive national tobacco policy.

6.4 Necessity

The next question under Article 24(3) of the TPD is whether the proposed prohibition is "necessary" 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 to prevent an increase in the use of new types of tobacco for oral use among children and young people, and thereby protect them from the addiction and health risks associated with the use of such products. 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 a 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 …".[10] Thus, there cannot exist other, less trade restrictive measures having the effect of fully achieving the objectives at the level of protection chosen.

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

The Ministry notes that under the current regulation, all products falling within the broad definition of “tobacco for oral use” in the TPD are exempt from the requirements of the authorisation scheme. The Ministry cannot see that any other, less restrictive measures would be equally effective in protecting children and young people against new types of tobacco for oral use. This must be seen in light of the fact that a prohibition on such products has already been in place in Norway for several decades.

The Ministry refers to the above-mentioned health risks associated with the use of tobacco and nicotine products, as well as these products’ appeal to children and young people. 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 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 refers to the Commission’s assessment on the effectiveness of preventive measures before nicotine addiction takes hold and maintains that the same reasoning applies in Norway to tobacco products for oral use other than snus. As noted, with one recent exception, no new tobacco products for oral use have established themselves on the Norwegian market, and it is therefore important that the prohibition is introduced as soon as possible to prevent this from happening. This is a measure intended to take effect before dependence develops and is therefore more effective than remedial measures that could be introduced after the prohibition is lifted.

The Ministry also agrees with the European Commission’s emphasis that the addictive nature of tobacco products justifies early preventive measures, particularly where, as in Norway, the population – and especially young people – display increased vulnerability or susceptibility to certain categories of tobacco products. The Ministry considers that the widespread use of traditional snus in Norway, especially among young people, entails a particularly high risk of widespread use also of other tobacco products in the category of tobacco for oral use.

In the Ministry’s view, the proposed prohibition on “tobacco for oral use” other than snus is necessary to achieve the objective of protecting public health at the particularly high level of protection chosen by Norway. Specifically, a prohibition is considered necessary to prevent

an increase in the use of tobacco products among children and young people, and thereby protect these groups from the addiction and health risks associated with the use of such products. This must be seen in light of the fact that such a prohibition has already been in place in Norway for several decades.

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

Finally, under Article 24(3) of the TPD, the prohibition must not constitute arbitrary discrimination or a disguised restriction on trade between Member States. The Ministry submits that the draft prohibition will apply to potential domestic and imported products alike. Currently there is only one small-scale producer of tobacco for oral use that does not constitute traditional snus in Norway.

The Ministry also refers to the fact that EU/EEA law allows Member States to treat novel products 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*, para. 71, and Case C-434/02 *Arnold André*, para. 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, para. 26 and 35–63. In the Ministry's view, these cases are relevant by analogy to the present matter. Thus, the Ministry considers that a prohibition on tobacco for oral use other than snus, compared to the established category of traditional snus, does not constitute arbitrary discrimination. The Ministry further considers that the proposed prohibition does not amount to a disguised restriction on trade between Member States. With the exception of two producers engaged in small-scale production of snus and the producer of the above-mentioned pill-like product, there is no production of tobacco for oral use in Norway.

The fact that there is a general prohibition on tobacco for oral use in the EU, justified by the aim of preventing the introduction into the Union of a product that is addictive and harmful to health even if it is less harmful than existing products, demonstrates that EEA law does not preclude less harmful products than those already on the market from being prohibited or not approved.

Furthermore, the prohibition is proposed as part of the national tobacco strategy, aimed at reducing the consumption of tobacco products in Norway. The prohibition will apply equally to imported products and to products produced in Norway. In the Ministry's view, this reinforces that the condition is met.

On this basis, the Ministry considers that the proposed prohibition does not constitute either arbitrary discrimination or a disguised restriction on trade between Member States.

7. Conclusion

On this basis, the Ministry concludes that the proposed prohibition on the import, manufacture and placing on the market of tobacco for oral use other than traditional snus, 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. The Ministry further considers that the proposed measure does not constitute arbitrary discrimination or a disguised restriction on trade. Thus, the proposed regulatory provision meets the requirements set out in Article 24(3) of the TPD. The Ministry considers that an assessment of proportionality under Article 13 of the EEA Agreement would involve the same considerations and lead to the same conclusion.