ROYAL NORWEGIAN MINISTRY
OF HEALTH AND CARE SERVICES

EFTA Surveillance Authority
Rue Belliard 35
B-1040
BELGIUM

Your ref	Our ref	Date
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Information concerning Norwegian rules on novel nicotine products in relation to tobacco-free snus and electronic cigarettes

Reference is made to your letter dated 24 July 2019 with a request for information regarding Norwegian rules on novel nicotine products. Reference is also made to our latter dated 13 August 2019 with a request for an extended deadline, and your reply dated 14 August 2019 granting an extended deadline until 25 September 2019.

As an introductory remark, the Ministry would like to emphasise that we are currently in somewhat of a transitional period, preparing for the implementation of the Tobacco Products Directive 2014/40/EU (the TPD). The TPD introduces a completely new regime for electronic cigarettes containing nicotine and for novel tobacco products. The TPD entered into force in the EU in May 2016, and the Norwegian Parliament enacted necessary legislative amendments to the Tobacco Control Act in December 2016, cf. Act no. 5 of 10 February 2017 (Act 5/2017).[1],[2] The EEA incorporation process has unfortunately been delayed, but it seems to be coming to an end this autumn, and we expect the TPD-related legislative amendments to enter into force early 2020.

Draft regulations that will supplement Act 5/2017 were on public consultation in Norway in 2016, and Norway plans to send the final draft regulations on notification according to directive 98/34 shortly.

Question 1: Please explain the interaction between the Norwegian Tobacco Act on the one hand and Regulation No 1044 on the other, as regards instances where one and

[1] https://www.stortinget.no/no/Saker-og-publikasjoner/Vedtak/Beslutninger/Lovvedtak/2016-2017/vedtak-201617-026/
[2] https://lovdata.no/dokument/LTI/lov/2017-02-10-5

Postal address	Office address	Telephone	Department	Reference
Postboks 8011 Dep	Teatergt. 9	+47 22 24 90 90	Department of Public Health	Helena Wilson
0030 Oslo		Org. nr.		+47 22 24 87 52
postmottak@hod.dep.no	www.hod.dep.no	983 887 406		Katrine Espantaleón
				+47 22 24 84 51

the same product, like tobacco free snus and electronic cigarettes, fall under the scope of both acts?

The Norwegian Tobacco Control Act no. 14 of 9 March 1973 (Act 14/1973) regulates all tobacco products, tobacco surrogates, tobacco imitations, tobacco accessories, electronic cigarettes, refill mechanisms and herbal products for smoking, provided that they are not classified as medicines or medical equipment. This is most clearly stated in the Act for electronic cigarettes and refill mechanisms, cf. § 3 second paragraph. The Medicines Act no. 132 of 4 December 1992 (Act 132/1992) is considered *lex specialis* and products classified as medicinal products are not subject to the Tobacco Control Act.

Regulation no. 1044 of 13 October 1989 concerning the prohibition against novel tobacco and nicotine products (Regulation 1044/1989) has its statutory basis in the Product Control Act no. 79 of 11 June 1976 (Act 79/1976). Regulation 1044/1989 bans the import into and sale in Norway of all novel tobacco and nicotine products, cf. § 2:

> *"It is prohibited to produce, bring to Norway, sell or hand over to others new types of tobacco and nicotine-containing products. The same applies to tobacco and nicotine-containing products which are intended to be used in other ways than those normally practised in Norway."*

Which products the ban applies to is defined in § 3:

> *"In these regulations, the term "new types" of tobacco and nicotine-containing products means all products containing tobacco or nicotine, with the exception of the products which, by tradition, are or have been sold in Norway (cigarettes, cigars, cigarillos, smoking tobacco, chewing tobacco and snuff).*
>
> *In these regulations, the expression "intended to be used in other ways" means intake of tobacco and nicotine-containing products to the human body in ways other than the form of smoking, taking snuff and chewing used today."*

In § 4, it is clearly stated that nicotine products which are classified as medicinal products are not subject to the ban.

The Directorate of Health may grant exemptions from the ban *"if the manufacturer or importer can document that a new product or its manner of use is significantly less harmful to health than products already on the market"*, cf. § 8. Relevant cases are presented under point 6 below.

Electronic cigarettes containing nicotine may – under certain conditions – be imported into Norway by consumers as travel goods or as medicinal products for personal use when imported from another EU/EEA State, cf. Regulation no. 1441 of 2 November 2004 § 3-2.[3]

[3]

A product which is covered by the ban in Regulation 1044/1989 will nevertheless be subject to the Tobacco Control Act 14/1973 §§ 20 (ban on free distribution), 22 (advertising ban), 23 (sponsorship ban) and Chapter 5 (smoking ban etc).

Once the TPD-provisions enter into force in Norway, Regulation 1044/1989 will be repealed and replaced by the new § 34d of Act 5/2017 and its regulations.

Question 2: What are the conditions for nicotine products to be classified as medicinal products pursuant to Act No 132/1992? Are there any specific conditions as regards nicotine powder for oral use or electronic cigarettes?

The Norwegian Medicines Agency is responsible for the classification of substances, herbs and products as medicinal or non-medicinal products according to the Norwegian Act on Medicinal Products no. 132/1992. The definition of «medicinal product» in Directive 2001/83/EC is implemented in the Norwegian Act on Medicinal Products. For a nicotine product to be classified as medicinal products it will need to be covered by the definition either by presentation or function, taking into account case law from the ECJ.

The Medicines Agency's evaluations of the classification of specific products as medicinal or non-medicinal is done on a case-by-case basis, taking into account all aspects of the product. If a product is classified as a non-medicinal product, the Agency does not evaluate what other legislation the product will be regulated by.

There are no specific conditions as regards nicotine powder for oral use or electronic cigarettes. The classification of a nicotine product as a medicinal product follows from Directive 2001/83/EC and the definition of medicinal product in its Article 1 no. 2. If a nicotine product is classified as a medicinal product it is not covered by the Tobacco Control Act no. 14/1973 but by the Act on Medicinal Products no. 132/1992.

Question 3: Seeing as Norway allows snus containing tobacco to be placed on the market, does the Norwegian Government consider that the prohibition on the placing on the market of snus not containing tobacco derived from Section 2 of Regulation No 1044 can be justified by the reasons set out in Article 13 EEA? Please elaborate, in particular, on the proportionality and the necessity of the measure.

As mentioned above, tobacco-free nicotine snus products are prohibited in Norway under Regulation 1044/1989, unless they are classified as medicinal products. Following the adoption of the TPD, the Norwegian Ministry of Health and Care Services put forward a bill to the Norwegian Parliament in June 2016, *Prop. 142 L (2015–2016) Endringer i tobakksskadeloven*.[4]

[4] https://www.regjeringen.no/contentassets/67c3412a150845349d390b075a3ec4b1/no/pdfs/prp201520160142000dddpdfs.pdf

In the bill, the Ministry proposed that the longstanding prohibition on novel tobacco and nicotine products should be replaced by an authorisation scheme based on TPD Article 19(3). The government emphasised its desire to facilitate harm reduction for established smokers by permitting the import and sale of electronic cigarettes and other novel tobacco and nicotine products, although under strict notification and authorisation schemes.

The Ministry stresses that even though the government chose to propose a mild policy change in this regard, this does not entail that a continued ban would have been unlawful. As will be argued below, the EU/EEA States have a wide discretion when it comes to choosing the level of protection for public health and the means to achieve it. Until the TPD-related legislative amendments enter into force, the current ban should be upheld.

Proportionality assessment

There is no question that the Norwegian ban on novel tobacco and nicotine products is a trade restriction according to the EEA Agreement Art. 11. The Ministry is however of the opinion that the restriction is suitable and necessary, and thus justified according to the EEA Agreement Art. 13.

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 Art. 13, 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 very high degree of protection when it comes to tobacco control. The same goes for related products, which will still be under strict regulation when the ban is lifted following the implementation of the TPD.

The objective of the current ban on novel tobacco and nicotine products is to protect public health, especially for children and young people. More specifically, the ban aims at preventing the known and potential harmful effects to health from the use of such products, preventing uptake among young people and avoiding potential negative impacts on tobacco control efforts. All tobacco and nicotine products, such as tobacco-free snus, are addictive and harmful to health.

The Court of Justice and the EFTA Court have underlined that it is up to the EEA States to decide upon the level of health protection and how to achieve this. The EEA States thus have a margin of appreciation, though within the frame of the proportionality principle. According to Case E-4/04 *Pedicel* para. 56, this means that the measures in question must be "suited to achieve the objective sought, and that the same objective may not be as effectively achieved by measures which are less restrictive of intra-EEA trade."

The proportionality test thus consists of two elements; suitability and necessity. When assessing this closer, regard must be taken to the fact that the isolated effect of various tobacco control issues are difficult to measure, and that the effect often manifests over time.

Suitability

The Ministry is of the opinion that the Norwegian ban on novel products is suited to obtain the objectives described above. The suitability test requires that it must be "reasonable to assume" that the measures will be able to contribute to the protection of public health, cf. Case E-16/10 *Philip Morris* para. 83. This applies even where there is some scientific uncertainty and where the effects may appear over some time.

The purpose of Regulation 1044/1989 was to stop the introduction of novel tobacco and nicotine products on the Norwegian market, and only allow product groups that were already on the market in 1989 or which fulfilled the conditions for an exemption, in addition to medicinal nicotine products.

The Regulation was based on a report, "Nikotin-rapporten", from the State Tobacco Control Council in 1989. According to this report, a creative product development was to be expected in the future, even though at that time only traditional tobacco products and medicinal products containing nicotine were on the Norwegian market.

It is important to keep in mind that tobacco use was, and still is, the single most important cause of premature death and illness in Norway, accounting for 16 % of all deaths. A ban on novel tobacco and nicotine products, as proposed in the report, was seen as the only possible and effective solution to stop children and young people from becoming the next generation addicted to nicotine and exposed to the health risks this involves.

In some countries, untraditional products such as tobacco- or nicotine-containing lollipops, bottled water, candy and jelly, creams, mouth strips etc. have entered the market. Such products have a novelty factor that is especially appealing to children and young people. Also, novel products like heated tobacco products and electronic cigarettes entered the EU market before there was any EU-harmonised regulations and few national rules. In several countries, this has led to a sharp increase in the use of such novel products among children and young people. In Norway, however, no such products have entered the market due to Regulation 1044/1989. The Directorate has carefully assessed all applications for exemption, as is described under question 6 below.

The Ministry is of the view that it is important for the authorities to have complete overview and control of such novel products, especially as they may have a greater appeal among children and young people than traditional products where the government for decades has run anti-campaigns and awareness raising initiatives.

There is no doubt that novel tobacco and nicotine products may be less harmful to health than established tobacco products listed in Regulation 1044/1989 § 3. They may also be more harmful. Nevertheless, all tobacco and nicotine products involve some health risks, especially for vulnerable groups like children and young people, foetuses and people with cardiovascular problems.

The Nicotine report from 1989 reads in the introduction:

> *"As long as nicotine containing products are available on the market, the tobacco industry will obtain new life-long customers. It is especially serious that nicotine addiction is established among children and young people."*

The report continues on page 5 concerning health risks and addiction:

> *"Nicotine is an addictive and harmful substance. (…) Nicotine addiction develops quickly and WHO compares this addiction with the one that is developed with hard narcotic drugs. It will therefore have substantial health consequences if continuous novel products maintain nicotine addiction. It is also shown a gateway effect to cigarette smoking among those that establish their nicotine addiction with the use of snus and chewing tobacco."*

The Ministry notes that even though the knowledge basis has developed since 1989, the main conclusions are still valid.

The Norwegian Public Health Institute in 2014 published a report called "Health risks from Scandinavian snus consumption (English summary)".[5] Regarding the health hazards from nicotine, the Institute states that nicotine is a toxic and highly addictive substance. Furthermore:

> *"Nicotine has acute effects on the cardiovascular system and causes increased heart rate and increased blood pressure, but the long-term effects are less clear. Animal studies have shown that nicotine exposure in utero and in young animals leads to adverse structural and functional changes in the brain and behavioural changes.(…)*
>
> *Nicotine may also affect cellular processes that are involved in cancer development, but there is insufficient scientific evidence to determine whether nicotine can cause or promote cancer development in humans. (…)*
>
> *There is convincing evidence that snus consumption during pregnancy may lead to reduced birth weight, increased risk of premature birth and stillbirth. There are some indications that it may contribute to pre-eclampsia, and increase the risk of respiratory failure (neonatal apnoea) among new-born babies and lip/palate malformations.(…) Based on animal studies and knowledge of nicotine-related effects of smoking, it cannot be ruled out that snus could also interfere with foetal development at critical time points, although this has not been observed in epidemiological studies. With the rapidly increasing consumption among young women, the risk of more pregnant women using snus will increase in the coming years. The consequences could be an increase in adverse pregnancy outcomes and developmental disorders in the foetus and infant.(…)*

[5] https://www.fhi.no/globalassets/dokumenterfiler/rapporter/2014/helserisiko-ved-bruk-av-snus-pdf.pdf

There is a particular risk of developing diabetes mellitus type 2 with a consumption level of 5 or more snus boxes per week. If the effect of snus is related to nicotine exposure, the use of snus with a higher nicotine content, e.g. 20 mg/g, would also affect those with lower consumption."

An updated report on health risks from snus use, including health effects related to nicotine, is expected to be published by the Institute in October 2019.

The Norwegian Directorate of Health in 2018 commissioned a report from the Norwegian Institute of Public Health where they assessed the health risk information on nicotine snus provided by the producers. The report dated 22 May 2019 concludes as follows:

- *It is often argued that the use of traditional snus products lead to a substantial and concrete reduction of health risks compared to tobacco smoking. This statement often does not take into consideration the harmful effects of nicotine.*
- *Use of tobacco-free nicotine snus will probably substantially reduce the risk of cancer compared to traditional snus. This is due to the lower levels of the carcinogenic substances NNN and NNK (reduced health risk). Since we do not have knowledge of exposure and use pattern, it is however difficult to quantify the size of the reduced cancer risk.*
- *For other adverse health consequences which are mainly linked to nicotine, including cardiovascular effects, development of the foetus, cognitive functions and mental health, the total health risk from these novel products will probably not be reduced if the user is exposed to the same level of nicotine as when using traditional snus. The data available does however not allow for a more concrete quantification of the total health risk change. The nicotine content of the products will pose the highest risk for youngsters, pregnants and people with cardiovascular illness in addition to an increased risk of developing diabetes type 2.*
- *We are of the opinion that the question of whether these types of products may lead to the use of other nicotine-containing products (traditional snus/electronic cigarettes/ordinary cigarettes/dual use) is not concluded. The most exposed group will be younger age groups, who might develop nicotine addiction, which again might dispose for use of other tobacco products with a higher health risk. The product may however reduce the use of older tobacco users who are finding it difficult to quit cigarettes and tobacco snus. It is noted that older smokers often have cardiovascular diseases.*

There is no requirement for the Member States to regulate all or nothing in order to be consistent, if they can reasonably justify why a certain regulation is limited to a certain situation or specific product groups. How long the products in question have been on the market may be one reason to treat them differently. In C-210/03 *Swedish Match* para. 71 the ECJ concluded that tobacco snus could be treated differently from chewing tobacco based on the fact that tobacco snus was new on the market. The same reasoning follows from C-

477/14 *Pillbox* para. 62. Of relevance in this assessment, is whether the products have different objective characteristics, including different ingredients.

Regarding the question of whether there is a basis for treating tobacco snus and tobacco-free snus differently, the Ministry points to the fact that the product groups belong to different product categories relating to ingredients (tobacco vs. non-tobacco), with different regulatory frameworks. Furthermore, tobacco snus is a traditional product with a long history on the Norwegian market while nicotine snus is a novel product that has not been evaluated when it comes to health risks, user potential etc. The TPD only regulates tobacco snus and electronic cigarettes, not other nicotine products. Tobacco snus and nicotine snus are thus different product groups and need not be regulated equally.

For the record, the Ministry would like to point out that the EU itself has banned oral tobacco from entering the market. The reasoning behind the ban is a desire to avoid a new product group on the market which may be appealing to youth, although this product is undisputedly less harmful to health than cigarettes and many other smokeless tobacco products.

Finally, the Ministry would like to emphasise that the current ban on novel products is not a total ban. The Directorate may grant exemptions after carefully evaluating the concrete product's health risks and effects on public health. The ban will, when the amendments in Act 5/2017 enters into force, be replaced by an authorisation scheme, but in practice both regimes require the producer or importer to submit information to be assessed by the competent authority relating to effects of the product on the individual and on society.

Based on the above, the Ministry is convinced that the measure in question is suitable to protect public health by preventing youth uptake and reducing potential negative health effects from such products. The prohibition on novel products is part of a consistent and coherent tobacco policy since the early 1970s. On this basis, the Ministry argues that the measure is suitable according to the EEA Art. 13.

Necessity

It then follows that the measure must be necessary to achieve the objective, and cannot be equally effective with less trade restrictive measures, cf. E-3/06 *Ladbrokes* para. 58.

Whether the measure is necessary is to be assessed based on the actual and legal context, and as mentioned above the States have a margin of appreciation.

The Ministry considers that there is no basis for arguing that a ban on novel products is not necessary when tobacco snus is allowed on the Norwegian market. According to TPD Article 24(3), a Member State may prohibit a certain category of tobacco products or related products on grounds relating to the specific situation in that Member State and provided the provisions are justified by the need to protect public health. Several EU States have introduced prohibitions on certain product types based on the reasoning that the product type is not established on the national market or is a novel product. For instance, Finland has

banned certain types of smokeless tobacco, despite allowing more harmful tobacco products on the market. This has been accepted by the EU Commission.

In the TPD preamble it is underlined that all tobacco products are harmful to health and that it is therefore important to monitor developments as regards novel tobacco products. This is the basis for Article 19 which requires that novel products must be subject to a notification or authorisation scheme, "without prejudice to the power of the Member States to ban or to authorise such novel products", cf. the preamble point 34.

In point 55 of the preamble it is also stated that Member States retain the right to "regulate or ban paraphernalia used for tobacco products (including waterpipes) and for herbal products for smoking as well as regulate or ban products resembling in appearance a type of tobacco or related product".

The Ministry submits that the chosen level of protection in Norway concerning tobacco control is very high, and that there are no less restrictive alternatives to the current ban which protects public health to the same degree. To the contrary, the Ministry considers that the ban operates in an appropriate and targeted manner to limit the recruitment of children and young people to nicotine dependence. The ban on novel products is therefore necessary to obtain the objectives.

It may be argued that an alternative measure to the ban could be an authorisation scheme, like the one the Norwegian Parliament has already adopted, cf. Act 5/2017 § 34 d. The new authorisation scheme was adopted as a consequence of the TPD introducing harmonised rules for novel products. The TPD in Article 19 mandates the States to choose between a notification scheme and an authorisation scheme. Norway has chosen the strictest option and proposed several conditions for approval. To the extent that the authorisation scheme will not provide the same level of protection as today's prohibition, this is due to EEA commitments, not to an inconsistent policy from the Norwegian government. The EU has chosen a different system where they in addition to introducing a notification or authorisation scheme, explicitly mandates the States to also prohibit certain product categories, cf. Article 24(3).

We also note that Regulation 1044/1989 allows for exemption from the ban, and thus provides for a concrete assessment of the necessity of the ban in each individual case.

All tobacco and nicotine products are addictive and harmful to health. When Regulation 1044/1989 was introduced the objective was to hinder the tobacco industry from recruiting children and young people to addiction through creative novel products.

A prohibition was in 1989 seen as the only possible solution to such a development. Our knowledge today of the tobacco industry's attempts to create "safer products" like "light cigarettes and filter cigarettes, support this cautious viewpoint. The product development in the tobacco snus segment the last two decades has contributed to a snus epidemic among

young people in Norway. The government has reacted to this by, among other things, introducing stricter regulations, like standardised packaging, and mass-media campaigns. However, we have not seen the same youth uptake of novel tobacco and nicotine products as in other countries. The ban on novel products has thus achieved its objective.

In our view, it is necessary for the authorities to have a complete overview of the novel products and to monitor the market development, especially regarding uptake among young people, the effect on smoking cessation and harmful substances. An authorisation scheme will accommodate such needs, and the system is currently under establishment. Until then, the Ministry finds it necessary to maintain the current ban on novel products in order to uphold the high level of protection of public health.

Conclusion
Norway strives for a high degree of protection for public health, in particular when it comes to tobacco control. The long-term objective of the Tobacco Control Act is to achieve a tobacco free society. Today we have a ban on novel tobacco and nicotine products. Following the implementation of the TPD, we will lift this ban and replace it with an authorisation scheme. Based on the above, the Ministry finds that the measure is suitable and necessary to protect public health.

Question 4: How will the amendments to the Norwegian Tobacco Act, cf. Act No 5/2017, affect the possibilities for the placing on the market of tobacco free snus once they enter into force?

When Act No. 5/2017 enters into force, all novel tobacco and nicotine products (which are not classified as medicines) will be subject to a new authorisation scheme. The scheme is based on TPD Article 19. The conditions for being granted an authorisation are part of the draft regulations which will be notified shortly.

Each application will be assessed individually by the Norwegian Directorate of Health and it is not possible for the Ministry to make any assumptions as to whether a specific product group, such as tobacco-free nicotine snus, will be granted an authorisation or not.

Question 5: Taking into consideration that research seems to suggest that electronic cigarettes pose less health risks than regular cigarettes, does the Norwegian Government consider that the prohibition to the placing on the market of electronic cigarettes derived from Section 2 of Regulation No 1044 can be justified by the reasons set out in Article 13 EEA, in particular as regards the proportionality and the necessity of the measure?

Today, electronic cigarettes containing nicotine are subject to the ban on novel nicotine products in Regulation 1044/1989. The ban will be lifted once Act 5/2017 enters into force. Electronic cigarettes may thus be sold legally once the EU harmonised system for assessing such products is in place. The Norwegian Medicines Authority is currently establishing a

system for assessing the electronic cigarettes and refill mechanisms that will be notified to Norway through the EU Common Entry Gate (EU-CEG). Both ingredients, labelling and the user manual will be examined before the products will be available on the market for consumers.

Background

Electronic cigarettes were invented in 2006, and is a relatively new product category on the European market. All electronic cigarettes heat a solution (e-liquid) to create an aerosol which frequently contains flavourings, usually dissolved into propylene glycol or/and glycerine. Most electronic cigarettes contain nicotine. Although generally considered a single product class, these products constitute a diverse group with potentially significant differences in the production of toxicants and delivery of nicotine.

Following the adoption of the TPD, the Norwegian Ministry of Health and Care Services in 2014 commissioned three reports on electronic cigarettes:

- A report on health risks from the Norwegian Institute of Public Health
- A report on policy recommendations from the Norwegian Directorate of Health
- A report on the medicines regulations from the Norwegian Medicines Agency.

Also, the World Health Organization has produced reports on electronic cigarettes and presented policy recommendations, the latest in August 2016.[6]

Based on these reports and the subsequent public consultation on draft legislative amendments to the Tobacco Control Act, the Ministry put forward a bill to the Norwegian Parliament in June 2016, *Prop. 142 L (2015–2016) Endringer i tobakksskadeloven*.[7]

In the bill, the Ministry proposes that electronic cigarettes should be regulated according to the TPD. The Directive covers all electronic cigarettes except non-refillable electronic cigarettes without nicotine, cf. Article 2(16). In addition, refill containers without nicotine falls outside the definition in Art. 2(17). Nonetheless, the Ministry proposes in the bill that also non-refillable electronic cigarettes and refill containers without nicotine should be subject to the notification system mandated by the TPD Article 20. The Norwegian Medicines Agency will be the competent authority for electronic cigarettes following the implementation of the TPD in Norway.

Proportionality assessment

There is no question that the current ban on electronic cigarettes and refill mechanisms containing nicotine is a trade restriction according to the EEA Agreement Art. 11. The Ministry is however of the opinion that such a restriction is suitable and necessary, and thus justified according to the EEA Agreement Art. 13.

[6] Report by WHO, Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS), August 2016: http://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf?ua=1

[7] https://www.regjeringen.no/contentassets/67c3412a150845349d390b075a3ec4b1/no/pdfs/prp201520160142000dddpdfs.pdf

We refer to our submissions under point 3 above regarding the elements of suitability and necessity under the proportionality test.

Suitability
The Ministry is of the opinion that the ban on electronic cigarettes with nicotine is suited to protect public health. The suitability test requires that it must be "reasonable to assume" that the measure will be able to contribute to the protection of public health, cf. Case E-16/10 *Philip Morris* para. 83. This applies even where there is some scientific uncertainty and where the effects may appear over some time.

The adopted Act 5/2917, which is based on the TPD, aims at controlling the use of electronic cigarettes with a view to preventing the known and potential harmful effects to health from the use of such products, ensuring a high level of product quality and safety and avoid potential negative impact on tobacco control efforts.

The Norwegian Medicines Agency has stated that as of today there is limited knowledge on the health risks associated with heating and inhalation of additives contained in electronic cigarettes both with and without nicotine.[8],[9]

As part of the TPD-implementation, the Commission has established the EU Common Entry Gate. Through this, the Norwegian Medicines Agency will get a full overview of the electronic cigarette market in Norway, and be able to test products for additives with health risk and supervise the entire product category. The notified information will be standardised in the same way in the entire EU/EEA area.

The objective of the notification system is to enable the Medicines Agency to protect consumers from potentially harmful products and additives. The concept of potential health risks from additives is also expressed in the TPD itself. The Directive puts an obligation on producers and importers to notify information on all ingredients and all emissions resulting from the use of the product, cf. TPD Art. 20(2)(b).

According to TPD Art. 20(2)(c) there is also a requirement to submit toxicological data regarding the products ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, inter alia, any additive effect. The requirement to submit these data facilitates the control task of the Medicines Agency, and allows for the assessment of health risk associated with any ingredient contained in electronic cigarettes and refill containers.

With the exception of nicotine, it is a requirement in the Directive that the liquid only contains ingredients that do not pose a health risk in heated or unheated form, cf. TPD Art. 20(3)(e).

[8] Barrington-Trimis et al, Flavourings in Electronic Cigarettes An Unrecognized Respiratory Health Hazard?, JAMA 2014, 312 (23):2493, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4361011/pdf/nihms669335.pdf
[9] Henkler og Luch, More extensive tests for e-cigarettes, Nature 2015, 525: 187, http://www.nature.com/nature/journal/v525/n7568/pdf/525187d.pdf

The TPD Art. 20(3)(c) states that the nicotine-containing liquid must not contain additives listed in Art. 7(6). In addition, the TPD sets up a requirement that only ingredients of high purity shall be used for the manufacture of nicotine-containing liquid, cf. TPD Art. 20(3)(d).

In a report on the potential risks to public health associated with the use of refillable electronic cigarettes dated 20 May 2016, the Commission states that certain flavourings used in electronic cigarettes are classified as hazardous to health according to the CLP regulation and that more research is needed.[10] It is also stated that flavourings and propylene glycol found in e-liquid can cause skin irritation.

In the above mentioned WHO report, it is stated that electronic cigarettes typically produce aerosol that ordinarily includes glycols, aldehydes, volatile organic compounds (VOCs), polycyclic aromatic hydrocarbon (PAHs), tobacco-specific nitrosamines (TSNAs), metals, silicate particles and other elements. Dicarbonyls (glyoxal, methylglyoxal, diacethyl) and hydroxycarbonyls (acetol) also are thought to be important compounds in the aerosol. Many of these substances are toxicants that have known health effects resulting in a range of significant pathological changes.

According to WHO, the number and level of known toxicants in electronic cigarettes are on average lower or much lower than in cigarette smoke. However, the levels of toxicants can vary enormously across and within brands and sometimes reach higher levels than in tobacco smoke. This is probably due, among other things, to the increased thermal decomposition of e-liquid ingredients with rising applied temperatures in open system devices. A number of metals - including lead, chromium, and nickel and formaldehyde - have been found in the aerosol of some electronic cigarettes at concentrations equal to or greater than traditional cigarettes under normal experimental conditions of use.

WHO states that there are close to 8000 unique e-liquid flavours. The health effects of heated and inhaled flavourings used in e-liquids have not been well studied. Heated and inhaled popcorn, cinnamon and cherry flavourings are potentially hazardous, with the limited literature on the topic indicating that most flavourings may pose appreciable health risks from long-term use, especially those that are sweet. Many are irritants, which may increase airway inflammation; some are more cytotoxic than unflavoured aerosol although less so than tobacco smoke, or increase the susceptibility of airway cells to viral infection after direct contact with e-liquid, although the relevance of direct effects of contact with e-liquid, as opposed to aerosol, is unclear.

The WHO concludes that it is very likely that electronic cigarettes are less toxic than cigarette smoke. However, they also underline that electronic cigarettes are unlikely to be harmless, and long-term use is expected to increase the risk of chronic obstructive pulmonary disease,

[10] Report from the Commission to the European Parliament and the Council on the potential risks to public health associated with the use of refillable electronic cigarettes: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=COM:2016:269:FIN&from=EN

lung cancer, and possibly cardiovascular disease as well as some other diseases also associated with smoking. There is not enough research to quantify the relative risk of electronic cigarettes over combustible tobacco products.

In 2015, the Norwegian Institute of Public Health published a report on health risks associated with electronic cigarettes.[11] The Institute concluded:

> *"Since there are limited studies of exposure to e-cigarettes and adverse health outcomes, the present assessment is almost exclusively based on studies of the individual components of e-cigarettes. There are many different types of e-cigarettes, with varying contents of nicotine and other substances. Both this and different usage patterns could affect health outcome. The main component of e-cigarettes is nicotine. This applies both to the "desired" stimulatory effect, but also for the "unwanted" adverse health effects that can be expected with e-cigarettes. The intake of nicotine from e-cigarettes seems to be similar to that found with tobacco smoking and snus consumption, indicating that similar nicotine-related effects are expected on the cardiovascular system, lung development in unborn children and in later life, reproductive health (premature birth, stillbirth and preeclampsia) and cognitive effects. It is reasonable to assume that people with existing cardiovascular disease will be more vulnerable to adverse effects on the cardiovascular system (both acute and chronic) than people without heart disease. Furthermore, unborn babies, children and adolescents are considered to be particularly sensitive to nicotine exposure. Substances such as propyleneglycol and acrolein may cause irritation during e-cigarette use. TSNA, formaldehyde, acetaldehyde, PAH compounds and various metals (nickel, cadmium) are known to contribute to the carcinogenic effect of tobacco smoking. Exposure concentrations to these substances with e-cigarette use are very low and we consider the cancer risk to be negligible. However, this conclusion is based on the separate assessment of the individual substances in aerosols. Further research based on inhalation of aerosols from e-cigarettes is required to verify these conclusions. The effects of long term use of e-cigarettes must be evaluated, particularly in terms of cancer risk, cardiovascular disease and other adverse health outcomes. From a public health perspective, it is important to prevent new generations from becoming addicted to nicotine, and using e-cigarettes as a gateway to other forms of nicotine such as regular smoking and snus consumption. For smokers who are unable to quit smoking, it must be assumed that a full transition to e-cigarettes will incur a risk reduction, particularly with regards to cancer development. Until now there have been no independent data that document how smokers as a group switch to e-cigarettes. It is therefore very uncertain to what extent the use of e-cigarettes, combined with regular smoking, will lead to reduced health risks. It should be emphasized that the use of e-cigarettes alone will still involve a risk of adverse health outcomes among users, particularly associated with the intake of nicotine. The health risks from long-term e-cigarette use in the population is unknown. Nicotine levels in the environment from passive exposure to aerosols from e-cigarettes*

[11] https://www.fhi.no/globalassets/dokumenterfiler/rapporter/2015/health-risks-associated-with-e-cigarettes---english-summary-pdf.pdf

can result in similar high nicotine levels in the blood of a passive smoker of regular cigarettes. This means that similar harmful nicotine-related effects can be expected for passive exposure to e-cigarettes as for regular cigarettes. This means that passive exposure to aerosol from e-cigarettes may act on the cardiovascular system, have stimulatory effects and contribute to addiction."

In addition to the product requirements set up by the TPD, producers and importers of electronic cigarettes and refill mechanisms are required to have systems in place to collect information regarding suspected adverse effects on human health and notify the competent authority of such information arising from the use of these products. The competent authorities in the EU Member States are also required to notify each other and the Commission about suspected or confirmed adverse health effects.

Norway is not granted access to the EU-CEG or to the inter-EU alert system until the TPD is incorporated into the EEA Agreement. Until then, the Ministry is convinced that the ban on novel products, including electronic cigarettes, is warranted and suitable.

Necessity
It then follows that the measures must be necessary to achieve the objective, and cannot be equally effective with less trade restrictive measures.

The Ministry fails to see that other less restrictive measures than a ban could achieve the same objectives *at this time*. It is important to the Norwegian government that electronic cigarettes are as safe and of as good quality as possible, and that the effects of electronic cigarettes are monitored well to see how this new product group influences on tobacco use, especially uptake and quitting. It is also important to gain more knowledge of potentially harmful substances in electronic cigarettes and refill containers. Based on the experiences from EU Member States, the EU-CEG system is an important element in achieving this.

In the past months, there has been vast media attention to an outbreak in the US of hundreds of cases of lung disease and 8 deaths due to young people using electronic cigarettes. To our knowledge, there has been no such cases in the EU. This is not unlikely due to the fact that the TPD carefully regulates electronic cigarettes and its components, and EU Member States are controlling the products through the EU-CEG database.

In our view, it is necessary for the authorities to have a complete overview of the electronic cigarette market and to monitor the market development, especially regarding uptake among young people, the effect on smoking cessation and harmful substances in the e-liquid. As soon as the TPD is included in the EEA Agreement and Norway is granted access to the EU-CEG, we will lift the current ban on electronic cigarettes with nicotine and make use of the tools developed by the EU to control the electronic cigarette market.

Based on the above, the Ministry finds that the measure is suitable and necessary to protect public health.

Conclusion

Norway strives for a high degree of protection for public health, in particular when it comes to tobacco control. The long-term objective of the Tobacco Control Act is to achieve a tobacco-free society. Today, we have a ban on electronic cigarettes with nicotine. Following the implementation of the TPD, we will lift this ban and replace it with specific product regulations following the TPD provisions. Until then, the ban is a suitable and necessary measure to protect public health.

Question 6: Has the Directorate of Health received any applications for exemptions from the general prohibition of Section 2 of Regulation No 1044, as provided for in Section 8 of the regulation? If so, have any such exemptions been granted?

The Directorate has made a search in their electronic archives from the year 2000 until 2019. They have identified 9 applications for exemption from the ban during this period. The first applications concerned electronic cigarettes and e-liquids and also one tobacco inhalator:

- RGB Holding/electronic cigarette, 2011
- Zandera/E-lites, 2012
- Scandinavian Considaret/tobacco inhalator, 2012
- Alfa Solutions AS /e-liquid, 2014
- Damp Import Nuf /electronic cigarette, 2014

All of the applications above were rejected on the basis of lack of lack of documentation. The Regulation 1044/1989 requires applicants to "*document that a new product or its manner of use is significantly less harmful to health than products already on the market",* and requires applicants to submit *"information necessary to evaluate the properties and effects of the product",* cf. § 8 first and second paragraph.

The Directorate pointed to the before mentioned 2010 report from the WHO Study Group on Tobacco Product Regulation, which makes recommendations for clinical trials and other research required for regulatory approval, including behavioural and physiological consequences of using electronic cigarettes, monitoring of short- and long-term effects of human exposure and post-marketing studies to determine patterns of use, such as dual use, to monitor adverse effects and to determine the implications for initiation and cessation at individual and population level.[12] None of the applicants provided such documentation.

In 2017 and 2018 the Directorate received four applications for exemption for tobacco-free nicotine snus products:

- Fresh Free/Fresh Free (2017 – later withdrawn by the applicant)
- British American Tobacco/"Lyft" (formerly "Epok") 2018
- Imperial Tobacco/"Skruf" 2018

12 https://apps.who.int/iris/bitstream/handle/10665/44213/9789241209557_eng.pdf;jsessionid=F8A92E66024E78D2B045F83596757C83?sequence=1

- Swedish Match/"Zyn" 2018

The application for the tobacco-free snus "Lyft" was rejected on the basis of not having documented that the health risks linked to the product was substantially less harmful compared to traditional tobacco products.

As part of the case handling, the Directorate of Health requested the Public Health Institute to conduct an assessment of the health risks of the tobacco-free nicotine snus. Based on this report, the Directorate concluded that the product is not substantially less harmful than tobacco-containing snus, as only the tobacco-specific health risk are removed, while the health risks linked to nicotine remain. Subsequently, the Directorate rejected the application in May 2019. The decisions of the Directorate may be appealed to the Ministry. The applicant did not submit any appeal to the Ministry.

The Directorate also pointed to the following elements concerning tobacco-free nicotine snus:

- The main objective of Regulation 1044/1989 is to prevent uptake of tobacco- and nicotine products among children and young people.
- Since nicotine is highly addictive and harmful to health, the government wanted to prevent the industry from creating new and untraditional products that would appeal to young people.
- In Norway, there has been a dramatic increase in the use of snus among young people since year 2000, also among girls. This is a concern as the use of snus during pregnancy is severely harmful to the foetus.
- Norwegian tobacco control policy has since the 1970s strived for a high protection of public health and the regulation of novel products with uncertain effects on public health is based on the precautionary principle. In this regard, both the harmful effect on individuals, but also the harmful effect on population level, must be taken into consideration.
- Nicotine snus products are already available on the market for consumers as a pharmaceutical product, without prescription. Established tobacco users are thus not hindered from using nicotine snus as a harm reduction or cessation tool.

The last two applications are still under review in the Directorate.

The Norwegian Ministry of Health and Care Services has above attempted to reply to your questions as thoroughly as possible. Please let us know if there are any aspects where you would like us to elaborate further.

Yours sincerely,

Geir Stene-Larsen
Director General

Lilly Sofie Ottesen
Director

This document is signed electronically and has therefore no handwritten signature