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Innovation and Less Harmful Alternatives to Tobacco:
The Case of Nicotine Pouches Regulation

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INTRODUCTION

The market for tobacco or tobacco-like products is changing fast. Consumers are increasingly motivated to substitute classic cigarettes with products that are less damaging to health. The COVID-19 crisis, and the growing evidence from the World Health Organisation (WHO) and others that smoking increases the risk of dying from COVID-19, is likely to increase that trend.[1] Alongside measures to reduce tobacco consumption, public-health authorities in some countries have also been at the vanguard of pushing product substitution. There is also vibrant innovation in the market with old and new firms coming up with new products that reduce the harm of tobacco consumption. E-cigarettes are one among such products. A less known example is nicotine pouches.

For some years now, tobacco-free nicotine pouches – a tobacco-free version of pre-portioned snus – have been available on the Swedish market. Although the use of the product is increasing and is marketed outside Europe, nicotine pouches are not subject to any specific product regulation – neither in Europe nor elsewhere. That makes the product unique because similar products are regulated in both international treaties and national legislation.

It is a matter of time before nicotine pouches will get regulated and the purpose of this report is to provide an analysis of different regulatory approaches and what they entail. This is chiefly done by observing key trends in tobacco-prevention policies and analyzing how the regulation of similar products has developed over time. Because of their product-specific similarities, the reference products for the analysis are snus and e-cigarettes. Obviously, these similarities include aspects of their harm-reduction potential (when compared to cigarettes) but also factors such as nicotine dependence, number of users, and the specifics of their regulation. The analysis is particularly focused on the regulation of these products in Europe and North America, and also takes stock of the factors that shaped the debate and affected the outcome of these regulations. Consideration is also given to the possibility that new conflicts may emerge in the wake of the increased use of nicotine pouches and how this may affect future regulation. In light of this analysis, the report provides a scenario for the regulation of nicotine pouches.

[1] http://www.emro.who.int/tfi/know-the-truth/tobacco-and-waterpipe-users-are-at-increased-risk-of-covid-19-infection.html

CURRENT REGULATION OF NICOTINE POUCHES

WHO

The product has not been the subject of discussion in any of the World Health Organization's conference of parties, held every other year. The EU and other members are bound by the WHO's 2003 framework convention on tobacco control.

EU

The EU has no common guidelines for how Member States should regulate nicotine pouches. The product is not covered by the EU Tobacco Products Directive (TPD); nor does it belong to any other specifically regulated product category. However, nicotine pouches are, as all non-regulated consumer goods, covered by the General Product Safety Directive.

Products containing nicotine but not tobacco were discussed on March 21, 2019, at a meeting with the Expert Group on Tobacco Policy[2]. Seven Member States reported that this type of product was sold in their markets and the European Commission affirmed that nicotine pouches are not considered as tobacco products under TPD Article 2 (4). However, the possibility of using other sector-specific legislation to the products was discussed, including pharmaceutical legislation.

In February 2020, the European Commission published an evaluation of the functioning of the Tobacco Taxation Directive (2011/64/EU). The evaluation examined if the excise duty rates applied to manufactured tobacco have protected public health and ensured a proper functioning of the internal market. In that evaluation, the European Commission points out that the current scope of the Directive cannot address the development of the next generation of products, such as nicotine pouches, already coming into the market and that these products can be a substitute to cigarettes. They describe the current lack of a proper definition of nicotine pouches and like products in the tobacco tax Directive as an issue due to the potential substitution of cigarettes and therefore loss of tax revenues.[3]

So far, two Member States have taken decisions about the regulatory identity of nicotine pouches. The Swedish National Food Agency has established that nicotine pouches are not a food product and indirectly approved the product to be placed on the market. Austria's chemical authority has used the EU's Classification, Labelling and Packaging Regulation – demanding that all products containing nicotine must be labelled with comprehensive warning text and warning symbols – in their approach to nicotine pouches.

Sweden

Nicotine pouches are not covered by any Swedish product-specific regulation, apart from tax regulation[4], and are available without restrictions on the market. Nor is it clear how the pouches will be classified by future regulation. Previously, snus-like products without nicotine and tobacco were handled by the National Food Agency and largely regulated through food legislation. However, the National Food Agency last year suggested a different approach, proposing that "tobacco-free products intended to be used in the same way as snus do not constitute food within the meaning of Article 2 of Regulation (EC) No 178/20021 of the European Parliament and of the Council."[5] It added that "This assessment applies regardless of the product's possible content of nicotine".

[2] https://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20190321_sr_en.pdf

[3] https://ec.europa.eu/taxation_customs/business/excise-duties-alcohol-tobacco-energy/excise-duties-tobacco/revision-excise-rules-tobacco_en

[4] https://skatteverket.se/foretagochorganisationer/skatter/punktskatter/nikotinskatt.4.41f1c61d16193087d7fc7fe.html

[5] https://www.livsmedelsverket.se/om-oss/press/nyheter/pressmeddelanden/livsmedelsverket-tobaksfritt-snus-ar-inte-livsmedel/?AspxAutoDetectCookieSupport=1

When the Swedish Food Agency notified its decision to the Ministry of Industry, it also called on the government to decide on how nicotine pouches should be regulated in the future.

Sweden has become the first country to begin the process of defining and categorising nicotine pouches. It is likely that the National Food Agency's interpretation of how nicotine pouches relate to the EU Food Regulation can be a reference point for other countries and for the EU. If nicotine pouches had been considered to be a food product, it would have meant that the product would be banned: nicotine is a prohibited food additive in Europe. The government has appointed a special commissioner with the task or proposing a new regulation on e-cigarettes and nicotine pouches. There is no call from the government to ban any of these products. The proposals should be presented no later than the 31st of March 2021. This means that new legislation will be in place in 2022 at the earliest.

Since tobacco-free snus does not contain tobacco, and thus is not covered by Swedish tobacco legislation, it can be marketed and sold in a way that is different from traditional tobacco products. However, Swedish manufacturers have committed to a voluntary industry standard for, among other things, moderation in marketing and sales. For example, sales should not be made to persons under the age of 18. Still, nicotine pouches are marketed in a way that would be directly illegal if they were considered a tobacco product.

Norway

There are products similar to nicotine pouches that are marketed in Norway, but a key difference is that they contain small amounts of tobacco. A range of pure-nicotine-pouch products was marketed in Norway, but these products had to be taken off the market in July 2018 because there has been a ban since 1989 on producing, importing or marketing new tobacco and nicotine products, other than those traditionally found on the Norwegian market (cigarettes, cigars, cigarillos, smoked tobacco, snus and chewing tobacco).[6] Consequently, tobacco was added to the pure nicotine pouches. The ban aims to reduce health damages because of tobacco use but includes an exemption for drug-classed nicotine products aimed to help quit smoking. When the Norwegian Public Health Authority decided that nicotine pouches should be considered a new nicotine product, it became banned under the 1989 regulation of tobacco.[7] Despite this, the nicotine pouches-like product segment in Norway is a growing part of the oral tobacco and nicotine products market: its market share increased from 4 to 12 per cent between 2017 and 2018.[8]

Norway's Public Health Authority has acknowledged the somewhat peculiar situation: products that are less harmful than tobacco products are banned while tobacco products are not.[9] The authority claims that harm reduction has had a relatively small impact on Norwegian tobacco policy, but stress that less harmful tobacco products may still attract people to the use of tobacco. Consequently, it recommends new harm-reducing products to be relatively strictly regulated. The Norwegian Tobacco Act is also about to change, based on a decision in Parliament 2016 aiming to implement the new European Tobacco Products Directive (TPD).[10] The new legislation, which is expected to come into force in 2020, replaces the old ban on new nicotine and tobacco products with a new approval procedure. The exact form of this approval procedure is still unclear but aims to verify that new products are safe and have harm-reducing potential. It is, therefore, reasonable to assume that pure nicotine pouches could apply for and be granted government approval under this new procedure.

[6] https://lovdata.no/dokument/SF/forskrift/1989-10-13-1044/§2

[7] https://www.toll.no/no/varer/alkohol-og-tobakk/privat_import_av_tobakk_og_snus/

[8] https://www.svd.se/swedish-match-tobaksfri-tillvaxt

[9] https://www.helsedirektoratet.no/rapporter/folkehelse-og-baerekraftig-samfunnsutvikling/Folkehelse%20og%20bærekraftig%20samfunnsutvikling.pdf/_/attachment/inline/3bee41d0-0b38-4957-913e-bedad965e37a:a89f2b8d35a30992c90f-2f4c4f872d2ffdd0abaa/Folkehelse%20og%20bærekraftig%20samfunnsutvikling.pdf

[10] https://www.stortinget.no/no/Saker-og-publikasjoner/Vedtak/Beslutninger/Lovvedtak/2016-2017/vedtak-201617-026/

USA

Since the Tobacco Control Act from 2009, the manufacturing, distribution and marketing of tobacco products in the United States are regulated by the US Food and Drug Administration (FDA). Since 2016, Electronic Nicotine Delivery Systems (ENDS), such as e-cigarettes, have also been included in their mandate.[11] As a consequence, the FDA also became responsible for regulating nicotine pouches.

Nicotine pouches currently face relatively low entry barriers compared to other similar products.[12] In 2014, Swedish Match introduced nicotine pouches on the US market for the first time,[13] and during the second quarter of 2019 the company launched the product nationwide.[14] Today, the US FDA requires all tobacco-free snus to be sold with the following warning; "This product contains nicotine. Nicotine is an addictive chemical."[15] As the product is aimed at adult nicotine and tobacco users, the manufacturers' voluntary code of conduct states that the product is only made for sale to consumers over 21 years. However, in December 2019 the FDA decided to restrict the sale of tobacco products and e-cigarettes to people 21 years or older: presumably, there will be a legal 21-years age limit for nicotine pouches as well.

Australia

Nicotine pouches, along with e-cigarettes and all other smokeless tobacco and nicotine products, are prohibited in Australia[16].

New Zealand

As in Australia, nicotine pouches, e-cigarettes and other smokeless tobacco and nicotine products were for a long time banned in New Zealand. In 2017, however, New Zealand authorities reviewed their tobacco policy and adopted a harm reduction strategy, intending to make New Zealand smoke-free by 2025.[17] This legislation, which entered into force in 2018, states that non-smoking tobacco products and new nicotine products must be given prior approval to be sold in the country. To obtain such prior approval, the manufacturer must demonstrate that the product is significantly less harmful than tobacco smoking and that the product can help make New Zealand smoke-free.[18]

CURRENT REGULATION OF SNUS

WHO

The WHO has a disapproving attitude to snus and smokeless tobacco. It argues that there is no scientific support for smokeless tobacco to be part of a harm-reduction strategy – and, consequently, that manufacturers of snus shouldn't be allowed to claim that their products are less harmful than tobacco smoking. Nor should they be allowed to freely flavour smokeless tobacco. Furthermore, the WHO wants to restrict the entry of smokeless tobacco into new markets.[19] However, the WHO recommendations are very old and have not been updated in the last 15 years.

[11] https://www.fda.gov/media/102420/download

[12] https://www.di.se/nyheter/tobaksfritt-snus-visar-stor-potential/

[13] https://www.swedishmatch.com/sv/Media/Pressmeddelanden-och-nyheter/Nyheter/helvit-storsatsning-pa-zyn--nytt-format-och-ny-smak-lanseras/

[14] https://www.swedishmatch.com/globalassets/reports/interim-reports/2019_q3_swedish-match_en.pdf

[15] https://www.zyn.com/us/en/questions/

[16] https://www.productsafety.gov.au/products/health-lifestyle/personal/tobacco-related-products/smokeless-tobacco-products

[17] https://www.stuff.co.nz/national/health/95358772/chewing-tobacco-snus-and-inhaled-nicotine-products-to-be-legalised-in-new-zealand

[18] https://www.beehive.govt.nz/release/new-pathway-smokeless-tobacco-products

[19] https://www.who.int/tobacco/sactob/recommendations/en/smokeless_en.pdf

EU

The sale of snus has been prohibited in the EU since 1 July 1992. In a Council Directive from that year, an earlier directive was amended by adding a ban on placing certain types of tobacco for oral use on the market. The 1992 directive states that the new products for oral use are particularly attractive to young people and that several Member States intend to impose a total ban on the products. The demand for a ban was raised by the UK already in 1990, where snus had then been introduced. One reason that contributed to the EU ban on snus was that the users in the EU were few and mainly located in countries that were not yet members of the Union at the time, such as Sweden. Another motivation was that snus remained unregulated in most Member States, giving the EU the freedom to design new regulations without causing too much conflict with existing national legislation.

Today, tobacco products in the EU are regulated by the Tobacco Products Directive (2014/40 / EU), which was implemented in the Member States by 20 May 2016. The directive repealed and replaced the previous tobacco directive of 2001 (2001/37 / EC). Both the current and the old directive confirm the ban on snus. The current one states that the ban "should be retained to prevent the introduction of an addictive product with harmful health effects into the Union". More specifically, it instructs all Member States to "prohibit the placing on the market of tobacco for oral use", with the exemption for Sweden, which regulated its use of snus in the accession act. Article 28 (2014/40 / EU) states that a report on the implementation on the Directive shall be made by the Commission no later than five years after 20 May 2016, that is in May 2021. It also states that special consideration should be given to whether parts of the directive should be changed, and that special consideration should be given to, among other things, the market trend for new tobacco products and market development that represents a significant change in circumstances.

Sweden

In the 1994 Act of Accession of Austria, Finland and Sweden, Sweden was specifically exempted from the prohibition within the Union on the sale of oral tobacco. However, Sweden is covered by an export ban on snus, which states that Sweden must "take the necessary measures to ensure that the product referred to… is not placed on the market in Member States where Directive 89/622 / EEC and 92/41 / EEC are fully applicable."

In Sweden, snus is regulated by the Tobacco and Similar Products Act (2018: 2088), which became effective on July 1, 2019. It replaced both the previous Tobacco Act (1993: 581) and the Electronic Cigarettes and Refill Containers Act (2017: 425). Labelling and packaging are also regulated, and the product must "be provided with texts and illustrations that disclose the health risks associated with the use of tobacco". It is not allowed to imply that snus is less harmful than other similar products. However, prohibitions on taste, fragrance and additives in tobacco products do not apply to snus. The regulation on the marketing of tobacco products is also very strict. Marketing may take place, inter alia, at points of sale as long as it is not intrusive, using outreach methods or encouraging the use of tobacco. A license is required to sell tobacco and it does not allow selling to anyone under 18.[20]

Norway

Norway is not covered by the EU ban on snus and snus is an approved tobacco product. However, like all tobacco products, snus is more regulated than in Sweden. From July 1, 2018, it is prohibited to sell tobacco products that do not have a standard packaging, so-called plain packaging. The

[20] https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-20182088-om-tobak-och-liknande-produkter_sfs-2018-2088

packaging must have a certain type of colour and font for the company name, and some of the manufacturers' symbols, logos or colours are not allowed.

The Norwegian Tobacco Act of 1975 also prohibits all marketing of tobacco products. In order to strengthen this ban, it is since 2010 prohibited for retailers to visibly display tobacco products.

The Norwegian legislation on health warnings is based on the EU Tobacco Products Directive, and states that packaging must be labelled with health warnings and that cigarettes must include pictures that illustrate the health risks of product use.[21]

UK

As long as the UK is a member of the EU, the sale of snus is illegal. However, Brexit may change the prohibition of snus. Generally, the UK has taken a more positive attitude to harm-reduction products in tobacco-prevention policies than the rest of the EU. It is also the largest market in Europe for e-cigarettes. Calls on the government to allow the sale of snus after Brexit have been raised by among others British Members of Parliament, although there are conflicting views also among them.[22]

USA

In the US, all tobacco is regulated by the FDA in accordance with the Tobacco Control Act of 2009: snus is regulated under the category "smokeless tobacco".[23] Since July 2010, there is a requirement that smokeless tobacco products must have a clear and comprehensive warning text on their packages. Smokeless tobacco products can only be sold to persons over the age of 18 and cannot be sold through vending machines that minors have access to. Nor can such products be given away for free.[24]

Harm reduction has for long been accepted in the American debate and the regulation of tobacco products. Through the 2009 Tobacco Control Act, there is the possibility for companies to submit an application to the FDA for their product to be considered a so-called Modified Risk Tobacco Product, MRTP. In practice, an MRTP stamp means that the product may be considered as risk-reducing in terms of tobacco-related diseases, and can thus be sold and marketed as such. In October 2019, the FDA for the first time approved an application to classify a tobacco product as MRTP. The approval was given to eight Swedish Match snus products that previously had been sold without the MRTP stamp. This means that the producer can claim that "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis". The MRTP stamp is product specific and lasts for five years, after which a new application must be made.[25]

Australia

In Australia, the sale of smokeless tobacco, including snus, is prohibited. However, carrying a smaller quantity (1.5 kg) for personal use when entering the country is allowed.

[21] https://www.helsedirektoratet.no/english/tobacco-control-in-norway

[22] https://inews.co.uk/news/health/brexit-snus-oral-tobacco-lift-ban-mps-recommend-265397

[23] https://www.fda.gov/tobacco-products/products-ingredients-components/smokeless-tobacco-products-including-dip-snuff-snus-and-chewing-tobacco

[24] https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/selling-tobacco-products-retail-stores#smokeless

[25] https://www.fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products

New Zealand

Like in Australia, smokeless tobacco and snus were prohibited for a long time in New Zealand. But when New Zealand re-examined its legislation in 2017 and implemented a new tobacco law in 2018, snus was granted approval. Snus was then launched in New Zealand by national distributor NZ Smokeless Tobacco.[26] However, NZST now seems to have abandoned traditional snus in favour of selling only nicotine pouches. There may be legal reasons for this.

CURRENT REGULATION OF E-CIGARETTES

WHO

In 2005, the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) entered into force. It is a legally binding agreement between 181 parties (including the EU)[27] aimed at reducing tobacco use and limiting its supply through, for example, taxes on tobacco products and labelling requirements.[28] The WHO guidelines have a major impact on national legislation.

The signatories to the WHO FCTC meet every second year to discuss issues related to tobacco and similar products. E-cigarettes and other electronic nicotine delivery systems (ENDS) have been discussed at the party conferences since 2008. During COP6, held in 2014, different objectives were set for the use of e-cigarettes. These objectives were, among other things, to prevent the use of e-cigarettes among young people and non-smokers, to minimize any health risks for e-cigarettes users and to prevent the sale of e-cigarettes with unproven claims to be harm reducing. To achieve these objectives, the parties were invited to adopt various proposed regulations during COP7 when this was held in 2016, among them to "prohibit or restrict the manufacturing, import, distribution, presentation, sale and use of ENDS".

With regard to the first objective of preventing use among young people, the proposed regulations were, among other things, to prohibit the sale of e-cigarettes to minors, to prohibit or limit the flavour offerings targeting young people and to tax the products so that younger people cannot afford them. The parties of the WHO FCTC that have not completely banned e-cigarettes are recommended by COP7 to at least introduce measures to protect users of e-cigarettes by regulating the labelling of the product, require manufacturers to report any adverse effects of its use, and to require manufacturers' to make the table of contents of products available to the government. To protect non-users, health warnings are proposed, and to limit where e-cigarettes may be used. A number of proposals aim to prevent e-cigarettes from being sold with unproven claims for harm reduction. These include a ban on claiming to be a method to quit smoking unless such claims have been approved by an authority, a ban on claiming that the product is not addictive and a ban on comparing the product's safety or degree of dependence with other products, unless approved by an authority.[29]

E-cigarettes were also discussed at the last meeting in 2018, COP8. Discussions focused mainly on the progress made, market developments and that countries have taken different positions on how e-cigarettes should be defined. Today, e-cigarettes are defined as a tobacco product, tobacco-like product, medical product, consumer product, a poison or simply as e-cigarettes. At the Conference of the Parties, there was a call for more research and more scientific evidence as to whether or not e-cigarettes can be considered safe. It was also mentioned that national regulations should

[26] Swedish Snus finally arrives in New Zealand! | Scoop Newshttps://www.scoop.co.nz › Health

[27] https://www.who.int/fctc/cop/en/

[28] https://apps.who.int/iris/bitstream/handle/10665/42811/9241591013.pdf;jsessionid=79B4C83B6495226611712A-27D6212525?sequence=1

[29] https://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf?ua=1

be "flexible enough to cover new products and delivery systems". Also invited to COP8 was the Director-General of the EU Directorate-General for Health and Food Safety, Anne Bucher. She expressed concern both about young people's tobacco habits and the increasing popularity of e-cigarettes.[30]

EU

Since 2014, e-cigarettes have been regulated in the EU Tobacco Products Directive. The inclusion of e-cigarettes in the directive was a response to several Member States having already regulated the product in different ways, and therefore there was a need for an overall regulation to ensure the functioning of the internal market. That there were already national regulations in place made it more difficult to establish an equally stringent and far-reaching regulation at the EU level than for snus. The outcome was therefore somewhat of a compromise, with details being left to the member states to decide for themselves. Another factor that affected the outcome of the regulation was that there were already a large number of e-cigarette users throughout Europe. A total ban would therefore have resulted in widespread condemnation.

One of the requirements imposed on e-cigarettes and refill containers is that manufacturers must submit an application to relevant authorities to obtain market approval. The application must include a list of content, quantity, toxicological ingredients and addictive effects as well as information on nicotine doses and uptake.

Liquids placed on the market must not contain more than 20 mg/ml nicotine, and e-cigarettes must deliver a steady level of nicotine doses during normal use. The packaging of e-cigarettes and refill containers must inform consumers that the product is not recommended for non-smokers or adolescents, and state the toxicity of the product and its addictive properties. Packaging must also provide information on the content of the product, including the amount of nicotine. There must also be one of the following warning texts: "This product contains nicotine which is a very addictive substance" or "This product contains nicotine which is a highly addictive substance. It is not recommended for non-smokers".

Manufacturers must also annually report to authorities about the users of e-cigarettes and their preferences, and sales volumes. The directive also demands that market developments must be analysed to detect if the products are a gateway to traditional tobacco products, especially for young people and non-smokers. Authorities also have the right to take provisional measures if it is suspected that e-cigarettes or refill containers pose a threat to public health.

However, Member States themselves have the right to decide on rules regarding the flavour of E-cigarettes. Similarly, the directive does not specify an age limit for the purchase of this product.

Sweden

In Sweden, e-cigarettes are regulated by the Tobacco and Similar Products Act (2018: 2088), which replaced the previous law (2017: 425) on electronic cigarettes and refill containers. Manufacturers and importers are required to notify products to the Public Health Authority at least six months before they are placed on the market. Manufacturers must report their sales figures and data about consumer preferences every year. Manufacturers, distributors and importers must also collect data on any harmful health effects from using e-cigarettes and submit these to the Public Health Authority upon request.

[30] https://www.who.int/fctc/cop/sessions/cop8/COP8_Report_en.pdf?ua=1

In terms of labelling, the packages of e-cigarettes and refill containers must have a health warning in order to be sold on the market. Like other tobacco products, there is an age limit of 18 years for purchasing the product. The products are not allowed to be presented as less harmful than other similar products or compared to food. Nor can references be made to flavours, fragrances or additives.

Norway

In Norway, e-cigarettes are prohibited by the law of 1989 that prevents new tobacco and nicotine products (other than cigarettes, cigars, cigarillos, smoked tobacco, snus and chewing tobacco) from being produced, imported or marketed.[31] However, in December 2016 the Norwegian Parliament decided to lift the ban on selling e-cigarettes containing nicotine, a decision that will enter into force in 2020.[32] The coming legislation states that e-cigarettes may only be sold after being registered by the Norwegian Medicines Agency, no later than six months before the product is released on the market. The process is based on the market-access rules in the EU Tobacco Products Directive. Manufacturers must also provide annual reports regarding for example sales and volumes.[33]

USA

Since 2016, Electronic Nicotine Delivery Systems (ENDS), which includes e-cigarettes, have been regulated by the FDA. In order to legally provide tobacco products, including e-cigarettes, on the US market a manufacturer must get approval by the FDA, for instance through a Pre Market Tobacco Approval (PMTA).[34] Because e-cigarettes existed before the entry of the regulation, there are products being sold today without the explicit permission from the FDA. The FDA stated last summer that there are no approved e-cigarettes on the US market,[35] but the same authority has given manufacturers until May 2020 to retroactively apply for approval of their products. If it cannot be proven by that date that products are "suitable for the protection of public health", manufacturers may be prohibited from selling them.[36]

Major changes were ushered in when the FDA began to regulate the product in 2016. Many of the rules that apply to the sale of smokeless tobacco then started to apply also to e-cigarettes, including the 18 years age limit, the ban on distributing the products for free, and the use of vending machines where minors have access. Selling and marketing e-cigarettes also requires a warning text about health risks.

In recent months, however, it has been discovered that thousands of people in the US have developed lung diseases after using e-cigarettes. A number of them have subsequently died.[37] At the time of writing, it has not been established what caused these diseases. In October last year, the FDA issued a statement advising consumers against the use of e-cigarettes containing THC, a marijuana plant derivative, and vitamin E acetate – both substances that have been identified as potential causes for the diseases.

The illnesses and deaths associated with the use of e-cigarettes have triggered a federal debate about flavoured nicotine products and their health risks. In September 2019, Donald Trump announced an intention to ban flavoured e-cigarettes, a position he then backed away from in November.[38]

[31] https://lovdata.no/dokument/SF/forskrift/1989-10-13-1044/§2

[32] https://www.helsedirektoratet.no/tema/tobakk-royk-og-snus/e-sigaretter-elektroniske-sigaretter-og-regelverk

[33] https://www.stortinget.no/no/Saker-og-publikasjoner/Vedtak/Beslutninger/Lovvedtak/2016-2017/vedtak-201617-026/

[34] https://www.fda.gov/news-events/press-announcements/fda-finalizes-guidance-premarket-tobacco-product-applications-electronic-nicotine-delivery-systems

[35] https://www.fda.gov/news-events/press-announcements/fda-finalizes-guidance-premarket-tobacco-product-applications-electronic-nicotine-delivery-systems

[36] https://time.com/5685936/state-vaping-bans/

[37] https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#what-we-know

[38] https://www.nytimes.com/2019/11/17/health/trump-vaping-ban.html

But the number of people affected and the uncertainty about exactly what has caused the illness has also led to a number of states taking their own action to prevent e-cigarettes from causing further illness and death.[39]

During the autumn of 2019, governors in several states tried to ban flavoured e-cigarettes but encountered problems in court. The governor of Michigan was the first governor to announce the intention of banning flavoured e-cigarettes: a ban subsequently entered into force on the 18th of September. The ban was supposed to last for 180 days, but a court ruled already in October that the governor overstepped his power; the sale of e-cigarettes could thus continue. In New York, flavoured e-cigarettes were banned as an emergency measure in September but the ban was stopped in October, before it even entered into force. However, in late November 2019 a state law was passed that bans flavoured e-cigarettes in New York as of July 1, 2020.[40] [41] In late September 2019, Massachusetts also decided to immediately ban all types of e-cigarettes, including marijuana, a ban that will last until January 25, 2020.[42] Just after Massachusetts announced its ban, Rhode Island announced that it also wanted to see a 120-day ban on flavoured e-cigarettes as an emergency measure, with the option to extend the ban for another 60 days. The case was brought to court, but the ban could not be stopped.[43] In Montana, a ban was due to enter into force on 22nd of October 2019, but was stopped in court just days earlier. Flavoured e-cigarettes are banned for 120 days in Washington since early October 2019. The 120-day ban could not be stopped despite some attempts to do so.[44] A planned six-month ban on flavoured e-cigarettes in Oregon was stopped in court in October 2019. In California, no formal steps have been taken towards introducing a ban, even though the state governor has expressed a wish to introduce one.[45]

Other cities that in the United States that have taken initiatives to ban e-cigarettes are for example San Francisco, which has decided on a ban on e-cigarettes as from 2020[46], and Los Angeles that is discussing a similar proposal.[47]

Australia

Nicotine is regulated in Australia under the Therapeutic Goods Act 1989. The regulations classify medicines and poisons into Schedules which determine how freely they will be available to the public. There are 10 different schedules and nicotine is assigned to schedule 7 and thus considered a "dangerous poison" that can harm people even at low exposure. Nicotine in tobacco products intended for smoking is exempted from schedule 7, meaning that regular cigarettes are differently regulated. Nicotine is also exempt from schedule 7 when it is used for therapeutic purposes, such as quitting smoking. Nicotine classified at schedule 7 may only be available to approved users.[48] E-cigarettes are classified as schedule 7 and therefore prohibited in all states of Australia.[49]

New Zealand

In many respects, New Zealand has previously followed the example of Australia in its regulation of tobacco and similar products. It used to be a prohibition to sell or market e-cigarettes containing nicotine. Also, e-cigarettes containing nicotine were not considered an acceptable method to quit

[39] https://time.com/5685936/state-vaping-bans/

[40] https://www.cnbc.com/2019/11/26/new-york-city-council-approves-ban-on-all-flavoured-e-cigarettes.html

[41] https://www.wsj.com/articles/new-york-city-bans-flavoured-e-cigarettes-11574800984

[42] https://www.mass.gov/news/governor-charlie-baker-declares-public-health-emergency-announces-temporary-four-month-ban-on

[43] https://turnto10.com/news/local/judge-to-issue-ruling-in-suit-over-ban-on-flavoured-vaping-products

[44] https://www.spokesman.com/stories/2019/nov/08/washington-ban-on-flavoured-vape-products-stands-as/

[45] https://time.com/5685936/state-vaping-bans/

[46] https://www.theverge.com/2019/11/6/20951495/san-francisco-vote-e-cigarette-ban-proposition-c-results

[47] https://www.latimes.com/california/story/2019-10-08/e-cigarettes-vaping-devices-proposed-ban-los-angeles

[48] https://www.legislation.gov.au/Series/F2020L00017

[49] https://sydneyvapeco.com.au/blogs/news/australian-nicotine-laws

smoking and therefore banned.[50] However, New Zealand has had an extensive debate in recent years about harm reduction which has resulted in a more liberal view of e-cigarettes and their role in the ambition to replace cigarettes. In 2017, New Zeeland decided to legalise the sale of e-cigarettes and since 2018 it is allowed to sell e-cigarettes to people over the age of 18, as long as it is not claimed that the products fulfil therapeutic purposes.[51]

HOW MAY FUTURE REGULATION OF NICOTINE POUCHES DEVELOP?

General development and the WHO

Nicotine pouches will be eventually addressed by legislators worldwide. Most likely, the content of future regulations will depend on two considerations: first, whether tobacco-prevention methods will include harm-reduction strategies and, second, if nicotine addiction will be a significant concern in countries where tobacco use is decreasing while the use of e-cigarettes is increasing.

A growing interest in harm reduction is expected, albeit from a fairly low level, and can lead to an approval of nicotine pouches under strict regulations. However, the role of harm reduction in government regulation is likely to rise faster in countries where tobacco-related mortality is higher than elsewhere, which is in less-developed countries. In other countries, the attitude to harm reduction may not be supportive. For instance, while there is a global and European interest in applying harm reduction strategies to address narcotics addiction, there is a dismissive attitude to harm reduction as part of tobacco prevention. In Australia, for example, harm reduction has for a long time been a central part of the country's drug policy:[52] the country is edging closer to the legalisation of marijuana[53] while it maintains a ban on e-cigarettes and snus, and continues to pursue one of the most strict tobacco laws in the world.

At the international level, the WHO can go in different directions. One the one hand, it may focus more on harm reduction in tobacco-prevention policies because tobacco-related harm continues to rise and the measures that the WHO have recommended show limited effects. On the other hand, the WHO may also devote more attention to nicotine dependence: for instance, the WHO already has a sceptical attitude to e-cigarettes[54] and it seems reasonable that the same attitude will be taken to nicotine pouches.

There is a growing concern about nicotine dependence in countries where the number of smokers has gone down. This is at the heart of the reaction to e-cigarette-related illnesses in the US. Another example is Norway: nicotine addiction is increasingly debated. Generally, the prime concern is that young people will develop nicotine addiction and that products like e-cigarettes and snus (and nicotine pouches) will attract consumers that never have been smokers.[55] All this and more may lead to demands for tougher legislation on nicotine pouches.

A common reaction to these concerns is the attempt to regulate the attractiveness of the products, usually by banning flavours and restricting marketing. This is the approach in the EU Tobacco Directive, which regulates characteristic flavours in traditional tobacco products, and in the regulation of e-cigarettes in many countries, such as Finland where flavoured e-cigarettes are banned.[56] While it is usually argued that nicotine and tobacco flavouring is especially used to attract young people, mint and menthol are often treated differently than other flavours. This is the case in the

[50] https://www.otago.ac.nz/wellington/otago644048.pdf

[51] https://vapingfacts.health.nz/the-facts-of-vaping/vaping-law-and-policy/

[52] https://www1.health.gov.au/internet/publications/publishing.nsf/Content/drugtreat-pubs-volatile-toc~drugtreat-pubs-volatile-pa2~drugtreat-pubs-volatile-pa2-9

[53] https://www.nytimes.com/2019/09/25/world/australia/marijuana-cannabis-recreational-legal.html

[54] https://medicalxpress.com/news/2019-07-e-cigarettes-undoubtedly.html

[55] https://www.utdanningsnytt.no/danmark-helse-rus/45-prosent-av-danske-videregaende-elever-royker-e-sigaretter/205599

[56] https://www.valvira.fi/web/en/tobacco/faq

EU Tobacco Directive, which prohibits flavoured tobacco but allows a long period to phase out menthol,[57] and in the FDA's new strategy to reduce the use of e-cigarettes among young people. In the US, flavoured e-cigarettes (other than those flavoured by mint or menthol) are not allowed to be sold in premises attracting young people.[58] It is likely that, sooner or later, there will be a similar debate about flavoured nicotine pouches in many countries.

Moreover, rules about age limits and marketing are usually motivated by the ambition to reduce the attractiveness of different products to young people and preventing them from developing an addiction. These rules apply to traditional tobacco products and e-cigarettes: they will eventually apply to nicotine pouches as well.

In general, we can expect that the debate and legislation on e-cigarettes in a country will have a major impact on how nicotine pouches are regulated. New regulation of nicotine pouches has come as a direct consequence of new rules that are primarily aimed at allowing or re-regulating e-cigarettes in some countries, such as in Norway and New Zealand.

The WHO's attitude towards nicotine pouches may have an impact on how different countries choose to shape their own regulation of the product. This is especially true in Europe, where new legislation is often justified by the WHO's position on a specific product. Furthermore, the EU and its Member States are some of the most active parties in the WHO, thus having a major impact on how the WHO eventually shapes its positions. As a consequence, a market approval for nicotine pouches in the EU would therefore influence how global regulation will be shaped. However, it should be observed that the tobacco debate in the WHO and the organisations have limited influence on US legislation.

Europe

The EU will eventually need to decide whether to ban or regulate nicotine pouches. A ban can be made relatively quickly by, for example, an interpretative communication in which the Commission calls on the Member States to consider nicotine pouches as food or snus (or possibly a pharmaceutical product that must obtain approval). However, the legal basis for such an interpretative communication can be questioned. And it is unlikely that the European Commission would approach it that way unless Member States raise major concerns with the product and call for quick and decisive action from the Commission.

Regulating nicotine pouches most likely requires a revision of the Tobacco Product Directive (TPD). When the EU regulated e-cigarettes in 2014 it did so through a revision of the TPD despite the product not containing tobacco. Every other product-specific legislation cannot be used to regulate another product than the one concerned. However, there is no apparent wish to revise the TPD yet again. After all, the prior revision has recently been implemented in the Member States and, according to several Commission representatives, the experience of the 2014 revision was not good. The Commission will present an implementation report in May 2021 and it will give a first indication on how and when the EU plans to next update the TPD.[59] It would be surprising if this report does not address nicotine pouches in any way, and the way the Commission will present nicotine pouches and their markets will signal the future intention.

[57] https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_sv.pdf

[58] https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access

[59] https://ecigintelligence.com/eu-commission-and-parliament-kick-off-tpd-revision-assessment-procedure/

A revision of the TPD may also result in a ban on nicotine pouches. This option was considered for e-cigarettes in the last revision of the TPD. However, the possibility for stakeholders to influence a potential update of the TPD is much greater than in the process for establishing an interpretative communication from the Commission. It is also important to remember that an interpretation communication can always be repealed by a new regulatory framework, such as a revision of the TPD or the Food Regulation. In conclusion, all this means that it is a long and cumbersome process to develop a new legal framework for nicotine products and that final legal clarity for nicotine pouches in the EU will not emerge anytime soon.

Arguably, the EU approach to nicotine pouches will depend mainly on three factors:

- If Member States call for the EU to ban the product.
- The arrival of product-specific regulations or bans in Member States that are likely to be in conflict with future European legislation.
- The size of the product's consumer base and the fear of stoking reactions among the public created by a ban or restrictive regulation. During the 2014 revision of the TPD, it was clear that engaged and vocal consumers were one of the most important reasons that e-cigarettes were not banned, despite strong forces lobbying in favour of a ban.

How individual countries decide to regulate nicotine pouches in their markets will be crucial for a future EU regulation. A clear example of this logic is when the EU banned snus in 1992, which followed a highly criticised launch of a type of oral tobacco called Skoal Bandits in the UK and Ireland. The European Parliament then called for a ban of oral tobacco in September 1987. National ban on oral tobacco then came to Ireland in 1988 and in the UK in 1990.[60] These national bans and the need for harmonisation of legislation motivated the European Commission to ban oral tobacco in its Labelling Directive in 1992.

Regulatory attitudes in the Member States to a new nicotine product such as nicotine pouches depend in turn on the consumers base, how fast it grows, the attraction of nicotine pouches to young consumers and how aggressively the manufacturers launch the product. Much therefore depends on the responsibility taken by manufacturers. Obviously, it is difficult balancing the desire to grow the consumer base and avoiding aggressive marketing that will provoke hard regulatory responses, let alone a ban. This highlights the importance of responsible manufacturers on the actual regulatory design.

The order in which nicotine pouches is being launched geographically can also be important. Countries have different views on products that are similar to nicotine pouches, such as snus and e-cigarettes, and might react differently to the introduction of nicotine pouches on their market. It is also connected to the interest pursuing a harm-reduction strategy. Differences are often evident. On the one hand there are countries like Finland, which has led the most aggressive campaign against snus and regulates e-cigarettes harder than the rest of the EU. Countries like the UK and the Czech Republic, on the other hand, have a clearer harm-reduction ambition in tobacco prevention, and have therefore taken a more liberal approach than Finland.

[60] https://www.tobaccotactics.org/index.php/Snus:_EU_Ban_on_Snus_Sales#cite_note-2

Beside Sweden and Norway, there countries are of particular interest:

- Denmark: it is subject to the EU ban on snus, but has its own snus manufacturers and managed to maintain its own snus culture, thanks in large part to its proximity to Sweden and Norway. Denmark is also about to review its tobacco legislation and include nicotine pouches in it.

- The Czech Republic: it is one of the Member States with the largest use of e-cigarettes.[61]The Czech authorities have also shown a clear interest in harm reduction as part of their tobacco prevention strategy.

- Germany: it's not just the largest Member States, and thus central to the future regulation of nicotine pouches; German manufacturers have also started organising themselves and are in the process of developing common industry standards for the sale and marketing of nicotine pouches.

A future revision of the TPD will certainly also review the legislation of e-cigarettes in the EU. The current rules are first-generation and are not fully harmonizing the EU market. On the back of the US debate, there may also be a push in the EU to move towards stricter regulations. And should a future TPD revision strengthen rules on e-cigarettes, it could be difficult to decide permissible rules for nicotine pouches at the same time. Notably, the next revision of the TPD will also be done without the United Kingdom as a Member State. Given that country's accepting attitude to harm-reduction policies – and the size of its market for e-cigarettes – its absence may gush the EU into a more restrictive posture.

Even if the EU regulates nicotine pouches in a future revision of the TPD, some legal uncertainty may still remain. There could still be significant space for individual Member States to opt for stricter regulation – or ban the pouches entirely. Such gold plating is not uncommon when new and controversial products are regulated by the EU. While it risks fragmenting the internal market, gold plating can also serve as a way to bridge conflicts between Member States and allow for more permissive EU legislation. To some extent, this is how disputes over e-cigarettes were handled in the last TPD revision: a generally permissive attitude with opportunities for individual member states to adopt stricter measures.

Sweden

Nicotine pouches are now well established in the Swedish market, yet the product still isn't covered by a product-specific regulation. The government has stated that a regulation of nicotine pouches is urgent and tasked in February 2020 a commissioner to propose new regulation on e-cigarettes and nicotine pouches by the end of March next year. New legislation will be in place in 2022 at the earliest.[62]

The government has not called for a ban on any of these products. Since the product is so established in Sweden, parliament won't be able to ban the product without stoking massive consumer criticism. The Swedish Food Agency's classification of nicotine pouches (not being a food product) is possibly another sign that regulators are unwilling to ban the product. Therefore, it is highly unlikely that Sweden would down this route. However, the government has expressed concern about nicotine pouches, claiming that marketing and flavouring are targeting young people.

[61] https://data.europa.eu/euodp/en/data/dataset/S2146_87_1_458_ENG

[62] https://www.regeringen.se/4906aa/contentassets/6dd172eb91b2423dbe496579aaf0b459/dir.-2020_9.pdf

Three factors are likely to influence the restrictiveness of the regulation:

- How responsibly manufacturers are perceived to market the product.
- How popular the product becomes among people who have not previously used tobacco (especially young people).
- The increasing support for harm reduction in tobacco-prevention policies in the Swedish parliament.

While nicotine pouches are considered by many to be comparable to snus, they are differences in regulation that have an impact on, for example, marketing. Manufacturers of nicotine pouches thus have marketing opportunities than producers of traditional tobacco products in everything from sampling and advertising to sponsorship and product placement. This discrepancy will probably remain because it is difficult under the Swedish Freedom of the Press Act – a constitutional act – to limit or regulate the marketing of anything other than tobacco. However, if nicotine pouches are marketed irresponsibly, legislators can strengthen other regulations of the product.

The government is clearly concerned about the use of nicotine pouches among young people. This concern is amplified by public-health campaigners who now target nicotine products – not just tobacco products. Market data showing an increase in youth use could quickly strengthen the opinion in favour of new strict regulation of nicotine pouches. External factors like tendentious media reporting and irresponsible marketing of nicotine pouches could have an outsized impact on the regulatory direction.

There is strong political support for snus in Sweden. Nowadays, the support is less dependent on snus as national and cultural tradition; it is far more about snus being a harm-reduction product that reduces smoking. This context is important also for the future regulation of nicotine pouches. In a Parliament review of the government's overall strategy for Alcohol, Drugs, Doping and Tobacco (ANDT strategy) for 2021, calls have already been made by a majority of MPs to focus more of the prevention policy on harm reduction. And this ambition doesn't sit comfortably with the view that the market for nicotine pouches should be severely restricted.

Norway

Norway will get new tobacco legislation during 2020. Although the main purpose of this law is to re-regulate e-cigarettes, it has been stated that the current ban on new tobacco and nicotine products will be replaced by an approval procedure. This regulation will also cover nicotine pouches and the procedure will be based on the TPD's provisions on new tobacco products. The exact design of the approval procedure is unclear, and these details will be become in an implementing act by the government.

Moreover, as harm reduction increasingly features in the Norwegian debate about tobacco prevention, there is less risk for nicotine pouches to become expelled from the market. The country's Directorate of Health has already challenged the strange situation in Norway that cigarettes are currently allowed – but nicotine pouches aren't. For instance, the Directorate has stated that it would be reasonable to regulate cigarettes more strictly than less dangerous tobacco and nicotine products.[63] Taken together, the factors suggest that nicotine pouches won't just be allowed in Norway in the near future; they are also likely to face less restrictive regulations than those that apply on the sales and marketing of tobacco products.

[63] https://www.helsedirektoratet.no/rapporter/folkehelse-og-baerekraftig-samfunnsutvikling/Folkehelse%20og%20bærekraftig%20samfunnsutvikling.pdf/_/attachment/inline/3bee41d0-0b38-4957-913e-bedad965e37a:a89f2b-8d35a30992c90f2f4c4f872d2ffdd0abaa/Folkehelse%20og%20bærekraftig%20samfunnsutvikling.pdf

Denmark

In late 2019, a broad political agreement was reached on a new Action Plan on tobacco in Denmark.[64] It contains everything from plain packaging on cigarettes to a ban on the flavouring of tobacco and e-cigarettes. It also includes nicotine pouches – with a call for nicotine pouches to be regulated like other tobacco product rather than having them banned. Moreover, the Action Plan clearly states that nicotine pouches should be exempted from the ban on flavouring and plain-packaging rules. As a consequence, nicotine pouches (along with cigars and pipe tobacco) will become the least regulated in this category of products – significantly less regulated then e-cigarettes. It remains unclear when these different rules will enter into force.

USA

Nicotine pouches are expected to become regulated by the FDA in the future and, with the authority's clear focus on harm reduction, it is likely that the new attitude will be rather liberal. In addition, if the current concerns in the United States about e-cigarettes causing lung damages will remain, there may be greater acceptance of nicotine pouches. Still, the increased use of e-cigarettes has caused general concern about nicotine addiction, especially among young people. An increasing number of states are considering banning the flavouring of e-cigarettes or regulating them strictly. The FDA has also mentioned that it is pondering similar initiatives and rumours suggest that it is President Trump who so far has stopped them.[65] Consequently, there is an obvious risk that nicotine pouches get unintentionally affected by such legislation, and recent developments in Michigan is a case in point.[66]

In late February 2020, the House of Representatives adopted the Reversing the Youth Tobacco Epidemic ACT – a bill that addresses all tobacco and nicotine products in many different ways. The main objective of the bill was to prohibit the sale of flavoured nicotine tobacco or any products with "characterizing flavours". It also includes online sales of these products and orders the FDA to regulate the sale of products containing synthetic nicotine.[67]

However, it is unlikely that the bill ever will enter in to force or that the Senate will consider it. After all, the Senate is controlled by the Republican Party who is generally sceptical of regulating these products.[68] Moreover, the Executive Office of the President has stated that "If presented to the President in its current form, the President's senior advisors would recommend that he veto the bill". At the same time, an increasing number of states and cities in the US are introducing their own regulations of e-cigarettes, leading to a fragmented regulatory environment. This may also lead to less legal certainty for nicotine pouches.

The question is if nicotine pouches, like snus, could achieve the status of a Modified Risk Tobacco Product, MRTP? If that happens, it would be possible to sell and market nicotine pouches as a risk-reducing product for tobacco-related diseases. However, one difficulty for nicotine pouches obtaining MRTP status is that they are not in the strict sense a tobacco product. They will also have to be compared to other products when health impact and harm reduction are measured. The outcome depends on the choice of comparator product – e.g. if they are compared to cigarettes or e-cigarettes. If the risk-reducing potential of nicotine pouches is compared to the risk of tobacco-related damage from snus, it is difficult to say it is really possible to demonstrate any real risk mitigation.

[64] https://www.regeringen.dk/nyheder/handleplan-mod-boern-og-unges-rygning/

[65] https://www.statnews.com/2019/11/21/e-cigarettes-fda-hands-tied/

[66] https://www.cspdailynews.com/tobacco/michigan-clarifies-ban-flavoured-nicotine

[67] https://www.prnewswire.com/news-releases/house-to-vote-on-nationwide-flavor-ban-why-is-house-bill-hr-2339-so-important--provape-301013543.html

[68] https://www.convenience.org/Media/Daily/2020/Mar/2/1-House-Pass-Bill-Banning-All-Flavored-Tobacco_GR

Russia

Snus has been banned in the Russian Federation since December 30, 2015. This initiative was first proposed by the Republic of Tatarstan, which had banned snus already in 2014.[69] Products very similar to traditional snus was still sold in Russia, though, but they were marketed as chewing tobacco. Nicotine pouches were still legal and they also grew in popularity, even if Russian produced nicotine pouches contained substantially higher nicotine levels than products from European and US producers. Russian producers were also targeting young users in their marketing of nicotine pouches. As a consequence, there were soon demands for a new regulation.

In December 2019, a bill proposing a complete prohibition of retail and bulk sales of all non-smoking tobacco products was submitted to the State Duma.[70] On January 10th 2020, the Russian president declared that he had given instructions to take measures and stop the distribution of non-smoking nicotine-containing products in our country.[71] In the beginning of March 2020, a new proposal was introduced in the State Duma that would make the ban on smokeless tobacco to apply also to nicotine pouches.[72] The development in Russia has also lead to a debate within The EuroAsian Economic Union (EAEU). Representatives from the EuroAsian Economic Committee, the executive branch of EAEU, have declared that they are drafting a proposal to ban nicotine pouches in all EAEU member states.[73]

CONCLUSIONS

- Nicotine pouches are today not subject to specific product regulation anywhere in the world, but we will most certainly see new regulation adopted in all important markets in the coming years.

- The interest in harm reduction as an approach to tobacco prevention and the concern about nicotine dependence will be two decisive factors for how legislators decide to regulate nicotine pouches.

- Which countries that start to regulate nicotine pouches, and how these countries actually regulate the product, is likely to influence the global development of how nicotine pouches will be regulated.

- Sweden and Norway will most likely be the first countries with specific product regulations for nicotine pouches and we can expect these regulations to be a mix of current regulations on snus and e-cigarettes. Since their attitude is accepting of nicotine pouches, they can also influence how other European governments will shape the regulation.

- If a country decides to categorise nicotine pouches as a food product, snus or a pharmaceutical product, the pouches will be banned in their current form in that specific Member State.

- The EU will most probably regulate nicotine pouches under the scope of the TPD. However, this will not happen in the near future. An indication on how the European Commission views nicotine pouches can probably be found in the implementation report for the TPD that is to be presented in May 2021.

[69] http://www.euro.who.int/__data/assets/pdf_file/0007/339235/20170404_WHO-RussianCaseStudy-ENG-DRAFT07.pdf

[70] https://www.tellerreport.com/news/2019-12-03---for-the-sale-of-snus-and-nasvay-proposed-to-introduce-criminal-punishment-.BytlXlQaS.html

[71] https://tass.com/society/1107187

[72] http://rapsinews.com/legislation_news/20200304/305537657.html

[73] https://tass.com/society/1107187

- How the EU chooses to regulate nicotine pouches is influenced by at least three factors:

    1. Whether EU Member States calls on the EU to ban nicotine pouches, due to concern about the use of the product in Member States (which was the reason for the EU ban on snus).

    2. Whether there are already specific product regulations or national bans in individual Member States that a new European legislation may be in conflict with.

    3. The number of users of nicotine pouches, and thus a public opinion critical to a new restrictive legislation or ban. This was one of the reasons e-cigarettes were not banned in the 2014 TPD revision.

- Action taken by manufacturers will influence how legislators will react. A strict self-regulation and dialogue with authorities can reduce the desire among some to opt for very hard regulations. Irresponsible marketing or sales can quickly raise demands for bans.

- The way the EU regulated e-cigarettes in 2014 may give an indication on how the EU will regulate nicotine pouches in the future. This would indicate a focus on warning texts and introducing a strict maximum nicotine level.

- The debate around lung damage from e-cigarettes and the rapid increase in use of these among young people in the US are likely to have consequences for a future revision of TPD in the EU. This applies primarily to e-cigarettes, but could also affect the future regulation of nicotine pouches.

- Beside harmonisation, the aim of a future European regulation on nicotine pouches will probably be to reduce the attractiveness of the product. The current debate on e-cigarettes in the US and the ban on flavours introduced in the 2014 revision of TPD indicate that regulating flavours might be the main way to address the attractiveness of nicotine pouches.

- Flavours in nicotine pouches also risk becoming collateral damage in the same way that flavoured snus was close to getting banned in the EU as an unintended consequence of the ban on flavoured cigarettes.

- A possible future regulation of flavours in nicotine pouches might accept mint and menthol but ban other flavours. This was the case when mint and menthol flavours were exempted from the ban on flavours in tobacco products in the review of the TPD in 2014, and the same is done in current US legislation on e-cigarettes.

- Future regulation of nicotine pouches in the EU may leave considerable room for further regulation by Member States, and even national bans. This is true today for both traditional tobacco products and e-cigarettes in the EU.

- The EU's view on nicotine pouches can have a major impact on how nicotine pouches are viewed by the WHO. The WHO's position will at the same time play a major role in future EU legislation. However, it has less significance for how the US chooses to regulate nicotine pouches.

- The next Conference of Parties to the WHO Framework Convention on Tobacco Control (COP9) that will take place in the Netherlands in October 2020, will likely address nicotine pouches and can give an indication the future WHO view of the product.

- The United States has a clear harm reduction strategy in its tobacco-prevention policy and this should favour nicotine pouches in US legislation.

- While the US debate on e-cigarettes causing lung diseases could advantage nicotine pouches, the increasing use of e-cigarettes among young people in the United States has triggered general concerns about nicotine addiction. This debate may adversely affect the attitude to nicotine pouches.

- Concerns in the US about nicotine addiction among young people are increasing and so is the demand for a ban on flavouring e-cigarettes. Such a ban could, intentionally or not, affect nicotine pouches.

- Since snus can be marketed as a less dangerous tobacco product in the US, it is likely that nicotine pouches, after approval, could be allowed to be marketed as a less harmful alternative. However, this presupposes that the legislation on less dangerous tobacco products is judged to be applicable to nicotine pouches, even though it is not in the strict sense a tobacco product. It is also crucial for the future regulation if the health effects of nicotine pouches are compared with the health effects of cigarettes, e-cigarettes or snus (the negative health effects of these products differ substantially).

- Sweden is unlikely to have a new legislation in place that regulates nicotine pouches until 2021 at the earliest. This legislation should be relatively permissible: there is clear support in the Swedish Parliament for harm-reduction attitudes in tobacco policy. Moreover, the Freedom of the Press Act limits the possibility to regulate the marketing of products (other than tobacco products).

- Nicotine pouches are set to become legal in Norway in 2020 when the new tobacco law is introduced and replaces the current ban on new nicotine products. However, it is unclear how long and cumbersome the new approval procedure for nicotine pouches will become. It is equally unclear how strict the regulation of sales and marketing of nicotine pouches will be.