SUNDHEDS- OG ÆLDREMINISTERIET

This is a rough translation – NOT done by the Ministry of Health and the Elderly – since they have not cared to provide a translation, for the notification of the EU-Commission.
So someone else had to do it!

Sundheds- og Ældreministeriet

Enhed: FOPS
Sagsbeh.: SUMMSB
Koordineret med:
Sagsnr.: 1907151
Dok. nr.: 1145200
Dato: 16-04-2020

IMPACT ASSESSMENT

Proposal to law amending the Law prohibiting tobacco advertising, etc., the Law on Tobacco Products, etc., the Law on Electronic Cigarettes, etc. and various other laws (Implementation of "National action plan against smoking of children and young people")

1. Introduction

Tobacco smoking is the main preventable source of disease and death in Denmark. Ca. 13,600 people die annually as a result of smoking. 17 percent of all adult Danes smoke daily, and at the same time smoking is very skewed and thus also the single biggest factor that creates inequality in health in this country.

A particular problem relates to smoking by children and young people, as they are particularly vulnerable to the harmful effects of tobacco and other nicotine products. Every day, 40 Danish young people start smoking, and the number is increasing. At the same time, four out of five smokers start smoking before the age of 18, creating the nicotine addiction that can harm them for the rest of their lives. The latest figures show an increase in the proportion of young people who smoke daily. At the same time, the use of smokeless tobacco products by young people is a point of attention. In Denmark, 10 percent of 15-24-year old have daily or occasional consumption of smokeless tobacco.[1]

In 2017, the Danish Health Authority estimated that if the 11- to 17-year-olds who smoked at the time[2] continued to smoke for the rest of their lives, more than 18.000 of them would die from smoking. A significant reduction in the number of young smokers could therefore prevent thousands of those who are young today from becoming ill or dying from smoking – the greater the reduction in smoking, the greater the effect.

The bill therefore intends for the Ministry of Health and The Elderly to tighten up tobacco legislation in order to reduce the number of smokers – in particular that fewer young people start smoking or become dependent on other nicotine products. It is also the Ministry's intention to ensure that smoking or the use of other nicotine products does not appeal to children and young people and that children and young people are not confronted with it in the context of their schooling, for example.

The bill is a drafting of the agreement on a national action plan against smoking of children and young people, concluded on 18th of December 2019, between the government (Social Democrats), the Liberal Party, the Radical Left, the Socialist People's Party, the Unity List, the Conservative People's Party and the Alternative party. The agreement contains a wide range of initiatives aimed at stopping and preventing smoking and nicotine addiction by children and

[1] https://www.sst.dk/-/media/Udgivelser/2020/R%C3%B8gfri-tobak/Noegletal_Roegfri-Tobak.ashx?la=da&hash=16B0A81175FFC115CE620ECAFE68CC9409E82103

[2] Response of 17 November 2003 May 2017 on SUU alm. Del – spm. 800.

young people and implements a number of initiatives that patient associations and professionals have been requesting for several years.

2. Key points of the bill

The draft law contains a number of initiatives aimed at strengthening the existing tobacco legislation. Thus, a number of initiatives are being put together in this area to effectively help to put an end to and prevent smoking and use of electronic cigarettes and other nicotine products by children and young people.

With the proposal, the Ministry of Health and The Elderly wishes to send a clear signal to young people and adolescents that smoking is extremely harmful to health. It is the combination of all the initiatives that should effectively help to reduce the proportion of young people who smoke in Denmark and, in the long term, contribute to reducing health inequalities.

Amendments are proposed to the following six laws:

- - The Act on Prohibition on Tobacco Advertising, etc., cf. Statutory Order No. 1021 of October 21, 2008, as amended by section 2 of Act No. 327 of March 23, 2013.
- - The Tobacco Products Act, etc., cf. Statutory Order No. 965 of 26 August 2019.
- - Act No. 426 of 18 May 2016 on electronic cigarettes, etc., as amended by section 2 of Act 1558 of 18 December 2018.
- - Prohibition on the sale of tobacco and alcohol to persons under the age of 18, cf. Statutory Order No. 964 of 26 August 2019
- - Act on smoke-free environments, cf. Statutory Order No. 966 of August 26, 2019 Act to prohibit tobacco advertising, etc., cf. Statutory Order No. 1021 of October 21, 2008, as amended by section 2 of Act No. 327 of March 23, 2013.
- - The Medicines Act, cf. Statutory Order No. 99 of 16 January 2018, which includes: amended by § 2 of Act No. 1554 of December 18, 2018 and most recently by § 5 of Act No. 1436 of December 17, 2019.

2.1. Display ban

Children and adolescents should not be able to meet tobacco products, tobacco surrogates, herbal smoking products and electronic cigarettes and refill containers with and without nicotine at points of sale.

Tobacco surrogates are products with nicotine content, that are not tobacco products, within the time of Section 2(2) of the Tobacco Products Act, etc., or electronic cigarettes, within the time of Section 2(1) of the Law on Electronic Cigarettes, etc., which are not authorised by a marketing authorisation under the Law on Medicinal Products or rules of EU law establishing Community procedures for the authorisation of medicinal products for human use, as well as equipment intended to be used with these products.

Hiding tobacco products appear to be able to help prevent children and adolescents from starting to smoke or relapse after quitting smoking. In this context, reference is made to ***"Prevention of smoking by children and young people – what works?"*** from the Knowledge Council for Prevention[3]. The Ministry of Health and the Elderly therefore considers that a proposal for a ban on visible display and placement at points of sale for tobacco products, tobacco surrogates, herbal smoking products and electronic cigarettes and refill containers with and without nicotine would be a relevant and effective tool to ensure that fewer children and young people smoke or start using other products with nicotine or electronic cigarettes and are exposed to tobacco exhibitions (advertising).

[3] Knowledge Council For Prevention: JVestbo, Charlotta Pisinger, Lotus Sofie Bast, Dorthe Gyrd-Hansen (2018). Prevention of smoking by children and young people. What works?

A number of supermarket chains have already chosen to hide the tobacco products on their own initiative. The Ministry of Health and The Elderly believes that requiring all retailers to hide tobacco products, tobacco surrogates, herbal smoking products, electronic cigarettes and refill containers with and without nicotine at the point of sale will create fair competition and increase the impact of the measures.

It is therefore proposed to introduce a requirement that all tobacco products, tobacco surrogates, herbal-based smoking products, electronic cigarettes and nicotine-free refill containers should be hidden at all outlets, including on the Internet, until a consumer specifically requests it.

The proposal is particularly targeted at buyers who are not already regular consumers of tobacco products, tobacco surrogates, herbal smoking products and electronic cigarettes and nicotine-free refill containers, such as children and adolescents. Regular consumers of tobacco products know which products and brands they prefer, and this group needs no visual reminder of this. It is therefore not intended to reduce the supply of tobacco products, tobacco surrogates, herbal smoking products and electronic cigarettes and refill containers with and without nicotine less than under the current rules, but rather to prevent children and adolescents from being tempted to start smoking or relapse after smoking cessation by visible display or placement.

It will be up to each point of sale to determine how the items can be hidden. This freedom of method is due, inter alia, to the fact that physical shops are as differently designed as they are many, and therefore each point of sale should be able to adapt, as they see fit. It is therefore up to the individual point of sale whether it will hide the goods in cupboards, at or under payment boxes, behind drapes, etc., provided that the goods are hidden from buyers at the point of sale. What matters is that each point of sale chooses a method in which the goods in question are effectively hidden between purchases in order to ensure that young people in particular are not tempted to use them.

It is also proposed that the prohibition should apply to the visible placement and display of goods on the Internet, except for the sale of pipes. In this context, internet sales also cover sales through app features. Thus, when selling such goods on the Internet, no pictures of the product may be displayed. It is also proposed that the prohibition of visible placement and display by the Law should not apply to the sale of electronic cigarettes and refill containers with and without nicotine and pipe, pipe tobacco or cigars at a physical point of sale specialising in the sale of these products.
If the physical point of sale sells other tobacco products etc., e.g. cigarettes or smokeless tobacco, these products must be hidden.

The Ministry of Health and The Elderly considers that an exemption for such specialised shops does not contravene the purpose of the proposed rules on hidden tobacco products, tobacco surrogates, herbal smoking products and electronic cigarettes and nicotine refill containers, since it must be assumed that the customers of specialist shops generally seek out the business of their own volition to purchase the goods or to obtain information about the goods in question. Since the buyer independently visits the specialty store in order to purchase goods or obtain information about them, the buyer's decision to do so has been taken prior to the visit to the store. The purchase call for visible display or placement of the goods will therefore be of less importance to the target group who buys goods in

specialty stores. The situation, on the other hand, is different when a buyer is in a regular convenience store and does not necessarily have a conscious desire to be greeted by visibly placed goods. In addition, the proposal for a ban on exhibitions is particularly targeted at those buyers who are not all the regular consumers of the goods, such as children and young people, who are not immediately considered to be the target group for the particular purchase of pipe, pipe tobacco and cigars.

It is proposed that outlets, including points of sale on the Internet, may, at the request of the buyer, provide the buyer with neutral information on which goods are sold at the point of sale, and at what prices the goods are sold for. Thus, a neutral list must be available at the point of sale which does not highlight some products, brands or prices over others.

2.2. Tightened rules for advertising

Advertising is generally prohibited in Denmark. Generally known, the Framework Convention on Tobacco Control (FCTC) also deals with advertising, promotion and sponsorship, and Article 13 of the Framework Convention states that a comprehensive ban on advertising, promotion and sponsorship would limit the consumption of tobacco products. A report prepared by, among others, WHO Europe and the Danish Cancer Society[4] has recommended that Denmark protect children and young people from exposure to the tobacco industry's marketing by ensuring that the current advertising ban covers all forms of tobacco advertising, promotion and sponsorship, for example, in connection with music festivals. The report also points out that *"the tobacco industry has the potential to influence Danish health policy and is not sufficiently regulated in terms of transparency, donations or corporate social responsibility (CSR)"*.

The Ministry of Health and The Elderly considers that tightening up the ban on tobacco advertising could help to combat the tobacco industry's attempts to promote both traditional and new tobacco products or brands. Therefore, the Ministry considers it important to clarify that the ban on tobacco advertising also includes communications which have only the indirect effect of promoting the sale of tobacco products.

It is therefore proposed that advertising in the Law prohibiting tobacco advertising, etc., should be understood as any action for commercial purposes which is intended to promote the sale of a tobacco product or with it as a direct or indirect effect.

The proposed amendment to the advertising rules above would also apply to tobacco surrogates and herbal smoking products. There is therefore the same health protection to consumers in relation to the promotion of tobacco surrogates and herbal smoking products as against tobacco products.

2.3. Tightened rules for sponsorship and distribution

The Ministry of Health and The Elderly considers it inappropriate, for example, that under the current rules it is permissible for a tobacco company to make an annual financial contribution to a festival in order to ensure that the company's products are sold at the festival, as long as the tobacco company's name, logo, etc. is not mentioned or displayed. The Ministry of Health and The Elderly believes that tightening the ban on sponsorship in favour of tobacco products could help to combat the tobacco industry's attempts to promote tobacco products.

[4] Capacity Assessment on the Implementation of Effective Tobacco Control Policies in Denmark, january 2018

It is therefore proposed that no economic or other aid should be granted for media production, events, activities, individuals, etc., with the direct or indirect effect of promoting the sale of tobacco products, tobacco surrogates or herbal smoking products.

The proposal would strengthen the ban in relation to current law to include situations where financial contributions or other support for media production, events, activities, individuals or the like would simply have the indirect effect of promoting the sale of tobacco products, tobacco surrogates or herbal smoking products.

The Ministry of Health and The Elderly also wants to strengthen the ban on distribution, which aims to promote the marketing of tobacco-based tobacco surrogates and herbal smoking products. It is therefore proposed that the Law prohibiting tobacco advertising, etc., should include that distribution, which has the direct and indirect effect of selling tobacco products, is prohibited.

2.4. Standardized packages

The bill proposes to introduce standardized packages for all tobacco products, herbal smoking products and electronic cigarettes except cigars, pipe tobacco and pipes - giving the packets a uniform expression. Standardization implies, inter alia, that the manufacturer's and product names must appear in a standardised manner, that logos must not appear and that the colour of the packaging, etc. is standardised. Standardization limits the advertising effect of packages.

See more of this in section 3 below.

2.5. Smoke-free premises and smoke-free school hours

School children should not be tempted to start smoking or using other tobacco products, electronic cigarettes or nicotine products during the school day – and should therefore not be confronted with these products either on school premises or from their schoolmates outside the school area.

Therefore, the bill proposes that all educational institutions with youth education etc., e.g. Vocational schools and institutions with pre-primary education must be covered by the requirement for smoke-free matriculation, as the three-year secondary education already is today, and that the ban be extended to tobacco surrogates and herbal-based smoking products. Thus, teachers, students and others must not smoke or use electronic cigarettes, tobacco surrogates or herbal-based smoking products in the institutions.

It is also proposed to introduce requirements for smoke-free school hours in all schools, boarding schools, after-schools, secondary education. Smokeless school hours mean not only a ban on smoking, but also a ban on the use of electronic cigarettes, tobacco surrogates and herbal smoking products.

In addition, it is proposed that the sale of tobacco products, tobacco surrogates, herbal smoking products and electronic cigarettes and nicotine-free refill containers should not be permitted in schools, including the requirement of smoke-free school hours. The proposal should be seen as an additional step towards ensuring that pupils are not confronted with these products during their schooling.

2.6. Prohibition of certain flavourings

The bill proposes to ban flavourings that could entice children and young people to use tobacco products and electronic cigarettes. Thus, it is prohibited to sell electronic cigarettes, etc. with characteristic aromas other than tobacco flavours and menthol flavours. The same is proposed for tobacco products not already covered by the prohibition of flavourings, excluding pipe tobacco and cigars and herbal smoking products.

See more of this in section 4 below.

2.7. Regulation of tobacco surrogates

New products containing nicotine, but not tobacco, in particular products consumed in the same way as snuff, are being launched on an ongoing basis. These products are currently not subject to advertising bans or purchase age limits and are promoted, among other things, through influencers on social media.

The Danish Health and Medicines Authority states that there is evidence that nicotine is highly addictive. Children and adolescents develop addiction faster than adults, and nicotine can affect the further development of their immature brains. Nicotine can also affect the development of the foetus' brain and lungs. The Danish Health and Medicines Authority is concerned that these products may encourage or maintain tobacco consumption. At the same time, the Ministry of Health and The Elderly and the Danish Health and Medicines Authority are concerned that the products can act as an opportunity to genuinely promote tobacco products.

Increased regulation can be justified by a protection consideration in relation to children and youth in particular.
The Ministry of Health and The Elderly therefore considers it appropriate to regulate products containing nicotine that are not tobacco products or electronic cigarettes and which are not authorised medicinal products or devices intended to be used with those products. These products are collectively referred to as tobacco surrogates.

Tobacco surrogates are thus products with nicotine content, that are not tobacco products, within the time of Section 2(2) of the Tobacco Products Act, etc., or electronic cigarettes, within the time of Section 2(1) of the Law on Electronic Cigarettes, etc., which are not authorised by a marketing authorisation under the Law on Medicinal Products or rules of EU law establishing Community procedures for the authorisation of medicinal products for human use, or equipment intended to be used with those products.

It is proposed that tobacco surrogates should be regulated in line with tobacco products in terms of advertising bans, sponsorship, bans on visible placement and display, age limit, smokeless school surroundings and smoke-free school hours, as well as health warnings on packages in line with those found on electronic cigarettes.

2.8. Better age control and tightening of penalties, as well as rules on disqualification for infringements of prohibitions on the sale of tobacco to persons under the age of 18

It is essential that there is effective enforcement of the age limit of 18 years for the sale of tobacco products, tobacco surrogates, herbal smoking products and electronic cigarettes and refill containers with and without nicotine, in order to ensure that children and young people are not allowed to buy these products.

The authorities should therefore have the best means of enforcing the age limit when shopping on the Internet, which is why it is proposed that retailers of such products

should operate a system that effectively verifies the age of the buyer when purchasing over the Internet, including in-app purchases.
It must be ensured that the right solution available for an age control system can be implemented by dealers before the requirement is implemented. At the same time, therefore, it is proposed that the Minister of Health and the Elderly determine the date of entry into force of the requirement for an effective age control system.
The Ministry of Health and The Elderly considers it important to strengthen the enforcement of the age limits for tobacco sales. It is therefore intended to provide directly for the law prohibiting the sale of tobacco and alcohol to persons under the age of 18 to waive the right to place tobacco on the market in particularly serious repeat cases for a period of time. This period shall be 6 months in the case of a first offence. The fact that the retailer has twice previously sold tobacco to minors is a prerequisite for the temporary withdrawal of the right to market tobacco.
In order to further encourage increased compliance, the penalties in the Law prohibiting the sale of tobacco and alcohol to persons under the age of 18 are proposed tightened.
Thus, it is proposed that the future fines should be DKK 25,000 for the first instance and then DKK 40,000 for the second instance. In the case of subsequent infringements, the amount of the fine will depend on a specific assessment which will depend on willfulness, etc. In case of particularly serious or repeated offenses thereafter, the right to market tobacco for a minimum of 6 months may be deprived, cf. above. In conjunction with the current provision in the law prohibiting the sale of tobacco and alcohol to persons under the age of 18, the Ministry of Health and Elderly's proposal corresponds to more than a doubling of the current penalty rates.

2.9. Toughening of penalties for violations of the Smoke-Free Environments Act

In order to ensure that effective action can be taken against employers, owners, restaurateurs, managers and tenants who allow smoking in breach of the rules of the Smoke-Free Environment Act, it is important that fines of a certain level can be imposed. This can help to encourage compliance.

The proposal assumes that the penalty imposed on the employer, owner, restaurateur, manager, and tenant who allows smoking in breach of the rules of this Law is doubled compared to the previous level of punishment. Thus, it is assumed that, in the first instance, the fine will in future be punishable by a fine of DKK 10,000. In the second and in the third instance, the fines are calculated at DKK 20,000 and DKK 40,000 respectively.

2.10. Free handout of smoking cessation medicines

The bill proposes to introduce an explicit exception to the prohibition on the free delivery of medicines in respect of the municipal councils' free delivery of smoking drugs when this is not done for advertising purposes.

With the proposal that municipal councils – without having to apply to the Danish Medicines Agency for authorisation – can supply smoking cessation medicinal products to the public free of charge if the delivery is not for advertising purposes, both municipalities and the Danish Medicines Agency will be administratively relieved, since municipalities no longer have to submit waiver applications and periodic re-applications to the Danish Medicines Agency, which, on the other hand, does not have to process such applications.

2.11. Consistency with other efforts

The bill should be seen in the context of the increase in the tobacco tax, which was passed by Act 1588 of December 27, 2019 amending the Tobacco Tax Act and the Act on Miscellaneous Consumption Taxes, and as a result of the Finance Act for 2020, funds have been allocated to control age limits and to trials of smoking cessation courses and free smoking cessation drugs for the socially vulnerable.

3. In particular for standardised packages

3.1. Applicable national law

In accordance with the applicable rules of the Tobacco Products Act, etc. a number of requirements are imposed on the single packaging and possible outer packaging of tobacco products.

It follows from Paragraph 19(1) of the Act that the person who places a tobacco product on the market in this country must ensure that each package and any outer packaging bears health warnings in Danish. Section 19(2) authorises the Minister for Health and the Elderly to lay down rules on:
(1) the number and type of health warnings to be provided by each category of tobacco product.
(2) the shape, wording, layout, location and size of the health warnings.
(3) prohibition of concealing or breaking health warnings in whole or in part when the tobacco products are placed on the market.

The authorization was utilized with Executive Order No. 669 of May 30, 2016 on limit values, health warnings and age control system, etc. of tobacco products, etc.

Section 10(1) of the Regulation on limit values, health warnings and age control systems, etc. of tobacco products, etc., states, inter alia, that each package and any outer packaging on cigarettes, roll-your-own tobacco and hookah tobacco shall bear a general warning, an information message and a combined health warning.
In addition, pursuant to Section 20(1) of the Tobacco Products Act, etc., the person who places a tobacco product on the market in this country shall ensure that each package and any outer packaging does not contain elements or features which:
(1) promote or encourage its use by giving a false impression of the characteristics, effects, risks or emissions of the products;
(2) gives the impression that a particular tobacco product is less harmful than others or is intended to reduce the effect of certain harmful components in the smoke;
(3) gives the impression that a particular tobacco product has vitalising, energising, healing, rejuvenating, natural, ecological or other positive purposes or other positive health or lifestyle effects;
(4) refer to taste, fragrance, flavourings or other additives or indicate that the product does not contain such,
5) makes the product look like a food or cosmetic product; or
(6) gives the impression that a particular tobacco product has an improved biodegradability or other environmental benefits.

The person who places a tobacco product on the market in this country shall ensure that a single package and any outer packaging are not labelled with information on the nicotine, tar and carbon monoxide content of the tobacco product, as referred to in § 20(2).

It follows from section 21 of the Tobacco Products Act, etc., that the National Board of Health sets detailed rules on requirements for size, shape, functionality, and constituents in relation to individual packages of cigarettes and rolling tobacco. The authorization was used by Executive Order No. 1064 of 4 July 2016 on studies of specific additives in tobacco products and specific requirements for the labelling and packaging of cigarettes and rolling tobacco, etc.

This is stated in section 7 (2) of the Executive Order. 1, that individual packages of cigarettes must be box shaped. This is further stated in section 7 (2). 2, that a single pack of cigarettes may be made of cardboard or a soft material and must not have an opening that can be closed or sealed again after the first opening, except for flip-top lids and folding cases with a hinged lid. For flip-top and hinged lids, the lid may only be hinged on the back of the single pack. It is also stated in § 7 (2). 3, that individual packages of cigarettes must contain at least 20 cigarettes. As regards individual packs of roll tobacco, section 8 (2) provides. 1 of the Executive Order, that single packets of rolling tobacco must be box-shaped, cylindrical or have the shape of a purse. Purse is a single pack which is in the form of either a rectangular pocket with a flap covering the opening (rectangular purse) or an upright purse. Finally, it follows from section 8 (2) of the Executive Order. 2, that individual packs of rolling tobacco must contain at least 30 grams of tobacco.

Furthermore, according to current law, the person marketing tobacco products in the country must ensure that each individual package and any outer packaging does not contain coupons offering discounts, free distribution, two one-off offers or other similar offers. , cf. section 22 of the Tobacco Products Act, etc.
Anyone who markets tobacco products in this country must also ensure that each individual package of tobacco products is affixed with a unique identity mark issued by the Danish ID issuer, cf. section 22a (1). 1 of the Tobacco Products Act, etc. It also follows that for two-backed goods manufactured outside the EU, the requirements for unique identity labels apply only to products intended for or marketed in Denmark, cf. section 22a (2) of the Act. 2, and that unique identity marks must be printed or affixed in such a way that they cannot be removed or deleted, and they must not be hidden or broken, cf. 3. Finally, the person marketing tobacco products in this country must ensure that each individual pack of tobacco products is affixed with a safety stamp mark in accordance with section 22 (b). 1 of the Tobacco Products Act, etc. According to section 22 b (1) of the Act, the Minister of Taxation has. 2, laying down detailed rules on the technical standards for safety marking on tobacco products in Executive Order No. 1012 of 1 October 2019 on safety marking on tobacco products. It is clear from this that safety stamp marks must be affixed to individual packages of tobacco products in such a way that 1) they are in no way hidden or broken by price marks or other elements required by law; all the while a tobacco product is being marketed and 2) they are protected from being replaced, reused or altered in any way.

Thus, current Danish legislation imposes a number of requirements on the packaging of tobacco products and any external packaging, but manufacturers and others. still have the option of affixing their name, logo, colour, other characteristics, etc. on the packaging and any outer packaging.

It follows from Section 8 of the Law on Electronic Cigarettes, etc., that the Minister for Health and the Elderly lay down rules on the labelling of electronic cigarettes and nicotine refill containers, including rules prohibiting the use of elements or features of the labelling which may give an erroneous picture of the purpose, use or effects of the products.

In addition, it follows from section 9 of the Act that manufacturers and importers who have submitted a notification pursuant to section 5 (2). 1 shall ensure that electronic cigarettes and nicotine refill containers which they market are provided with a health warning. In Ministerial Order No 499 of 30 May 2016 on the quality, labelling, age control system and advertising, etc., the Minister of Health and the Elderly of electronic cigarettes and refill containers, etc. laid down rules on the wording, form and placement of the health warning.

3.2. The rules of the bill

The proposed standardized packages are proposed to be inserted in a new section 21 a of the Tobacco Advertising Act, etc. (section 2 (10) of the Bill) and in a corresponding provision in a new section 9a of the Electronic Cigarettes Act, etc. (Section 3 (5) of the Bill):

»**§ 21 a.** The person who places tobacco products on the market in this country must ensure that each package and any outer packaging has a standardised design. However, this does not apply to cigars, pipe tobacco and pipes.
Paragraph 2. The Minister for Health and the Elderly shall lay down detailed rules on the design of standardisation.'

»§ 9 a. The person who markets electronic cigarettes and refill containers with and without nicotine in this country must ensure that each package and any outer packaging has a standardised design.
Paragraph 2. The person who markets electronic cigarettes and refill containers with and without nicotine in this country shall ensure that each package and any outer packaging is applied to a product ID.
Paragraph 3. The Minister for Health and the Elderly shall lay down detailed rules on the design of standardisation in accordance with paragraph 1 and the application of product ID in accordance with paragraph 2.«

3.3. Comments on the provisions

In accordance with the proposed section 21a (1). 1 of the Tobacco Advertising Act, etc. For example, the person marketing tobacco products in the country must ensure that each individual package and any outer packaging have a standardized design.
The proposal for standardization implies that packages must not have logos or other types of branding elements, but only brand name, product name, manufacturer name and the other elements, including health warnings provided by legislation. Thus, all the packages will have the same colour and the same standard font.

The standardized design of tobacco products does not apply to cigars, pipe tobacco and pipes. This is because these products do not particularly appeal to children and adolescents, to whom the standardized proposal is highly targeted.

It is proposed in § 21a (2). 2 of the Tobacco Advertising Act, etc., that the Minister of Health and Elderly establish detailed rules on the formulation of standardization. According to the proposed provision, the Minister of Health and the Elderly will, among other things, be able to set rules on colour, shape, appearance, text, material, and labelling. The rules are expected to be inspired by already existing solutions from countries that have introduced standardized packages.

It should be noted that the standardization is proposed to be introduced so that reasonable time is given for the settlement of inventory at the dealers. Thus, it is proposed that for tobacco products manufactured before 1 January 2021, the rules on standardization of packages will not take effect until 1 January 2022.

It is proposed in § 9a (2). 1 of the Electronic Cigarette Act, etc., the person who markets electronic cigarettes and refill containers with and without nicotine in this country must ensure that each individual package and any outer packaging have a standardized design.

The proposal for standardization means that the products must not have logos or other types of branding elements on individual packages and any outer packaging, but only stipulated information such as brand name, product name, manufacturer name and other statutory elements, including health warnings. Thus, all products will have the same colour and the same standard font.

It is proposed in section 9 a. Article 2 (2) of the Electronic Cigarette Act, etc., that the person marketing electronic cigarettes and refill containers with and without nicotine in this country must ensure that every single package and any outer packaging is affixed with a product ID. Product ID shall mean the unique ID that each product is affixed to in accordance with section 5 of Executive Order No. 599 of June 3, 2016 on notification of electronic cigarettes and refill containers, etc., here referred to as the e-cigarette ID (EC-ID). With the proposed paragraph. 2 it will be a requirement that each product package and any outer packaging must be affixed with a product ID (EC-ID). With this unique number for each product, it will be possible to identify the product unambiguously on the published list of legal products, cf. section 6 of the Electronic Cigarette Act. The requirement for the application of a product ID (EC-ID) will apply to all products covered by the registration obligation under section 5 of the Electronic Cigarette Act. The requirement will thus also apply e.g. nozzles and batteries. The applied Product ID (EC-ID) must be affixed to each individual package and any outer packaging in such a way that it is human readable. When marketing electronic cigarettes and refill containers with and without nicotine over the Internet, the Product ID (EC ID) must be presented in such a way that a consumer can easily identify the Product ID (EC ID) 'one). This can be done, for example, by placing the product ID (EC ID) immediately next to the product price information.

It is proposed in § 9a (2). 3 of the Electronic Cigarette Act, etc., that the Minister of Health and the Elderly establish detailed rules on the formulation of standardization in accordance with subsection (3). 1 and application of product ID according to par. 2. The Minister of Health and Elderly may, in accordance with the proposed provision in relation to the formulation of standardization, be able to lay down rules on, inter alia, colour, shape, appearance, text, material and labelling as well as any. allow additional product information on the package. According to the proposed provision, the Minister of Health and the Elderly will be able to lay down rules on, inter alia, the application of product ID. text, colour, and location of the product ID.
It should be noted that the standardization and requirements for product ID are proposed to be introduced so that reasonable time is given for the settlement of inventory at the dealers. It is proposed to introduce the standardization and the requirement for product ID so that reasonable time is given for the settlement of inventory at the dealers. Thus, it is proposed that for electronic cigarettes and refill containers with and without nicotine manufactured before 1 January 2021, the rules on standardization and product ID on the packages will not take effect until 1 January 2022.

3.4. Ministry of Health and The Elderly's considerations

The proposal to introduce standardised design of tobacco products, equipment, herbal smoking products and electronic cigarettes and refill containers with and without nicotine, will restrict the ability of manufacturers to use the goods as branding and advertising. Standardization means, among other things, that the goods do not have logos or other types of branding elements and have the same colour and the same standard font.

Standardised design of packets of tobacco products, herbal smoking products and electronic cigarettes and nicotine-free refill containers is particularly targeted not by already regular consumers, such as children and adolescents. The proposal for standardised design is thus not targeted at those who are already consumers, but rather especially children and young people who have not yet used the products and are thus more sensitive to branding elements, characteristics, etc.

3.4.1. Knowledge of impact

Several European countries, as well as countries outside the EU, have introduced or are introducing standardized tobacco packages, so that the area currently available to the producer must also have a specific appearance. Standardized tobacco packages are a relatively new initiative, and the evidence is therefore sparse, but the Danish Health and Medicines Authority estimates, based on the available studies and experience, that this will have an effect on children and adolescents in particular. The amount of research into the effect of standardized packages is increasing as more countries introduce it.

The National Board of Health states that research on standardized packages shows the effect of smokers 'thoughts and attempts on smoking cessation, as well as the appeal of the cigarette package, the users' experience of smoking, etc. The National Board of Health considers that standardized tobacco packages, which limit manufacturers' ability to use the cigarette package as advertising, are particularly targeted at young people.

The National Board of Health refers to a Cochrane Review from 2017[5], which concludes that standardized cigarette packages affect (especially young people's) attitudes towards cigarettes and that the packages are perceived as less attractive (appeal). Based on existing behavioral research, it is expected to lead to a reduction in the proportion that starts with smoking and an increase in the proportion who stop smoking. The Cochrane Review also describes several studies examining the effect of standardized cigarette packages on smoking prevalence or smoking cessation trials. Among other things, this is a central study from Australia, which estimates that standardized cigarette packages have led to a reduction in smoking prevalence of 0.55 percentage points from December 2012 to September 2015.

In addition, the National Board of Health based their knowledge on a review by Drovandi et al. of 2019[6], which focuses on young people's experience of standardized cigarette packages and image warnings, and, in line with the conclusions of the 2017 Cochrane Review, concludes that graphic health warnings and standardized tobacco packages appear to increase young people's awareness of the dangers of tobacco use. Standardized packages contribute to raising awareness among young people about the health risks of smoking and to reducing the attractiveness, popularity and "coolness" of the packages and smoking. In addition, according to the review, it is well documented that the tobacco industry's marketing strategies target teenagers and young adults, because it is crucial to the survival of the industry to attract the next "generation" of smokers.

In addition, the Danish Health and Medicines Authority refers to the report from Knowledge Council for Prevention "Prevention of smoking by children and young people. What works?" [7], which states that the age of consent for having tried to smoke an entire cigarette has increased in Australia

[5] Cochrane: McNeill, a., Gravely, S, Hitchman, S. C., Bauld, L., Hammond, D., & Hartmann-Boyce, J. (2017). Tobacco packaging design for reducing tobacco use (Review).
[6] https://www.ncbi.nlm.nih.gov/pubmed/30654833
[7] Knowledge Council For Prevention: Jørgen Vestbo, Charlotta Pisinger, Lotus Sofie Bast, Dorthe Gyrd-Hansen (2018). Prevention of smoking by children and young people. What works?

during the period when standardised tobacco packets were introduced in Australia. The report also states that young people are extremely sensitive to branding and advertising.

For further studies to support that standardized packages can affect smoking, especially children and adolescents, please refer to the Dutch Trimbos Institute fact sheet on Generic Tobacco Packaging[8]

3.4.2. International perspective

Article 11 of the WHO Framework Convention on Tobacco Control provides for specific requirements for the design and labelling of tobacco products. In addition, the WHO recommends the introduction of rules on standardised packages[9], as this will make tobacco products less attractive to children and young people and reduce the advertising effect of packages. Standardized packages amplify the effect of health warnings and remove the items on the package that give the impression that some variants are less harmful than others.

Standardised packages have been introduced or are being introduced in Australia, France, Great Britain,New Zealand, Norway, Ireland, Hungary, Spain,Uruguay, Canada, Belgium, Georgia, Romania and Thailand, among others.

Tobacco and electronic cigarettes are covered by the free movement of goods resulting from the EDF Treaty. Member States must therefore not, as a rule, lay down requirements which impede the free movement of goods. However, it also follows from the EDF Treaty that the free movement of goods may be restricted in the interests of, inter alia, the free movement of goods. public health, which is the concern sought by this bill.

Directive 2014/40/EU of the European Parliament and of the Council of 3 December 2004 on the approximation of the It is therefore necessary to provide for the approximation of the laws, regulations and administrative provisions of the Member States relating to the manufacture, presentation and sale of tobacco and related products and the repeal of Directive 2001/37/EC (referred to as the 'Tobacco Products Directive'). presentation and sale of tobacco and electronic cigarettes.

Under the Tobacco Products Directive, Member States may choose to lay down standardisation requirements for tobacco products and thus go beyond the Directive without prejudice to the principles of the free movement of goods. Thus, reference may be made to preamble to Paragraphs 53 and 55 of the Directive and article 24(2) of the Directive, which states that the Directive does not affect the right of a Member State to maintain or impose additional requirements applicable to all products placed on the market in the Member State in the standardisation of the packaging of tobacco products where justified on grounds of public health, taking into account the high level of health protection guaranteed by this Directive. Such measures shall be proportionate to the objective and shall not constitute a means of arbitrary discrimination or a disguised restriction of trade between Member States.

The proposal to import standardised tobacco products, herbal smoking products, electronic cigarettes and nicotine-free

[8] Factsheet generic tobacco packaging (plain packaging), Trimbos June 2019.

[9] WHO. Guidelines for implementation of Article 11 of the WHO FCTC on "Packaging and labelling of Tobacco Products" (decision FCTC/COP3(10)).
WHO. Guidelines for implementation of Article 13 of the WHO FCTC on" Tobacco advertising, promotion and sponsorship" (decision FCTC/COP3(12))

refill containers is justified in order to safeguard public health and achieve the desired objective of effectively stopping and preventing smoking and use of electronic cigarettes and other nicotine products by children and young people. This is a detailed piece of legislation setting the framework for standardisation, which will subsequently be translated into administrative rules. However, there is no less intrusive regulation that can achieve the same objectives.

The proposal for a standardized design of tobacco products, herbal-based smoking products as well as electronic cigarettes and refill containers with and without nicotine is one initiative in a comprehensive action plan against children and adolescents smoking, which is required by law. Children and adolescents are particularly vulnerable to the harmful effects of tobacco and other nicotine products, and a significant reduction in the number of young smokers could prevent thousands of young people today from becoming ill or dying from smoking - the greater the reduction. in smoking, the greater the effect. As stated under cl. 3.4.1. For example, standardized packages can affect especially children and adolescents 'smoking, as it will limit manufacturers' ability to use the cigarette package as advertising aimed specifically at children and adolescents. Therefore, the proposal for a standardized design is also proportionate to achieving the desired purpose of strengthening public health and, in particular, to stop and prevent children and adolescents' smoking, which cannot be achieved through other alternative and less intrusive measures that can provide a corresponding result.

As a trade-off against the interests of manufacturers, etc. it is proposed with the Bill that a reasonable transitional period be granted for the settlement of inventories at the dealers. Thus, it is proposed that for tobacco products, herbal-based smoking products as well as electronic cigarettes and refill containers with and without nicotine manufactured before 1 January 2021, the package standardization rules will not take effect until 1 January 2022.

Finally, it should be noted that the proposal for a standardized design applies to all tobacco goods (except cigars and pipe tobacco), herbal-based smokers and electronic cigarettes and refill containers with and without nicotine sold in Denmark, and therefore no discrimination is made.

In view of the above, the Ministry of Health and the Elderly considers the proposal for standardized design of tobacco products, herbal-based smoking products and electronic cigarettes and refill containers with and without nicotine necessary, proportionate and reasonable and in accordance with Article 24 (2) of the Tobacco Products Directive.

4. Especially with the case ban on flavourings

4.1. Applicable national law

Existing rules on the regulation of flavours in tobacco products are regulated in the Tobacco Products Act, etc. According to section 14 (1) of the Act. 1, cigarettes and rolling tobacco with a distinctive aroma must not be marketed in this country. In accordance with paragraph 2 of the provision. 2, the National Board of Health may lay down detailed rules on the prohibition in subsection (2). 1, including rules on whether a specific cigarette or type of rolling tobacco is covered by the prohibition in paragraph 1. 1, and on limit values for the content of cigarettes and rolling tobacco of additives or combinations of additives which give a distinctive aroma.

Pursuant to section 15 of the Tobacco Products Act, cigarettes and rolling tobacco containing flavouring substances in their constituents, such as filters, paper, packaging, capsules or any technical function that allows the odour or taste of the tobacco products in question or their smoke development intensity, must not be marketed. in this country.

For cigarettes and rolling tobacco with a characteristic aroma of menthol, section 14 (2). 1, and section 15 of the Tobacco Products Act, etc. first applied on 20 May 2020 in accordance with Article 7 (41) of the Tobacco Products Directive.

4.2. Rules of the proposal

The proposal for a ban on flavouring in other tobacco products, cigarettes and rolling tobacco is proposed to be inserted in a new section 14, 3 and 4, and a new section 15 a of the Tobacco Products Act, etc. (section 2 (5) and (6) of the Bill and in a corresponding provision in a new section 25 a of the Electronic Cigarette Act, etc. (Section 3, Item 10 of the Bill):

Section 14 (3). Tobacco products not covered by paragraph 1, and herbal based smokers with a distinctive aroma other than tobacco and menthol may not be marketed in this country. However, this does not apply to pipe tobacco and cigars.

Section 14 (4). The National Board of Health may lay down detailed rules on the prohibition in subsection (1). 3, including rules on whether a specific tobacco product or herbal based smoking product is covered by the prohibition, and on limit values for the content of tobacco products or herbal based smoking products of additives or combinations of additives that give a distinctive aroma.

§ 15 a. Equipment used in connection with tobacco products and herbal-based smoking products that enable the odour or taste of the tobacco products and herbal-based smoking products to be altered or their smoke development intensity shall not be marketed in this country. "

§ 25 a. Electronic cigarettes, refill containers with and without nicotine and flavourings for use in electronic cigarettes with a distinctive aroma must not be marketed in this country. However, the prohibition does not apply to the characteristic aroma of menthol or tobacco.
Paragraph 2*.* Equipment used in connection with electronic cigarettes which allow the scent or taste of the electronic cigarettes concerned to be altered shall not be marketed in this country.
Paragraph 3*.* The National Board of Health may lay down detailed rules on the prohibition in subsection (1). 2. Paragraph 1, including rules on whether a specific product is covered by the prohibition and on limit values for the content of products of additives or combinations of additives which give a distinctive flavour. '

4.3. Comments on the provisions

Section 14(3) of the Tobacco Products Act, etc., proposes that tobacco products not covered by paragraph 1 and herbal smoking products with a distinctive aroma other than tobacco and menthol may not be placed on the market in this country.

The provision will cover tobacco products not covered by paragraph 1, i.e. all tobacco products which are not cigarettes and roll-your-own tobacco. In addition, the provision will cover herbal-based smoking products, meaning products based on plants, herbs or fruits which do not contain tobacco, and which can be consumed through an incineration process. The provision will not cover pipe tobacco and cigars and certain products must therefore continue to be placed on the market with all types of characteristic flavourings.

This means ensuring that characteristic aromas cannot obscure the taste of tobacco and replace it with flavours that appeal to more people, which can make the use of tobacco products more appealing, especially for children and young people for whom

there is a particular protection interest. It is noted that flavourings can also help to facilitate inhalation, as it can make tobacco more soft in taste.

In addition, it is proposed that a new section 14 (2) be inserted. 4 of the Tobacco Products Act, etc., according to which the National Board of Health may lay down detailed rules on the prohibition in subsection (1). 3, including rules on whether a specific tobacco product or herbal based smoking product is covered by the prohibition, and on limit values for the content of tobacco products or herbal based smoking products of additives or combinations of additives that give a distinctive aroma.

It is also proposed that a new section 15a of the Tobacco Products Act, etc., be inserted, whereby equipment used in connection with tobacco products and herbal-based smoking products that make it possible to change the odour or taste of the tobacco products or their smoke development intensity must not be marketed here. in the country.
This means that neither tobacco products nor herbal-based smoking products must be added to flavouring or additives that cause a distinctive flavour in the equipment used in connection with the products. In this way, it is ensured that the prohibition in the proposed section 14 (1). 3, cf. section 2 (3) of the bill against certain characteristic aromas is not attempted to be circumvented by adding the flavours to the equipment used in connection with tobacco products or herbal based smokers rather than directly in the products or their constituents. Equipment means, for example, filters, paper, packaging, capsules or any other technical function that makes it possible to change the odour or taste of the tobacco products and herbal based smoking products or their smoke development intensity.

It is proposed in section 25 (1) of the Electronic Cigarette Act, etc., that electronic cigarettes, refill containers with and without nicotine and flavourings for use in electronic cigarettes with a distinctive aroma must not be marketed in this country. However, the prohibition does not apply to the characteristic aroma of menthol or tobacco.

According to the circumstances, flavours that are not explicitly marketed for use in electronic cigarettes may fall under the ban. This may be the case, for example, if the flavouring is marketed at a point of sale, which sells electronic cigarettes, especially specialty stores, and where it is considered that the buyers of the context are given the understanding that the flavouring can be used in electronic cigarettes.

In addition, it is proposed in section 25 (2) of the Electronic Cigarette Act, etc., that equipment used in connection with electronic cigarettes, which makes it possible to change the scent or taste of the electronic cigarettes concerned, must not be marketed in this country.

This means that it will not only be prohibited to market electronic cigarettes, refill containers with and without nicotine and flavours for use in electronic cigarettes with a distinctive aroma, cf. 1, but also equipment used in conjunction with electronic cigarettes, which makes it possible to change the scent or taste of the products.

The proposed provision is intended to ensure that the prohibition in the proposed section 25 a (1). against certain distinctive aromas is not attempted to circumvent by adding the flavoring substances to the equipment used in connection with electronic cigarettes rather than directly into the products or their constituents.
The term equipment must be understood broadly, and thus may include, for example, pouches of flavours to attach to the products, etc.

Finally, Section *25(3)* of the Electronic Cigarettes Act, etc., proposes that the Danish Health and Medicines Authority may lay down more detailed rules on the prohibition referred to in paragraph 1,including rules on whether a specific product is covered by the prohibition and on the content of products of additives or combinations of additives which give a characteristic aroma.

Under the proposed provision, the Danish Health and Medicines Authority will be able to lay down rules on, among other things, the use of the whether specific products are covered by the prohibition referred to in paragraph 1 and limit values for additives.

It should be noted that the ban on flavourings other than menthol and tobacco is proposed in such a way as to allow a reasonable amount of time for the disposal of stocks by dealers. It is therefore proposed that for products manufactured before 1st of January 2021, the rules prohibiting certain flavourings will not take effect until 1st of January 2022.

4.4. Ministry of Health and The Elderly's considerations

The proposal for a ban on certain flavourings in tobacco products other than cigarettes and roll-your-own tobacco, herbal smoking products and electronic cigarettes and nicotine-free refill containers reduces the attractiveness of these products, particularly to children and adolescents.

4.4.1. Studies

Approximately 25% of 15-year-old Danish adolescents have tried e-cigarettes. Half of 16- to 19-year-old boys have tried e-cigarettes. There is a significantly higher proportion of children and adolescents who do not smoke who have tried e-cigarettes than adults who do not smoke who have tried e-cigarettes.[10].

The National Academies of Science, Engineering, and Medicine (NASEM) concludes that the use of e-cigarettes increases the risk of smoking tobacco later in life.[11] One of the studies included in the NASEM report is a meta analysis involving 17,389 people aged 14-30 years. The study shows that the risk of starting to smoke tobacco is 3.5 times greater in people who have tried e-cigarettes than in those who have[12]not.

The WHO writes in their "Report on the Global Tobacco Epidemic 2019" that children and adolescents who have never smoked and who use[13]e-cigarettes appear to at least double their risk of starting to smoke cigarettes later in life.

A 2018 Canadian study found that adolescents who had used e-cigarettes within the last 30 days had an increased risk of having tried smoking cigarettes,[14]compared to those who did not have e-cigarettes within the last 30 days.

[10] Danish Health and Medicines Authority. E-cigarettes and health, 2019

[11] National Academies of Science, Engineering, and Medicine. Public health consequences of e-cigarettes. 2018. Washington DC: The National Academies Press.

[12] Soneji et al. Association Between Initial Use of e-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Young Adults. JAMA Pediatrics, 2017, 171(8): 788-797.

[13] WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization; 2019. Licence: CC BT-NC-SA 3.0 IGO.

[14] S. Aleyan et al. Risky business: a longitudinal study examining cigarette smoking initiation among susceptible and non-susceptible e-cigarette users in Canada. BMJ Open 2018.

A cohort study among about 6,000 children and adolescents in the United States from 2019 also found a[15] link between the use of e-cigarettes, and the increased risk of starting to use cigarettes.

Public Health England (PHE) writes in their 2018 report that never-smokers in the UK who try e-cigarettes are more likely to try smoking cigarettes later than those who have not tried e-cigarettes. However, the report assesses that there is no causal link and that e-cigarettes do not appear to have an impact on the decrease in tobacco use among young people in the UK[16].

A systematic review from 2018 has looked at the preferences of e-cigarette users for, among other things, the use of different flavours in different age groups. It seems that flavours are an important factor for teens (<18 years) to try e-cigarettes and that teenagers start their consumption of e-cigarettes, with e-cigarettes with flavours, especially sweet flavours. The study also found that users perceived sweet and fruity flavours as less harmful,[17] while tobacco flavours were perceived as more harmful.

A 2019 report by the Nordic Centre for Welfare concludes that flavours are a leading reason why children and adolescents try e-cigarettes. New users especially prefer the sweet flavours, such as sweets, fruit, chewing gum and soft drinks. In addition, e-cigarettes with a taste of fruit are perceived as less harmful to health than e-cigarettes with a taste of[18] tobacco.

A Norwegian report snuff from 2019 also showed that a plural of young people use snuff with taste[19].

Tobacco products, herbal smoking products and electronic cigarettes with a distinctive aroma can thus affect consumption patterns as well as the number of people who initiate consumption. Distinctive aromas can help to make smoking and the use of electronic cigarettes more appealing as they reduce the taste of tobacco, can make the taste less harsh and for some additives have a soothing effect. This means that the smoke is perceived to be less irritating when inhaled. The health concern is particularly that a milder or softer taste can be particularly attractive to young people and that characteristic aromas can lead to more young people starting to smoke or persist in their addiction.

E-liquids contain varying amounts and types of flavourings, depending on the manufacturer and product. There are over 7000 different flavouring substances on the market which are used in e-cigarettes.[20].

[15] K.M. Berry et al. Association of electronic cigarette use with subsequent initiation of tobacco cigarettes in US youths. JAMA Network Open. 2019.
[16] A. McNeill et al. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England.
[17] S. Zare, M. Nemati, Y. Zheng. 2018. A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine, strength, and type.
[18] Nordic Welfare Centre. The significance of flavour additives in the use of moist snuff and e-cigarettes – with a focus on young people and the Nordic region. January 2019.
[19] The Norwegian Institute of Public Health. Health risks of snuff use, version 2. Norwegian Institute of Public Health Report 2019. Oslo: Norwegian Institute of Public Health, 2019.
[20] J.m. Kitzen et al. E-cigarettes for smoking cessation: Do they deliver. Journal of Clinical Pharmacy and Therapeutics, 2019, 1-6.

4.4.2. International perspective

The WHO calls for e-cigarettes to be regulated by law and for legislation to be regulated on the basis of the latest evidence in this area. The WHO is concerned about developments and lacks any evidence that e-cigarettes are not harmful to health. The WHO is particularly concerned about the health consequences of the use of e-cigarettes, whether e-cigarettes cause non-smokers and especially young people to smoke, and the influence of the tobacco industry on product development and legislation.

Article 7(1) of the Tobacco Products Directive requires Member States to prohibit the placing on the market of cigarettes and tobacco products with a distinctive flavour.

In addition, Article 7(7) of the Directive does not allow the marketing of cigarettes and roll-your-own tobacco containing flavourings in their constituents such as filters, paper, packaging, capsules or any technical function enabling the smell, taste or smoke development intensity of the tobacco products concerned to be altered. Filters, paper and capsules in cigarettes and roll-your-own tobacco must also not contain tobacco or nicotine.

It follows from preamble 47 of the Tobacco Products Directive that Member States are responsible for the adoption of rules on flavouring substances in relation to e-cigarette products. The Ministry of Health and The Elderly is aware that Finland, Estonia and Hungary (in part) are prohibited from selling electronic cigarettes and e-liquids(both with and without nicotine) with flavourings in addition to tobacco flavours.

By extension, it is noted that Article 24(3) of the Tobacco Products Directive states that a Member State may also prohibit a particular category of tobacco products or related products because of the special circumstances of that Member State if the provisions are justified by the need to protect public health, taking into account the high level of health protection ensured by this Directive.

In preamble No. 54 moreover, it appears that, in order to take account of possible future developments on the market, Member States should also be able to prohibit a particular category of tobacco or related products because of the special circumstances of the Member State concerned, provided that the provisions are justified by the need to protect public health, taking into account the high level of protection achieved by this Directive.

Finally, it should be noted that the Tobacco Products Directive allows for further regulation of tobacco products, etc. As stated, inter alia, in preamble recital 55, a Member State should be able to maintain or introduce national law applicable to all products marketed in that State on aspects not covered by the Directive, provided that the provisions are compatible with the TFEU. and does not jeopardize the full application of the Directive. Thus, under these conditions, a Member State will: be able to regulate or prohibit accessories for tobacco products (including hookahs) and for herbal-based smoking products, and to regulate or prohibit products that look like a type of tobacco or related product.

The proposal to ban certain flavours in tobacco products other than cigarettes and rolling tobacco, herbal-based smoking products, and in electronic cigarettes and refill containers with and without nicotine is justified to ensure public health and achieve the desired purpose of effectively stopping and preventing children and adolescent smoking and use of electronic cigarettes as well as other nicotine products. There is no less intrusive regulation that can meet the same goals.

The proposal for a ban on certain flavours in tobacco products other than cigarettes and rolling tobacco, herbal-based smoking products and in electronic cigarettes and refill containers with and without nicotine is one step in a comprehensive action plan against children and adolescents smoking, which is required by law. Children and adolescents are particularly vulnerable to the harmful effects of nicotine. As stated under 4.4.1. flavours are the leading reason why children and adolescents try electronic cigarettes. New users are particularly attracted to sweet flavours such as sweets, fruits, chewing gum, soft drinks and so on, and studies show that many young people have a perception that e-cigarettes with, for example, fruit flavours are less harmful to health than e-cigarettes with the taste of tobacco. This will probably also apply to tobacco products other than cigarettes and rolling tobacco. Therefore, the proposal to ban certain flavours in tobacco products other than cigarettes and rolling tobacco, herbal-based smoking products and in electronic cigarettes and refill containers with and without nicotine is also proportionate to achieving the desired purpose, which cannot be achieved through other alternative and less intrusive measures. which can give a similar result.

As a trade-off against the interests of manufacturers, etc. it is proposed with the bill that a reasonable transitional period be granted for the settlement of inventories at the dealers. Thus, it is proposed that for tobacco products other than cigarettes and rolling tobacco, herbal-based smoking products, and electronic cigarettes and refill containers with and without nicotine manufactured before 1st of January 2021, the ban on certain flavours will not take effect until 1st of January 2022.

In addition, it should be noted that the proposal for a ban on certain flavours in tobacco products other than cigarettes and rolling tobacco, herbal-based smoking products, and in electronic cigarettes and refill containers with and without nicotine applies to all such products sold in Denmark, why that is not discriminated against.

Finally, it should be noted that, as a result of the precautionary principle, safeguard measures can be taken without waiting for the full extent of the health risk to be demonstrated and its extent.

In light of the above, the Ministry of Health and the Elderly finds the proposal to ban certain flavours in tobacco products other than cigarettes and rolling tobacco, herbal-based smoking products and in electronic cigarettes and refill containers with and without nicotine as necessary, proportionate and reasonable and justified by the need. to protect public health, taking into account the high level of health protection guaranteed by the Tobacco Products Directive.

5. Economic impact on public and business

The proposal is expected to contribute to a reduction in children's and adolescent smoking, the use of electronic cigarettes and other nicotine products. It is not possible to estimate the effect of the proposal on total tobacco consumption or sales. To the extent that the proposal has an effect on total tobacco sales, it will otherwise result in less tobacco tax revenue than would otherwise have been the case. Reduced tobacco consumption will, in the longer term, save costs for the treatment of tobacco-related diseases, sickness absence costs, etc.

The bill aims to limit the use of tobacco products, tobacco surrogates, herbal-based smoking products and electronic cigarettes, especially among children and adolescents. Therefore, the sales figure is expected to fall, partly due to the amount of sub-elements in this bill and partly due to the increase in the tax on products over the coming years. With the political agreement underlying the bill, it has been decided to introduce a number of measures recommended

by the National Board of Health and other professionals, despite the fact that there is currently no basis for further assessing the effect of the measures in a Danish context. - individually or collectively. Furthermore, there is no basis for further assessing the derived consequences in the form of a decline in revenue and earnings and the impact on the overall business base of the various players selling the products covered by the bill. This generally applies to the decline in consumption as well as the influence of consumption patterns of existing consumers on measures affecting the supply and availability of products, including whether these switch to product categories offered by the same players.