



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Message 201

Communication from the Commission - TRIS/(2024) 3395

Directive (EU) 2015/1535

Notification: 2024/0326/DK

Forwarding of the response of the Member State notifying a draft (Denmark) to comments (5.2) of Sweden.

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1. MSG 201 IND 2024 0326 DK EN 18-12-2024 17-12-2024 DK ANSWER 18-12-2024

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4. 2024/0326/DK - S00S - HEALTH, MEDICAL EQUIPMENT

5.

6. Denmark would like to thank Sweden for its comments on the notified draft. EU Member States have a common interest in ensuring that measures are in line with EU law, and Denmark will therefore take this opportunity to elaborate on the reasons for introducing the measure banning characterising flavours in tobacco surrogates, on which Sweden has commented.

I. Regarding the general need to introduce additional measures to prevent and stop smoking and nicotine addiction among children and young people

Tobacco is the most important preventable cause of illness and death in Denmark. However, nicotine itself is harmful to health and addictive. Especially children and young people are sensitive to the harmful effects of nicotine; for example, nicotine can have a serious impact on the ability to learn, concentrate and pay attention. Nicotine can also have a detrimental effect on mental health and help provoke symptoms of anxiety and depression.

Research also shows that nicotine increases the likelihood of becoming addicted to both cigarettes and drugs in general. Nicotine can thus be a stepping stone for children and young people to start smoking.

In Denmark, nearly 36 per cent of children and young people aged 15–29 use at least one tobacco or nicotine product, with the use of new nicotine products particularly increasing since 2020. Especially with regard to the use of smokeless



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nicotine products, the proportion of people who use smokeless nicotine products on a daily or occasional basis has increased from 9.1 per cent to 13 per cent among 15–29-year-olds in Denmark (Source: 'SRØG – En undersøgelse af tobak, adfærd og regler' [§SMOKE – A survey of tobacco, behaviour and rules], National Institute of Public Health, 2024).

In addition to the worrying increase in children and young people's consumption of tobacco and nicotine products, Denmark has in recent years also seen more and more new nicotine products come onto the market, many of which particularly appeal to children and young people, for example with sweet flavours. The Danish study 'SRØG – En undersøgelse af tobak, adfærd og regler' (report 5) shows, among other things, that smokeless nicotine products with the taste of fruit, candy or other sweet flavours are particularly used among the youngest. For example, 23.4 per cent of 15–17-year-olds using smokeless nicotine products use this flavour, compared to 8.7 per cent of 25–29-year-olds.

In the interest of public health, there is a need to respond to the worrying trend. There is thus a well-founded need to introduce further measures to prevent and stop the use of tobacco and nicotine products by children and young people.

II. Introduction of a ban on characterising flavours, with the exception of tobacco and menthol, in tobacco surrogates

As indicated in the notified draft, tobacco and nicotine products benefit from the free movement of goods under the TFEU. Member States may therefore normally not set conditions that impede the free movement of goods. However, it also follows from the TFEU that the free movement of goods can be restricted in consideration of, among other things, public health, which is the consideration that is sought to be protected with the current Bill.

As further stated in the explanatory notes to the Bill, tobacco surrogates are not regulated in the Tobacco Products Directive (2014/40/EU) and are currently subject to more limited regulation in Denmark. The Bill foresees that the regulation of tobacco surrogates should reflect the corresponding regulation of tobacco products and electronic cigarettes resulting from, respectively, the Act on tobacco products etc. and the Act on electronic cigarettes etc. The proposed initiatives will be an obstacle to the free movement of goods, but on public health grounds it is considered both appropriate and necessary. It should also be noted that Articles 34 and 36 TFEU leave a wide margin of discretion to the Member States to determine the desired level of protection of public health, according to the case-law of the Court of Justice of the European Union (CJEU). In doing so, Member States may rely on a precautionary principle whereby Member States do not have to wait until the extent of the harmful effects of new products on the tobacco market — such as tobacco-free nicotine pouches, electronic cigarettes and heated tobacco products — is fully documented by scientific studies.

As stated in the explanatory notes to the Bill, studies show that children and young people use flavoured tobacco and nicotine products more often compared to other age groups and that products with a taste are often the first products that young people try (Sources: 'Inspiring lives free from smoking van. Flavored tobacco use among youth and young adults', Truth Initiative, 2021, & 'Impact of the FDA flavour enforcement policy on flavoured electronic cigarette use behaviour changes', Dongmei L, Deborah JO, Maansi B-T, Zidian X, 2022).

In addition, research shows that children and young people generally perceive flavoured tobacco and nicotine products as less harmful than products without flavour (Source: 'Effects of flavour and modified risk claims on nicotine pouch perceptions and use intentions among young adults who use inhalable nicotine and tobacco products: a randomised controlled trial', Vogel EA, Tackett AP, Unger JB, Gonzalez MJ, Peraza N, Jafarzadeh NS, et al., 2023).

The Bill L 53 'Draft Act amending the Act on tobacco products etc. and various other acts' introduces that tobacco surrogates and flavourings for use in tobacco surrogates with a characterising flavour shall not be marketed in Denmark. However, the ban does not apply to a characterising flavour of tobacco or menthol. In addition, equipment used in connection with tobacco surrogates which makes it possible to change the smell or taste of the tobacco surrogates in question shall also not be marketed in Denmark.

The proposed regulation of flavourings in tobacco surrogates will thus be similar to the regulation of electronic cigarettes in Denmark.



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The comment from Sweden points out whether Denmark has considered the existence of less intrusive measures. We would like to inform you that over a number of years Denmark has taken a large number of measures to protect public health, e.g. in the form of higher prices, age limits, health warnings and display bans.

With reference to the notification and the above, Denmark considers that the proposal to ban characterising flavours, with the exception of tobacco and menthol, in tobacco surrogates is proportionate to achieving the desired objective of strengthening public health and, in particular, preventing smoking and nicotine addiction in children and young people, which cannot be achieved through other alternative and less intrusive measures. The measure is justified on the grounds set out in Article 36 TFEU, it is proportionate to the objective pursued and it does not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

European Commission

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