



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market Enforcement

Notification of Regulatory Barriers

Notification Number : 2022/0417/B (Belgium)

Royal Decree prohibiting the manufacture and placing on the market of certain similar products

Date received : 15/06/2022

End of Standstill : 16/09/2022 (16/12/2022) (closed)

Message

Message 002

Communication from the Commission - TRIS/(2022) 02106

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2022/0417/B

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késéket - Ma' jiftaħx il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 202202106.EN)

1. MSG 002 IND 2022 0417 B EN 15-06-2022 B NOTIF

2. B

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4. 2022/0417/B - X00M

5. Royal Decree prohibiting the manufacture and placing on the market of certain similar products

6. Nicotine pouches and cannabinoid pouches

7. -



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8. The purpose of the draft Royal Decree is to prohibit the placing on the Belgian market of nicotine pouches and cannabinoid pouches. Nicotine pouches being defined as: "any tobacco-free product for oral use consisting wholly or partly of synthetic or natural nicotine in the form of powder, particles or paste or in any combination of such forms, in particular those presented in portions of sachets or in porous sachets". Cannabinoid pouches being defined as: "any product for oral use consisting of or containing a cannabinoid or cannabinoids or its derivatives, in the form of powder, particles or paste or in a combination of such forms, in particular those in portions of sachets or porous sachets"

9. The purpose of this draft Royal Decree is to prohibit nicotine pouches and cannabinoid pouches.

These products are small powder sachets containing nicotine, CBD or other cannabinoids but not containing tobacco. These are placed under the upper lip and the nicotine or cannabinoid is absorbed by the mucous membranes and saliva.

The aim of the ban is to prevent the known and potential adverse health effects of the use of these new products, to discourage their use by young people and to avoid possible negative effects on anti-tobacco efforts.

The emergence of nicotine pouches is hazardous to public health. They are not specifically regulated insofar as their composition or labelling is concerned. They are not covered by the Royal Decree of 5 February 2016 on the manufacture and trade of tobacco products and herbal smoking products.

However, they can be considered as products similar to tobacco products. In a judgement of 16 December 2021 before the Constitutional Court, the Court ruled as follows:

By definition, "similar products" are products that do not contain tobacco but that resemble tobacco products. That similarity must relate to the manner in which the similar product is consumed or the effect which is intended by means of this product. The concept of 'similar products' satisfies the requirement of predictability.

In Belgium, we strive to achieve a very high level of protection when it comes to tobacco control. The same applies to similar products.

Nicotine pouches serve as a substitute for conventional tobacco-based products and can give rise to similar health risks and social consequences.

More specifically, they have a very similar presentation and effect to those of snus, a tobacco-based product that is already banned. There is therefore a real possibility for a nicotine pouch user to switch to snus.

Preamble 32 of Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products states as follows:

" The ban on the sale of tobacco for oral use should be maintained in order to prevent the introduction into the Union (except Sweden) of this product which leads to dependence and has adverse effects on human health."

A similar argument applies to nicotine pouches.

Nicotine pouches are also considered to be similar products abroad. Countries that regulate them as a tobacco substitute include Australia (with a total ban), Hungary, Denmark, Latvia, Luxembourg, New Zealand and Norway. In the latter two countries, they are prohibited until it is proven that they are less harmful than ordinary tobacco-based products. So far, this has not been done.

Nicotine pouches are harmful to health, especially because of their potential for addiction.

An investigation has already been carried out in the Netherlands. This study clearly shows the danger of nicotine pouches.



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“They contain enough nicotine to have effects on heart rate, to induce and maintain nicotine dependence, and to have an adverse effect on the development of the young brain.

Nicotine pouches can also make it easier to keep up nicotine dependence because they can also be used in places where smoking is prohibited.”

These products present a particular hazard to minors due to the fact that their consumption is difficult to perceive. As a result, there is a lack of social control on the part of parents or other adults, which can perpetuate a possible addiction. In addition, due to their low body weight, children are more prone to adverse side effects.

In the Netherlands, therefore, these products are currently also prohibited. If the nicotine pouch contains more than 0.035 mg of nicotine, it is considered a dangerous and harmful food product.

The fact that these products pose a real danger to public health is not only demonstrated by research carried out by RIVM in the Netherlands, but FAMHP also points to possible risks:

“ However, the product remains a nicotine-based product, a substance that can prove to be toxic.”

Accidental exposure or excessive nicotine consumption can have serious consequences. According to the poison control centre, a 10 mg dose of nicotine can cause severe poisoning in children. The minimum fatal dose for adults is 0.5 to 1 g of nicotine, depending on body weight.

An analysis of BfR (Germany) shows that nicotine pouches containing 47.5 mg of nicotine are available on the market.

Last but not least, nicotine pouches are gaining popularity.

A recent survey in the Netherlands shows that 75% of young people surveyed know about nicotine pouches; 25% also use them. Among children under 12 years of age, 1.2% use nicotine pouches. Denmark also reports that nicotine pouches are used by young people. Used packaging materials and pouches can be found in school waste, including in primary schools.

There is no doubt that the presence of these products is on the rise in Belgium.

The Cancer Foundation had already warned in October 2021 of the increased presence of these products. In addition, several press articles published in recent months have confirmed this trend.

This increase is likely to also apply to actual sales of these products, although we do not have official figures; nicotine pouches need not be notified.

FPS Public Health monitors have recently discovered these products in places that attract young people, such as dancing cafés, clubs and mass events such as festivals.

In addition, traditional tobacco manufacturers who have included these products in their range are increasingly promoting them, including via social networks.

On the British American Tobacco website, nicotine sachets are presented as a healthy alternative to traditional tobacco-based products, as they contain pure ingredients. The impression is given that there is no health risk.

The products are also available in a variety of flavours, including the menthol flavour that has recently been banned in



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ordinary tobacco-based products. This is an element that makes the product even more attractive for young people as well as for non-smokers.

Nicotine pouches are also much cheaper than ordinary tobacco-based products, which further contributes to their great appeal within the general population.

In short, nicotine pouches are harmful because, like tobacco-based products, they have the potential to maintain or induce addiction (to nicotine). Such a product has no place on the market.

Due to the increasing popularity of these products, the protection of children and adolescents from nicotine use and addiction through legislation is necessary. We base this prohibition on the precautionary principle.

For CBD products, there is less information available, but due to the great similarities (appearance, mode of use), this is also prohibited.

10. No reference text exists

11. No

12. -

13. No

14. No

15. -

16. TBT aspect

NO - The draft does not have a significant impact on international trade.

SPS aspect

NO - The draft does not have a significant impact on international trade.

European Commission

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