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| **Title** |
| **14 MARCH 2023. - Royal Decree prohibiting the placing on the market of certain similar products**  **Source: PUBLIC HEALTH, SAFETY OF THE FOOD CHAIN AND THE ENVIRONMENT**  **Publication: 24-03-2023 number:   2023041247 page: 33805       PDF:**[**original version**](https://www.ejustice.just.fgov.be/mopdf/2023/03/24_1.pdf#Page343)[**consolidated version**](https://www.ejustice.just.fgov.be/img_l/pdf/2023/03/14/2023041247_F.pdf)  **File number: 2023-03-14/04**  **Entry into force/Effect:**   |  |  | | --- | --- | | 01-07-2023 |  | | 01-10-2023 |  | |

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| **Article 1-5** | | |

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| **Article [1](https://www.ejustice.just.fgov.be/eli/arrete/2023/03/14/2023041247/justel" \l "Art.2). Definitions**  **For the application of this Decree, the following mean:**  **(1) nicotine pouch: any tobacco-free product for oral use consisting in whole or in part of synthetic or natural nicotine including those presented in portions of sachets or in porous sachets, and those in the form of powder, particles or paste or in any combination of such forms;**  **(2) cannabinoid pouch: any product for oral use consisting of or containing one or more cannabinoids or derivatives thereof, including those presented in portions of sachets or in porous sachets and in the form of powder, particles or paste or in any combination of such forms;**  **(3) retailer: any point of sale at which products are placed on the market, including by a natural person.**  **[Article](https://www.ejustice.just.fgov.be/eli/arrete/2023/03/14/2023041247/justel" \l "Art.1er)**[**2**](https://www.ejustice.just.fgov.be/eli/arrete/2023/03/14/2023041247/justel#Art.3)**. Prohibited**  **It is forbidden to place nicotine pouches and cannabinoid pouches on the market.**  **[Article](https://www.ejustice.just.fgov.be/eli/arrete/2023/03/14/2023041247/justel" \l "Art.2)**[**3**](https://www.ejustice.just.fgov.be/eli/arrete/2023/03/14/2023041247/justel#Art.4)**. Criminal penalties**  **§ 1. The products listed in Article 2 of this Order are to be considered harmful within the meaning of Article 18 of the Law of 24 January 1977 on the protection of the health of consumers with regard to foodstuffs and other products.**  **§ 2. Infringements of this Decree shall be investigated, recorded, prosecuted and punished in accordance with Articles 11 to 19 of the Law of 24 January 1977 on the protection of the health of consumers with regard to foodstuffs and other products.**  **[Article](https://www.ejustice.just.fgov.be/eli/arrete/2023/03/14/2023041247/justel" \l "Art.3)**[**4**](https://www.ejustice.just.fgov.be/eli/arrete/2023/03/14/2023041247/justel#Art.5)**. Entry into force**  **This Decree shall enter into on the first day of the fourth month after its publication in the Belgian Monitor except for the retailer for which this Decree enters into force on the first day of the seventh month after its publication in the Belgian Monitor.**  **[Article](https://www.ejustice.just.fgov.be/eli/arrete/2023/03/14/2023041247/justel" \l "Art.4) 5. Final provision**  **The Minister of Public Health shall be responsible for the implementation of this Decree.** | | |

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| **Brussels, 14 March 2023.**  **PHILIPPE**  **By the King:**  **The Minister for Public Health,**  **F. VANDENBROUCKE** | | | |

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| **Preamble** | [**Text**](https://www.ejustice.just.fgov.be/eli/arrete/2023/03/14/2023041247/justel#texte) | [**Table of contents**](https://www.ejustice.just.fgov.be/eli/arrete/2023/03/14/2023041247/justel#tablematiere) | [**Start**](https://www.ejustice.just.fgov.be/eli/arrete/2023/03/14/2023041247/justel#top) |
| **PHILIPPE, King of the Belgians,**  **To all present and those to come, Greetings.**  **Having regard to the Law of 24 January 1977 on the protection of consumer health with regard to foodstuffs and other products, Article 2, al. 1, Article 6(1)(a), as amended by the Law of 22 March 1989 and Article 18(1), replaced by the Law of 22 March 1989 and amended by the Law of 22 December 2003;**  **Having regard to the opinion of the Finance Inspectorate, issued on 4 January 2023;**  **Having regard to the communication to the European Commission, dated 15 June 2022, pursuant to Article 5(1) of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services;**  **Having regard to opinion 72.952/3 of the Council of State, issued on 20 February 2023, pursuant to Article 84, § 1(1)(2), of the Laws on the Council of State, consolidated on 12 January 1973;**  **On the proposal of the Minister for Public Health,**  **I have decreed and hereby decree:** | | | |

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| **REPORT TO THE KING**  **Sire,**  **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 emergence of nicotine pouches is hazardous to public health.**  **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.**  **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 based 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.**  **In society, the terms are often used interchangeably, even by police forces. They talk about snus, but actually mean nicotine pouches. The confusion of language is understandable, as nicotine pouches are also called snus by traders, deliberately, for commercial reasons perhaps, or unconsciously. For example, https://zweedsesnus.nl/collections/nicotinevrije-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 addiction and has adverse effects on human health. "**  **A similar argument applies to nicotine pouches.**  **As regards the separate regulation of products similar to tobacco based products, recital 55 of this same directive states as follows: " A Member State should remain free to maintain or introduce national legislation applicable to all products placed on its national market with regard to aspects not regulated by this Directive, provided that it is compatible with the Treaty on the Functioning of the European Union and does not jeopardise the full application of this Directive. Consequently, and under these conditions, Member States could in particular regulate or prohibit equipment used for tobacco products (including waterpipes) and for herbal smoking products and to regulate or prohibit products apparently similar to a type of tobacco or related products. Prior notification is required for national technical regulations in accordance with Directive 98/34/EC”**  **Furthermore, Article 5.2(b) of the WHO Framework Convention on Tobacco Control also justifies strict regulation of these products:**  **" Article 5 (...)**  **2. To this end, each Party according to its capabilities shall:**  **(...)**  **b) adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, where appropriate, with other Parties to develop appropriate policies to prevent and reduce tobacco consumption, nicotinic addiction and exposure to tobacco smoke. (...) "**  **In this regard, “the Parties to the Convention agreed to consider applying regulatory measures to prohibit or restrict the manufacture, import, distribution, presentation, sale and use of ENDS, in accordance with their national laws and public health objectives. If other new tobacco or nicotine products emerge, the way in which they are treated should be considered in the same manner. “(1)**  **Abroad, nicotine pouches are also considered and regulated as similar products. 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.**  **“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.**  **Indications and complaints also reach schools through the inspection department. One school noted that the products seem popular with boys and that the “being tough” aspect comes into play here. Nicotine pouches are also exchanged amongst children at the school premises. According to teachers, children who consumed nicotine would be less attentive in class and more irritable.**  **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 pouches 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 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 still contributes to their great appeal to the general population, as well as to non-smokers.**  **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 to this substance 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.**  **Article by article comments**  **Article 1. Article 1 concerns the definitions set out in the Decree.**  **Article 2. Article 2 refers to the prohibitions themselves: banning nicotine pouches and cannabinoid pouches.**  **Article 3. Article 3 deals with the investigation, finding, prosecution and punishment of offences.**  **Article 4. Article 4 specifies the date on which the Decree will enter into force. For retailers, the Decree will come into effect 3 months later.**  **Article 5. Article 5 designates the competent minister who will ensure the application of the provisions of this Decree. This is the Minister of Health.**  **I have the honour to be,**  **Sire,**  **of Your Majesty**  **the most respectful and faithful servant,**  **The Minister for Public Health,**  **F. VANDENBROUCKE**  **Notes**  **(1) https://fctc.who.int/newsroom/news/item/19-09-2017-who-framework-convention-on-tobacco-control-secretariat-s-statement-on-the-launch-of-the-foundation-for-a-smoke-free-world**  **(2) https://www.rivm.nl/publicaties/nicotineproducten-zonder-tabak-voor-recreatief-gebruik**  **(3) https://www.rivm.nl/sites/default/files/2021-11/FO\_nicotinezakjes%20tox\_20211101\_def\_anon.pdf**  **(4) Nieuws — Snus nog populairder dan gedacht, blijkt uit NOS-investigation (tabaknee.nl)**  **(5) Bast, Lotus S., et al. 2022. “Use of Tobacco and Nicotine Products among Young People in Denmark-Status in Single and Dual Use” International Journal of Environmental Research and Public Health 19, no. 9: 5623.**  **(6) https://www.theguardian.com/business/2021/nov/08/firms-under-fire-for-using-uk-influencers-to-push-nicotine-products** | | | |

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