14 June 2023
Tukes 6287/00.00.01/2023

Interim decision pursuant to section 45b, subsection 3 of the Chemicals Act restricting the placing on the market of certain products containing nicotine

Prohibition of sale

Pursuant to section 45b subsection 3 of the Chemicals Act (599/2013), the Finnish Safety and Chemicals Agency (Tukes) prohibits the placing on the market in Finland of nicotine pouches with a nicotine dose of 20 mg/pouch or more. *Nicotine pouch* denotes a single-dose pouch that can be placed in the mouth and includes a mixture containing nicotine (CAS 54-11-5 or CAS 22083-74-5) or other nicotine compounds.

Placing on the market means offering, selling or otherwise supplying in the course of a business operation.

This prohibition does not apply to products that are deemed to be medicines within the meaning of the Medicines Act (395/1987).

Entry into force and expiry of decision

The decision takes effect immediately on notification, meaning on the **seventh** day following publication of an announcement concerning the decision on the Tukes website.

The decision remains in force until the Government decision referred to in Section 45b, subsection 1 of the Chemicals Act has taken effect.

Grounds for the decision

1 Fulfilment of the requirements of section 45b, subsection 3 of the Chemicals Act

No restrictions under the REACH Regulation:

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Annex XVII (Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles) to the REACH Regulation (Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals) restricts the use or placing on the market of certain substances as such, or in a mixture or articles. The said Annex imposes no restrictions on nicotine (CAS number 54-11-5 or 22083-74-5) or other mixtures containing nicotine compounds (hereinafter referred to as *nicotine*).

Serious hazard:

When assessing the serious hazard, Tukes has considered the information and instructions required for the product, the ability of a consumer to detect the hazard caused by the product, and especially the risks of accidental poisoning. Section 2 of this decision sets out a more detailed position on the assessment of serious hazard.

Urgency:

The situation calls for rapid measures by Tukes, owing to the nature of the hazard and to the unpredictability of the circumstances. The more products sold in retail stores and the higher their nicotine content, the more likely are life-threatening cases of poisoning among young children, for example, and the more extensive are the serious hazards that may be caused by using the product. Large doses of nicotine can also cause poisoning in adults. The most important characteristic of nicotine is its addictive influence on the central nervous system. Young adults can already develop a powerful dependency when initially experimenting. Nicotine also has adverse effects on the heart and circulatory system, for example. Neither national legislation nor European Union chemicals legislation currently impose any upper limit on the nicotine contained in nicotine pouches, and no prior approval is required for the retail sale of nicotine pouches to consumers in compliance with the provisions of the Tobacco Act concerning tobacco substitutes, and with the notification, registration, information provision, packaging and labelling obligations of chemicals legislation.

Studies by Tukes indicate that the packaging and flavours of products are often designed to attract young users in particular, and that the amount of nicotine is often not marked on the packaging of nicotine pouches using a commonly applied scale of measurement that would give the consumer clear information about the strength of the product. Chemicals of this kind have not previously been freely available on the Finnish market for the purpose in question. Only a swiftly enforced prohibition on placing on the market may be considered a sufficiently effective means of preventing serious harm to health and an increase in demand for and use of strong nicotine pouches in particular under circumstances in which marketers of these products are actively seeking to capture a new market.

The consequences will be unpredictable and difficult to control retrospectively through legislation or official measures if the availability of these nicotine pouches, particularly those intended for use as an intoxicant, increases on the Finnish market, with children in particular suffering serious adverse effects.

A prohibition is necessary as a matter of urgency to prevent a serious risk to health, as it can be demonstrated on the grounds set out in section 2 below that such products pose a risk of accidental poisoning and can be life-threatening, especially for babies and small children. Having regard to the active marketing measures of operators, the ever-increasing use of nicotine pouches, their sudden removal from the scope of strict regulation, and the proposed future regulation under the Tobacco Act, there is a risk that the strongest nicotine pouches will swiftly enter the Finnish market for wider distribution. Concern is amplified in particular by the availability of nicotine pouches in a wide range of flavours, such as apple, blueberry, strawberry and cola, and packaging of these products in visually attractive boxes. This increases the likelihood already noted that small children will be exposed to nicotine pouches. There is also a risk that the prominent flavours will lead new users in particular to overlook the ability of nicotine pouches of higher concentration to cause serious poisoning, even in adults.

Section 4 of this decision explains the background to this matter and the state of the market in greater detail.

Interim character of the decision:

The decision remains in force until further notice, with Tukes immediately submitting the matter to the Government for decision as provided in section 45b, subsection 1 of the Chemicals Act. The interim order from Tukes must be complied with until the Government has issued a decision on the case pursuant to the said subsection. The Act provides no precise time limit for the validity of an order from Tukes, or for hearing of the case by the Government.

2 Grounds for the measures ordered by Tukes

2.1 A serious health hazard caused by the product

Nicotine pouches meet the definition of a tobacco substitute under section 2, paragraph 14 of the Tobacco Act, meaning that they are products that correspond to tobacco in their intended use but do not contain tobacco. Chemicals legislation is also applied to nicotine pouches and they are defined as mixtures containing nicotine and other substances (Chemicals Act, section 6, paragraph 2).

Commission Regulation (EU) 2018/1480 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776 was issued 4 on October 2018. The amending Regulation included an amendment of Annex VI to the CLP Regulation with respect to acute toxicity (oral) of nicotine (CAS 54-11-5) to the category Acute Tox. 2, H300 "Fatal if swallowed" (ATE = 5 mg/kg bodyweight). A hazard classification under the CLP Regulation is based on a scientific assessment that reflects research on the effects of nicotine on animals (known as the RAC-opinion[1]). Nicotine pouches may also contain nicotine sources other than pure nicotine, for example (±)-nicotine. Two classification notifications for (±)-nicotine (CAS 22083-74-5) have been submitted to ECHA, where it is classified in terms of toxicity as Acute Tox. 3, H301; Acute Tox. 2, H310; Aquatic Chronic 2, H411; and Acute Tox 1, H300 and Acute Tox 2, H310. The toxicological properties of (±)-nicotine are similar to those of nicotine, and may therefore be subject to nicotine risk assessments. The hazard characteristics of any other nicotine compounds contained in nicotine pouches are also equated with the hazard characteristics of nicotine.

Tukes notes that the weights of nicotine pouches that may be ordered online vary between 0.3 and 1.3 grams[2]. While a German study[2] finds that pouches contain as much as 50 mg of nicotine, online searches made by Tukes suggest that a single dose may even contain approximately 100 mg of nicotine.

Based on the ATE value of nicotine, it may be estimated that a single pouch containing 50 milligrams of nicotine can be fatal to a child weighing 10 kg if all of this nicotine is absorbed when swallowed. Strong nicotine pouches can also cause nicotine poisoning or nausea in young people and adults. Tukes estimates that pouches containing 20 milligrams or more of nicotine can pose a serious hazard (death) to babies and small children within the meaning of section 45b of the Chemicals Act. The nicotine limit of 20 mg/pouch set by Tukes includes a safety margin of 2.5 times for small children compared to the ATE value.

Tukes is not currently aware of any confirmed deaths related to nicotine pouches to date.[3].

[1] https://echa.europa.eu/documents/10162/23665416/clh_opinion_nicotine_5579_en.pdf/0103fadb-e945-4839-c4f4-17d20854adf0.
[2] Mallock, N. et al.: Levels of nicotine and tobacco-specific nitrosamines in oral nicotine pouches. Tobacco Control, 2022: p. tobaccocontrol-2022-057280 (https://tobaccocontrol.bmj.com/content/tobaccocontrol/early/2022/08/05/tc-2022-057280.full.pdf), Table 1.
[3] Bundesinstitut fur Risikobewertung: Health risk assessment of nicotine pouches. Updated BfR Opinion no. 023/2022, 7 October 2022 (https://mobil.bfr.bund.de/cm/349/health-risk-assessment-of-nicotine-pouches.pdf).

2.2 Grounds for the chosen measures

Section 45b, subsection 3 of the Chemicals Act empowers Tukes to issue interim orders concerning necessary restrictions and prohibitions if the use of a chemical or an article containing a chemical is found or can be justifiably assessed to cause serious harm or hazard to health or the environment. The sales prohibition seeks to prevent small children in particular from ingesting nicotine as a potentially fatal single dose from one nicotine pouch. A restriction on sales is accordingly necessary to ensure the safety of consumers, and especially the health of small children. As the decision is based on urgent measures in circumstances of serious hazard, the risk assessment ignores other known adverse health impacts of nicotine and the content limit imposed is not the limit for safe use of nicotine.

The *travaux préparatoires* to the Chemicals Act state that the chemical that causes serious harm or hazard referred to in the legislation may be classified as hazardous, or may be a chemical whose known specific use causes serious harm or hazard, even if the classification does not take this into account (HE 38/2013 vp, p. 48). The restriction is based on the toxicity of nicotine, on the oral manner of use and the flavour of the product, and on the attractive appearance of the packaging. Having regard to these factors, extending the prohibition of retail sales and other distribution to the dose content of the pouch set out in greater detail in section 2.1 is a justified measure from the point of view of chemicals legislation. The general principles governing the operation of section 19 of the Chemicals Act also require operators to be aware of the nicotine dose of an individual pouch of this type of product, and also to comply with the chemicals classification and packaging requirements of the CLP Regulation with respect to the hazardous substance or mixture contained therein.

With a restriction based on dose, the sale and other distribution of nicotine pouches of acute toxicity classification in category 1-3 under the CLP regulation will still be permitted after this decision if the amount of nicotine in the nicotine pouch falls below the dose content imposed by this decision.

3 Competence of Tukes and general statutory requirements

Under section 8 of the Chemicals Act, Tukes supervises compliance with the said Act, with national decrees issued pursuant thereto, with the REACH Regulation, the CLP Regulation, the Detergent Regulation, and the Biocidal Products Regulation, and with articles 3 and 4 of the POP Regulation, unless otherwise provided in the said Act.

Under section 45 of the Chemicals Act, market surveillance of chemicals complies with the Act on the Market Surveillance of Certain Products (1137/2016), unless otherwise provided in the Chemicals Act. Subsection 2 of the said section provides that market supervision is governed by section 45b, subsection 3 of the Chemicals Act, notwithstanding the provisions of subsection 1 of the said section 45.

Section 45b, subsection 3 of the Chemicals Act empowers Tukes to issue interim orders concerning necessary restrictions and prohibitions to the extent that a chemical is not restricted under the REACH Regulation and if the use of such a chemical or an article containing the chemical is found or can be justifiably assessed to cause serious harm or hazard to health or the environment and urgent measures are required to prevent such harm or hazard. Tukes may issue a decision in such cases limiting or prohibiting the manufacture, import, placing on the market and other supply, export, use or other equivalent processing of a chemical or an article containing the chemical for a specified period or until further notice, and may order restrictions and conditions concerning the operation. The matter must be submitted without delay to the Government for decision, pursuant to section 45b, subsection 3 of the Chemicals Act.

Section 45 of the Chemicals Act provides that, when applying the said Act, a product referred to in the Act on the Market Surveillance of Certain Products is deemed to be a chemical, an article containing a chemical, or a processed article, and an economic operator is deemed to be a party who manufactures, or who imports, places on the market, exports, stores, packs or distributes a product in person or in the role of sole representative in the manner referred to in the Chemicals Act or in European Union chemicals legislation.

Section 45, subsection 3 of the Chemicals Act provides that the provisions of European Union chemicals legislation concerning the definitions of placing on the market apply when market surveillance measures for chemicals are applied to an economic operator. With regard to nationally approved biocidal products, placing on the market means placing on the market in Finland, but the provision does not cover the meaning of placing on the market when applying Section 45b of the Chemicals Act directly.

The means of market surveillance applicable to market surveillance are laid down in sections 17-20 of the Act on the Market Surveillance of Certain Products.

4 Background to the case and reports received

A reassessment issued on 4 April 2023 by the Finnish Medicines Agency Fimea found that nicotine pouches that have not been authorised under the Medicines Act may generally no longer be classified as medicines. This new Fimea policy means that nicotine pouches are governed by the Tobacco Act and the Chemicals Act. While a nicotine pouch contains a mixture containing nicotine, it does not contain tobacco. Nicotine pouches on sale may contain large quantities of nicotine, which is a chemical that is hazardous to health and the environment. Mixtures may not be placed on the market (meaning imported, sold or supplied free of charge) unless they meet the requirements of the CLP Regulation (EC) No. 1272/2008.

The Finnish market has nicotine pouches on retail sale under a marketing authorisation for a medicinal product for self-medication as a means of quitting smoking. Consumers have likewise been able to import a certain number of nicotine pouches for personal use, which have been correspondingly considered as a self-medication product if their nicotine content does not exceed the 4 mg permitted under the marketing authorisation for a medicine. Fimea already observed indications that a change of distribution channel had caused a change in the purpose of use of nicotine products from detoxification to other uses after nicotine pouch sales were transferred from pharmacies to ordinary shops in 2006[4].

The change of interpretation made by Fimea in Finland on 4 April 2023 brought nicotine pouches within the scope of chemicals legislation, following which Tukes issued a bulletin on 19 April 2023 providing information on the requirements of chemicals legislation concerning nicotine pouches. Before publishing this bulletin, Tukes asked the Poison Information Centre for details of previous cases of poisoning related to nicotine pouches in Finland. According to the information provided by the Poison Information Centre, annual poisoning inquiries related to nicotine pouches had increased between 1 January 2017 and 31 December 2022 from a total of 11 inquiries in 2017 to a total of 51 inquiries in 2022. At the same time, the proportion of inquiries concerning individuals under the age of 18 years increased from 27 per cent in 2017 to 49 per cent in 2022, and this proportion was remarkably high at 57 to 66 per cent in 2019-2021. No information has been available on how serious the suspected poisoning was in these inquiries.

The first chemical notification to the chemical product register under section 20 of the Chemicals Act was submitted to Tukes for the purpose of placing nicotine pouches on the market in Finland on 10 May 2023. Notifications have subsequently increased, and also include nicotine pouches of a kind that give cause for finding that there are plans to bring stronger nicotine pouches with doses potentially exceeding 20 mg onto the market as a new product.

Pursuant to section 34, subsection 2, paragraph 4 of the Administration Act (434/2003), no hearing of concerned parties has been conducted in this matter, as a hearing could have jeopardised realisation of the purpose of this decision, and the delay in considering the case caused by the hearing could have caused considerable harm to public health.

[4] https://www.fimea.fi/documents/160140/1153780/28244 KAI 1 2015.pdf/1288d5a2-8558-4d37-a762-d0fe2e71b8dl, p. 11.

Publication

The number of parties affected by this decision is not known and this decision will be published as a general notification.

The document will remain on public display until 31 July 2023. The public display of the decision will be announced on the Tukes website at www.tukes.fi. Service of this decision is deemed effected on the seventh day after publication of the foregoing notification on Tukes website.

Review

Pursuant to section 55, subsection 2 of the Chemicals Act, this decision is not open to review.

Provisions applied

Chemicals Act (599/2013), section 45, section 45b subsection 3, section 55 subsection 2

Administrative Procedure Act (434/2003), section 34 subsection 4, and sections 54, 55 and 62

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14 June 2023

Tiina Putkonen, Director
14 June 2023