

Decision (Draft)

30.6.2023

VN/20729/2023

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Decision under section 45b, subsection of the chemicals act restricting marketing of products containing nicotine

Decision

The Government prohibits the placing on the market in Finland of nicotine pouches with a nicotine dose of 20 mg/pouch or more, pursuant to section 45b subsections 1 and 3 of the Chemicals Act (599/2013). 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).

Validity of decision

The decision takes effect immediately on notification, meaning on the seventh day following publication of an announcement on the Government website (www.XXX.fi) concerning the decision. The announcement was published on xx.xx.xxxx, so the decision will take effect on xx.xx.xxxx.

The decision is in force until further notice.

Grounds*Background:*

Nicotine pouches are products that, in appearance and manner of use, resemble tobacco intended for oral use, as referred to in section 2, paragraph 12 of the Tobacco Act (549/2016). Nicotine pouches contain nicotine that has either been extracted from the tobacco plant or synthetically manufactured, together with cellulose and other components, such as sweeteners. Nicotine pouches do not contain tobacco plant material.

The Finnish Medicines Agency (hereinafter referred to as Fimea) previously classified nicotine pouches as medicinal products in Finland. Fimea held that nicotine pouches satisfy the definition of a medicine based on the pharmacological effect of nicotine. It followed from classification as a medicine that nicotine pouches could not be sold in Finland without a marketing authorisation under the

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Medicines Act (395/1987), which also restricted importing of nicotine pouches. With the exception of products for which a marketing authorisation had been granted, nicotine pouches have accordingly not previously been sold in Finland. Products with more than 4 milligrams of nicotine were likewise equated with prescription medicines, and could not be imported without a prescription.

Fimea announced on 4 April 2023 that it had altered its interpretation of nicotine pouches, concluding that they do not fall within the scope of the Medicines Act unless they are explicitly marketed for medicinal use or it can otherwise be shown that they are typically used in the manner of a medicine. Following the revised Fimea interpretation, nicotine pouches are only governed by the provisions of the Tobacco Act and the Chemicals Act (599/2013). Nicotine pouches may therefore currently be sold in Finland without a marketing authorisation for retail sale. Nor may any limits on the nicotine content of nicotine pouches etc. be inferred from the Tobacco Act.

Online product advertising has intensified since Fimea altered its interpretation of nicotine pouches, even though the current Tobacco Act already prohibits marketing of tobacco substitutes. Importing of nicotine pouches has clearly increased, with products already put on sale in grocery shops, kiosks and filling stations. Media coverage suggests that at least some retailers have only sold nicotine pouches with a nicotine content that does not exceed a certain limit, such as 16 milligrams per gram. Information received from the Finnish Safety and Chemicals Agency (Tukes), on the other hand, indicates that some notifications have also been made to the agency under the Chemicals Act concerning stronger nicotine pouches. Tukes notes that the weights of nicotine pouches that may be ordered online vary between 0.3 and 1.3 grams. While a German study 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.

On 14 June 2023 Tukes issued an interim decision (registry number 6287/00.00.01/2023) pursuant to section 45b subsection 3 of the Chemicals Act prohibiting the placing of nicotine pouches containing 20 milligrams or more of nicotine on the Finnish market. This decision is based in particular on the need to protect children and young adults from nicotine poisoning. The Tukes decision estimates that pouches containing 20 milligrams or more of nicotine can pose a serious hazard to babies and small children within the meaning of section 45b of the Chemicals Act.

Section 45b subsection 3 of the Chemicals Act provides that an interim decision issued by Tukes must be submitted to the Government for decision without delay.

Legislation

Section 1 of the Chemicals Act provides that the objective of the Act is to protect health and the environment from hazards and harm caused by chemicals. Section 2 of the Act provides that the Act implements European Union chemicals legislation and certain national obligations regarding chemicals. Nicotine pouches fall within the scope of the Chemicals Act, and are defined as mixtures containing nicotine and other substances pursuant to section 6, paragraph 2 of the said Act.

Under section 45 subsection 1 of the Chemicals Act, chapter 7 of the Act (Supervision) applies to supervision other than market surveillance of chemicals. Subsection 2 of the said section provides that the market surveillance of chemicals is governed by section 45a and section 45b, subsection 3 notwithstanding the provisions of subsection 1 of the said section 45. Section 45, subsection 3 of the said Act further provides that, unless otherwise provided in the Chemicals Act, market surveillance of chemicals complies with the Act on the Market Surveillance of Certain Products. A chemical, an article containing a chemical or a processed article is deemed to be a product referred to in the Act on the Market Surveillance of Certain Products, and 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 is deemed to be an economic operator when applying the said Act.

Section 45 subsection 4 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 respect to placing on the market and biocides. The placing of nationally approved biocidal products on the market nevertheless refers to placing them on the market in Finland.

Section 45b subsection 1 of the Chemicals Act provides that to the extent that a chemical is not restricted in the REACH Regulation, the Government may take a decision to restrict or ban, for a specified period of time or until further notice, the manufacture, import, placing on the market and other supply, export or use of the chemical or article containing the chemical or other handling of the chemical equivalent thereto, and issue orders concerning restrictions and conditions for operations if

use of the chemical or article containing the chemical is found or justifiably assessed to cause serious harm or a hazard to human health or the environment.

Subsection 3 of the said section provides that if preventing the harm or hazard referred to in subsection 1 requires rapid measures, then the Safety and Chemicals Agency may issue temporary orders on the necessary bans and restrictions. The matter must be referred to the Government for decision without delay in such cases.

The travaux préparatoires to the Chemicals Act (HE 38/2013 vp) state that a chemical that causes serious harm or hazard 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.

Serious hazard or harm to health

As Tukes has found in its interim decision, nicotine pouches pose a risk of accident due to poisoning, and may be life-threatening, especially for babies and small children.

Nicotine has acute toxic effects if it is swallowed or comes into contact with the skin or eyes in large quantities. Strong nicotine pouches can cause serious harm or hazard to human health, as swallowed nicotine pouches can cause nicotine poisoning, which may even be life-threatening. While nicotine pouches can be particularly hazardous to small children and babies, large doses of nicotine may also cause poisoning in adults.

The Tukes decision refers to the hazard classification under Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (hereinafter referred to as the CLP Regulation). Nicotine is classified in Annex VI to the CLP Regulation as Acute Tox. 2, H300 "Fatal if swallowed" (ATE = 5 mg/kg body-weight). Based on the ATE value of nicotine, Tukes has 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. The nicotine limit set by Tukes of 20 milligrams per pouch includes a safety margin of 2.5 times for small children compared to the ATE value.

There is no regulation of nicotine pouch flavours, many of which are designed to appeal to young users in particular, and may even attract small children. Nicotine pouches are available in such flavours as fruity, licorice and cola. These products are also packed in visually attractive boxes, which may further increase the interest of even very young children. There is a risk of children swallowing nicotine pouches and sustaining nicotine poisoning, which can cause serious health problems and even death.

Based on the foregoing and on the facts set out in the Tukes decision, it is the view of the Government that the health of the population, and of small children in particular, may be seriously jeopardised within the meaning of section 45b, subsection 1 of the Chemicals Act if nicotine pouches delivering a nicotine dose of 20 mg/pouch or more remain on the market. The Government considers that the placing of such nicotine pouches on the market should be prohibited.

Hearing

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Publication

The concerned parties directly affected by the decision are the manufacturers, importers and sellers of the products to which the decision relates. The number of parties affected by this decision is not known, and this decision will be published as a general notification. Public posting of the decision will be announced on the Government website at www.XXXX.fi.

Service of this decision is deemed effected on the seventh day after publication of the foregoing notice on the Government website.

Review

This decision may be appealed to the Supreme Administrative Court pursuant to section 8 of the Administrative Judicial Procedure Act (808/2019).

The decision must be complied with notwithstanding appeal, as its enforcement cannot be postponed due to a public interest (Administrative Judicial Procedure Act, section 122).

Provisions applied

Chemicals Act (599/2013), sections 1, 6, 45, and 45b subsections 1 and 3

Administrative Procedure Act (434/2003), section 34 subsection 1, and sections 54, 55 and 62

Administrative Judicial Procedure Act (808/2019), section 8 subsection 1, and section 122 subsection 3 paragraph 3

Inquiries:

Further details are available from XXX