SOSIAALI- JA TERVEYSMINISTERIÖ

Decision

21.9.2023

VN/20729/2023
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Government Decision under section 45b of the Chemicals Act to restrict the placing on the market of certain nicotine-containing products

Decision

Under section 45b, subsections 1 and 3 of the Chemicals Act (599/2013), the Government prohibits the placing on the market in Finland of nicotine pouches with a nicotine dose of 20 mg or more per pouch. Nicotine pouch means a single-dose pouch for oral use containing nicotine (CAS 54-11-5 and/or CAS 22083-74-5) or a mixture containing other nicotine compounds.

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

This prohibition does not apply to products which are considered to be medicinal products within the meaning of the Medicines Act (395/1987).

This Decision replaces the interim decision of the Finnish Safety and Chemicals Agency (Tukes) of 14 June 2023, issued pursuant to section 45b, subsection 3 of the Chemicals Act, to restrict the placing on the market of certain nicotine-containing products (record number: 6287/00.00.01/2023).

Validity of the Decision

The Decision enters into force as soon as it is notified, i.e. on the seventh day after the notice of the Decision is published on the Government website. The Decision is valid until further notice.

Rationale

Background

Nicotine pouches are products that resemble tobacco for oral use referred to in section 2, subsection 12 of the Tobacco Act (549/2016). Nicotine pouches contain nicotine that is either extracted from the tobacco plant or synthetically produced, and cellulose and other ingredients, such as sweeteners. Nicotine pouches do not contain tobacco.

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In Finland, the Finnish Medicines Agency (Fimea) previously classified nicotine pouches as medicinal products. Fimea considered that nicotine pouches meet the definition of medicinal product based on the pharmacological effect of nicotine. The classification as medicinal products meant that nicotine pouches could not be sold in Finland without a marketing authorisation under the Medicines Act, and the import of nicotine pouches was also restricted under the Medicines Act. Nicotine pouches have therefore not been available for sale in Finland in the past, except for products for which a pharmaceutical licence has been granted. Similarly, products containing more than 4 milligrams of nicotine were treated as prescription medicines and could not be imported without a prescription.

On 4 April 2023, Fimea announced that it had changed its interpretation of nicotine pouches and had concluded that nicotine pouches did not fall within the scope of the Medicines Act unless they were specifically marketed for a medicinal purpose or it could be otherwise demonstrated that they are typically used as a medicinal product. As a result of the change in the interpretation by Fimea, the provisions of the Tobacco Act and the Chemicals Act apply to nicotine pouches. Consequently, nicotine pouches can currently be sold in Finland without a retail licence. The Tobacco Act also does not impose limits on, for example, the nicotine content of nicotine pouches.

Since Fimea changed its interpretation of nicotine pouches, advertising of these products online has increased, despite the fact that the marketing of tobacco substitutes is prohibited under the Tobacco Act in force. Imports of nicotine pouches have increased significantly, and products are sold in grocery stores, kiosks and service stations. According to information in the media, at least some retailers have only offered for sale nicotine pouches with a nicotine content not exceeding a certain limit, e.g. 16 milligrams per gram. On the other hand, according to information received from the Finnish Safety and Chemicals Agency (Tukes), stronger nicotine pouches have also been notified to the Agency in accordance with the Chemicals Act. According to Tukes, the weights of nicotine pouches that can be ordered online range from 0.3 to 1.3 grams. According to a German study, the pouches can contain up to 50 mg of nicotine, but based on online searches conducted by Tukes, there are indications that one dose can contain up to 100 mg of nicotine.

On 14 June 2023, Tukes issued an interim decision under section 45b, subsection 3 of the Chemicals Act (register number 6287/00.00.01/2023), prohibiting the placing on the Finnish market of nicotine pouches containing 20 milligrams or more of nicotine. The decision is based in particular on the need to protect children and adolescents from nicotine poisoning. In its decision, Tukes considered that pouches containing 20 milligrams or more of nicotine could pose a serious risk to babies and young children within the meaning of section 45b of the Chemicals Act.

According to section 45b, subsection 3 of the Chemicals Act, an interim decision issued by Tukes is referred without delay to the Government for decision.

Legislation

According to section 1 of the Chemicals Act, the purpose of the Act is to protect human health and the environment from hazards and harms caused by chemicals. According to section 2 of the Act, the Act provides for the implementation of the European Union’s chemicals legislation and certain national obligations concerning chemicals. Nicotine pouches fall within the scope of the Chemicals Act and are defined as mixtures containing nicotine and other substances on the basis of section 6, subsection 2 of the Chemicals Act.

According to section 45, subsection 1 of the Chemicals Act, chapter 7 of the Act (Supervision) applies to supervision other than the market surveillance of chemicals. According to subsection 2 of section 45, by way of derogation from subsection 1, section 45a and subsection 3 of section 45b apply to the market surveillance of chemicals.

When measures for the market surveillance of chemicals are taken in respect of an economic operator, under section 45, subsection 4 of the Chemicals Act, the definitions of placing on the market and, in the case of biocides, making available on the market, are governed by the European Union chemicals legislation. However, the placing on the market of nationally authorised biocidal products means placing on the market in Finland.

Section 45b, subsection 1 of the Chemicals Act provides that, in so far as a chemical is not restricted in the REACH Regulation, the Government may, by its decision, restrict or prohibit for a limited period or until further notice the manufacture, import, placing on the market or otherwise making avail-

able, export, use or other similar handling of a chemical or article containing a chemical, and may impose operational restrictions and conditions if the use of the chemical or article containing the chemical is found to cause serious harm or hazard to human health or the environment.

Subsection 3 provides that if the prevention of harm or hazard referred to in subsection 1 requires urgent action, the Finnish Safety and Chemicals Agency may temporarily impose the necessary prohibitions and restrictions. In such cases, the matter is referred without delay to the Government for decision.

According to the preparatory work for the Chemicals Act (HE 38/2013 vp), a chemical causing serious harm or hazard may be classified as hazardous or it may be a chemical whose specific use causes serious harm or hazard, even if the classification does not take this into account.

Serious hazard or harm to human health

As Tukes stated in its interim decision, nicotine pouches pose a risk of accidental poisonings and can be life-threatening, especially for babies and young children.

Nicotine has acute toxic effects if ingested or when large amounts of it come into contact with the skin or eyes. Strong nicotine pouches can cause serious harm or danger to human health, since when swallowed, nicotine pouches can cause nicotine poisoning that may even be life-threatening. Nicotine pouches can be especially dangerous for small children and babies, but high doses of nicotine can also cause poisoning in adults.

In its decision, Tukes referred 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 (the CLP Regulation). Nicotine is in the ‘Acute Tox.’ hazard class in Annex VI to the CLP Regulation. 2, H300 “Fatal if swallowed” (ATE= 5 mg/kg bw). Based on the ATE of nicotine, Tukes has estimated that one pouch containing 50 milligrams of nicotine may be fatal for a child weighing 10 kg if all the nicotine in the pouch is absorbed when swallowed. The nicotine limit set by Tukes (20 mg/pouch) includes a safety factor of 2.5 times the ATE value for young children.

The flavourings of nicotine pouches are not regulated, and many of the flavours of nicotine pouches are designed to attract young users in particular and may appeal even to young children. Nicotine pouches are available in fruit, liquorice and cola flavours, for example. Flavourings form the main perceptible flavour of the product. The products are also packed in attractive-looking boxes, which may cause increased interest in the products among even very young children. There is therefore a risk that children will swallow nicotine pouches and get nicotine poisoning, which can cause serious health harms and even death.

On the basis of the above and the factors set out in the Tukes decision, the Government considers that the health of the population, especially that of young children, may be exposed to serious risk within the meaning of section 45b, subsection 1 of the Chemicals Act if nicotine pouches with a nicotine dose of 20 mg or more are available on the market. The Government considers that the placing on the market of such nicotine pouches should be prohibited.

Statements

Statements were requested with a public notice, as the number of persons affected by the Decision was not known.

The public notice and the documents related to the request for statements were published on 30 June 2023 on the website of the Ministry of Social Affairs and Health and at the Government Distribution Centre at Ritarikatu 2 B, Helsinki.

Stakeholders have been given the opportunity to express their views by 11 August 2023 on the decision to prohibit the placing on the Finnish market of nicotine pouches with a nicotine dose of 20 mg or more in accordance with section 45b, subsections 1 and 3 of the Chemicals Act. No statements from stakeholders have been received.

Notifications to the European Commission and the other Member States and to the World Trade Organisation

The draft Decision was notified to the European Commission and other Member States on 28 June 2023 in accordance with 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. The reference number of the notification in the database for draft regulations is 2023/396/FIN. The communication included a request for the application of the urgency procedure referred to in Article 6(7) of said Directive. On 6 July 2023, the Commission decided that the request for urgent approval was justified. The decision is therefore not subject to the standstill periods laid down in Article 6 of said Directive.

The draft Decision has been notified to the World Trade Organisation under the WTO Agreement on Technical Barriers to Trade on 2 August 2023. The notification number is G/TBT/N/FIN/87.

Notification

The stakeholders directly affected by the decision are the manufacturers and importers of the products covered by the Decision, as well as the operators selling the products. The number of individuals covered by the Decision is unknown and the Decision is notified as a service by publication. Information on the publication of the Decision will be announced in the public data network on the Government website.

Notification of the Decision is deemed to have taken place on the seventh day following the publication of the above-mentioned notice on the Government website.

Appeals

On the basis of section 8 of the Act on Proceedings in Administrative Matters (808/2019), this Decision can be appealed to the Supreme Administrative Court.

In the public interest, the execution of the Decision cannot be postponed and the Decision must be complied with despite any appeals (section 122 of the Act on Proceedings in Administrative Matters).

Applicable provisions

Sections 1, 6, 45 and section 45b, subsections 1 and 3, of the Chemicals Act (599/2013)

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

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

Additional information

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Laura Terho, Ministerial Adviser

Annexes	Decision of Tukes of 14 June 2023 (Tukes 6287/00.00.01/2023): Interim decision under section 45b, subsection 3 of the Chemicals Act to restrict the placing on the market of certain nicotine-containing products Instructions for lodging an appeal with the Supreme Administrative Court
For information	Special Adviser Niilo Heinonen Tukes