

Decision pursuant to section 1, subsection 1 of the Provincial Act (1990:32) on the application in the Province of Åland of national laws on chemicals regarding restrictions on the placing on the market of certain nicotine products

Decision

The Åland Provincial Government prohibits the placing on the market in Åland of nicotine pouches with a nicotine content of 20 mg or more per pouch. The Decision is made pursuant to section 1, subsection 1 of the Provincial Act (1990:32) on the application in the Province of Åland of national laws on chemicals, hereinafter the In blanco Chemicals Act, and section 45b, subsection 1 of the Chemicals Act (599/2013), hereinafter the Chemicals Act, applicable to Åland through the In blanco Chemicals Act.

Nicotine pouches refer to single-dose pouches for oral use containing nicotine (CAS 54-11-5 and/or CAS 22083-74-5) or a mixture of other nicotine compounds. Placing on the market means the supply, sale or other transfer in the course of a commercial activity.

The prohibition does not apply to products classified as medicinal products under the Medicines Act (395/1987).

Entry into force and validity of the Decision

The Decision will take effect immediately when it has been notified, i.e. on the seventh day following the announcement of the Decision on the website of the Åland Provincial Government.

The Decision shall be valid for the time being.

Statement of reasons for the Decision

Background

Nicotine pouches contain nicotine that is extracted from the tobacco plant or synthetically produced, as well as cellulose and other ingredients, such as sweeteners. Nicotine pouches do not contain tobacco.

In Finland, the Finnish Medicines Agency (Fimea) previously classified nicotine pouches as medicinal products. Fimea considered that nicotine pouches meet the definition of a medicinal product based on the pharmacological effect of nicotine. The classification as a medicinal product meant that nicotine pouches could not be sold in Finland without a marketing authorisation under the Medicines Act (395/1987), and imports of nicotine pouches were also restricted under the Medicines Act. Nicotine pouches have therefore not previously been available for sale in Finland, with the exception of products for which a medicinal products marketing authorisation has been granted. Products containing more than 4 milligrams of nicotine were classified as prescription drugs and could not be imported without a prescription. Medicinal products fall within national legislative competence under section 27, paragraph 30, of the Autonomy Act for the Province of Åland (1991:71) and Fimea's provisions also applied in Åland.

On 4 April 2023, Fimea announced that it had changed its interpretation regarding 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 medical purpose or it could otherwise be

demonstrated that they are typically used as medicinal products. Fimea's new interpretation of nicotine pouches meant that only the provisions of the In blanco Chemicals Act and the Chemicals Act apply to nicotine pouches in Åland and that nicotine pouches could be offered for sale in Åland without a retail licence and without restrictions on nicotine content. Nicotine pouches are not covered by the Provincial Act (1978:52, as amended by Act 2016/52) on tobacco and related products as they are not covered by any of the current definitions in the Act.

Following Fimea's reassessment of the legislation, the marketing, import and sale of nicotine pouches has increased significantly. The Åland Provincial Government has assessed the information and reports of the Finnish Safety and Chemicals Agency (Tukes), and has found that there is data to suggest that there may be nicotine pouches on the market with a nicotine content of up to 50 to 100 mg.

On 27 June 2023, the Åland Provincial Government issued an interim decision pursuant to section 1, subsection 1 of the In blanco Chemicals Act and section 45b, subsection 3 of the Chemicals Act, prohibiting the placing on the Åland market of nicotine pouches containing 20 mg or more of nicotine per pouch. The decision is based in particular on the need to protect children and adolescents from nicotine poisoning. In its interim decision, the Åland Provincial Government considered that pouches containing 20 mg or more of nicotine may pose a serious hazard to infants and young children under section 45b of the Chemicals Act. Under section 45b, subsection 3 of the Chemicals Act, an interim decision shall be forwarded without delay for a decision pursuant to section 45b, subsection 1 of the Chemicals Act.

In its decision, the Provincial Government relied on the expertise of the Finnish National Safety and Chemicals Agency (Tukes).

Legislation

Under section 18, subsection 12 of the Autonomy Act for the Province of Åland (1991:71), Åland has legislative competence in matters relating to health care, and under section 18, subsection 10 of the Autonomy Act, Åland has legislative competence in the area of nature and environmental conservation, to which areas chemicals are assigned.

The Chemicals Act (599/2013) applies to Åland on the basis of section 1, subsection 1 of the Provincial Act (1990:32) on the application in the Province of Åland of national laws on chemicals.

Under section 3 of the Provincial Act (1990:32) on the application in the Province of Åland of national laws on chemicals, administrative tasks that are the responsibility of the national government shall in the Province be carried out by the Provincial Government, in so far as administration is based on the Province's legislative and administrative powers in the relevant area. This means that the Provincial Government shall be responsible for the tasks which, according to the Chemicals Act, shall be entrusted to both Tukes and the Government, in so far as they fall under the Province's legislative and administrative competence in the relevant area.

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 contains provisions on the implementation of European Union chemicals legislation and on certain national obligations relating to 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, subsection 2 of the Chemicals Act.

According to section 45, subsection 1 of the Chemicals Act, the provisions of chapter 7 of the Chemicals Act shall apply to supervision other than market surveillance of chemicals. By way of derogation from subsection 1, section 45a and subsection 3 of section 45b of the Chemicals Act shall apply to market surveillance of chemicals. Under section 45, subsection 3 of the Chemicals Act, the provisions of the Market Surveillance Act shall apply to the market surveillance of chemicals, unless otherwise provided in this Act. For the purposes of this Act, a 'product' within the meaning of the Market Surveillance Act shall be considered to be a chemical, an article containing chemicals or a treated article, and an 'economic operator' shall mean an entity which within the meaning of this Act or European Union chemicals legislation manufactures, itself or in the role of sole representative imports, introduces, places on the market, exports, stores, packages or distributes a product.

Under section 45, subsection 4 of the Chemicals Act, where measures for market surveillance of chemicals are directed at an economic operator, the provisions of European Union chemicals legislation on the definition of placing on the market and, in the case of biocides, the definition of making available on the market, shall apply. However, the placing on the market of nationally authorised biocidal products means the placing on the market in Finland.

Section 45b, subsection 1 of the Chemicals Act provides that, in so far as a chemical is not subject to restrictions under the REACH Regulation, the Government may, if it is established that use of a chemical or article containing the chemical causes or is reasonably deemed to cause serious harm or hazard to human health or the environment, decide to restrict or prohibit the manufacture, import, placing on the market or any other transfer, export, use or other comparable handling of the chemical or article containing the chemical, for a certain period or indefinitely, and to issue restrictions and conditions for the operation.

Subsection 3 of section 45b of the Chemicals Act 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 issue the necessary prohibitions and restrictions. The matter shall then be referred without delay to the Government for decision.

According to the preparatory work for the Chemicals Act, a chemical causing serious harm or hazard may have been classified as hazardous, but it may also be a chemical which, when used in a specific way, causes serious harm or hazard even if the classification does not take this into account (HE 38/2013 vp, p. 53).

Serious harm or hazard to human health

In its interim decision, the Provincial Government stated that nicotine pouches pose a serious risk of poisoning and may be life-threatening, especially for infants and young children.

The more products with increasing nicotine levels that are sold in retail outlets, the larger the likelihood of e.g. life-threatening poisoning among young children and the greater the serious hazards that may arise when the product is used. Large nicotine doses can also cause poisoning in adults. The most tangible feature of nicotine is its addictive effect on the central nervous system. Young people can become severely dependent on nicotine after trying it. Nicotine also has negative effects on the heart and blood vessels. Neither national legislation

nor Union chemicals legislation currently provides for an upper limit for the nicotine content of nicotine pouches.

The interim 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 (CLP Regulation). Nicotine is classified as Acute Tox. in Annex VI to the CLP Regulation. 2, H300 "Fatal if swallowed" (ATE= 5 mg/kg body weight). Based on the ATE for nicotine, it can be calculated that a pouch containing 50 mg of nicotine can be fatal for a child weighing 10 kg if all the nicotine in the pouch is ingested orally and absorbed into the body. The limit of 20 mg nicotine per pouch has been determined on the basis of a safety factor 2.5 (small children) compared with the ATE value.

Also, the flavouring of nicotine pouches is not regulated, and many of the flavours of nicotine pouches are designed to attract especially young users and may also appeal to small children. Nicotine pouches are available in e.g. fruit, licorice and cola flavours and scents. The products are packed in attractive packages, which may appeal to very young children. There is a risk that children may swallow nicotine pouches and get nicotine poisoning, which can cause serious health harms.

In view of the above and the factors set out in the Provincial Government's interim decision, the Provincial Government considers that nicotine pouches with a nicotine dose of 20 mg or more may cause serious harm or hazard to health within the meaning of section 45b, subsection 1 of the Chemicals Act. Especially for young children, the hazard may be fatal. The Provincial Government considers that the placing on the market of such nicotine pouches should be prohibited.

Notification

The number of parties covered by this Decision is unknown and the Decision is therefore announced as service by publication pursuant to section 50, subsection 2 and section 57 of the Administrative Act (2008:9) for the Province of Åland.

The Decision is available on the Åland Provincial Government's website until xx.xx. A notice that the decision is available on the Authority's website is published on the Provincial Government's electronic bulletin board, www.regeringen.ax. Notification is deemed to have taken place on the seventh day following the publication of the notice on the Provincial Government's electronic bulletin board.

Hearing

XXXXX

Appeals

Instructions for appeal are attached.

Applicable provisions

Provincial Act (1990:32) on the application in the Province of Åland of national laws on chemicals, sections 1 and 3.

Chemicals Act (599/2013), sections 1, 6, and 45, and subsections 1 and 3 of section 45b. Administrative Act (2008:9) for the Province of Åland, section 28, subsection 1, and sections 49, 50 and 57.

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