



Minutes taken in plenary meeting presentation

Department of Social Affairs, Health and the Environment
Office of the Environment, S4

Present VT, RH, AH-J, AH, CW	Absent HJ, FK	Adjusted Immediately
Chairperson Head of the Government of Åland Veronica Thörnroos	Rapporteur Minister Christian Wikström	Recorder Environmental engineer Mia Westman

No 6

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

ÅLR 2023/5193

The case has been transferred from individual presentation on 9 October 2023.

Decision on prohibition of sale

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).

This Decision replaces the Government of Åland's interim Decision S423E46 No 66 of 27 June 2023 to restrict the placing on the market of certain nicotine products by virtue of section 1, subsection 1 of the *In blanco Chemicals Act* and section 45b, subsection 3 of the *Chemicals Act*.

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

Background

Nicotine pouches are products, the external appearance and manner of use of which resemble tobacco for oral use as referred to in section 2a of the Provincial Act (1978:52) on tobacco and related products, hereinafter the *Tobacco Act*. Nicotine pouches contain nicotine that is either extracted from the tobacco plant or synthetically produced, as well as cellulose and other ingredients, such as sweeteners. Nicotine pouches do not contain tobacco.

The Finnish Medicines Agency, hereinafter *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. Due to the classification as a medicinal product, 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 on the basis of the Medicines Act. With the exception of products authorised under the Medicines Act, nicotine pouches were not available for sale in Finland. Products containing more than 4 milligrams of nicotine were considered to be equal to prescription drugs, which may not be imported without a prescription.

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 expressly marketed for a medical purpose or it could otherwise be demonstrated that they are generally used in the same way as medicinal products. Because Fimea has changed its interpretation, the Medicines Act is no longer applicable to nicotine pouches and nicotine pouches can therefore be sold in Finland without a retail licence.

Nicotine pouches are not covered by the *Tobacco Act* as they are not covered by any of the current definitions in section 1 of the Act. The nicotine pouches that are sold may contain large amounts of nicotine, a chemical as defined in section 6, subsection 1, paragraph 2 of the Chemicals Act, and therefore the Chemicals Act applies to nicotine pouches. Chemical mixtures shall not be placed on the market (i.e. imported, sold or transferred free of charge) unless they comply with Article 1(1) of the CLP Regulation (EC) No 1272/2008.

Since Fimea changed its interpretation relating to nicotine pouches, imports of nicotine pouches have increased significantly and these products have started to be sold in grocery stores, kiosks and service stations. Some retailers stock only nicotine pouches with a nicotine content that does not exceed a certain limit, e.g. 16 milligrams per gram. However, according to information provided by the Finnish Safety and Chemicals Agency, hereinafter *Tukes*, the Agency has also received notifications under the Chemicals Act relating to stronger nicotine pouches. *Tukes* believes that the weight of

nicotine pouches that can be ordered online varies between 0.3 and 1.3 grams. According to a German report, the pouches may contain up to about 50 mg of nicotine, but in web searches carried out by Tukes, there have been indications that the nicotine content in one dose may amount to approximately 100 mg.

On 27 June 2023, the Government of Åland 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, on restricting the placing on the market of certain nicotine products (S423E46 No 66). The Decision was taken as a matter of urgency and the justification was primarily the need to protect children and adolescents against nicotine poisoning. In its Decision, the Government of Åland considered that pouches containing 20 milligrams or more of nicotine may pose a serious hazard to infants and young children as referred to in section 45b of the Chemicals Act. Under section 45b, subsection 3 of the Chemicals Act, the interim Decision shall be forwarded without delay for a decision pursuant to section 45b, subsection 1 of the Chemicals Act.

Jurisdiction of the Provincial Government and general requirements of 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. Under section 27, subsection 30 of the Autonomy Act, the State shall have legislative competence in respect of medicinal products.

Pursuant to section 3 of the In blanco Chemicals Act and section 8 of the Chemicals Act, the Government of Åland shall monitor compliance with the Chemicals Act and regulations issued pursuant to it, as well as compliance with the REACH Regulation, CLP Regulation, Detergents Regulation, Biocidal Products Regulation and POP Regulation (Articles 3 and 4) of the EU, unless otherwise provided in the In blanco Chemicals Act or the Chemicals Act.

According to section 1, the purpose of the Chemicals Act is to protect human health and the environment from hazards and harms caused by chemicals. According to section 2, 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 legislation and are defined as mixtures containing nicotine and other substances in accordance with section 6, subsection 2 of the Chemicals Act.

According to section 45b, subsection 1 of the Chemicals Act, the Provincial Government may, in so far as a chemical is not subject to restrictions under the REACH Regulation and 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.

Serious harm or hazard to human health or the environment

The Provincial Government stated already in its interim Decision that nicotine pouches entail a risk of accidental poisoning and that they may be life-threatening, in particular for infants and young children. Nicotine has acute toxic effects if it is swallowed or ends up in large amounts on the skin or in the eyes. Strong nicotine pouches can cause serious harm or hazard to human health because ingestion of nicotine pouches can cause life-threatening nicotine poisoning. Nicotine pouches may be particularly dangerous to young children and infants, but large doses of nicotine can also cause poisoning in young people and adults.

The most tangible feature of nicotine is its addictive effect on the central nervous system. Young people can quickly become severely dependent on nicotine. Nicotine also has negative effects on e.g. 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, and the sale of nicotine pouches to consumers is permitted without prior approval, provided that the provisions of the chemicals legislation, including notification, registration, information, packaging and labelling obligations, are observed.

In the interim Decision, the Provincial Government referred to the hazard classification under the CLP Regulation. Nicotine is in the Acute Tox 2, H300, "Fatal if swallowed" (ATE= 5 mg/kg bw) category in Annex VI to the CLP Regulation. Tukes has determined that the nicotine limit (20 mg/pouch) for young children includes a safety factor 2.5 times greater than the ATE value. Based on the ATE for nicotine, it is therefore possible to calculate 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 flavourings of nicotine pouches are not subject to any provisions and the flavours of the products are often designed to attract particularly young users and even young children. The main flavour of the product consists of flavourings and nicotine pouches are sold in a variety of flavours such as fruit, licorice and cola. The products are packed in attractive boxes, which may add to the appeal of these products among even very young children. These aspects limit the consumer's ability to identify the risk of the product and, in particular, the risk of accidental poisoning. There is a risk that children who swallow nicotine pouches will suffer nicotine poisoning, which can cause serious health harms and may even be fatal.

On the basis of the circumstances set out above and the circumstances presented in the interim Decision, the Provincial Government considers that the health of the population, in particular of young children, may be seriously compromised as referred to in section 45b, subsection 1 of the Chemicals Act if there are nicotine pouches with a nicotine content of 20 mg/pouch or more on the market.

Hearing

The hearing in the case pursuant to section 28, subsection 1 of the Administrative Procedure Act (2008:9) for Åland has been effected by public notification pursuant to section 50, subsection 2 of the Administrative Procedure Act, since the number of persons covered by the Decision is unknown.

A communication on the hearing and the documents relating to the hearing was published on 5 July 2023 on the Provincial Government's electronic bulletin board and website. The parties concerned have been given the opportunity to express their opinion on the matter by 31 August 2023. No opinions on the matter have been received during the hearing period.

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

The draft Decision was notified to the European Commission and the other Member States of the European Union on 30 June 2023, in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services. The registration number is 2023/0404/FI in the Tris database, which contains draft technical regulations. The notification requested the application of the urgency authorisation procedure referred to in Article 6(7) of the Directive. The Commission announced on 12 July 2023 that it considers the request for urgent authorisation to be justified. Consequently, the standstill periods referred to in Article 6 of that directive do not apply to the Decision.

A notification of the draft Decision was made to the World Trade Organisation on 19 July 2023 in accordance with the World Trade Organisation's Agreement on Technical Barriers to Trade. The number of the notification is G/TBT/N/FIN/86.

Notification

Because the number of parties covered by this Decision is unknown, the Decision is announced as service by publication pursuant to section 50, subsection 2 and section 57 of the Administrative Procedure Act.

The Decision is available on the Åland Provincial Government's website until 18 November 2023. A notice that the Decision is available on the Authority's website is published on the Provincial Government's electronic bulletin board. 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.

Appeals

Pursuant to section 25, subsection 2 of the Autonomy Act (1991:71) for Åland and section 9, subsection 3 of the Administrative Judicial Procedure Act (808/2019), amendments to this Decision may be applied for by appeal to the Supreme Administrative Court.

Appeals shall not prevent enforcement of this Decision since enforcement cannot be postponed due to a public interest in accordance with section 122, subsection 3, paragraph 3 of the Administrative Judicial Procedure Act.

Applicable provisions

Provincial Act (1990:32) on the application in the Province of Åland of national laws on chemicals (1995/60), section 1, subsection 1; and section 3. Chemicals Act (599/2013), section 45b, subsection 1. Administrative Act (2008:9) for the Province of Åland, section 28, subsection 1; section 49; section 50, subsection 2; and section 57. Act on the Autonomy of Åland (1991:71), section 25, subsection 2.

Additional information

The Provincial Government decided on 16 May 2023 to issue recommendations regarding the sale of nicotine pouches. The recommendation is not to sell nicotine pouches containing more than 10 mg of nicotine per pouch. Read the full Decision here:

<https://www.regeringen.ax/sites/default/files/attachments/protocol/nr10-2023-enskild-S3.pdf>

The import and sale of nicotine pouches is subject to the obligations of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures. The obligations include, among other things, requirements for hazard classification as well as warnings, child-resistant design and sealing of packages. Packaging labels must be available at least in Swedish. The requirements set out in the REACH Regulation shall also apply to nicotine pouches. Read more about the obligations here:

<https://tukes.fi/sv/-/kemikalielagstiftningen-tillampas-ocksa-pa-nikotinpasar>
