



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market Enforcement

Notification of Regulatory Barriers

Notification Number : 2023/0396/FI (Finland)

Decision under section 45b, subsection 1 of the Chemicals Act to restrict the placing on the market of nicotine-containing products

Date received : 28/06/2023

End of Standstill : Not applicable (closed)

Message

Message 001

Communication from the Commission - TRIS/(2023) 1946

Directive (EU) 2015/1535

Notification: 2023/0396/FI

Notification of a draft text from a Member State

Notification – Notification – Notifizierung – Нотификация – Oznámení – Notifikation – Γνωστοποίηση – Notificación – Teavitamine – Ilmoitus – Obavijest – Bejelentés – Notifica – Pranešimas – Paziņojums – Notifika – Kennisgeving – Zawiadomienie – Notificação – Notificare – Oznámenie – Obvestilo – Anmälan – Fógra a thabhairt

Does not open the delays - N'ouvre pas de délai - Kein Fristbeginn - Не се предвижда период на прекъсване - Nezahajuje prodlení - Fristerne indledes ikke - Καμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késéset - Non fa decorrere la mora - Atidējimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħ il-perijodi ta' dewmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Nu deschide perioadele de stagnare - Nezačína oneskorenia - Ne uvaja zamud - Inleder ingen frist - Ní osclaíonn sé na moilleanna

MSG: 20231946.EN

1. MSG 001 IND 2023 0396 FI EN 28-06-2023 FI NOTIF

2. Finland

3A. Työ- ja elinkeinoministeriö
Työllisyys ja toimivat markkinat -osasto
PL 32
FI-00023 VALTIONEUVOSTO
Puhelin +358 29 5047437
maaraykset.tekniset.tem@gov.fi

3B. Sosiaali- ja terveysministeriö
Turvallisuus ja terveys -osasto
PL 33
FI-00023 VALTIONEUVOSTO
Puhelin +358 295 16001
kirjaamo@stm.fi



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

4. 2023/0396/FI - C00C - Chemicals

5. Decision under section 45b, subsection 1 of the Chemicals Act to restrict the placing on the market of nicotine-containing products

6. Nicotine pouches for oral use containing 20 mg or more of nicotine per pouch

7.

8. The Decision would prohibit the placing on the market in Finland of nicotine pouches with a nicotine dose of 20 mg or more per pouch. The Decision would be issued because the sale of nicotine pouches has been liberalised as a result of the change in interpretation of the Medicines Act.

Finland is preparing an amendment to the Tobacco Act, the aim of which is to issue further provisions on nicotine pouches. However, the amendment to the Act is still pending and it is currently not known when the Act will enter into force.

9. The purpose of the Decision is to prevent accidents related to nicotine poisoning. Strong nicotine pouches can cause serious harm or danger to human health because ingested nicotine pouches can cause nicotine poisoning, which could even be fatal. Nicotine pouches are especially dangerous for small children and babies, but high doses of nicotine can also cause poisoning in adults.

10. Basic text references: The basic texts have been provided in connection with an earlier notification:
2023/0219/FIN

11. Yes

12. Additional information on the grounds of urgency are in the technical annex. There is no upper limit laid down on the nicotine content of the products, although high levels of nicotine can lead to nicotine poisoning that could even be fatal.

13. No

14. No

15. Yes

16.

TBT aspects:

The draft is a technical regulation or a conformity assessment

The draft is not in conformity with an international standard

The draft has significant impact on international trade

SPS aspects:

The draft is a sanitary or phytosanitary measure

The content is not the same as that of an international standard; directive or recommendation

The draft has significant impact on international trade

European Commission

Contact point Directive (EU) 2015/1535

email: grow-dir2015-1535-central@ec.europa.eu