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

Notification Number : 2023/0030/S (Sweden)

The Public Health Agency of Sweden’s regulations on tobacco-free nicotine products

Date received : 25/01/2023
End of Standstill : 26/04/2023 (closed)

Message

Message 002

Communication from the Commission - TRIS/(2023) 00229
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2023/0030/S

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késéseket - Ma’ jiftaħx il-perijodi ta’ dawmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 202300229.EN)
1. MSG 002 IND 2023 0030 S EN 25-01-2023 S NOTIF

2. S

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4. 2023/0030/S - X40M

5. The Public Health Agency of Sweden’s regulations on tobacco-free nicotine products

6. Tobacco-free nicotine products

7. -

8. The regulations contain provisions on the manner in which product notification, reporting and notification of product deficiencies/corrective measures are to be carried out. There are also provisions on how the declaration of contents and health warnings on packaging are to be designed and the stipulation that these must be in Swedish. Health warnings shall be designed in accordance with proposed regulations, including in commercial advertisements.

Sweden has previously notified these regulations (notification number 2023/23/S). The wrong version of the regulations, with Section 10 missing, was notified by mistake. That notification has now been withdrawn. The regulations that are now notified include Section 10 and are otherwise identical to the previously notified regulations.

9. The purpose of the regulations is to supplement the associated Act and Ordinance and, by doing so, contribute to strengthening the protection of human health. The Public Health Agency’s assessment is that the provisions are necessary and proportionate.

There is no mutual recognition clause in the regulations. The purpose of the provisions is to protect human health by ensuring that consumers in Sweden are informed in Swedish about the content and risks of the products. For consumers to benefit from the information, the design also needs to be sufficiently clear and prominent. The Agency’s assessment is that the labelling requirements being proposed here are those which are necessary to enable consumers to benefit from the information on the content and properties of the product. For this reason, no other language or design of the label can be accepted.

10. No basic texts available

11. No

12. -

13. No

14. No

15. Yes

16. TBT aspect

NO - The project has no significant impact on international trade.

SPS aspect

No - The draft is neither a sanitary nor phytosanitary measure

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European Commission

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