Message 001

Communication from the Commission - TRIS/(2026) 1241

Directive (EU) 2015/1535

Notification: 2026/0223/PL

Notification of a draft text from a Member State

Notification – Notification – Notifzierung – 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 - Καμμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késéseket - Non fa decorrere la mora - Atidėjimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħx 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: 20261241.EN

1. MSG 001 IND 2026 0223 PL EN 05-05-2026 PL NOTIF

2. Poland

3A. Ministerstwo Rozwoju i Technologii,
Departament Obrotu Towarami Wrazliwymi i Bezpieczeństwa Technicznego,
Plac Trzech Krzyży 3/5, 00-507 Warszawa,
tel.: (+48) 22 411 93 94, e-mail: notyfikacjaPL@mrit.gov.pl

3B. Ministerstwo Zdrowia
Departament Prawny
ul. Miodowa 15,
00-952 Warszawa
e-mail: kancelaria@mz.gov.pl lub dep-pr@mz.gov.pl

4. 2026/0223/PL - S00S - HEALTH, MEDICAL EQUIPMENT

5. Draft Act amending the Act on protection of health against the consequences of consumption of tobacco and tobacco products

6. Disposable e-cigarettes containing e-liquid with or without nicotine, nicotine pouches, other nicotine products, and packaging for e-liquid containers. Health protection.

7.

8. The proposed amendment to the Act on protection of health against the consequences of consumption of tobacco and tobacco products includes a number of key changes aimed at strengthening regulations on new nicotine products and e-cigarettes, as well as bringing the legislation into line with international and EU standards. The project primarily envisages:
- introducing a ban on the sale of disposable e-cigarettes, both with and without nicotine,
- extending the ban to include flavoured nicotine pouches and other nicotine products that are not currently covered by Directive 2014/40/EU or the provisions of the Act – it is proposed that these products should only be available through the pharmaceutical channel, subject to the relevant authorisations;
- the introduction of new criminal penalties to ensure effective enforcement of the regulations, including substantial fines and restrictions on personal liberty for breaching the sales ban and for obstructing the sampling of such products;
- the introduction of labelling on packaging for e-cigarette liquid containers, enabling their identification;
- setting transitional periods for the withdrawal from the market of products not complying with the new requirements.
The draft Act is part of a broader effort to reduce the availability and harmfulness of new forms of consumption of nicotine and tobacco products, with the aim of protecting public health and bringing Polish law into line with international standards.

9. Nicotine products are not ordinary goods; in light of the particularly harmful impact of tobacco on human health, protecting health should be treated as a priority when compared to other values in terms of freedom of economic activities.
According to the World Health Organisation report prepared for COP10 (FCTC/COP/10/7), States Parties to the FCTC should consider strong regulations, including a ban on the sale of such products, in order to protect the health of children and young people.
The National Institute of Public Health NIH – National Research Institute notes that, since their introduction to the Polish market, disposable e-cigarettes have been most popular among young people, particularly those aged 18–24 and younger. It is worth noting that a significant number of users reported having first used them when they were under 18. In the light of the above, action should be taken to limit as quickly and effectively as possible the access of these products to the Polish market and, consequently, to the (retail) end-user.
In the area not harmonised with Directive 2014/40/EU, the proposed ban on the placing on the market of disposable electronic cigarettes (containing nicotine) set out in the draft Act also requires notification pursuant to Article 24(3) of Directive 2014/40/EU. To the extent that a ban on disposable nicotine-free electronic cigarettes is proposed, it is subject to the procedure provided for in Directive (EU) 2015/1535.
Furthermore, it is necessary to grant the President of the Office for Chemical Substances – as is the case with tobacco products – the right to commission tests on the composition of e-cigarette liquids, and to draw up a list of laboratories that will carry out such tests, taking into account their capacity and independence from the nicotine products industry.
The current market situation, which permits the sale of nicotine pouches containing ingredients that impart a

scent or flavour other than that of tobacco, is undoubtedly harmful to public health in the broadest sense. The World Health Organisation emphasises that scientific studies indicate that people aged 13–20 most frequently used nicotine pouches with mint/menthol (30.5%), sweet (29.2%) and fruit (23.6%) flavours, whereas the tobacco flavour was popular among only 7.5% of these individuals. With this in mind, only products containing ingredients that impart solely the smell or taste of tobacco should be permitted for sale. Furthermore, given the possibility that other nicotine-containing products may appear on the market which are not currently subject to the provisions of Directive 2014/40/EU, such as chewing gums, strips and toothpicks for 'recreational absorption of nicotine, its compounds or derivatives by the human body, e.g. through the oral mucosa, the skin or by inhalation', it is necessary to further clarify the ban on the sale of these products. Products of this kind should only be placed on the market under the pharmaceutical regime, following a successful evaluation of the registration dossier detailing their pharmacodynamic and pharmacokinetic properties and confirming their efficacy and safety.
In order to enable the identification of the notification documentation for the electronic cigarette and refill container under examination, it has been proposed to introduce an obligation to indicate on the packaging of these products an e-cigarette identifier (EP-ID) within the meaning of Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers (OJ EU L 309, 26.11.2015, p. 15).

9a. Nicotine products are not ordinary goods; in light of the particularly harmful impact of tobacco on human health, protecting health should be treated as a priority when compared to other values in terms of freedom of economic activities.
According to the World Health Organisation report prepared for COP10 (FCTC/COP/10/7), States Parties to the FCTC should consider strong regulations, including a ban on the sale of such products, in order to protect the health of children and young people.
The National Institute of Public Health NIH – National Research Institute notes that, since their introduction to the Polish market, disposable e-cigarettes have been most popular among young people, particularly those aged 18–24 and younger. It is worth noting that a significant number of users reported having first used them when they were under 18. In the light of the above, action should be taken to limit as quickly and effectively as possible the access of these products to the Polish market and, consequently, to the (retail) end-user.
In the area not harmonised with Directive 2014/40/EU, the proposed ban on the placing on the market of disposable electronic cigarettes (containing nicotine) set out in the draft Act also requires notification pursuant to Article 24(3) of Directive 2014/40/EU. To the extent that a ban on disposable nicotine-free electronic cigarettes is proposed, it is subject to the procedure provided for in Directive (EU) 2015/1535.
Furthermore, it is necessary to grant the President of the Office for Chemical Substances – as is the case with tobacco products – the right to commission tests on the composition of e-cigarette liquids, and to draw up a list of laboratories that will carry out such tests, taking into account their capacity and independence from the nicotine products industry.
The current market situation, which permits the sale of nicotine pouches containing ingredients that impart a scent or flavour other than that of tobacco, is undoubtedly harmful to public health in the broadest sense. The World Health Organisation emphasises that scientific studies indicate that people aged 13–20 most frequently used nicotine pouches with mint/menthol (30.5%), sweet (29.2%) and fruit (23.6%) flavours, whereas the tobacco flavour was popular among only 7.5% of these individuals. With this in mind, only products containing ingredients that impart solely the smell or taste of tobacco should be permitted for sale. Furthermore, given the possibility that other nicotine-containing products may appear on the market which

are not currently subject to the provisions of Directive 2014/40/EU, such as chewing gums, strips and toothpicks for ‘recreational absorption of nicotine, its compounds or derivatives by the human body, e.g. through the oral mucosa, the skin or by inhalation’, it is necessary to further clarify the ban on the sale of these products. Products of this kind should only be placed on the market under the pharmaceutical regime, following a successful evaluation of the registration dossier detailing their pharmacodynamic and pharmacokinetic properties and confirming their efficacy and safety.
In order to enable the identification of the notification documentation for the electronic cigarette and refill container under examination, it has been proposed to introduce an obligation to indicate on the packaging of these products an e-cigarette identifier (EP-ID) within the meaning of Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers (OJ EU L 309, 26.11.2015, p. 15).

9b. Nicotine products are not ordinary goods; in light of the particularly harmful impact of tobacco on human health, protecting health should be treated as a priority when compared to other values in terms of freedom of economic activities.
According to the World Health Organisation report prepared for COP10 (FCTC/COP/10/7), States Parties to the FCTC should consider strong regulations, including a ban on the sale of such products, in order to protect the health of children and young people.
The National Institute of Public Health NIH – National Research Institute notes that, since their introduction to the Polish market, disposable e-cigarettes have been most popular among young people, particularly those aged 18–24 and younger. It is worth noting that a significant number of users reported having first used them when they were under 18. In the light of the above, action should be taken to limit as quickly and effectively as possible the access of these products to the Polish market and, consequently, to the (retail) end-user.
In the area not harmonised with Directive 2014/40/EU, the proposed ban on the placing on the market of disposable electronic cigarettes (containing nicotine) set out in the draft Act also requires notification pursuant to Article 24(3) of Directive 2014/40/EU. To the extent that a ban on disposable nicotine-free electronic cigarettes is proposed, it is subject to the procedure provided for in Directive (EU) 2015/1535.
Furthermore, it is necessary to grant the President of the Office for Chemical Substances – as is the case with tobacco products – the right to commission tests on the composition of e-cigarette liquids, and to draw up a list of laboratories that will carry out such tests, taking into account their capacity and independence from the nicotine products industry.
The current market situation, which permits the sale of nicotine pouches containing ingredients that impart a scent or flavour other than that of tobacco, is undoubtedly harmful to public health in the broadest sense. The World Health Organisation emphasises that scientific studies indicate that people aged 13–20 most frequently used nicotine pouches with mint/menthol (30.5%), sweet (29.2%) and fruit (23.6%) flavours, whereas the tobacco flavour was popular among only 7.5% of these individuals. With this in mind, only products containing ingredients that impart solely the smell or taste of tobacco should be permitted for sale.
Furthermore, given the possibility that other nicotine-containing products may appear on the market which are not currently subject to the provisions of Directive 2014/40/EU, such as chewing gums, strips and toothpicks for ‘recreational absorption of nicotine, its compounds or derivatives by the human body, e.g. through the oral mucosa, the skin or by inhalation’, it is necessary to further clarify the ban on the sale of these products. Products of this kind should only be placed on the market under the pharmaceutical regime, following a successful evaluation of the registration dossier detailing their pharmacodynamic and pharmacokinetic properties and confirming their efficacy and safety.

In order to enable the identification of the notification documentation for the electronic cigarette and refill container under examination, it has been proposed to introduce an obligation to indicate on the packaging of these products an e-cigarette identifier (EP-ID) within the meaning of Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers (OJ EU L 309, 26.11.2015, p. 15).

9c. Nicotine products are not ordinary goods; in light of the particularly harmful impact of tobacco on human health, protecting health should be treated as a priority when compared to other values in terms of freedom of economic activities.
According to the World Health Organisation report prepared for COP10 (FCTC/COP/10/7), States Parties to the FCTC should consider strong regulations, including a ban on the sale of such products, in order to protect the health of children and young people.
The National Institute of Public Health NIH – National Research Institute notes that, since their introduction to the Polish market, disposable e-cigarettes have been most popular among young people, particularly those aged 18–24 and younger. It is worth noting that a significant number of users reported having first used them when they were under 18. In the light of the above, action should be taken to limit as quickly and effectively as possible the access of these products to the Polish market and, consequently, to the (retail) end-user.
In the area not harmonised with Directive 2014/40/EU, the proposed ban on the placing on the market of disposable electronic cigarettes (containing nicotine) set out in the draft Act also requires notification pursuant to Article 24(3) of Directive 2014/40/EU. To the extent that a ban on disposable nicotine-free electronic cigarettes is proposed, it is subject to the procedure provided for in Directive (EU) 2015/1535.
Furthermore, it is necessary to grant the President of the Office for Chemical Substances – as is the case with tobacco products – the right to commission tests on the composition of e-cigarette liquids, and to draw up a list of laboratories that will carry out such tests, taking into account their capacity and independence from the nicotine products industry.
The current market situation, which permits the sale of nicotine pouches containing ingredients that impart a scent or flavour other than that of tobacco, is undoubtedly harmful to public health in the broadest sense. The World Health Organisation emphasises that scientific studies indicate that people aged 13–20 most frequently used nicotine pouches with mint/menthol (30.5%), sweet (29.2%) and fruit (23.6%) flavours, whereas the tobacco flavour was popular among only 7.5% of these individuals. With this in mind, only products containing ingredients that impart solely the smell or taste of tobacco should be permitted for sale.
Furthermore, given the possibility that other nicotine-containing products may appear on the market which are not currently subject to the provisions of Directive 2014/40/EU, such as chewing gums, strips and toothpicks for ‘recreational absorption of nicotine, its compounds or derivatives by the human body, e.g. through the oral mucosa, the skin or by inhalation’, it is necessary to further clarify the ban on the sale of these products. Products of this kind should only be placed on the market under the pharmaceutical regime, following a successful evaluation of the registration dossier detailing their pharmacodynamic and pharmacokinetic properties and confirming their efficacy and safety.
In order to enable the identification of the notification documentation for the electronic cigarette and refill container under examination, it has been proposed to introduce an obligation to indicate on the packaging of these products an e-cigarette identifier (EP-ID) within the meaning of Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers (OJ EU L 309, 26.11.2015, p. 15).

10. References to basic texts:

11. No

12.

13. No

14. No

15. Yes

16.
TBT aspects:
The draft is a technical regulation or a conformity assessment
The draft has significant impact on international trade

SPS aspects: No

****
European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu