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

Message 201

Communication from the Commission - TRIS/(2025) 1239

Directive (EU) 2015/1535

Notification: 2025/0055/PL

Forwarding of the response of the Member State notifying a draft (Poland) to comments (5.2) of European Commission.

MSG: 20251239.EN

1. MSG 201 IND 2025 0055 PL EN 28-04-2025 08-05-2025 PL ANSWER 28-04-2025

2. Poland

3A. Ministerstwo Rozwoju i Technologii, Departament Obrotu Towarami Wrażliwymi 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. 2025/0055/PL - S00S - HEALTH, MEDICAL EQUIPMENT

5.

6. Additional information concerning the draft Act
amending the Act on protection of health against the consequences of consumption of tobacco and tobacco products, notified under number 2025/55/PL

Re 1: In response to question 1 concerning the definition of ‘electronic cigarette’ and the need to use appropriate health warnings, it should be pointed out that the definition of electronic cigarettes contained in the draft will not interfere with the requirements applicable to electronic cigarettes under Directive 2014/40/EU. According to the draft Act, the health warning: ‘This product contains nicotine, which is a highly addictive substance’ will need to be placed on all electronic cigarettes that can be used to consume nicotine-containing vapour. If it is possible to refill an electronic cigarette with nicotine-containing liquid, the product may be used for the consumption of nicotine-containing vapour. The draft Act does not introduce any changes in this regard. Only with regard to electronic cigarettes that can solely be used to consume nicotine-free vapour, the draft Act provides for the obligation to place on them the health warning: ‘Product harmful to health’. If the product in question can only be used for the consumption of nicotine-free vapour, it does not meet the definition of an electronic cigarette set out in Article 2(16) of Directive 2014/40/EU.

Re 2 and 3: In response to questions 2 and 3 concerning the definition of refill containers and related products, it should be noted that the inclusion of the extended definitions in the draft will not cause confusion as to the scope of application of the relevant requirements for refill containers set out in Directive 2014/40/EU. All existing requirements for refill containers of nicotine-containing liquid remain unchanged and the draft Act does not introduce any changes in this respect. The proposed legal solutions are aimed at covering currently unregulated products, such as nicotine-free liquids and nicotine pouches, by statutory provisions.

Re 4:
With regard to question 4, PL believes that the reporting of information on nicotine pouches will not affect the reporting of information on products regulated by Directive 2014/40/EU and Commission Implementing Decision 2015/2186. The information reported will not interfere with each other. The way products are reported via the EU-CEG system

presupposes that each report has its own individual number which identifies it. Information provided in a report is assigned to this number, so the information on nicotine pouches will not affect the information on tobacco products and herbal products for smoking.
PL will indicate the product category 'Other' as appropriate for the reporting of nicotine pouches. Tobacco products and herbal products for smoking have their own categories intended for the reporting of those products. The reporting of nicotine pouches will therefore not create confusion as to the type of reported product, as they will not use category designations intended for other products.
It should be noted that several Member States currently already use the EU-CEG system to report products that are not regulated in Directive 2014/40/EU (e.g. e-cigarettes, which can only be used for the consumption of nicotine-free vapour and refill containers with nicotine-free liquid). The current practical functioning of the EU-CEG does not indicate that such use of the system leads to misunderstandings.

****

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