

<p>Draft name Draft Act amending the Act on protection of health against the consequences of consumption of tobacco and tobacco products</p> <p>Lead ministry and cooperating ministries Ministry of Health</p> <p>Person responsible for the draft: Minister, Secretary of State or Undersecretary of State Wojciech Konieczny – Secretary of State at the Ministry of Health</p> <p>Contact details for the draft supervisor Department of Public Health at the Ministry of Health e-mail dep-zp@mz.gov.pl phone: 22 53-00-318</p>	<p>Date of preparation 13 December 2024</p> <p>Source: own initiative</p> <p>Number in the List of Legislative and Programming Works of the Council of Ministers: UD86</p>
--	--

REGULATORY IMPACT ASSESSMENT

1. What issue is being addressed?

Amendment to the Act of 9 November 1995 on protection of health against the consequences of consumption of tobacco and tobacco products (Journal of Laws of 2024, item 1162), hereinafter ‘the Tobacco Act’, is necessary due to the urgent need to reduce the use of electronic cigarettes by young people. These products pose a clear risk to public health, in particular to the young generation and non-smokers, which makes it necessary to prohibit the sales of all types of electronic cigarettes and refill containers to persons under 18 years of age, regardless of whether a given product contains nicotine.

Poland is a party to the World Health Organization Framework Convention on Tobacco Control (FCTC), which, as an international agreement, was ratified with a government declaration of 16 January 2007 on the binding force of the World Health Organization Framework Convention on Tobacco Control, drawn up in Geneva on 21 May 2003 (Journal of Laws of 2007, item 488) and constitutes an universally applicable law.

During the seventh session of the Conference of Parties to the FCTC (the so-called COP7), a decision (FCTC/COP/7/11) was adopted indicating the need for the Parties to the FCTC to consider additional regulations concerning nicotine-containing and nicotine-free liquids for electronic cigarettes, regarding, inter alia, the introduction of a ban on their sale to minors, the introduction of a ban on advertising, promotion, and sponsorship, and the need to regulate the issue of sales channels for such products. In addition, the document recommends prohibiting the use of electronic cigarettes containing nicotine-free liquid in those spaces where using other nicotine-containing products has already been banned, and suggests introducing appropriate health warnings on their packaging regarding the risks deriving from their use.

Furthermore, it is worth noting that according to the information contained in the World Health Organization report prepared for COP10 (FCTC/COP/10/7), the risk of tobacco addiction is more than twice as high among children and adults up to 20 years of age who use electronic cigarettes with nicotine and/or electronic cigarettes without nicotine.

In accordance with the provisions of Article 7(1) of the Tobacco Act, which transposes into national law the provisions of Article 17 of Directive 2014/40/EU, it is prohibited to manufacture or place on the market tobacco for oral use (with the exception of tobacco intended to be inhaled or chewed) made wholly or partly from tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets.

The pouches with synthetic nicotine currently available on the market are not a tobacco product, and therefore they are not governed by the above-mentioned provisions of the Act. In addition, according to the position of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, they have non-pharmaceutical character and are sold as consumer products. In view of the above, in the opinion of the Ministry of Health, it is necessary to urgently regulate the market for nicotine pouches.

2. The recommended solution, including planned intervention tools and expected impact

The current legal framework for the market for electronic cigarettes, defined with the Tobacco Act, is a consequence of the implementation into the national legal order of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1, as amended), hereinafter referred to as ‘Directive 2014/40/EU’. Directive 2014/40/EU regulates the market for nicotine-containing liquids for electronic cigarettes. The proposed regulations are intended to cover with statutory provisions the so-called ‘nicotine-free liquids’ and will result in:

- 1) banning their sale to persons under the age of 18;
- 2) limiting the spaces where it will be possible to use them, as in the case of electronic cigarettes with nicotine-containing liquid;
- 3) introducing a ban on sales in vending machines and on distance selling (including via the Internet);
- 4) introducing a ban on advertising and promotion;
- 5) a requirement to submit information on these products to the President of the Bureau for Chemical Substances;
- 6) a requirement to adapt their composition to the requirements of the Act (e.g. to the ban on the use of substances with CMR properties);

7) a requirement to label their packaging suitably.

Currently electronic cigarettes and refill containers with nicotine-free liquid do not meet the definitions of electronic cigarette and refill container set out in Article 2(18) and (20) of the Tobacco Act, so they are not subject at all to the requirements laid down in the Tobacco Act for electronic cigarettes and refill containers. Pursuant to the regulations currently in force, the President of the Office of Competition and Consumer Protection and the Trade Inspection are competent to verify those products in terms of their safety and to eliminate them from the market – Article 3(1)(1b) and (2) of the Act of 15 December 2000 on the Trade Inspection (Journal of Laws of 2024, items 312 and 1222). In accordance with Article 13 and Article 17(1) of the Act of 12 December 2003 on general product safety (Journal of Laws of 2021, item 222), they oversee the general product safety in the area of assessing whether a product is safe. The Trade Inspection is also the supervisory authority competent for the other products regulated with the Tobacco Act: tobacco products, herbal products for smoking, electronic cigarettes that can be used for consumption of nicotine-containing vapour, and refill containers with nicotine-containing liquid – Article 3(1)(1a) and (2) of the Act of 15 December 2000 on the Trade Inspection. In view of the above, it is reasonable to introduce regulations enabling greater supervision over nicotine-free liquids, among others by requiring submission of information on those products to the President of the Bureau for Chemical Substances and by requiring adaptation of their composition to the requirements of the Act (e.g. to the prohibition to use substances with CMR properties). It is also reasonable to directly indicate in the draft Act the bodies responsible for supervision over the market for tobacco and related products.

Currently, nicotine pouches are not covered by the provisions of the Tobacco Act; and the proposed regulations will result in:

- 1) categorising nicotine pouches as related products and defining them as all products for oral use, except those intended for inhalation, not containing tobacco but containing nicotine, whether or not mixed with other ingredients, which are presented in pouch portions or available in pouches;
- 2) banning their sale to persons under the age of 18;
- 3) introducing a ban on sales in vending machines, in self-service systems, and on distance selling (including via the Internet);
- 4) introducing a ban on advertising and promotion;
- 5) a requirement to submit information on these products to the President of the Bureau for Chemical Substances;
- 6) a requirement to adapt their composition to the requirements of the Act (e.g. to the ban on the use of substances with CMR properties);
- 7) a requirement to label their packaging suitably;
- 8) setting a maximum nicotine content of 20 mg/g.

In addition, in accordance with the provisions of Article 3(1)(1aa) of the Act of 15 December 2000 on Trade Inspection, the tasks of the Trade Inspection include checking whether products meet requirements, as defined in the Act of 13 April 2016 on conformity assessment and market surveillance systems (Journal of Laws of 2022, item 1854; and of 2024, item 1089), i.e. requirements referred to in the regulations implementing Union harmonisation legislation. The Tobacco Act implements Union harmonisation legislation, which includes the Tobacco Directive.

3. How has this problem been solved in other countries, in particular OECD/EU Member States?

Some Member States of the European Union have already introduced similar regulations for nicotine-free liquids (e.g. Austria, Belgium, the Czech Republic, Denmark, Estonia, Finland, Germany).

Belgium pointed to the need to regulate nicotine-free liquids, as in its view they are also harmful to health. It should be noted that the Belgian Supreme Health Council already stated in 2015 that ‘it recommends that the quality requirements for nicotine-containing e-cigarettes be identical to those for nicotine-free e-cigarettes (except for nicotine)’. The current Belgian regulations applicable to those products are similar to those for nicotine-containing liquids regulated in accordance with the provisions of Directive 2014/40/EU.

Another example is Denmark, which introduced in April 2021 a requirement to report nicotine-free refill containers to the Technical Safety Authority (similar legislation was introduced by Germany in January 2021).

In the Czech Republic, the regulation of the market for nicotine-free liquids for electronic cigarettes was established with statutory provisions of 31 May 2017.

Regulations concerning nicotine pouches apply, for example, in Austria, Belgium, Denmark, the Netherlands, Finland, Romania, Slovenia, the Czech Republic and Sweden. It should be stressed that currently nicotine pouches are not subject to the provisions of Directive 2014/40/EU.

4. Entities affected by the Draft

Group	Size	Data source	Impact
President of the Bureau for Chemical Substances	1	not applicable	Nicotine-free liquids and liquids for electronic cigarettes, as well as nicotine pouches, will be subject to notification to the President of the Bureau for Chemical Substances at least 6

			months before the planned date of starting their sale, which will involve an extension of the scope of the Bureau's duties consisting in collecting, processing, analysing, and making available information on notified products, collecting fees for notifications, taking other actions if it is found based on the documentation received that notified products do not comply with the requirements of the Act, as well as imposing pecuniary penalties.
manufacturers or importers of electronic cigarettes and liquids for refilling them	664	data from the Bureau for Chemical Substances	The requirement to notify the Bureau for Chemical Substances of nicotine-free liquids, the prohibition of distance selling and of selling to persons under 18 years of age, as well as the requirement to properly label the packaging of products containing nicotine-free liquids and to adapt their composition to the requirements of the draft act.
manufacturers, importers, intra-Community buyers and suppliers of nicotine pouches	4	data from the Ministry of Finance	The requirement to properly label the packaging of nicotine pouches, the limitation on the sale of nicotine pouches with a concentration greater than 20 mg/g, as well as the obligation to notify the aforementioned products to the President of the Bureau for Chemical Substances at least 6 months before the planned date of starting their sale.

5. Information on the scope and duration of consultations, and summary of consultation results

The bill was not subject to pre-consultation.

Due to the urgency of the matter – the draft Act is aimed at protecting the health of minors – it was made available for public consultation and opinions were sought from the following entities, which had 21 days for making their comments:

- 1) Naczelna Rada Lekarska [Supreme Medical Council];
- 2) Naczelna Rada Pielęgniarek i Położnych [Supreme Council of Nurses and Midwives];
- 3) Naczelna Rada Aptekarska [Supreme Pharmacy Council];
- 4) Krajowa Rada Diagnostów Laboratoryjnych [National Council of Laboratory Analysts];
- 5) Krajowa Rada Fizjoterapeutów [National Council of Physiotherapists];
- 6) Instytut Kardiologii im. Prymasa Tysiąclecia Stefana Kardynała Wyszyńskiego [Cardinal Stefan Wyszyński Institute of Cardiology]
- 7) Prezes Biura do spraw Substancji Chemicznych [President of the Bureau for Chemical Substances];

- 8) Narodowy Instytut Zdrowia Publicznego – Państwowy Zakład Higieny w Warszawie [National Institute of Public Health – National Institute of Hygiene in Warsaw];
- 9) Centrum Onkologii – Instytut im. Marii Skłodowskiej-Curie [Maria Skłodowska-Curie Institute – Oncology Centre]
- 10) Polskie Towarzystwo Onkologiczne [Polish Society of Oncology];
- 11) Polskie Towarzystwo Kardiologiczne [Polish Society of Cardiology];
- 12) Polskie Towarzystwo Diabetologiczne [Polish Society of Diabetology];
- 13) Polskie Towarzystwo Chorób Płuc [Polish Respiratory Society];
- 14) Polskie Towarzystwo Zdrowia Publicznego [Polish Society of Public Health];
- 15) Federacja Związków Zawodowych Pracowników Ochrony Zdrowia i Pomocy Społecznej [Federation of Healthcare and Social Welfare Employees’ Trade Unions];
- 16) Federacja Pacjentów Polskich [Federation of Polish Patients];
- 17) Sekretariat Ochrony Zdrowia KK NSZZ „Solidarność 80” [Health Protection Secretariat of the National Commission of the Independent Self-Governing Trade Union ‘Solidarity 80’];
- 18) Niezależny Samorządny Związek Zawodowy „Solidarność” [Independent Self-governing Trade Union ‘Solidarity’];
- 19) Ogólnopolskie Porozumienie Związków Zawodowych [All-Poland Alliance of Trade Unions];
- 20) Ogólnopolski Związek Zawodowy Lekarzy [National Union of Physicians];
- 21) Ogólnopolski Związek Zawodowy Pielęgniarek i Położnych [National Trade Union of Nurses and Midwives];
- 22) Forum Związków Zawodowych [Forum of Trade Unions];
- 23) Porozumienie Pracodawców Ochrony Zdrowia [Healthcare Employers’ Alliance];
- 24) Kolegium Lekarzy Rodzinnych w Polsce [College of Family Physicians in Poland];
- 25) Federacja Związków Pracodawców Ochrony Zdrowia „Porozumienie Zielonogórskie” [‘Porozumienie Zielonogórskie’ Healthcare Employers’ Unions Federation];
- 26) Związek Pracodawców Ochrony Zdrowia „Wielkopolskie Porozumienie Zielonogórskie” [‘Wielkopolskie Porozumienie Zielonogórskie’ Healthcare Employers’ Union];
- 27) Krajowe Stowarzyszenie Przemysłu Tytoniowego [National Tobacco Industry Association];
- 28) Polskie Stowarzyszenie Przemysłu Tytoniowego [Polish Tobacco Industry Association];
- 29) Business Centre Club;
- 30) Konfederacja Lewiatan [‘Lewiatan’ Confederation];
- 31) Polish Chamber of Commerce [Krajowa Izba Gospodarcza];
- 32) Pracodawcy Rzeczypospolitej Polskiej [Polish Employers];
- 33) Rada Krajowa Federacji Konsumentów [National Council of the Federation of Consumers];
- 34) Rada Dialogu Społecznego [Council of Social Dialogue];
- 35) Komisja Wspólna Rządu i Samorządu Terytorialnego [Joint Commission of the Government and Local Government];
- 36) Federacja Pacjentów Polskich [Federation of Polish Patients];
- 37) Związek Rzemiosła Polskiego [Polish Union of Craftsmen];
- 38) Instytut Praw Pacjenta i Edukacji Zdrowotnej [Institute for Patients’ Rights and Health Education];
- 39) Krajowy Konsultant w dziedzinie zdrowia publicznego [National Consultant in the field of public health];
- 40) Krajowy Konsultant w dziedzinie psychoterapii uzależnień [National Consultant in the field of addiction psychotherapy];
- 41) the Head of the Personal Data Protection Office;
- 42) the Head of the Office for Competition and Consumer Protection;
- 43) Stowarzyszenie Zdrowych Miast Polskich [The Polish Healthy Cities Association];
- 44) Związek Powiatów Polskich [The Association of Polish Counties];
- 45) Związek Przedsiębiorców i Pracodawców [Union of Entrepreneurs and Employers];
- 46) Polskie Towarzystwo Prawa Medycznego [Polish Society of Medical Law];
- 47) Polskie Towarzystwo Gospodarcze [Polish Economic Society];
- 48) Związek Pracodawców Branży Vapingowej [Vaping Industry Employers Association].

In accordance with Article 5 of the Act of 7 July 2005 on lobbying activities in the process of law making (Journal of Laws of 2017, item 248; and of 2024, item 1535) and with Article 52 of Resolution No. 190 of the Council of Ministers of 29 October 2013 – Rules of Procedure of the Council of Ministers (Polish Gazette of 2024, item 806), the Draft was made available in the Public Information Bulletin on the website of the Government Legislation Centre in the Government Legislative Process tab.

The results of the public consultation and the opinions have been presented in the report on public consultations and opinions attached hereto.

6. Impact on the public finance sector													
(fixed prices for [year])		Impact over 10 years from implementing the amendments [PLN million]											
		0	1	2	3	4	5	6	7	8	9	10	Total (0–10)
Total income		19.73	7.33	8.23	9.23	10.33	11.53	12.93	14.43	16.13	18.03	20.13	148.03
state budget		19.73	7.33	8.23	9.23	10.33	11.53	12.93	14.43	16.13	18.03	20.13	148.03
local government units		0	0	0	0	0	0	0	0	0	0	0	0
other units (separately)		0	0	0	0	0	0	0	0	0	0	0	0
Total expenditure		0	0	0	0	0	0	0	0	0	0	0	0
state budget		0	0	0	0	0	0	0	0	0	0	0	0
local government units		0	0	0	0	0	0	0	0	0	0	0	0
other units (separately)		0	0	0	0	0	0	0	0	0	0	0	0
Total balance		19.73	7.33	8.23	9.23	10.33	11.53	12.93	14.43	16.13	18.03	20.13	148.03
state budget		19.73	7.33	8.23	9.23	10.33	11.53	12.93	14.43	16.13	18.03	20.13	148.03
local government units		0	0	0	0	0	0	0	0	0	0	0	0
other units (separately)		0	0	0	0	0	0	0	0	0	0	0	0
Sources of financing		The regulation in question will have an impact on the revenue of the state budget (revenue from fees paid by entrepreneurs). It will not affect the expenditure of the state budget or the revenues and expenditures of the budgets of local government units.											
Additional information, including the identification of data sources and assumptions made in the calculation		<p>The design of the excise duty rate for liquid for electronic cigarettes is not linked to any additional elements such as product price, nicotine content or packaging. However, the Ministry of Finance has data on the revenue from excise duty on the total amount of liquid for electronic cigarettes. The figures are as follows (in PLN million): 2021 – 179.5; 2022 – 229.9; 2023 – 443.6. It is assumed that the draft will not have any significant impact on public finances.</p> <p>When estimating the revenues of the state budget, the obligation to pay a fee for products covered by the new regulation should be taken into account. A notification is subject to a fee equal to the average monthly remuneration in the enterprise sector, excluding profit-related bonuses for the previous year, as announced by the President of the Statistics Poland. In 2024, the amount of the fee is PLN 7,443.28. In accordance with Article 11b(6) of the Tobacco Act, medium-sized enterprises are entitled to pay this fee at 50 % of the normal fee, and micro and small enterprises are entitled to pay this fee at 30 % of the normal fee. It was assumed that the number of notifications of electronic cigarettes and refill containers with ‘nicotine-free’ liquid would be similar to the number of notifications of electronic cigarettes and refill containers with nicotine-containing liquid reported in individual years after the implementation of Directive 2014/40/EU into Polish legislation. The revenue has been therefore estimated on the basis of the receipts from the fee for notifications of electronic cigarettes and refill containers received by the Bureau for Chemical Substances in previous years.</p> <p>It should be emphasised that legal regulations will not have additional financial consequences for public administration and that the expenditure limits set annually include funds for the implementation of the planned duties, without any need to increase them.</p> <p>Currently, nicotine pouches are not subject to excise duty rates. The proposed legal regulations introduce a requirement for the manufacturer or importer of nicotine pouches to pay an annual fee, similar to that for smokeless tobacco products. Assuming that nicotine pouches will be sold by 4 manufacturers, the proceeds to the state budget will amount to approximately PLN 0.03 million.</p>											
7. Impact on the competitiveness of the economy and entrepreneurship, including the functioning of enterprises and impact on families, citizens and households													
Impact													
Time (in years) since entry into force of the amendments		0	1	2	3	4	5	6	7	8	9	10	Total (0–10)
In monetary terms (PLN millions, fixed prices for ... (year))	large enterprises	-2.03	-0.73	-0.83	-0.93	-1.03	-1.23	-1.33	-1.43	-1.63	-1.83	-2.03	-15.037
	micro-, small- and medium-sized enterprises	-17.7	-6.6	-7.4	-8.3	-9.3	-10.4	-11.6	-13	-14.5	-16.2	-18.1	-133.1
	families, citizens and households												
In non-	large enterprises	The proposed regulation will have an impact on the activities of large											

monetary terms		entrepreneurs involved in trading in nicotine-free products or nicotine pouches.
	micro-, small- and medium-sized enterprises	The proposed regulation will have an impact on the activities of micro, small, and medium-sized enterprises involved in trading in nicotine-free products or nicotine pouches.
	family, citizens and households	It should be noted that the risk posed by nicotine-free liquids is not significantly lower than that associated with nicotine-containing products. The popularity of nicotine-free products increases the risk of increased access of young people to tobacco products to the same extent as it is increased by electronic cigarettes with nicotine. With this in mind, it should be considered justified to restrict the sale of nicotine-free liquids to persons under 18 years of age, as well as to prohibit their sales in vending machines or via the Internet. Moreover, the current lack of regulation on the maximum allowable nicotine concentration in nicotine pouches and the absence of age limits on the possibility of purchasing them should be considered a direct threat to the health of consumers.
Immeasurable		

Additional information, including indication of data sources and assumptions used for calculations	<p>Currently, nicotine-free liquids are subject to the provisions of the Act of 12 December 2003 on general product safety. According to the 2022 Global Youth Tobacco Survey (GYTS), carried out among children aged 12-15 in our country, currently 22.3 % of children (21.2% of boys and 23.4 % of girls) use electronic cigarettes. Since the use of nicotine-free liquids is a real threat to the health of young people, it is necessary to cover such products with the provisions of the Tobacco Act.</p> <p>Data collected by the Bureau for Chemical Substances was used for estimating the costs to be incurred by enterprises. The notification of nicotine-free liquids covered by the new regulation will be subject to a fee equal to the average monthly remuneration in the enterprise sector, excluding profit-related bonuses for the previous year, as announced by the President of the Statistics Poland, as is currently the case with notifications of nicotine-containing electronic cigarettes and refill containers. The costs to be incurred by enterprises have been therefore estimated on the basis of the receipts from the fee for notifications received by the Bureau for Chemical Substances in previous years. To calculate the impact on enterprises broken down by size (large and others), the percentage of fee receipts from large companies was determined for the years 2021–2023, and then the average of these three values was calculated. The estimated fees determined on the basis of this average have been used to calculate the expected fees for large enterprises and for micro, small and medium-sized enterprises, respectively.</p> <p>Notification of nicotine-free liquids will affect their quality, as it will be verified if the composition of electronic cigarettes and refill containers includes prohibited substances, i.e.:</p> <ol style="list-style-type: none"> 1) vitamins or other additives that create the impression that a product has a health benefit or presents reduced health risks; 2) caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality; 3) additives having colouring properties for emissions; 4) additives that have carcinogenic, mutagenic or toxic to reproduction properties in unburnt form. <p>If such a violation is found, the President of the Bureau for Chemical Substances will issue an administrative decision in the case pursuant to Article 11b(11)(2) of the Tobacco Act. In accordance with Article 12c(9a) of the Tobacco Act, making available for the first time for resale or for placing on the market electronic cigarettes or refill containers in respect of which a decision has been issued pursuant to Article 11b(11) of the Tobacco Act constitutes a criminal offence punishable with a fine of up to PLN 200,000 or with a community order, or with both of these penalties together.</p> <p>Notifications of nicotine pouches will be subject to an annual fee equal to the average monthly remuneration in the enterprise sector, excluding profit-related bonuses for the previous year, as announced by the President of the Statistics Poland, just as in the case of smokeless products. The notification will affect the quality of nicotine pouches, as in the case of notifications of nicotine-free liquids.</p>
--	--

8. Change in the regulatory burdens (including disclosure obligations) resulting from the project

<input type="checkbox"/> not applicable	
Burdens are placed outside those strictly required by the EU (for details, see reverse side of the correlation table)	<input type="checkbox"/> yes <input type="checkbox"/> no

	<input checked="" type="checkbox"/> not applicable
<input type="checkbox"/> reduction in the number of documents <input type="checkbox"/> reduction in the number of procedures <input type="checkbox"/> shortening of the time to settle the matter <input type="checkbox"/> other:	<input type="checkbox"/> increase in the number of documents <input checked="" type="checkbox"/> increase in the number of procedures <input type="checkbox"/> extension of the time to settle the matter <input type="checkbox"/> other:
The introduced burdens are suitable for digitisation.	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> not applicable
<p>Comment:</p> <p>In accordance with Article 11b(1) of the Tobacco Act, electronic cigarettes are subject to notification at least 6 months before the planned date of making them available. The notifications of nicotine-free liquids are made through the EU-CEG system.</p> <p>In accordance with the proposed Article 11ha(1), nicotine pouches will be subject to notification to the President of the Bureau for Chemical Substances. The format for the submission and making available of information on nicotine pouches is laid down in Commission Implementing Decision (EU) 2015/2186.</p>	
9. Impact on the labour market	
No impact	
10. Impact on other aspects	
<input type="checkbox"/> natural environment <input type="checkbox"/> regional standing and development <input type="checkbox"/> common, administrative, or military courts	<input type="checkbox"/> demographics <input type="checkbox"/> state property <input type="checkbox"/> other:
	<input type="checkbox"/> computerisation <input checked="" type="checkbox"/> health
Discussion of the impact	Limiting the sales of nicotine-free liquids for electronic cigarettes and of nicotine pouches, and the requirement to notify them to the Bureau for Chemical Substances, will contribute to reducing the use of such products among young people and will create real opportunities for quality control.
11.Planned implementation of the provisions of the act	
<p>The draft Act will enter into force 14 days after the date of its announcement. The draft Act provides for a 6-month transitional period for electronic cigarettes and refill containers containing nicotine-free liquid placed on the market before the date of entry into force of the Act. In the case of electronic cigarettes and refill containers with nicotine-free liquid placed on the market before the date of entry into force of the Act, it is proposed that the notification of a given product to the President of the Bureau for Chemical Substances, as referred to in Article 11b(1) of the Tobacco Act, be made within 6 months from the date of entry into force of the Act.</p> <p>The manufacturer or importer of nicotine pouches placed on the market before the date of entry into force of this Act submits to the President of the Bureau for Chemical Substances the list referred to in Article 11ha(1) of the Act amended with Article 1, in the wording laid down by this Act, within 6 months of the date of entry into force of this Act.</p> <p>Due to the fact that the draft introduces, among others, a restriction on the sales of ‘nicotine-free’ liquids and nicotine pouches to persons under 18 years of age and a ban on their sales on the Internet, it requires notification within the meaning of the Cabinet Regulation of 23 December 2002 on the functioning of the national system for notification of standards and legal acts (Journal of Laws, item 2039; and of 2004, item 597), which implements Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification) (OJ L 241, 17.9.2015, p. 1). The notification period is 3 months (during which time work on the draft must be suspended). The notification is carried out after the draft Act has been adopted by the Council of Ministers. In view of the above, the draft Act should enter into force in the second quarter of 2025.</p>	
12.How and when will the impact of the Draft Regulation be assessed, and what measures will be applied?	
The evaluation of the effects of the draft will take place after the entry into force of the Act, as part of the reports and statistics prepared in relation to the monitoring of the use of tobacco products in the Republic of Poland.	
13.Annexes (important source documents, research, analyses, etc.)	
Public consultation and opinion report.	