Draft name Draft Act amending the Public Health Act **Lead ministry and cooperating ministries** Ministry of Health **Person responsible for the draft: Minister, Secretary of State or Undersecretary of State** Mr Wojciech Konieczny, Secretary of State at the Ministry of Health **Contact details for the draft supervisor** Ms Dagmara Korbasińska-Chwedczuk, Director of the Department of Public Health, dep-zp@mz.gov.pl	**Date of preparation** 20 February 2025 **Source:** own initiative **Number in the List of Legislative and Programming Works of the Council of Ministers:** UD123

REGULATORY IMPACT ASSESSMENT

1. What issue is being addressed?

It is necessary to notify the provisions contained in Chapter 3b on the marketing and labelling of beverages with added caffeine or taurine and Chapter 4a on penal provisions in the Public Health Act of 11 September 2015 (Journal of Laws [Dziennik Ustaw] of 2024, item 1670). The Act of 17 August 2023 amending the Public Health Act and certain other acts (Journal of Laws, item 1718), which introduced the above provisions, required notification at the level of the World Trade Organisation (WTO) and the European Commission, to which the Ministry of Health drew the attention of the Sejm of the Republic of Poland [lower house of the Polish Parliament] during the drafting process. Despite this, no such notification has been made. The draft was not notified to the European Commission nor was it notified at the WTO level. In the course of the work on the Act, objections to the proposed provisions were formally reported by the administrations of the United Kingdom (UK) and the United States of America (USA) (through the World Trade Organisation's contact points for Technical Barriers to Trade (TBT WTO) to the Polish WTO TBT contact point at the Polish Committee for Standardisation [PKN]), and informally raised by the Swiss administration in communication with the Permanent Mission of the Republic of Poland to the WTO. As these concerns relate to technical issues in trade and the introduction of, inter alia, a marketing ban and labelling requirements, which may have an impact on international trade, the above-mentioned countries have requested the administration of the Republic of Poland to make an appropriate notification at the WTO level, within the framework of the Committee on Technical Barriers to Trade (TBT), so that comments could be made. According to the procedures adopted under the WTO's TBT rules, matters such as product labelling requirements are regarded as technical requirements for trade. In addition, the USA has requested the removal of the ban on the sale of energy drinks to persons under the age of 18 and the general ban on the sale of energy drinks in vending machines to persons of all ages. In terms of labelling, the USA took the view that member companies of the International Council of Beverage Associations are obliged to act responsibly and not to promote or suggest excessive or irresponsible consumption of energy drinks. The UK, in turn, on 24 May 2024, raised concerns about the mere fact of non-notification and pointed out that the main problem was that companies had not been given enough time to adapt to the new requirements during the implementation of the rules. The UK requested the Republic of Poland to suspend the implementation of these measures in order to facilitate the notification in accordance with the required procedure and to allow time for consideration of the comments and any subsequent amendments. It should be pointed out that if the above-mentioned notification is not carried out, a risk exists that these countries may initiate a trade dispute against the Republic of Poland as part of the proceedings of the WTO's TBT Committee.

Moreover, failure to notify the provisions currently prevents proceedings from being conducted on the basis of those provisions and courts deem there is no need to adjudicate on the initiated proceedings, citing the relevant case-law of the Court of Justice of the European Union. The criminal provisions repealed in the draft act cannot be used as the basis for conducting criminal proceedings and proceedings in offence cases, since they have not been notified to the European Commission. The notification will effectively enable the carrying out of appropriate criminal proceedings and proceedings in offence cases due to non-compliance with the provisions of the Act.

Initially, as a result of the notification, no change in the wording of the provisions is expected, but ultimately this will depend on the nature of the comments made and the possible presentation of new scientific data.

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

The draft Act amending the Public Health Act is technical in nature. The Public Health Act of 11 September 2015 repeals the provisions of Chapter 3b on the marketing and labelling of beverages with added caffeine or taurine and of Chapter 4a on penal provisions and introduces them, with identical wording, in the proposed Chapter 3c and Chapter 4b. This will allow for TBT notifications to the WTO and to the European Commission. This will serve the purpose of transparency in the adoption of regulations by the Republic of Poland as a member of the WTO, as well as will testify to the willingness of the Polish administration to co-operate with the European Commission and individual WTO countries in order to clarify the existing doubts regarding the introduced regulations. Moreover, the notification will effectively enable the carrying out of appropriate criminal proceedings and proceedings in offence cases due to non-compliance with the provisions of the Act (currently, proceedings are discontinued due to failure to notify the provisions).

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

The arrangements in force in other countries are unrelated to the subject matter of the draft Act.

4. Entities affected by the draft			
Group	Size	Data source	Impact
producers of energy drinks, importers of energy drinks, intra-Community supplies of energy drinks	no conclusive data	-	a specific labelling requirement for energy drinks and a ban on the sale of energy drinks to persons under 18 years of age and in vending machines
entrepreneurs marketing energy drinks	no conclusive data	-	ban on the sale of energy drinks to persons under 18 years of age
persons under 18 years of age	approx. 7,000,600	census carried out in 2021 (GUS [Central Statistical Office of Poland], 2022)	no possibility to buy an energy drink

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

The draft Act has not been submitted to pre-consultation.

The draft Act was submitted for opinion and public consultation with a 21-day deadline for submitting comments to the following entities:

1) Komisja Wspólna Rządu i Samorządu Terytorialnego [Government and Local Government Joint Committee];
2) Polskie Towarzystwo Onkologiczne [Polish Society of Oncology];
3) Polskie Towarzystwo Kardiologiczne [Polish Cardiac Society];
4) Polskie Towarzystwo Diabetologiczne [Polish Diabetes Society];
5) Polskie Towarzystwo Chorób Płuc [Polish Society of Lung Diseases];
6) Polskie Towarzystwo Zdrowia Publicznego [Polish Public Health Association];
7) Lotnicze Pogotowie Ratunkowe [Polish Medical Air Rescue];
8) Naczelna Rada Lekarska [Supreme Medical Council];
9) Naczelna Rada Pielęgniarek i Położnych [Supreme Council of Nurses and Midwives];
10) Naczelna Rada Aptekarska [Supreme Pharmaceutical Council];
11) Krajowa Rada Diagnostów Laboratoryjnych [National Chamber of Laboratory Diagnosticians];
12) Krajowa Rada Fizjoterapeutów [National Council of Physiotherapists];
13) Unia Metropolii Polskich [Union of Polish Metropolises];
14) Związek Miast Polskich [Association of Polish Towns and Cities];
15) Związek Gmin Wiejskich RP [Association of Rural Municipalities of the Republic of Poland];
16) Związek Województw RP [Association of Provinces of the Republic of Poland];
17) Związek Powiatów Polskich [Union of Polish Districts];
18) Federacja Związków Gmin i Powiatów RP [Federation of Associations of Municipalities and Districts of the Republic of Poland];
19) Federacja Związków Zawodowych Pracowników Ochrony Zdrowia i Pomocy Społecznej [Federation of Healthcare and Social Welfare Trade Unions];
20) Sekretariat Ochrony Zdrowia KK NSZZ ‘Solidarność’ [Health Protection Secretariat of Health of the National Commission of the Independent Self-governing Trade Union ‘Solidarity’];
21) Krajowy Sekretariat Ochrony Zdrowia NSZZ „Solidarność 80” [National Health Protection Secretariat of the the Independent Self-governing Trade Union ‘Solidarity 80’];
22) Forum Związków Zawodowych [Forum of Trade Unions];
23) Pracodawcy Medycyny Prywatnej [Employers of Non-public Medicine Industry];
24) Ogólnopolskie Porozumienie Związków Zawodowych [National Alliance of Trade Unions];
25) Ogólnopolskie Stowarzyszenie Szpitali Prywatnych [National Association of Private Hospitals];
26) Ogólnopolski Związek Pracodawców Szpitali Powiatowych [National Association of Employers of District Hospitals];
27) Ogólnopolski Związek Zawodowy Lekarzy [National Union of Physicians];
28) Ogólnopolski Związek Zawodowy Pielęgniarek i Położnych [National Trade Union of Nurses and Midwives];
29) Ogólnopolski Związek Zawodowy Położnych [National Trade Union of Midwives];
30) Federacja Związków Zawodowych Pracowników Ochrony Zdrowia [Federation of Health Care and Social Welfare Trade Unions];
31) Porozumienie Pracodawców Ochrony Zdrowia [Healthcare Employers’ Alliance];
32) Kolegium Lekarzy Rodzinnych w Polsce [College of General Practitioners in Poland];
33) Pracodawcy Rzeczypospolitej Polskiej [Employers of Poland];
34) Porozumienie Zielonogórskie Federacja Związków Pracodawców Ochrony Zdrowia [‘Porozumienie Zielonogórskie’ Federation of Health Care Employer Unions];

35) Federacja Związków Zawodowych Pracowników Ochrony Zdrowia i Pomocy Społecznej [Federation of Healthcare and Social Welfare Trade Unions];
36) Związek Pracodawców Business Centre Club [‘Business Centre Club’ Union of Employers];
37) Konfederacja Lewiatan ['Lewiatan' Confederation];
38) Stowarzyszenie Menedżerów Opieki Zdrowotnej [Association of Healthcare Managers];
39) Federacja Przedsiębiorców Polskich [Federation of Polish Entrepreneurs];
40) Narodowy Instytut Kardiologii Stefana Kardynała Wyszyńskiego – Państwowy Instytut Badawczy [Cardinal Stefan Wyszyński National Institute of Cardiology — State Research Institute];
41) Narodowy Instytut Onkologii im. Marii Skłodowskiej-Curie – Państwowy Instytut Badawczy [Maria Skłodowska-Curie National Institute of Oncology — State Research Institute];
42) Agencja Badań Medycznych [Medical Research Agency];
43) Instytut Matki i Dziecka [Mother and Child Institute];
44) Instytut Badań Edukacyjnych [Educational Research Institute];
45) Instytut Medycyny Wsi im. Witolda Chodźki w Lublinie [Witold Chodźko Institute of Rural Health];
46) Narodowy Instytut Zdrowia Publicznego PZH — Państwowy Instytut Badawczy [National Institute of Public Health at the National Institute of Hygiene — National Research Institute];
47) Instytut Praw Pacjenta i Edukacji Zdrowotnej [Institute of Patients' Rights and Health Education];
48) Konsultant Krajowy w dziedzinie zdrowia publicznego [National Public Health Consultant];
49) Konsultant Krajowy w dziedzinie pediatrii [National Paediatric Consultant];
50) Konsultant Krajowy w dziedzinie pediatrii metabolicznej [National Metabolic Paediatrics Consultant];
51) Konsultant Krajowy w dziedzinie epidemiologii [National Epidemiology Consultant];
52) Konsultant Krajowy w dziedzinie psychiatrii [National Psychiatric Consultant];
53) Polska Federacja Producentów Żywności [Polish Federation of Food Industry];
54) Polska Akademia Nauk [Polish Academy of Sciences];
55) Polskie Towarzystwo Prawa Medycznego [Polish Society of Medical Law];
56) Polskie Stowarzyszenie Dietetyków [Polish Association of Dietitians];
57) Polskie Towarzystwo Nauk Żywieniowych [Polish Society of Nutritional Science];
58) Polskie Towarzystwo Programów Zdrowotnych [Polish Society for Health Programmes];
59) Polskie Towarzystwo Medycyny Stylu Życia [Polish Society of Lifestyle Medicine];
60) Collegium Medicum im. Ludwika Rydygiera w Bydgoszczy Uniwersytetu Mikołaja Kopernika w Toruniu [Ludwik Rydygier Medical College in Bydgoszcz — Nicolaus Copernicus University in Toruń];
61) Collegium Medicum Uniwersytetu Jagiellońskiego [Jagiellonian University Medical College];
62) Federacja Konsumentów [Consumer Federation];
63) Gdański Uniwersytet Medyczny [Medical University of Gdańsk];
64) Instytut ‘Pomnik — Centrum Zdrowia Dziecka’ [Children's Memorial Health Institute];
65) Instytut Medycyny Pracy im. prof. J. Nofera w Łodzi [J. Nofer Institute of Labour Medicine in Łódź];
66) Krajowa Izba Gospodarcza Przemysłu Spożywczego i Opakowań [Polish Chamber of Food and Packaging Industries];
67) Krajowa Izba Gospodarcza [Polish Chamber of Commerce];
68) Polskie Towarzystwo Gospodarcze [Polish Economic Society];
69) Polska Organizacja Handlu i Dystrybucji [Polish Organisation of Trade and Distribution];
70) Polskie Towarzystwo Leczenia Otyłości [Polish Society for Treatment of Obesity];
71) Polskie Towarzystwo Badań nad Otyłością [Polish Association for the Study of Obesity];
72) Polskie Towarzystwo Dietetyki [Polish Society of Dietetics];
73) Polskie Towarzystwo Pediatryczne [Polish Society of Paediatrics];
74) Fundacja Polska Liga Walki z Rakiem [Polish League Against Cancer Foundation];
75) Pomorski Uniwersytet Medyczny w Szczecinie [Pomeranian Medical University in Szczecin];
76) Stowarzyszenie Krajowej Unii Producentów Soków [Polish Association of Juice Producers];
77) Stowarzyszenie Zdrowych Miast Polskich [Polish Healthy Cities Association];
78) Szkoła Główna Gospodarstwa Wiejskiego w Warszawie [Warsaw University of Life Sciences];
79) Śląski Uniwersytet Medyczny w Katowicach [Medical University of Silesia in Katowice];
80) Uniwersytet Medyczny im. Karola Marcinkowskiego w Poznaniu [Karol Marcinkowski Medical University in Poznań];
81) Uniwersytet Medyczny im. Piastów Śląskich we Wrocławiu [Wrocław Medical University];
82) Uniwersytet Medyczny w Białymstoku [Medical University in Białystok];
83) Uniwersytet Medyczny w Lublinie [Medical University of Lublin];
84) Uniwersytet Medyczny w Łodzi [Medical University of Łódź];
85) Warszawski Uniwersytet Medyczny [Medical University of Warsaw];
86) Związek Pracodawców Ratownictwa Medycznego SP ZOZ [SP ZOZ Emergency Medical Services Employers’ Association];
87) Związek Pracodawców Ratownictwa Medycznego Samodzielnych Publicznych Zakładów Opieki Zdrowotnej [Association of Employers of Emergency Medical Services of Independent Public Health Care Establishments];
88) Związek Przedsiębiorców i Pracodawców [Union of Entrepreneurs and Employers];
89) Federacja Przedsiębiorców Polskich [Federation of Polish Entrepreneurs];
90) Związek Rzemiosła Polskiego [Polish Craft Association];

91) Rada Działalności Pożytku Publicznego [Public Benefit Works Council];
92) Rada Dialogu Społecznego [Council for Social Dialogue].

The shortening of the deadline for public consultation with trade unions was related to the fact that the purpose of the legislative procedure contained in the draft Act was solely to notify the provisions originally introduced by the Act of 17 August 2023 amending the Public Health Act and certain other acts.
At the time of submission for consultation, the draft Act was published in the Public Information Bulletin on the website of the Ministry of Health, pursuant to the Act of 7 July 2005 on lobbying in the law-making process (Journal of Laws 2017, item 248; and 2024, item 1535) and on the website of the Government Legislation Centre, pursuant to Cabinet Resolution No 190 of 29 October 2013 — Rules of Procedure of the Council of Ministers (Journal of Laws 2024, item 806).
The results of the public consultation and opinion-seeking process were presented in the consultation report attached to the RIA.

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 revenue												
state budget												
local government units												
other units (separately)												
Total expenditure												
state budget												
local government units												
other units (separately)												
Total balance												
state budget												
local government units												
other units (separately)												

Sources of financing	Not applicable.
Additional information, including the identification of data sources and assumptions made in the calculation	The draft Act will have no impact on the public finance sector.

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	5	10	*Total (0–10)*
In monetary terms (in PLN million, fixed prices for [year])	large enterprises							
	micro-, small- and medium-sized enterprises							
	families, citizens and households							
	(add/remove)							
In non-monetary terms	large enterprises	The draft Act will have an impact on the activities of micro, small, medium and large enterprises, as it imposes an obligation on them to label energy drinks and a ban on marketing these drinks to people under 18 years of age.						
	micro-, small- and medium-sized enterprises							
	family, citizens and households, the elderly and people with disabilities	No impact is expected on family, citizens, households, elderly or people with disabilities.						
	(add/remove)							
Unmeasurable	(add/remove)							

	(add/remove)	
Additional information, including the identification of data sources and assumptions made in the calculation	None.	

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

☒ not applicable

Burdens are placed outside those strictly required by the EU (see the inverted compatibility table for details).	☐ yes ☐ no ☐ not applicable
☐ reduction in the number of documents ☐ reduction in the number of procedures ☐ shortening of the time to settle the matter ☐ other:	☐ increase in the number of documents ☐ increase in the number of procedures ☐ extension of the time to settle the matter ☐ other:
The introduced burdens are suitable for digitisation.	☐ yes ☐ no ☐ not applicable

Comment:

9. Impact on the labour market

None.

10. Impact on other aspects

☐ natural environment ☐ regional standing and development ☐ ordinary, administrative or military courts	☐ demography ☐ state property ☒ other: International trade	☐ computerisation ☒ health

Discussion of the impact	The proposed Act will have an impact on increasing the health protection of children and adolescents.

11. Planned implementation of the provisions of the Act

In view of the binding deadlines related to, inter alia, the need to carry out the notification procedure and, thus, the need to suspend legislative work, it is envisaged that the draft Act will enter into force on 1 January 2026.

12. How and when will the impact of the draft be assessed, and what measures will be applied?

Not applicable.

13. Annexes (important source documents, research, analyses, etc.)

Public consultation and opinion report.