

Draft name Draft Regulation of the Minister of Health amending the regulation on enriching substances added to foods	Date of preparation 28.10.2025
Lead ministry and cooperating ministries Ministry of Health/Chief Sanitary Inspectorate	Source: Article 28(2) and (3) of the Act of 25 August 2006 on food and nutrition safety (Journal of Laws of 2023, item 1448, and of 2025, item 1424)
Person responsible for the draft: Minister, Secretary of State or Undersecretary of State Mr Marek Grzesiowski, Chief Sanitary Inspector	Number on the list of legislative works of the Minister of Health: MZ 1808
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REGULATORY IMPACT ASSESSMENT

1. What issue is being addressed?

In accordance with the Resolution No. 1/2024 of the Food Supplements Team amending Resolution No. 6/2021 of 30 August 2021 on certain plant substances and raw materials not authorised for use in food supplements, due to the need to ensure health safety of consumers, celandine herb, swallowwort, greater celandine (*Chelidonium majus L.*) may not be used in food supplements. The aforementioned resolution of the Team is publicly available on the website of the Chief Sanitary Inspectorate: <https://www.gov.pl/web/gis/zespol-do-spraw-suplementow-diety>.

According to data from the Chief Sanitary Inspectorate, 33 notifications concerning products containing the above-mentioned ingredient have been submitted under the system for notifying the first placing on the market in the Republic of Poland of products classified as food supplements since 2007. Therefore, it is justified to prohibit the use of this ingredient.

The Team's resolutions are based on scientific data indicating a risk to consumer safety in the case of the use of the substances and plant materials covered by the resolutions in the production of food supplements. Resolutions were adopted on the basis of current knowledge, measures taken by other countries of the European Union, or positions taken by bodies of the European Union, and constitute an objective source of knowledge referring to risks associated with the use of the substances and plant materials specified therein in the manufacture of food supplements.

2. Recommended solution, including planned intervention tools, and expected impact

In the draft Regulation, celandine herb, swallowwort, greater celandine (*Chelidonium majus L.*) are added to the list of substances other than vitamins and minerals prohibited in the manufacture of foodstuffs, which is set out in the Annex to the Regulation of the Minister of Health of 13 March 2024 on enriching substances added to foods (Journal of Laws,item 420).

Entities placing foodstuffs, including food supplements, on the market will not be allowed to add or use celandine herb, , swallowwort, greater celandine (*Chelidonium majus L.*) in their food production. The regulation covered by the draft Regulation will apply to the verification of notifications concerning the first placing on the market of foodstuffs, including food supplements.

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

Substances other than vitamins and minerals prohibited in the manufacture of foodstuffs in the Member States of the European Union are regulated to varying degrees or are not regulated at all. Lists of substances other than vitamins and minerals prohibited in the manufacture of foodstuffs have been specified in the Czech Republic and Latvia. In Belgium, a regulation containing a list of plants not authorised for use in food has been introduced.

4. Entities affected by the draft

Group	Size	Data source	Impact
entrepreneurs involved in the production and marketing of food, including food supplements	potentially around 428,000 entities operating on the food market; according to data provided by the Chief Sanitary Inspectorate, from 2007 to 1 January 2024, 19 entrepreneurs were involved in the introduction of food supplements containing	data from the Central Statistical Office in accordance with MZ-48 forms for the year 2025	prohibition on the production and marketing of foodstuffs, including food supplements, containing celandine herb, , swallowwort, greater celandine (<i>Chelidonium majus L.</i>)

	the ingredient in question		
State Sanitary Inspectors	16 State Provincial Sanitary Inspectors, 318 State District Sanitary Inspectors, 9 State Border Sanitary Inspectors	Chief Sanitary Inspectorate	supervision of food business operators with regard to the application of provisions of the Regulation
consumers	potential recipients: 31 million (consumers understood as persons over 18 years of age)	Central Statistical Office	consumer health protection due to the ban on the production and marketing of foodstuffs, including food supplements, containing celandine herb, swallowwort, greater celandine (<i>Chelidonium majus</i> L.) in Poland

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

The draft Regulation has not been the subject of pre-consultations.

The draft Regulation has been submitted for public consultation and evaluation, with a 30-days deadline for submitting comments, to the following entities:

- 1) Polish Federation of Food Industry [Polska Federacja Producentów Żywności];
- 2) 'Food Industry' National Chamber of Commerce [Krajowa Izba Gospodarcza „Przemysł Spożywczy”];
- 3) National Council of Supplements and Nutrition [Krajowa Rada Suplementów i Odżywek];
- 4) Polish Association of Self-Medication Industry PASMI [Polski Związek Producentów Leków bez Recepty PASMI];
- 5) Polish Chamber of Commerce [Krajowa Izba Gospodarcza];
- 6) Polish Organisation of Commerce and Distribution [Polska Organizacja Handlu i Dystrybucji];
- 7) Polish Association of Juice Producers [Stowarzyszenie „Krajowa Unia Producentów Soków”];
- 8) National Chamber of Commerce “Bottling Industry” [Krajowa Izba Gospodarcza „Przemysł Rozlewniczy”];
- 9) Association of Polish Manufacturers of Chocolate Products and Confectionery ‘POLBISCO’ [POLBISCO Stowarzyszenie Polskich Producentów WYROBÓW Czekoladowych i Cukierniczych];
- 10) Confederation Lewiatan [Konfederacja Lewiatan];
- 11) Food Management Federation of the Republic of Poland (Federacja Gospodarki Żywnościowej RP);
- 12) Polish Chamber of Trade [Polska Izba Handlu];
- 13) Pracodawcy Rzeczypospolitej Polskiej [Polish Employers];
- 14) Naczelna Rada Lekarska [Supreme Medical Council];
- 15) Naczelna Rada Aptekarska [Supreme Pharmacy Council];
- 16) Union of Employers — Business Centre Club (Związek Pracodawców – Business Centre Club);
- 17) Związek Przedsiębiorców i Pracodawców [Union of Entrepreneurs and Employers];
- 18) Federacja Przedsiębiorców Polskich [Federation of Polish Entrepreneurs];
- 19) Children's Memorial Health Institute [Instytut „Pomnik – Centrum Zdrowia Dziecka”];
- 20) Institute of Mother and Child [Instytut Matki i Dziecka];
- 21) National Institute of Public Health PZH — National Research Institute [Narodowy Instytut Zdrowia Publicznego PZH – Państwowy Instytut Badawczy];
- 22) National Medicines Institute [Narodowy Instytut Leków];
- 23) National Council of the Federation of Consumers [Rada Krajowa Federacji Konsumentów];
- 24) Association of Polish Consumers [Rada Krajowa Federacji Konsumentów];
- 25) President of the Office for Competition and Consumer Protection [Prezes Urzędu Ochrony Konkurencji i Konsumentów].

The draft Regulation has been published in the Public Information Bulletin of the Ministry of Health in accordance with Article 5 of the Act of 7 July 2005 on lobbying activities in the legislative process (Journal of Laws of 2025, item. 677) and in the Public Information Bulletin of the Government Legislation Centre in accordance with § 52(1) of Resolution No. 190 of the Council of Ministers of 29 October 2013 – Rules of Procedure of the Council of Ministers (Polish Official Gazette of 2024, item 806, and of 2025, item 408).

Results of the public consultation and opinion were presented in the public consultation and opinion report annexed to this assessment.

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		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 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		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
Sources of financing													
Additional information, including the identification of data sources and assumptions made in the calculation		The draft Regulation shall not affect 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
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		Impact						
Time in years since entry into force of the amendments		0	1	2	3	5	10	Total (0–10)
In monetary terms (PLN million, fixed prices for [year])	large enterprises	0	0	0	0	0	0	0
	micro-, small- and medium-sized enterprises	0	0	0	0	0	0	0
	families, citizens and households	0	0	0	0	0	0	0
	(add/remove)							
In non-monetary terms	large enterprises	The draft Regulation will affect the large enterprise sector insofar as it will prohibit the use of celandine herb, , swallowwort, greater celandine. (<i>Chelidonium majus</i> L.) in foodstuffs, including in food supplements. Furthermore, 30 days after the entry into force of the Regulation, foodstuffs containing this plant will no longer be allowed to be present on the market.						
	micro-, small- and medium-sized enterprises	The draft Regulation will affect the small and medium-sized enterprise sector insofar as it will prohibit the use of celandine herb, swallowwort, greater celandine (<i>Chelidonium majus</i> L.) in foodstuffs, including in food supplements. Furthermore, 30 days after the entry into force of the Regulation, foodstuffs containing this plant will no longer be allowed to be present on the market.						
	families, citizens and households	The draft Regulation will not have a direct impact on families, citizens, and households.						
	the elderly and persons with disabilities	The draft Regulation will not have a direct impact on the elderly and disabled persons.						
Unmeasurable		The draft Regulation will have a positive impact on consumers' health and lives, as it will prohibit the use of celandine herb, swallowwort, greater celandine (<i>Chelidonium majus</i> L.) in foodstuffs, including food supplements, for the sake of consumer safety.						

Additional information, including the identification of data	Not applicable.
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sources and assumptions made in the calculation		
8. Change in the regulatory burdens (including disclosure obligations) resulting from the draft		
X 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		
The draft Regulation has no impact on the labour market.		
10. Impact on other aspects		
☐ natural environment ☐ regional standing and development ☐ common courts, administrative courts or military courts	☐ demography ☐ state property ☐ other:	☐ computerisation ☒ health
Discussion of the impact	The draft Regulation will have a positive impact on consumers' health and lives, as it will prohibit the use of celandine herb, swallowwort, greater celandine (<i>Chelidonium majus</i> L.) in foodstuffs, including food supplements, for the sake of consumer safety.	
11.Planned implementation of provisions of the act		
The draft Regulation will enter into force 14 days after its publication. In addition, § 2 of the draft provides that foodstuffs containing celandine herb, swallowwort, greater celandine (<i>Chelidonium majus</i> L.) , which were placed on the market in the territory of the Republic of Poland before the date of entry into force of the Regulation may remain on the market for no longer than 30 days from the date of entry into force of the Regulation.		
12. How and when will the impact of the draft be assessed, and what measures will be applied?		
From the date of entry into force of the draft Regulation, foodstuffs containing celandine herb, swallowwort, greater celandine (<i>Chelidonium majus</i> L.) listed in the draft Regulation may not be placed on the market.		
13.Annexes (important source documents, research, analyses, etc.)		
Public consultation and opinion report.		