

Draft
DECREE

of 2024

amending Decree No 58/2018 on food supplements and on the composition of foodstuffs

Pursuant to § 18(1)(a) and (s) of Act No 110/1997 on foodstuffs and tobacco products and amending certain related acts, as amended by Act No 316/2004, Act No 139/2014, Act No 180/2016 and Act No 174/2021, the Ministry of Agriculture lays down the following:

Article I

Decree No 58/2018 on food supplements and on the composition of foodstuffs is amended as follows:

1. Footnote 1 reads:

⁽¹⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, as amended by Commission Directive 2006/37/EC, Commission Regulation (EC) No 1170/2009, Commission Regulation (EU) No 1161/2011, Commission Regulation (EU) No 119/2014, Commission Regulation (EU) 2015/414, Commission Regulation (EU) 2017/1203, Commission Regulation (EU) 2021/418 and Commission Regulation (EU) 2024/248.’.

2. At the end of footnote 3 the following sentences are added on separate rows: ‘Commission Regulation (EU) 2017/1203 of 5 July 2017 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards organic silicon (monomethylsilanetriol) and calcium salt of phosphoryl oligosaccharides (POs-Ca®) added to foods and used in the manufacture of food supplements are added to foods.’ ‘Commission Regulation (EU) 2021/418 of 9 March 2021 amending Directive 2002/46/EC of the European Parliament and of the Council as regards nicotinamide riboside chloride and magnesium citrate malate used in the manufacture of food supplements and as regards the units of measurement used for copper’ and ‘Commission Regulation (EU) 2024/248 of 16 January 2024 amending Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards ferric hydroxide adipate tartrate used in the manufacture of food supplements.’.

3. In § 2(2) and in § 5(2), the words ‘plants and certain’ are inserted after the word ‘certain’.

4. At the end of footnote 4 and footnote 12, the words ‘, as amended’ are added.

5. In § 3(1)(c), the words 'applicable piece of legislation' are replaced by the words 'applicable legislation'.
6. At the end of footnote 5, the words 'and Commission Regulation (EU) 2021/418' are added.
7. In § 3(1)(d), the words 'directly applicable European Union legislation⁵⁾' are replaced by 'Regulation (EU) No 1169/2011 of the European Parliament and of the Council'.
8. At the end of § 3(1)(k), the word 'and' is replaced by a full stop and point (l) is deleted.
9. In § 5(1), the second sentence is deleted.
10. After § 5(1) a new paragraph (2) is inserted, which reads as follows, including footnote 13:

'(2) Foodstuffs containing narcotic or psychotropic substances¹¹⁾ substances listed in category I of directly applicable European Union legislation regulating drug precursors,¹²⁾ substances with anabolic and other hormonal effects,¹³⁾ substances of a hormonal nature or other substances that have been shown to have a toxic, genotoxic, teratogenic, hallucinogenic, narcotic or other adverse effect on the human body cannot be placed on the market.

¹³⁾ Government Regulation No 454/2009 laying down, for the purposes of the Criminal Code, what is considered to be substances with anabolic and other hormonal effects and what is considered, for the purposes of the Criminal Code, as a method of increasing the transfer of oxygen in the human body and as other methods with doping effect, as amended.'

Existing paragraph (2) is renumbered as paragraph (3).

11. At the end of footnote 11, the sentence 'Government Regulation No 463/2013 on lists of addictive substances, as amended.' is added on a separate line.
12. Annexes 1 and 2 read as follows:

Conditions of use of certain plants and certain other substances in food supplements

1. Conditions of use of certain plants

	Plant name	Plant part	Maximum permissible daily amount
1.	Cimicifuga racemosa (black cohosh)	Dried root and rhizome	40 mg
2.	Citrus aurantium (bitter orange)	Extract (recalculated for amount of synephrine)	20 mg synephrine
3.	Crataegus spp. (hawthorn)	dried leaves, flowers, fruit	1000 mg
4.	Echinacea spp. (coneflower)	dried root, stems and leaves	500 mg
5.	Garcinia cambogia (Malabar tamarind)	Peel (recalculated for amount of hydroxycitric acid)	2000 mg
6.	Ginkgo biloba (ginkgo biloba)	standardised 24/6 extract from leaves	60 mg
7.	Ginkgo biloba (ginkgo biloba)	dried leaf	4000 mg
8.	Hypericum perforatum (St. John's wort)	dried tops	900 mg
9.	Panax ginseng (panax ginseng)	dried root	2000 mg
10.	Ptychopetalum olacoides (muira puama)	dried wood	500 mg
11.	Rhodiola rosea (rhodiola rosea)	standardised root extract (4% rosavin)	100 mg
12.	Tribulus terrestris (tribulus terrestris)	dried tops, fruit	2000 mg
13.	Turnera diffusa (damiana)	dried leaves	1000 mg
14.	Uncaria tomentosa (vilcacora, cat's claw)	dried root	1000 mg
15.	Valeriana officinalis (valerian)	dried root	1000 mg

2. Conditions of use for certain other substances that are not plants

	Other substances	Maximum permissible daily amount
1.	Acetylcarnitine	500 mg
2.	Coenzyme Q10 (ubiquinone and ubiquinol)	200 mg
3.	Orotic acid	50 mg
4.	Pycnogenol	100 mg
5.	Taurine	2000 mg

List of certain plants and certain other substances prohibited in the manufacture of foodstuffs

1. Plants prohibited in food production

	Latin name	English name	Plant part
1.	Aconitum spp.	Monkshood	root
2.	Adonanthe spp. (Adonis spp.)	Pheasant's eye	tops
3.	Alkanna spp.	Alkanet	
4.	Alstonia spp.	Alstonia	bark
5.	Ammi visnaga (L.) LAM.	toothpickweed	fruit
6.	Andira spp.	Andira	
7.	Anchusa spp.	Anchusa	
8.	Apocynum spp.	dogbane	root
9.	Areca catechu L.	Areca nut	seed
10.	Aristolochiaceae	Birthwort family	
11.	Artemisia cina	santonica	
12.	Asarum spp.	wild ginger	tops
13.	Aspidosperma quebracho-blanco Schlecht.	Quebracho	bark
14.	Atropa spp.	belladonna, deadly nightshade	
15.	Azadirachta indica	Neem	
16.	Baccharis coridifolia	Baccharis	
17.	Baccharis megapotamica	baccharis megapotamica	
18.	Borago officinalis	Borage	Tops, flowers
19.	Bragantia wallichii	bragantia wallichii	
20.	Brachyglottis spp.	Senecio	
21.	Caltha palustris	Marsh-marigold	
22.	Cassia acutifolia (Cassia senna)	senna actufolia	leaf, fruit
23.	Cassia angustifolia VAHL	senna angustifolia	leaf, fruit
24.	Catharanthus roseus (L.) G.DON	Madagascar periwinkle	tops
25.	Cephaelis spp.	ipecacuanha	root
26.	Cinenaria spp.	Cinenaria	
27.	Citrullus colocynthis	Colocynth	fruit
28.	Clematis spp.	Clematis	root*)
29.	Cocculus spp. (Anamirta cocculus)	Indian gooseberry	
30.	Colchicum spp.	Autumn crocus	seed
31.	Conium maculatum	Hemlock	
32.	Convallaria majalis L.	Lily of the valley	Leaves, tops
33.	Corydalis spp.	Corydalis	root
34.	Croton tiglium	Purging croton	
35.	Cynoglossum spp.	Forget-me-not	
36.	Datura spp.	Datura	Leaves, tops, seeds
37.	Digitalis spp.	Foxglove	leaf
38.	Diploclisia affinis, Diploclisia chinensis	Diploclisia affinis Diploclisia chinensis	
39.	Dryopteris filix-mas	Dryopteris filix-mas	rhizome

40.	Duboisia spp.	Corkwood tree	leaf
41.	Ecballium elaterium A. RICH.	Squirting cucumber	fruit
42.	Ephedra spp.	Ephedra	Tops
43.	Erechthites spp.	Fire-weed	
44.	Erythroxylon sp.	Erythroxylum coca	
45.	Eschscholtzia californica CHAM.	California poppy	tops
46.	Eupatorium spp. (except Eupatorium perfoliatum)	Bonesets	
47.	Euphorbia spp.	spurge	leaves, juice
48.	Exogonium purga	Jalap	
49.	Frangula alnus MILL.	Alder buckthorn	bark
50.	Gelsemium sempervirens (L.) AIT.	Yellow jasmine	root
51.	Genista tinctoria	Dyer's greenweed	
52.	Gossypium spp.	Cotton	seed
53.	Heliotropium spp.	Heliotropes	
54.	Helleborus spp.	Hellebore	root
55.	Hydrastis canadensis L.	Goldenseal	root
56.	Hyoscyamus spp.	Henbanes	leaf, tops
57.	Chelidonium majus L.	Greater celandine	Root, leaves, tops
58.	Chenopodium ambrosioides	Wormseed	
59.	Ipomoea spp. **)	Ipomoea	
60.	Ledum palustre	Marsh Labrador tea	
61.	Lithospermum officinale	Common gromwell	
62.	Lobelia spp.	Lobelias	tops
63.	Mallotus philippinensis	Kamala tree	
64.	Mandragora officinarum L.	Mandrake	root
65.	Menispermum canadense, Menispermum dahuricum	Common moonseed Asian moonseed	
66.	Mucuna pruriens	Velvet bean	
67.	Nerium oleander L.	Oleander	leaf, tops
68.	Nicotiana spp.	Tobacco	leaf
69.	Papaver somniferum L.	Opium poppy	fruit other than ripe seeds, juice
70.	Pausinystalia yohimbe (K.SCHUM.) PIERRE	Yohimbe	bark
71.	Petasites spp.	Butterburs	
72.	Physostigma venenosum BALF.	Calabar bean	seed
73.	Pilocarpus spp.	Jaborandi	leaf
74.	Pinellia ternata	crow-dipper	
75.	Piper methysticum FORSTER	Kava (kava-kava)	
76.	Podophyllum peltatum L.	Mayapple	root
77.	Polygonum sachalinensis	giant knotweed	
78.	Polygonum cuspidatum	Japanese knotweed	
79.	Pulsatilla vulgaris	Pasque flower	
80.	Rauwolfia serpentina (L.) BENTH.	Indian snakeroot	root
81.	Rhamnus cathartica L.	Buckthorn	Bark, fruit
82.	Rhamnus purshiana DC.	Cascara buckthorn	bark
83.	Rheum officinale	Chinese rhubarb	root
84.	Rheum palmatum	Ornamental rhubarb	root
85.	Rhododendron ferrugineum L.	alpenrose	leaf
86.	Ricinus communis L.	castor bean	seed

87.	<i>Ruta graveolens</i>	Common rue	tops
88.	<i>Sarothamnus scoparius</i> (L.) WIMM.ex KOCH	Scotch broom	Flower, tops
89.	<i>Sassafras albidum</i>	Sassafras	
90.	<i>Scopolia carniolica</i> JACQ.	henbane bell	root
91.	<i>Senecio</i> spp.	Ragworts	
92.	<i>Schoenocaulon officinale</i> (SCHLECHT.et CHAM.) GRAY	Feathershank	seed
93.	<i>Sida cordifolia</i>	ilima	
94.	<i>Sinomenium acutum</i>	Chinese moonseed	
95.	<i>Spartium junceum</i> L.	Spanish broom	flower, tops
96.	<i>Spigelia</i> spp.	Pinkroot	root, tops
97.	<i>Stephania</i> spp.	Stephania	
98.	<i>Strophanthus</i> spp.	Strophanthus	seed
99.	<i>Strychnos</i> spp.	Strychnos	seed
100.	<i>Symphytum</i> spp.	Comfrey	root
101.	<i>Tabebuia impetiginosa</i> syn. <i>Handroanthus impetiginosus</i> (Mart. Ex DC.) Matto	Pink lapacho	bark
102.	<i>Taxus</i> spp.	Yew	
103.	<i>Thevetia peruviana</i> (PERS.) SCHUMANN	-	tops
104.	<i>Tussilago farfara</i>	Coltsfoot	Leaves, flowers
105.	<i>Urginea maritima</i> (L.) J.B.BAK.	Squill	bulb
106.	<i>Veratrum</i> spp.	false hellebores	root
107.	<i>Vladimiria souliei</i>	<i>Vladimiria souliei</i>	
108.	<i>Xysmalobium undulatum</i> R. BROWN	Milkwort	root

*) The prohibition applies where aristolochic acid is present. Roots without aristolochic acid content and other parts of the body of the plant are permitted.

**) Except for *Ipomoea batatas* (L.) Lam. and *Ipomoea aquatica* Forssk.

2. Certain other substances prohibited in the production of foodstuffs

1.	<i>Claviceps</i> spp. (ergot – sclerotium)
2.	Acetyltryptophan
3.	Colloidal silver
4.	Lactulose
5.	N-acetylcysteine

Article II

Technical regulation

This Decree was notified in accordance with 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.

Article III

Effective date

This Decree shall take effect on 1 January 2025.

Minister of Agriculture: