WIJ WILLEM ALEXANDER,
BIJ DE GRATIE GODS,
KONING DER NEDERLANDEN,
PRINS VAN ORANJE-NASSAU,
ENZ. ENZ. ENZ.

Decree of

amending the Commodities Act Decree on Herbal Preparations and the Commodities Act Decree on food supplements in connection with the designation of harmful substances in food supplements and of harmful substances or any material originating in whole or in part from plants and fungi in herbal preparations

[KetenID WGK028332]

On the proposal of Our Minister for Health, Welfare and Sport, of , reference PM;

Having regard to Articles 4(1)(a), 8(1)(c) and 32b of the Commodities Act;

Having heard the opinion of the Advisory Division of the Council of State (opinion of 08 April 2026, No. W13.26.00042/III);

Having regard to the further report by Our Minister for Health, Welfare and Sport of ,);

Have approved and hereby decree the following:

ARTICLE I

The Commodities Act Decree on Herbal Preparations [Warenwetbesluit Kruidenpreparaten] is hereby amended as follows:

A.

In Article 1(1), part c is deleted, and part d is renumbered part c.

B.

Article 4 now reads as follows:

Article 4

1. Herbal preparations shall not contain any of the substances listed in Annex I(A) or any material originating in whole or in part from the plants and fungi listed in Annex I(B).
2. Herbal preparations shall not contain any of the substances listed in Annex II (A) or any material originating in whole or in part from the plants and fungi listed in Annex II(B), except under the conditions specified therein.

3. In the case of herbal preparations containing any material originating in whole or in part from the plants and fungi listed in Annex III, the recommendations for use described therein are to be stated on the label.

C.

Article 7 now reads as follows:

Article 7
Herbal preparations placed on the market before [date of entry into force] and which comply with the Commodities Act Decree on Herbal Preparations as it stood on [date day prior to entry into force] may continue to be marketed until [date six months after entry into force].

D.

In Article 8, the words “Kruidenpreparaten” (Herbal Preparations) are replaced by “kruidenpreparaten” (herbal preparations).

E.

The Annex is deleted.

F.

The following three annexes are added:

Annex I as referred to in Article 4(1) of the Commodities Act Decree on herbal preparations

A. Substances
Aconitine or any derivatives thereof
Aristolochic acids or any derivatives thereof
Atropine or any derivatives thereof
1,3-dimethylamylamine (DMAA)
1,3-dimethylbutylamine (DMBA, nor-DMAA)
1,5-dimethylhexylamine (DMHA, octodrine)
Colchicine or any derivatives thereof
FEA (phenethylamine)
Halostachine or any derivatives thereof
Harmine or any derivatives thereof
Harmaline or any derivatives thereof
Higenamine or any derivatives thereof
Hordenine
Huperzine A
Hyoscyamine or any derivatives thereof
(nor)Ibogaine
Icariin or any derivatives thereof
Isopropyloctopamine or any derivatives thereof
Lysergic acid amide (LAA)
Lysergic acid amide stereoisomer (iso-LAA)
Methylsynephrine or any derivatives thereof
M- and o-synephrine or any derivatives thereof
Pilocarpine or any derivatives thereof
Scopolamine or any derivatives thereof
Strychnine or any derivatives thereof
Tetrahydroharmine (THH) or any derivatives thereof

B. Plants and fungi
Aconitum carmichaelii
Aconitum kusnezoffii
Aconitum napellus (monkshood or aconite)

Adonis vernalis (spring pheasant's eye and false hellebore)
Argyreia nervosa (Hawaiian baby woodrose)
Oil from Artemisia absinthium (common wormwood), without prejudice to the provisions of Article 6(2) and Annex III(B) of Regulation (EC) No 1334/2008 on permission for thujone to be present in certain compound foods
Artemisia cina (true wormseed)
Artemisia maritima (sea wormwood)
Atropa bella-donna (deadly nightshade)
Brassica nigra (Black mustard), subject to the use of the seed in food
Bryonia alba (red or white bryony)
Banisteriopsis caapi (caapi)
Cephaelis acuminata or Uragoga granatensis (including Ipecacuanhae radix)
Chenopodium ambrosioides (var. anthelminthicum) (fragrant goosefoot)
Chrysanthemum vulgare or Tanacetum vulgare (tansy or Common tansy)
Citrullus colocynthis (colocynth or bitter apple)
Claviceps purpurea (ergot)
Colchicum autumnale (autumn crocus)
Convallaria majalis (lily of the valley)
Convolvulus scammonia
Croton tiglium
Datura stramonium (thornapple)
Digitalis lanata (woolly foxglove)
Digitalis purpurea (foxglove)
Dryopteris filix-mas (male fern)
Exogonium purga or Ipomoea purga (jalappe)
Genista tinctoria (dyer’s greenweed)
Hyoscyamus niger (black henbane)
Huperzia serrata
Juglans regia (walnut tree), excluding the nuts
Juniperus sabina (savin juniper)
Ledum palustre (marsh rosemary)
Lobelia inflata (indian tobacco or puke weed)
Lycopus europaeus (gypsywort)
Mallotus philippensis or Rottlera tinctoria (kamala)
Mandragora officinarum (mandrake)
Nerium oleander (oleander)
Pausinystalia johimbe or Corynanthe johimbe
Pilocarpus jaborandi
Piper methysticum (kava kava)
Podophyllum peltatum (wild mandrake, American mandrake or mayapple), excluding the fruit
Pulsatilla vulgaris or Anemona pulsatilla (pasque flower or purple anemone)
Rauwolfia serpentina (chandrika)
Ricinus communis (castor oil plant), except for the use in herbal preparations of oil extracted from the seeds of ricinus communis, in so far as the recommendations for use and dosage advice referred to in Article 6(1) of the Commodities Act Decree on Herbal Preparations does not lead to a higher intake of this oil than 0.4 g per day
Rubia tinctorum (rose madder)
Sarothamnus scoparius or Cystisus scoparius (broom)
Scopolia carniolica (European scopolia or henbane bell)
Solanum dulcamara (bittersweet)
Strophantus kombe (Strofantus - kombe arrow poison)
Strychnos nux-vomica (strychnine tree)
Tabernanthe iboga
Teucrium chamaedrys (wall germander)
Urginea maritima or Scilla maritima (sea squill)
Vinca minor (lesser periwinkle)
Withania somifera (ashwagandha), except for the root

Annex II as referred to in Article 4(2) of the Commodities Act Decree on herbal preparations

A. Substances	Conditions
P-synephrine	Herbal preparations shall contain a maximum daily intake of 27 mg of p-synephrine, as per the instructions for use.

B. Plants and fungi	Conditions
Cimicifuga racemosa (L.) Nutt. (Black cohosh)	Herbal preparations shall contain a maximum daily intake of 40 mg of black cohosh rhizome, as per the instructions for use.

Annex III as referred to in Article 4(3) of the Commodities Act Decree on herbal preparations

Plants and fungi	Statement regarding recommendations for use on the label
Allium sativum (garlic)	When selling herbal preparations containing garlic*, the following recommendations for use are to be stated on the label: *This product may adversely affect the action of various medicines, including blood thinners and antiviral medicines.*
Camellia sinensis (green tea)	When selling herbal preparations containing green tea*, the following recommendations for use are to be stated on the label: *This product may adversely affect the action of various medicines, including anti-anxiety medicines, folic acid, blood pressure lowering medicines and cardiovascular medicines.*
Cimicifuga racemosa (L.) Nutt. (Black cohosh)	When herbal preparations containing black cohosh rhizome are sold, the following recommendations for use are to be stated on the label: *This product is not suitable for children up to and including the age of 17. Do not use this product if you are pregnant or breastfeeding.* Consult a doctor if you have a history of liver disease or are currently undergoing, or have previously undergone, treatment for (hormone-sensitive) cancer.
Curcuma longa (turmeric)	In the case of marketing of herbal preparations with turmeric*, the following recommendations for use are to be stated on the label: *This product may adversely affect the action of various medicines, including anticancer medicines, blood pressure-lowering medicines and anti-inflammatory drugs.*
Ginkgo biloba (maidenhair tree or ginkgo)	When selling herbal preparations containing ginkgo*, the following recommendations for use are to be stated on the label:

	This product may adversely affect the action of various medicines, including blood thinners and heart medicines.
Hypericum perforatum L. (St. John's wort)	When selling herbal preparations containing St John's wort, the following recommendations for use are to be stated on the label: *This product is not suitable for children up to and including the age of 17. Do not use this product if you are pregnant or breastfeeding. When using this product, avoid exposure to intense UV radiation (sunbathing, sunlamps, solariums).* *This product may adversely affect the efficacy of various medicines, including the contraceptive pill.*
Mucuna pruriens (monkey tamarind)	When selling herbal preparations containing Mucuna pruriens, the following recommendations for use are to be stated on the label: *Do not use this product if you are pregnant, breastfeeding or have liver and/or kidney problems. This product may adversely affect the action of various medicines.*
Panax quinquefolius (American ginseng)	When selling herbal preparations containing American ginseng*, the following recommendations for use are to be stated on the label: *This product may adversely affect the action of various medicines, including blood thinners.*
Salvia miltiorrhiza (danshen or red sage)	When selling herbal preparations containing red sage*, the following recommendations for use are to be stated on the label: *This product may adversely affect the action of various medicines, including blood thinners.*
Silybum marianum (milk thistle)	When marketing herbal preparations containing milk thistle*, the following recommendations for use are to be stated on the label: *This product may adversely affect the action of various medicines, including diabetes medicines, blood pressure lowering medicines, antibiotics and cardiovascular medicines.*
Valeriana officinalis (valeriaan)	When selling herbal preparations containing valerian*, the following recommendations for use are to be stated on the label: *This product may adversely affect the action of various medicines, including tranquillisers.*
Withania somnifera (ashwagandha), root	When marketing herbal preparations with the root of ashwagandha, the following recommendations for use are to be stated on the label: *Do not use this product if you are pregnant, breastfeeding or have liver and/or thyroid problems. Ashwagandha can cause liver*

	problems in very rare cases.

* With the exception of herbal teas as defined in the 'EMA Guideline on quality of herbal medicinal products/traditional herbal medicinal products': *Herbal tea: consists exclusively of one or more herbal substances intended for use in oral aqueous preparations by means of a decoction, infusion or maceration. It is prepared immediately before use. Herbal tea is usually sold in bulk or in tea bags.*

ARTICLE II

The Commodities Act Decree on food supplements (Warenwetbesluit voedingssupplementen) is amended as follows:

A.

An article is inserted after Article 4 and reads:

Section 4a
1. Food supplements do not contain any of the substances listed in Annex I.
2. In food supplements, substances listed in Annex II shall be authorised only under the conditions laid down therein.

B.

Article 8 now reads:

Article 8
Food supplements placed on the market before [date of entry into force] and which comply with the Commodities Act Decree on food supplements as it stood on [date day prior to entry into force] may continue to be marketed until [date six months after entry into force].

C.

Two Annexes are added, worded as follows:

Annex I as referred to in Article 4a(1) of the Commodities Act Decree on food supplements

Substances
Aconitine or any derivatives thereof
Aristolochic acids or any derivatives thereof
Atropine or any derivatives thereof
1,3-dimethylamylamine (DMAA)
1,3-dimethylbutylamine (DMBA, nor-DMAA)
1,5-dimethylhexylamine (DMHA, octodrine)
Colchicine or any derivatives thereof
FEA (phenethylamine)
Halostachine or any derivatives thereof
Harmine or any derivatives thereof
Harmaline or any derivatives thereof
Higenamine or any derivatives thereof
Hordenine
Huperzine A
Hyoscyamine or any derivatives thereof
(nor)Ibogaine
Icariin or any derivatives thereof
Isopropyloctopamine or any derivatives thereof
Lysergic acid amide (LAA)
Lysergic acid amide stereoisomer (iso-LAA)
Methylsynephrine or any derivatives thereof
M- and o-synephrine or any derivatives thereof
Pilocarpine or any derivatives thereof
Scopolamine or any derivatives thereof
Strychnine or any derivatives thereof
Tetrahydroharmine (THH) or any derivatives thereof

Annex II as referred to in Article 4a(2) of the Commodities Act Decree on food supplements

Substances	Conditions
P-synephrine	Food supplements shall contain a maximum daily intake of 27 mg of p-synephrine, as per the recommendations for use.

ARTICLE III

The Annex to the Commodities Act Decree on administrative penalties (Warenwetbesluit bestuurlijke boeten) is hereby amended as follows:

1. In the 'Content', in part C-22, “Warenwetbesluit Kruidenpreparaten” (Commodities Act Decree on Herbal Preparations) is replaced by “Warenwetbesluit kruidenpreparaten” (Commodities Act Decree on herbal preparations).
2. In the heading C-22, “Warenwetbesluit Kruidenpreparaten” (Commodities Act Decree on Herbal Preparations) is replaced by “Warenwetbesluit kruidenpreparaten” (Commodities Act Decree on herbal preparations).
3. In the heading C-22 of the Commodities Act Decree on Herbal Preparations, part C-22.4.1 is deleted.
4. In the heading C-26 of the Commodities Act Decree on food supplements, two parts are inserted after part C-26.1, which read as follows:

C-26.1.1	Article 2(1) in conjunction with Article 4a(1)	€525,-	€1.050,-	X
C-26.1.2	Article 2(1) in conjunction with Article 4a(2)	€525,-	€1.050,-	X

ARTICLE IV

This Decree shall enter into force on PM.

I hereby order this Decree and its associated explanatory memorandum to be published in the Bulletin of Acts and Decrees.

The Minister for Public Health,
Welfare and Sports,