



Powered by
वाणिज्य एवं
उद्योग मंत्रालय
MINISTRY OF
COMMERCE
AND INDUSTRY
सत्यमेव जयते

**BHARAT HEALTH
GLOBAL EXPO 2025**

INDIA'S WELLNESS REVOLUTION



Organised by
SHEFEXIL
Shellac And Forest Products
Export Promotion Council

4 5 6

SEPTEMBER 2025

Hall 4, FF, Bharat Mandapam, New Delhi

Nutraceuticals and Dietary Supplements: Research, Regulatory Affairs, and Innovation in Italy

Marco Leonti, Department of Biomedical Sciences
University of Cagliari (Italy)



Dietary supplements are regulated as foods

Since the late 1990s, > herbal products, (cut or powdered drugs, extracts: botanicals) → entered the market also as food, cosmetics, food supplements and novel food.

According to the EU General Food Law Regulation (EC) (178/2002) food supplements are considered foodstuffs.

→ Supplements are food products with some peculiarities regarding their forms of presentation, their consumption units and their pre-set daily supply.

→ European “hygiene package” regulation is followed but specific directives exist.

European directive has been implemented by every Member State into local norms, → Food supplement market NOT fully harmonised.

Dietary supplements are regulated as foods

Safety responsibility lies with the food business operator placing the product on the market.

The reference EU legislation of food supplements (Directive 2002/46/EC) → establishes harmonised lists of vitamins and mineral substances used in the manufacture of food supplements and the labelling requirements.

This directive **ONLY** specifies the rules for the use of vitamins and minerals in the manufacture of food supplements.

→ Use of substances other than vitamins or minerals in the manufacture of food supplements may be governed by national rules or may be subject to other specific EU legislations.

EU: Dietary and Food supplements are regulated as foods

EFSA provides scientific opinions on the safety of substances used in food supplements, particularly for those not previously used in the EU or upon request by a Member State and to support the evaluations carried out by the European Commission.



[Home](#) / [All topics](#)

Food supplements

Last reviewed date: 4 March 2025

| 9 minutes read

Share:    

<https://www.efsa.europa.eu/en/topics/topic/food-supplements>

EU: Dietary and Food supplements are regulated as foods

For a nutrient to be used in food, it must have a History of Safe Use within the EU. Failure to meet this criterion categorizes the substance as a "novel food" and requires prior authorization, even for use in supplements.

→ Novel food registration is at the EU level.

Dietary and Food supplements in Italy

Italy: Legislation does not distinguish between dietary supplements and nutraceuticals, → food supplements.

Italy ranks 1st in Europe for the consumption of food supplements and 8th in the list of world exporters.

Main sales channels are the pharmacy (share of ca. 80%) followed by large-scale distribution, para-pharmacy and e-commerce.

In the 2-year period 2020-2021, the most popular were immune stimulants (+30.2%), vitamin supplements (+30%) and products that promote sleep and night-time rest (+21%).

Italy: → Dietary supplements (incl. nutraceuticals) are regulated under a mix of European Union (EU) and national laws, with the EFSA doing the scientific assessment.

The Ministry of Health (MoH) Italy is the competent authority for food safety in Italy.

‘Blueberry fruits contribute to the well-being of vision’: Pure blueberry extract with 1% (!) anthocyanidins (according to Eur. Pharm. 25% anthocyanidins \geq 150 mg/serving). 100 g fresh fruits: 300-700 mg anthocyanins (glycosides)!



60
CAPSULE
VEGETALI


Colours of Life®
Integratore
Alimentare



MIRTILLO *PURØ*



Valori medi ingredienti caratterizzanti per dose giornaliera massima (2 capsule)

Mirtillo frutti e.s.* 600 mg
Di cui antocianidine 6 mg

*estratto secco

Modo d'uso: Assumere 1 o 2 capsule al giorno con un po' d'acqua o altra bevanda.

I frutti di Mirtillo contribuiscono al benessere della vista

Modalità di conservazione: Conservare a temperatura inferiore ai 30° C, evitare l'esposizione a fonti di calore localizzate, ai raggi solari e tenere al riparo dell'umidità. Il termine di consumo si riferisce al prodotto correttamente conservato in confezione integra.

Historically, to be defined as food supplements, products had to present nutritional features, (→ supply of vitamins and minerals).

→ This posed a problem for products containing other ingredients, like herbal extracts, that cannot be considered “nutrients”.

Classifying neither as food supplements, nor as medicines, a different classification was contemplated for herbal ingredients:

→ There were several attempts to regulate the admitted plants, not only at national level, → BELFRIT (**BEL**gium, **FR**ance, **IT**aly) project:

→ Joint initiative to harmonize regulations and to create a single list of plants, or parts thereof, allowed in supplements, → ensure greater consumer protection and free movement of products in Europe.

On Aug. 10, 2018, a Ministry of Health decree on the use of medicinal plants allowed in food supplements was published in the Official Gazette General Series No. 224 of Sept. 26.



Ministero della Salute

TROVA NORME SALUTE

TROVA NORME & CONCORSI SALUTE

Numero Atti : 81961 

Ultima Gazzetta Ufficiale del : 05 agosto 2025

Ultima Modifica : 06 agosto 2025

[Home](#) [Servizi](#) [News](#) [Newsletter](#)  [Direttive UE](#)   [NUOVA RICERCA](#)

Dettaglio atto

<https://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=65948&completo=true>

Art. 1: Scope

Establishing the list of vegetable substances and preparations allowed for use in food supplements and steps to be taken to support their safety. (The provisions of European and national food legislation applicable to food supplements containing herbal substances and preparations remain unaffected).

Article 2: Substances and herbal preparations allowed for use (Annex 1)

Annex 1: Single plant list, resulting from the integration of the **BELFRIT** list with the other plants on the Italian list favourably reevaluated by the Dietetics and Nutrition Section of the Technical Committee on Nutrition and Animal Health.

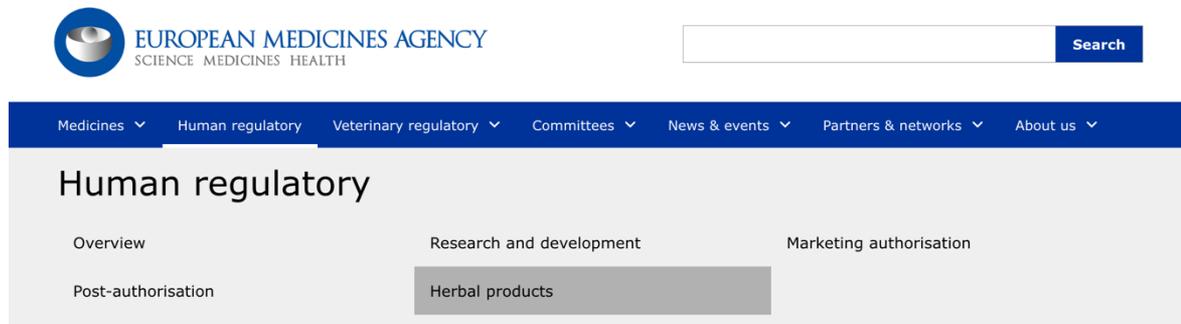
<https://www.trovanorme.salute.gov.it/norme/renderPdf.spring?seriegu=SG&datagu=26/09/2018&redaz=18A06095&artp=1&art=1&subart=1&subart1=10&vers=1&prog=001>

Annex 1: List incl. plant, fungi, algae derived crude drugs admitted for food supplements (30 pp.)

ALLEGATO 1					
NOME BOTANICO	FAMIGLIA	SINONIMO	PARTE TRADIZIONALMENTE IMPIEGATA	PRESCRIZIONI ETICHETTA	ALTRE PRESCRIZIONI
<i>Abelmoschus esculentus</i> (L.) Moench	Malvaceae		fructus		
<i>Abelmoschus moschatus</i> Medik.	Malvaceae		semen		
<i>Abies alba</i> Mill.	Pinaceae		aetheroleum, cortex, conus, ramus, folium, gemma, pinea, semen, resina		
<i>Abies balsamea</i> (L.) Mill.	Pinaceae		aetheroleum, balsamum, cortex, folium, resina, surculi		
<i>Abies fraseri</i> (Pursh) Poir.	Pinaceae		balsamum		
<i>Abies nordmanniana</i> subsp. <i>equi-trojani</i> (Asch. & Sint. ex Boiss.) Coode & Cullen	Pinaceae	<i>Abies pectinata</i> DC. var. <i>equi-trojani</i> Asch. & Sint. ex Boiss.	cortex, folium, gemma, ramus		
<i>Abies sibirica</i> Ledeb.	Pinaceae		cortex, folium, ramus, resina, semen		
<i>Abroma augusta</i> (L.) L.f.	Malvaceae		cortex ex radicibus		
<i>Acacia catechu</i> (L.f.) Willd.	Leguminosae		flos, gummi, lignum		
<i>Acacia decurrens</i> Willd.	Leguminosae		flos, cortex, gummi, lignum		
<i>Acacia farnesiana</i> (L.) Willd.	Leguminosae		flos, fructus, gummi, lignum		
<i>Acacia laeta</i> R. Br. ex Benth.	Leguminosae	<i>Acacia suma</i> (Roxb.) Kurz. ex Brandis	gummi		
<i>Acacia nilotica</i> (L.) Delile	Leguminosae	<i>Acacia arabica</i> (Lam.) Willd.	cortex, fructus, gummi		
<i>Acacia senegal</i> (L.) Willd.	Leguminosae		cortex, gummi		
<i>Acacia seyal</i> Delile	Leguminosae		gummi		
<i>Acalypha indica</i> L.	Euphorbiaceae		folium, radix		
<i>Acanthus mollis</i> L.	Acanthaceae		flos, folium, herba, radix		
<i>Acer campestre</i> L.	Sapindaceae		gemma		
<i>Acer negundo</i> L.	Sapindaceae		cortex		
<i>Acer saccharinum</i> L.	Sapindaceae		cortex, lignum		
<i>Achillea ageratum</i> L.	Compositae		herba cum floribus		
<i>Achillea atrata</i> L.	Compositae		herba cum floribus		
<i>Achillea erba-rotta</i> All.	Compositae		herba cum floribus		
<i>Achillea erba-rotta</i> subsp. <i>moschata</i> (Wulfen) I. Richardson	Compositae		aetheroleum, capitula, herba cum floribus		
<i>Achillea maritima</i> (L.) Ehrend. & Y.P. Guo	Compositae	<i>Diotis candidissima</i> Desf., <i>Otanthus maritimus</i> (L.) Hoffmanns. & Link	aetheroleum, herba cum floribus		
<i>Achillea millefolium</i> L.	Compositae		aetheroleum, capitula, herba cum floribus		
<i>Achillea nana</i> L.	Compositae		aetheroleum, herba cum floribus		
<i>Achillea ptarmica</i> L.	Compositae		herba cum floribus, radix, capitula		
<i>Achyranthes bidentata</i> Blume	Amaranthaceae		radix		
<i>Acmella oleracea</i> (L.) R.K. Jansen	Compositae		herba cum floribus		
<i>Actaea heracleifolia</i> (Kom.) J. Compton	Ranunculaceae	<i>Cimicifuga heracleifolia</i> Kom.	rhizoma	AVVERTENZA SUPPLEMENTARE Per l'uso e la durata dell'assunzione si consiglia di consultare il medico. Non utilizzare comunque in caso di disfunzioni o malattie epatiche	
<i>Actaea racemosa</i> L.	Ranunculaceae	<i>Cimicifuga racemosa</i> (L.) Nutt.	radix, rhizoma	AVVERTENZA SUPPLEMENTARE Per l'uso e la durata dell'assunzione si consiglia di consultare il medico. Non utilizzare comunque in caso di disfunzioni o malattie epatiche	
<i>Actinidia chinensis</i> Planch.	Actinidiaceae		fructus, gemma		
<i>Actinidia deliciosa</i> (A. Chev.) C.F.Liang & A.R.Ferguson	Actinidiaceae		fructus, gemma		
<i>Acorus calamus</i> L.	Acoraceae		rhizoma	AVVERTENZA SUPPLEMENTARE Non utilizzare in gravidanza	L'apporto massimo di beta-asarone con la dose giornaliera non deve superare 115 mcg e 2 mcg/Kg di peso corporeo.
<i>Adansonia digitata</i> L.	Malvaceae		cortex, folium, fructus, radix, semen		
<i>Adiantum capillus-veneris</i> L.	Pteridaceae		folium, herba, radix		
<i>Adiantum pedatum</i> L.	Pteridaceae		folium, herba, radix		
<i>Adoxa moschatellina</i> L.	Adoxaceae		herba		
<i>Aegle marmelos</i> Correa	Rutaceae		cortex, folium, radix, semen		
<i>Aegopodium podagraria</i> L.	Apiaceae		folium		

List may overlap with Eur. Pham. and HMPC monographs

The Committee on Herbal Medicinal Products (HMPC) → committee within the European Medicines Agency (EMA):
→ Assesses scientific data on herbal substances, preparations, and combinations, focusing on safety and efficacy → Support the harmonization of the European market for herbal medicines → Compiles monographs.



The screenshot shows the EMA website interface. At the top left is the EMA logo with the text "EUROPEAN MEDICINES AGENCY" and "SCIENCE MEDICINES HEALTH". To the right is a search bar with a "Search" button. Below this is a navigation menu with categories: Medicines, Human regulatory, Veterinary regulatory, Committees, News & events, Partners & networks, and About us. The "Human regulatory" section is expanded, showing sub-sections: Overview, Post-authorisation, Research and development, Herbal products (highlighted), and Marketing authorisation.

Asteraceae	116
Fabaceae	79
Lamiaceae	71
Rosaceae	60
Apiaceae	58
Brassicaceae	32
Poaceae	32
Rutaceae	26
Myrtaceae	26
Polygonaceae	25



The screenshot shows a sidebar menu with the following items: "EU monographs and list entries" (highlighted), "Regulatory and scientific support", "Scientific guidelines", "Q&A: Herbal medicines", and "Procedures".

European Union monographs and list entries

[← Share](#)

The Committee on Herbal Medicinal Products (HMPC) compiles and assesses scientific data on herbal substances, preparations and combinations with a focus on safety and efficacy. This work supports the harmonisation of the European market: national competent authorities are able to refer to one unique set of information on a herbal substance or preparation when evaluating marketing applications.

European Union monographs

Article 3: Notification procedure

The **notification procedure established by the EU** for the placing on the market of food supplements containing the herbal substances and preparations regulated by this decree for the evaluation of products in relation to the constituents as a whole, daily intakes, and label claims **shall remain in place.**

Article 4: Mutual recognition

The marketing of food supplements that do not comply with the provisions of this Decree shall be allowed in accordance with the principle of mutual recognition for products legally manufactured and marketed in another Member State of the European Union or in Turkey, or for products legally manufactured in an EFTA State...

Article 5: Transitional and final provisions...

Article 6: Update.

Annexes 1 and 2 to this decree are updated, by order of the director general for food hygiene and safety and nutrition, on the basis of new evidence or for the application of the principle of mutual recognition.

Annex 2: Guidance on the documentation required for the use of botanicals in food supplements and the controls to be carried out regarding safety and quality.:

1. Definition

...of herbal preparations...

2. Plant information

Scientific name (family, genus, species, variety), Common or trade name, Part used, Geographical origin, Growing conditions and harvest time, agricultural process, Database used for taxonomic identification.

3. Information on the plant substance or preparation as a raw material

...preparations obtained by methods of preparation **other than the usual ones, such that they result in compositional profiles different from those proven safe by the history of consumption in food supplements, requires the application of the Regulation (EU) 2015/2283 on novel foods.**

4. Information on the finished product

Analysis of risks and safety of the product under the recommended conditions of use. Possible interactions, Stability studies and storage conditions; Packaging materials used; Post-marketing surveillance of the food supplement.

Labelling requirements for food supplements in the EU market

→ Names of the categories of nutrients and specific substances that characterize the product

→ Portion of the product recommended for daily consumption

→ Warning not to exceed the stated recommended daily dose

→ Statement that food supplements should not be used as a substitute for a varied diet

→ Statement that the products should be stored out of the reach of young children.

→ Presentation and advertising must not attribute the property of preventing, treating or curing a human disease, or refer to such properties.

Substances prohibited or restricted for use in food supplements

The EC, on its own initiative or on the basis of information provided by the Member States and following an assessment by EFSA, may take a decision to include a certain substance in a list of substances whose use in foods is prohibited, restricted or under scrutiny.

This may happen when the addition of a substance in food products increases its exposure to levels greatly exceeding the normal consumption and/or poses a potential risk to consumers.