EXPORT GUIDE

Medicinal and aromatic plant ingredients and products

International Trade Centre

Funded by the European Union

The International Trade Centre (ITC) is the joint agency of the World Trade Organization and the United Nations.

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About the guide

Medicinal and aromatic plants are key ingredients to food, cosmetic and medicinal consumer products. The medicinal plants market alone was valued at over $3 billion in 2015 and is expanding as the use of natural ingredients grows.

This guide provides all that an exporter needs to describe a product, understand regulatory requirements, navigate sustainability standards, improve branding and find information on buyers and trade promotion.

Publisher: International Trade Centre

Title: Export Guide to Medicinal and Aromatic Plant Ingredients and Products

Publication date and place: Geneva, February 2023

Page count: 120

ITC Document Number: GIVC-23-114.E

Citation International Trade Centre (2023). *Export Guide to Medicinal and Aromatic Plant Ingredients and Products*. ITC, Geneva.

(or) Brendler, T. and Brinckmann, J. A. (2023). *Export Guide to Medicinal and Aromatic Plant Ingredients and Products*. International Trade Centre, Geneva, Switzerland.

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Foreword

The world's biodiversity is under threat from climate change, invasive species and habitat loss from land use change. This threat is compounded by human demand for plants and trees that we use in our everyday lives. Around 26,000 plant species are documented to have medicinal or aromatic uses. Most of these plants are collected from wild populations. They range from liquorice root and rhodiola root for medicinal products and health supplements, to argan kernel oil for cosmetics, acai berries and baobab for health drinks.

Trade in these plants has increased threefold since 1999. The top importers are the United States, Germany, Japan and China. The rush to supply these growing markets is placing intense pressure on the plant resources, resulting in their overexploitation and damage to wild populations.

Market deals in bulk trade are usually between producers and ingredient processors and distributors, and do not report on sustainability, benefit sharing and labour standards in the same manner expected of finished product brand holders. Regulations and standards have emerged to address these issues. These regulations and standards are now important market requirements for exporters in niche markets.

The medicinal and aromatic plants sector comprises many small enterprises. This guide helps them access information on markets, marketing and branding strategies, and certification. Others in the value chain can also benefit from the guide. They include public authorities in the forestry, agriculture and health sectors, the academic and research sector, and training and certification bodies.

ITC is committed to supporting trade to enable the green transition. I hope that our partners in developing countries, specifically small businesses, will find that this guide improves their capacity to trade, conserve and manage their local wild plant resources sustainably.

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Executive Director
International Trade Centre

Acknowledgements

The *Export Guide: Medicinal and aromatic plant ingredients and products* was prepared by Thomas Brendler and Josef Brinckmann under the direction of Alexander Kasterine, Senior Adviser and Hiba Batool, Division of Sustainable and Inclusive Value Chains at the International Trade Centre (ITC).

We also thank our ITC colleagues Alexandra Golovko, Ha Vu, Marie-Claude Frauenrath, Vanessa Erogbogbo, Mirhadi Seyedi, and Majid Bahrami (all ITC) for their valuable inputs and support to research and consultation process.

The guide benefited from the input and permission to include selected case studies of market access, including for a novel herbal food from Zimbabwe in the EU, an herbal food supplement from South Africa in the US, and a traditional Chinese medicine herbal medicinal product in the EU.

We thank Natalie Domeisen, who managed the editorial and production process with the support of Anne Griffin (both ITC). Thanks also to Janet Hill who edited the paper, Franco Iacovino (ITC) for layout and Serge Adeagbo (ITC) for printing support.

This guide was prepared with generous funding from the European Union.

Contents

Acronyms

Unless otherwise specified, all references to dollars ($) are to United States dollars, and all references to tonnes are to metric tons.

ABS	Access and benefit sharing
API	Active pharmaceutical ingredient
CAC	Codex Alimentarius Commission of the Joint FAO/WHO Food Standards Programme
CBD	Convention on Biological Diversity of the United Nations
CHED	Common health entry document
CITES	Convention on International Trade in Endangered Species of the United Nations
CN	Combined Nomenclature of the European Commission Taxation and Customs Union
CSR	Corporate social responsibility
CTD	Common technical document
EC	European Commission
EDQM	European Directorate for the Quality of Medicines and HealthCare
EEA	European Economic Area
EFEO	European Federation of Essential Oils
EFFA	European Flavour and Fragrance Association
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EHIA	European Herbal Infusions Association
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EMA	European Medicines Agency
ESA	European Spice Association
ESG	Environmental, social and governance
EU	European Union
EUROPAM	European Herb Growers Association
FAO	Food and Agriculture Organization of the United Nations
FCC	Food Chemicals Codex of the United States Pharmacopeial Convention
FDA	Food and Drug Administration of the United States
GACPs	Good agricultural and collection practices
GI	Geographical indication
GHPPs	Good herbal processing practices
GMO	Genetically modified organism
GMPs	Good manufacturing practices
GSP	General system of preferences
HACCP	Hazard analysis and critical control points
HMPs	Herbal medicinal products
HMPC	Committee on Herbal Medicinal Products of the European Medicines Agency
HS	Harmonized System nomenclature of the World Customs Organization
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICS	International Classification for Standards
IFEAT	International Federation of Essential Oils and Aroma Trades

IFOAM	International Federation of Organic Agriculture Movements
INCI	International Nomenclature of Cosmetic Ingredients
IOFI	International Organization of the Flavour Industry
ISO	International Organization for Standardization
ITC	International Trade Centre
IUCN	International Union for Conservation of Nature
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MAPs	Medicinal and aromatic plants
MRL	Maximum residue limit of pesticide
OTC	Over the counter
PAs	Pyrrolizidine alkaloids
PAHs	Polycyclic aromatic hydrocarbons
PhEur	European Pharmacopoeia
PPRC	Pharmacopoeia of the People's Republic of China
RASFF	Rapid Alert System for Food and Feed
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
SDGs	Sustainable development goals
SMEs	Small and medium-sized enterprises
TAMC	Total aerobic microbial count
TARIC	EU Customs Tariff
TAs	Tropane alkaloids
TCM	Traditional Chinese medicine
TYMC	Total combined yeasts/moulds count
UEBT	Union for Ethical BioTrade
UNCTAD	United Nations Conference on Trade and Development
USP-NF	United States Pharmacopoeia and National Formulary
VSS	Voluntary sustainability standard
WCO	World Customs Organization
WHO	World Health Organization
WTO	World Trade Organization

Executive summary

This export guide provides essential information needed by SME producers, processors and exporters of medicinal and aromatic plant (MAP) ingredients and the herbal products made from them, which are destined for buyers in Europe. Some comparisons are also provided against requirements of other markets.

This detailed information includes tariff and non-tariff measures and requirements as outlined in EU decisions, directives and regulations. This guide delineates requirements that are sector-specific; for example, limits that are established for the presence of certain contaminants may be different for MAP ingredients for use in food products vs those which will be used as active ingredients in herbal medicinal products (HMPs).

This guide provides small and medium-sized MAP exporters with useful shortcuts for understanding and navigating the myriad market access requirements, both regulatory and voluntary. While the guide provides a concise consolidation of the relevant requirements that a successful exporter must be aware of, the guide also makes liberal use of internet addresses that the user can simply click to access and download the referenced materials.

This is not a guide that will sit on the shelf for occasional use. Persons throughout an exporting operation will find answers to questions that can potentially save their shipments from being held up or refused entry by customs authorities or rejected by the buyer. Requirements are elaborated throughout the guide using certain MAP ingredients to illustrate the main points in easily understood figures, tables and tips boxes.

Depending on the size of the exporter operation, this guide may be used by managers of MAP farm or wild collection operations, post-harvest production and processing facilities, legal and regulatory compliance, sustainability standards compliance, quality assurance and quality control, and export sales and marketing.

Chapter 1 provides regulatory definitions of MAP ingredients in their crude or processed forms and definitions used for finished herbal products labelled and marketed as cosmetics, foods, food supplements or medicines.

Chapter 2 provides details on the European Union (EU) Combined Nomenclature (CN) and Integrated Tariff of the EU (TARIC) using certain MAP ingredients to illustrate.

Chapter 3 summarizes the EU regulatory requirements for herbal substances used in cosmetics, foods, food supplements or medicines, including quality assurance standards such as good agricultural and collection practices (GACPs) for MAPs and good manufacturing practices (GMPs) for processed MAP ingredients and finished products, the legal basis for the establishment of quality specifications and testing requirements, limits that have been established for certain known contaminants of MAP ingredients, and labelling.

Chapter 4 provides a summary of sustainable production and trade requirements of which exporters must be aware to succeed in the EU market and avoid bottlenecks and pitfalls. This chapter covers not only international conventions of the United Nations that may impact export-import trade, but also relevant EU directives and regulations concerning corporate social responsibility (CSR), genetically modified organisms (GMOs) and rules for labelling and marketing of certified organic MAPs and products. This chapter also summarizes selected voluntary sustainability standards that are of growing importance to buyers of MAP ingredients and products.

Chapter 5 deals with export marketing, outlining the main markets for MAP ingredients, the main MAP ingredients imported into the EU, distribution channels, meeting buyers at the right trade shows, and a list of selected import buyers, i.e. those companies known to be importing MAP ingredients with independent third-party evidence of sustainable production and trade, as evidenced by one or more certifications against relevant international VSS.


© Thomas Brendler, Matricaria recutica

Chapter 1
Product description

Medicinal and aromatic plant ingredients

Medicinal and aromatic plants (MAPs) is a broad category. The Medicinal Plant Specialist Group of the International Union for Conservation of Nature (IUCN) provides a useful definition:

> "[I]ncludes plants used to produce pharmaceuticals, dietary supplement products and natural health products, beauty aids, cosmetics, and personal care products, as well as some products marketed in the culinary/food sector."[1]

This section provides definitions of terms relevant to the import, processing, trade and use of herbal ingredients and products marketed in Europe. The definitions are excerpted from European legislation (decisions, directives and regulations of the European Commission, Council, Parliament) and/or from publications of EU agencies such as the European Food Safety Authority (EFSA) concerning foods and food supplements; the European Medicines Agency (EMA) and the European Directorate for the Quality of Medicines (EDQM), a directorate of the Council of Europe concerning herbal drugs and herbal medicinal products; and the Directorate General for Internal Market, Industry, Entrepreneurship and SMEs of the European Council concerning cosmetic products containing herbal ingredients.

Table 1 Terms used for MAP ingredients and definitions

Term	Definition
Botanical raw material	Depending on the country, 'botanical raw materials' may also be referred to as 'botanical drug', 'crude drug', 'herbal drug', 'herbal raw material' or 'plant raw material'. In the European Pharmacopoeia (PhEur),[2] 'herbal drugs' (Plantae medicinales) are defined as '… mainly whole, fragmented or broken plants or parts of plants in an unprocessed state, usually in dried form but sometimes fresh. The word "plant" is used in the broader sense to also include algae, fungi and lichens. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal drugs.'[3]
Essential oil	'Essential oils' (Aetherolea) are defined as an '…odorous product, usually of complex composition, obtained from a botanically defined plant raw material by steam distillation, dry distillation, or a suitable mechanical process without heating. Essential oils are usually separated from the aqueous phase by a physical process that does not significantly affect their composition.'[4]
Extract	The PhEur defines 'herbal drug extracts' (Plantarum medicinalium exracta) as: '… liquid (liquid extraction preparations), semi-solid (soft extracts and oleoresins) or solid (dry extracts) preparations obtained from "herbal drugs" using suitable solvents. An extract is essentially defined by the quality of the herbal drug, by its production process (extraction solvent(s), method of processing, etc.) and by its specifications.'[5]
Fatty oil	'Vegetable fatty oils' (Olea herbaria) are defined as: '… mainly solid or liquid triglycerides of fatty acids. They may contain small amounts of other lipids such as waxes, free fatty acids, partial glycerides or unsaponifiable matters. Vegetable fatty oils are obtained from the seeds, the fruit or the pit/stone/kernel of various plants by expression and/or solvent extraction, then possibly refined and hydrogenated.'[6]

Source: European Pharmacopoeia 11th edition. European Directorate for the Quality of Medicines, at https://www.edqm.eu/en/european-pharmacopoeia-ph.-eur.-11th-edition

[1] See page 5 of the 'International Standard for the Sustainable Wild Collection of Medicinal and Aromatic Plants', at https://www.bfn.de/en/publications/bfn-schriften/bfn-schriften-195-international-standard-sustainable-wild-collection

[2] Find information on the European Pharmacopoeia and how to subscribe to it at https://www.edqm.eu/en/european-pharmacopoeia

[3] Definition excerpted from the Herbal Drugs PhEur monograph, at: https://www.edqm.eu/en/european-pharmacopoeia

[4] Definition excerpted from the Essential Oils PhEur monograph, at https://www.edqm.eu/en/european-pharmacopoeia

[5] Definition excerpted from the Herbal Drug Extracts PhEur monograph, at https://www.edqm.eu/en/european-pharmacopoeia

[6] Definition excerpted from the Vegetable Fatty Oils PhEur monograph, at https://www.edqm.eu/en/european-pharmacopoeia

EU regulations further define herbal substances as 'all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author)' and herbal preparations as 'obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.'[7]

Finished herbal products

Herbal cosmetic products

The European Commission Directorate General for Internal Market, Industry, Entrepreneurship and SMEs maintains an online database of information on cosmetic substances and ingredients (CosIng®) authorized for use in cosmetic products in Europe.[8]

European regulations define 'cosmetic product' as: '… any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.'[9]

Box 1 Example of an herbal and mineral cosmetic product

A toothpaste could be marketed as a non-medicinal herbal or natural cosmetic product, containing mainly water and minerals (calcium carbonate, magnesium aluminium silicate or sodium bicarbonate) in combination with botanical ingredients such as vegetable glycerine obtained from the fatty oil of coconut (*Cocos nucifera*) fruit kernel, extract of calendula (*Calendula officinalis*) flowers (or extracts of other herbs), ammoniated glycyrrhizin obtained from the aqueous extract of liquorice (*Glycyrrhiza glabra*) root, star anise (*Illicium verum*) fruit essential oil, and xanthan gum produced by fermentation of a carbohydrate with the microorganism *Xanthomonas campestris*, among other possible natural cosmetic ingredients.

Source: Authors of this guide

[7] See Consolidated text of Directive 2001/83/EC, at http://data.europa.eu/eli/dir/2001/83/2022-01-01

[8] Access the European Commission CosIng® (Cosmetic Substances & Ingredients) online database: https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.simple

[9] See Consolidated text of Regulation (EC) No 1223/2009, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20220301

Figure 1 Calendula officinalis

Source: © Thomas Brendler

Figure 2 Cocos nucifera

Source: © Thomas Brendler

Herbal food products

European regulations define 'food' (or 'foodstuff') as 'any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. "Food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment.'[10]

'Food' does not include feed; live animals unless they are prepared for placing on the market for human consumption; plants prior to harvesting; medicinal products; cosmetics; tobacco and tobacco products; narcotic or psychotropic substances; residues and contaminants; or medical devices.

Box 2 Example of an herbal food product

A chewing gum could be marketed as a non-medicinal herbal food product, containing mainly herbal ingredients such as chicle (*Manilkara zapota*) tree gummy exudate, candelilla (*Euphorbia antisyphilitica*) leaf wax, acacia (*Acacia senegal*) tree gummy exudate, cane (*Saccharum officinarum*) sugar, vegetable glycerine obtained from the fatty oil of coconut (*Cocos nucifera*) fruit kernel, and non-therapeutic, food flavouring quantities of liquorice (*Glycyrrhiza glabra*) root extract and fennel (*Foeniculum vulgare*) fruit essential oil.

Source: Authors of this guide

Figure 3 Euphorbia antisyphilitica

Source: © Thomas Brendler

[10] See Consolidated text of Regulation (EC) No 178/2002, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02002R0178-20210526

Figure 4 Foeniculum vulgare

Source: © Thomas Brendler

Herbal food supplement products

The European Food Safety Authority (EFSA) defines 'food supplements' as concentrated sources of nutrients or other substances with a nutritional or physiological effect that are packed and marketed in a dosage form such as capsules, pills, tablets or liquids in measured doses. 'A wide range of nutrients and other ingredients might be present in food supplements, including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts.'

Regarding plant and herbal extracts, EFSA clarifies that the use of ingredients other than vitamins and minerals (e.g. botanicals) may be permitted for use in food supplements under other specific legislations depending on the nature of the substance (e.g. novel foods, substances for the fortification of food, foods for specific groups).[11]

Figure 5 Illicium verum

Source: © Thomas Brendler

[11] See EFSA Food Supplements information page, at https://www.efsa.europa.eu/en/topics/topic/food-supplements

Herbal medicinal products

EMA defines a 'medicinal product' as 'a substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action.' As a subset, 'herbal medicinal products' (HMPs) are defined as any medicinal product exclusively containing as active ingredients one or more herbal substances, one or more herbal preparations, or a combination of the two.[12]

Figure 6 Saccharum officinarum

Source: © Thomas Brendler

Chapter 2
European Union classification and tariffs

Combined nomenclature

As per the European Commission Taxation and Customs Union: 'The Combined Nomenclature (CN) is a tool for classifying goods, set up to meet the requirements both of the Common Customs Tariff and of the EU's external trade statistics. The CN is also used in intra-EU trade statistics. It is a further development (with special EU-specific subdivisions) of the World Customs Organization's Harmonized System (HS) nomenclature. This is a systematic list of commodities applied by most trading nations (and also used for international trade negotiations).'[13]

An annex to the CN Regulation is updated and published annually, including any changes that have been agreed at an international level, either at WCO, with regard to HS nomenclature, or within the framework of the World Trade Organization (WTO), with regard to conventional duty rates.[14]

The first two digits are the WCO chapter in the Harmonized System (HS) and first four digits represent the WCO HS heading. The first six digits are the HS subheading for the purpose of a global uniform classification. Building on the six-digit HS code, the CN code of the European Communities adds digits seven and eight. Based on the eight-digit CN code, customs duties, bans, restrictions or other measures relating to import authorizations are determined during import clearance. The ninth and 10th digits, known as TARIC (Integrated Tariff of the European Communities), encode community measures (e.g. antidumping rules, duty suspensions). An 11th digit is added for national use only, for example to encode VAT rates, national bans or restrictions. This is illustrated in Table 2 using saffron (*Crocus sativus*) as an example.

Table 2 HS, CN and TARIC codes using saffron as an example

	Code	Description	Conventional rate of duty (%) and measures
Chapter HS – 2 digits	09	Coffee, tea, maté and spices	–
Heading HS – 4 digits	0910	Ginger, saffron, turmeric (curcuma), thyme, bay leaf, curry and other spices:	–
Subheading HS – 6 digits	0910 20	Saffron:	–
Subheading CN – 8 digits	0910 2010	– – Neither crushed nor ground	Free
	0910 2090	– – Crushed or ground	8.5%
Subheading TARIC – 10 digits	0910 2010 00	– – Neither crushed nor ground	Third country duty: 0%; Tariff preference (selected countries): 0%; Import control of organic products; Restriction on entry into free circulation (selected countries)
	0910 2090 00	– – Crushed or ground	
National Code Number – 11 digits	Country specific 11th digit		

Source: As of 1 January 2021: Consolidated text: Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff, at https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A31987R2658

[13] European Commission Taxation and Customs Union Combined Nomenclature information, at https://ec.europa.eu/taxation_customs/business/calculation-customs-duties/customs-tariff/combined-nomenclature_en

[14] Council Regulation (EEC) on the tariff and statistical nomenclature and on the Common Customs Tariff, at https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A31987R2658

Other countries assign additional digits for various internal reasons. For example, 13 digits are used in the 'Import and Export Tariff of the People's Republic of China'. The first eight digits function as the commodity HS code, digits nine and 10 are customs supervisory additional numbers, and digits 11 to 13 are additional numbers used by China and Inspection Quarantine (CIQ).

European importers must always state an 11-digit code number on the import declaration, while export declarations require only the eight-digit code. Table 3 compares the European Union CN + TARIC codes of selected MAPs with the codes used by China (CCCS + CIQ), India (ITC) and the United States (HTSUS).

In some cases, specific codes are assigned for an item in its various commercially traded forms, such as whole, cut or powdered, distilled essential oil, dry or liquid extract, or extracted oleoresin. In cases where a specific code is not assigned, 'other' is used parenthetically, which indicates that the item is lumped together with other items in the same category.

Table 3 Tariff codes of selected MAPs used by EU, China, India and the US

Description	CN + TARIC	CCCCS + CIQ	HTSUS	ITC
Asafoetida (*Ferula* spp). oleo gum resin	1301 9000 00 (other gums and resins)	1301 9030 00 101 (plant product) 1301 9030 00 102 (medicinal use)	1301 9091 90 (other gums and resins)	1301 9013
Asafoetida oil	3301 2991 00 (other essential oils)	1301 9030 00 103	3301 2951 50 (other essential oils)	3301 2990
Citrus (e.g. orange), fruit peel, dried	0814 0000 00	0814 0000 00 103 (medicinal use)	0814 0010 00	0814 0000
Coriander (*Coriandrum sativum*) fruit, neither crushed nor ground	0909 2100 00	0909 2100 00 999	0909 2100 00	0909 2190
Coriander fruit, crushed or ground	0909 2200 00	0909 2200 00 999	0909 2200 00	0909 2200
Coriander fruit essential oil	3301 2991 00	3301 2999 99 178		3301 2922
Coriander fruit extracted oleoresin	3301 9030 00	3301 9010 90 101 (other extracted oleoresins)		3301 9023
Liquorice (*Glycyrrhiza glabra*, *G. inflata*, *G. uralensis*) root	1211 9086 00 (other medicinal plants)	1211 9036 00 101 (medicinal use) 1211 9036 00 102 (food additive use) 1211 9036 00 103 (edible liquorice)	1211 9089 90 (other medicinal plants)	1211 1000
Liquorice root extract	1302 1200 00	1302 1200 00 101 (food or medicine)	1302 1200 00	1302 1200
Liquorice root dry extract (powder)		1302 1200 00 102 (food additive)		
Liquorice root fluid extract (liquid)		1302 1200 00 103 (food additive)		
Liquorice root extract containing >10% of sucrose but no other added substances	1704 9010 00	–	–	–
Liquorice root and hop strobile extracted oleoresins	3301 9010 00	3301 9010 90 101 (other extracted oleoresins)	3301 9050 00 (other extracted oleoresins)	3301 9029 (other extracted oleoresins)

Description	CN + TARIC	CCCCS + CIQ	HTSUS	ITC
Saffron (*Crocus sativus*) stigma, neither crushed for ground	0910 2010 00	0910 2000 00 101 (medicinal use) 0910 2000 00 102 (seasoning)	0910 2000 00	0910 2010
Saffron stigma, crushed or ground	0910 2090 00			0910 2090
Saffron stamen	–	–		0910 2020

Notes: CCCCS, Commodity Classification for China Customs, Statistics People's Republic of China; CIQ, China and Inspection Quarantine; CN, Combined Nomenclature of the European Union; HTSUS, Harmonized Tariff Schedule of the United States; ITC, India Trade Classification, Department of Commerce

Sources: Trade classification and tariff schedules of the European Union, India, People's Republic of China and the United States

Integrated Tariff of the European Union (TARIC)

TARIC provides a multilingual consultation database integrating all measures related to EU customs tariff, commercial and agricultural legislation.[15] Using liquorice root extract as an example, Table 4 shows TARIC measures for selected countries relevant to the production and trade of liquorice root and extracts made from it.

Table 4 TARIC measures for liquorice root extract CN 1302 1200, selected countries

TARIC measures	Description	Countries
General system of preferences (GSP)	GSP-EBA – special arrangement for the least-developed countries – everything but arms (EBA 2005)	Afghanistan
	GSP – General arrangements (GSP 2020)	India, Syria, Tajikistan
	GSP+ – incentive arrangement for sustainable development and good governance (GSP+ 2027)	Pakistan, Uzbekistan
Import control of organic products	Subject to EU regulation R2306/21 See table note **CD808**	Afghanistan, Armenia, Azerbaijan, China (People's Republic of), Chinese Taipei, Georgia, India, Iran (Islamic Republic of), Japan, Kazakhstan, Korea (Republic of), Pakistan, Syria, Tajikistan, Turkey, Turkmenistan, Uzbekistan
Restriction	Restriction on entry into free circulation (06-01-2022 – 02-07-2022) See table note **CD597**	India, Korea (Republic of)
Tariff preference	0%	Afghanistan, Georgia, India, Japan, Korea (Republic of), Pakistan, Syria, Tajikistan, Turkey, Uzbekistan
Third country duty	3.20%. Subject to EU regulations R2658/87 and R2204/99	Afghanistan, Armenia, Azerbaijan, China (People's Republic of), Chinese Taipei, Georgia, India, Iran (Islamic Republic of), Japan, Kazakhstan, Korea (Republic of), Pakistan, Syria, Tajikistan, Turkey, Turkmenistan, Uzbekistan

[15] TARIC database, at https://ec.europa.eu/taxation_customs/business/calculation-customs-duties/customs-tariff/eu-customs-tariff-taric_en

Notes: CD597: The release for free circulation of consignments of food and feed listed in Annexes I and II to regulation (EU) 2019/1793 shall be subject to the presentation of a duly finalized common health entry document as provided for in Article 57(2)(b) of regulation (EU) 2017/625, which confirms that the consignment is in compliance with the applicable rules referred to in Article 1(2) of that regulation.

CD808: If goods bear a reference to organic production in the labelling, advertising or accompanying documents, the declarant has to present the certificate of inspection C644 as referred to in the Article 45(1)(ii) of regulation (EC) 834/2007 (equivalent products). If the goods are not equivalent products, code Y929 must be declared. These provisions shall apply in addition to the rules regarding the use of the common health entry document by the competent authorities at border control posts in accordance with Article 56(3), point (b)(i), of regulation (EU) 2017/625 and at control points in accordance with Commission delegated regulation (EU) 2019/2123 and with the rules on decisions on consignments laid down in Article 55 of regulation (EU) 2017/625.

Source: TARIC measures consultation database, search term ‘liquorice’


© Thomas Brendler, Foeniculum vulgare

Chapter 3
Regulatory requirements

Regulatory categories for herbal substances and finished products

Cosmetic ingredients/products

According to regulation (EC) 1223/2009, cosmetic products are defined as 'any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.'[16]

The same regulation governs manufacture, safety requirements, product documentation and marketing notification procedures. Its annexes further list prohibited and restricted substances, colourants, preservatives, and other additives. It replaced directive 76/768/EC and introduced some significant changes:

- Strengthened safety requirements for cosmetic products;
- Introduction of the notion of 'responsible person';[17]
- Centralized notification of all cosmetic products placed on the EU market;[18]
- Introduction of reporting of serious undesirable effects (SUE);[19]
- New rules for the use of nanomaterials in cosmetic products.[20]

CosIng® is the EC database with information on cosmetic ingredients contained in the appendices of regulation (EC) 1223/2009, the inventory of cosmetic ingredients and opinions on cosmetic ingredients of the Scientific Committee for Consumer Safety.[21]

Product labelling reflects the data compiled in the 'product information file' and is governed by the principles laid out in regulation (EC) 1272/2008 as amended.[22] Specifically, cosmetic product labels must include:

- Full commercial name;
- Product function;
- Particular precautions for use;
- Ingredients list;
- Expiry date;
- Responsible person name and address;
- Manufacturer name and address;
- Batch number;
- Product's country of origin (if made outside the EU);
- Nominal quantities.

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[16] Further details at http://data.europa.eu/eli/reg/2009/1223/2022-07-31

[17] Only cosmetic products for which a legal or natural person is designated within the EU as a 'responsible person' can be placed on the market. The responsible person compiles the 'product information file' and is responsible for the accurate labelling of a cosmetic product.

[18] The cosmetic product notification portal, at https://single-market-economy.ec.europa.eu/sectors/cosmetics/cosmetic-product-notification-portal_en

[19] More information on market surveillance requirements and SUE reporting at https://single-market-economy.ec.europa.eu/sectors/cosmetics/market-surveillance_en

[20] More information on the use of nanomaterials in cosmetics at https://single-market-economy.ec.europa.eu/sectors/cosmetics/cosmetic-products-specific-topics/nanomaterials_en

[21] The CosIng database can be found at https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.simple

[22] The consolidated text for regulation (EC) 1272/2008, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008R1272-20220301

Colipa, the umbrella body in Europe that governs all cosmetic and product care products, provides guidelines for the evaluation of the efficacy of cosmetic products. These guidelines aim to assist the cosmetics industry to comply with the applicable European regulations for the efficacy evaluation of cosmetic products. Because methodologically sound research is essential for the efficacy evaluation, these guidelines also provide an overview of established testing methodologies.[23]

Regulation (EU) 655/2013 provides some context for how claims related to cosmetic products need to be substantiated.[24] Additional guidance is provided by a technical document compiled by the Sub-Working Group on Claims.[25]

Food additives, enzymes, flavourings and other substances added to food

Towards the end of 2008, existing legislation was consolidated into simplified regulations covering all food improvement agents, namely regulation (EC) 1333/2008 on food additives, regulation (EC) 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods, regulation (EC) 1332/2008 on food enzymes, and directive 2009/32/EC on extraction solvents used in the production of foodstuffs and food ingredients.

Food additives are defined as 'any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods.'[26]

Food flavourings are defined as 'products not intended to be consumed as such, which are added to food in order to impart or modify odour and/or taste; made or consisting of the following categories: flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings, flavour precursors or other flavourings or mixtures thereof.'[27]

Food enzymes are defined as 'products obtained from plants, animals or microorganisms or products thereof including a product obtained by a fermentation process using microorganisms.'[28]

Regulation EC 1331/2008 introduced a common authorization procedure for these agents. Once authorized, these substances are included the EU lists of permitted food additives,[29] flavourings[30] and enzymes. The Union List of food enzymes will be adopted once EFSA has issued an opinion on each food enzyme included in the register.

EFSA's expert Panel on Food Additives and Flavourings conducts safety evaluations of food additives and flavourings. As part of its safety evaluations, EFSA seeks to establish an acceptable daily intake for each substance.

EFSA has developed and published guidance for submission for food additive evaluations,[31] data required for the risk assessment of flavourings[32] and submission of dossiers on food enzymes.[33] To support the

[23] The Colipa web portal: https://colipa.eu/

[24] Full text at http://data.europa.eu/eli/reg/2013/655/oj

[25] Guidance document at https://ec.europa.eu/docsroom/documents/24847

[26] The full text of regulation (EC) 1333/2008 on food additives at http://data.europa.eu/eli/reg/2008/1333/2022-07-20

[27] The full text of regulation (EC) 1334/2008 on flavourings at http://data.europa.eu/eli/reg/2008/1334/2021-11-24

[28] The full text of regulation (EC) 1332/2008 at http://data.europa.eu/eli/reg/2008/1332/2012-12-03

[29] Access the database at https://food.ec.europa.eu/safety/food-improvement-agents/additives/database_en

[30] Access the database at https://webgate.ec.europa.eu/foods_system/main/?sector=FFL&auth=SANCAS

[31] Guidance document at https://www.efsa.europa.eu/en/efsajournal/pub/2760

[32] Guidance document at https://www.efsa.europa.eu/en/efsajournal/pub/1623

[33] Guidance document at https://www.efsa.europa.eu/en/efsajournal/pub/6851

calculation by applicants of estimates of exposure to the food additive and its by-products, EFSA has developed a 'food additives intake model' template.[34]

All food additives are identified by an E number. Product labels must identify both the function of the additive in the finished food and the specific substance used, either by referring to the appropriate E number or its name. The former also applies to food enzymes.

Food ingredients (including novel and traditional foods) and products

In Europe, regulation (EC) 178/2002 lays out common principles and responsibilities pertaining to food law and food safety (including the establishment of EFSA). Therein, food is defined as 'any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.' The regulation also sets demarcations, e.g. it does not cover feed, medicinal (including medical devices), cosmetic or narcotic products, live animals, plants before harvest etc.; however, it leaves oversight largely to national legislation.[35]

Novel foods are a food subcategory in the context of this work; as of 2018, they are governed by Novel Foods Regulation (EU) 2015/2283. Foods are considered novel if they are without a history of significant consumption within the EU prior to May 1997. To bring a novel food to market, companies must apply for authorization, presenting data related to identity, composition, quality of manufacture, use and exposure, safety etc.[36]

The category of traditional foods from third countries (Article 14) is of relevance to this work as it provides new market opportunities for traditional foods that can be brought to the EU market following a relatively simple notification procedure.

This simplified procedure applies if the food or food ingredient:

- Is derived from microorganisms, fungi or algae, plants or animals, or cell/tissue cultures;
- Originates from primary production, i.e. rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter, and includes hunting and fishing and the harvesting of wild products, processed or unprocessed;
- Has a history of safe food use, confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country.

Data requirements and procedural steps for traditional foods from third countries are specified in Commission Implementing Regulation (EU) 2017/2468.[37]

If a novel food does not meet the criteria of a traditional food from third countries, a full authorization procedure is required in which EFSA carries out a safety assessment. Data requirements and procedural steps for full procedures are specified in Commission Implementing Regulation (EU) 2017/2469.[38]

Regulation (EC) 178/2002 also stipulates the creation of a Union List of Novel Foods. This positive list contains all authorized novel foods. New novel foods are added to the Union List by means of Commission Implementing Regulations. Once a novel food is added to the Union List, the authorization (new and old) becomes generic, i.e. once authorized, a novel food can be used by any food business operator provided the conditions of use and specifications are met.

[34] More information as well as the template at https://www.efsa.europa.eu/en/applications/food-improvement-agents/tools

[35] Full text of Regulation (EC) 178/2002 as amended, at http://data.europa.eu/eli/reg/2002/178/2022-07-01

[36] Full text of Regulation (EU) 2015/2283 as amended, at http://data.europa.eu/eli/reg/2015/2283/2021-03-27

[37] Full text of Commission Implementing Regulation (EU) 2017/2468 as amended, at http://data.europa.eu/eli/reg_impl/2017/2468/2021-03-27

[38] Full text of Commission Implementing Regulation (EU) 2017/2469 as amended, at http://data.europa.eu/eli/reg_impl/2017/2469/2021-03-27

Only newly developed scientific evidence and proprietary data can be protected for five years. This recently created category offers market access with reasonable effort for products that meet the criteria, even though the lack of protection may be contrary to efforts to protect traditional knowledge and access and benefit sharing (ABS).

Box 3 Case study: Market access for an herbal novel food in the EU

Traditional Novel Food from a third country: Bambara groundnut (BIZ, Zimbabwe)

Bambara groundnut (*Vigna subterranea* (L.) Verdc., syn. *Voandzeia subterranea* (L.) Thouars) is a tropical legume with a broad and extensive history of use as a staple food in Africa and elsewhere, including South-East Asia and Brazil. Traditional use is evidenced by a large body of literature, especially in Africa.

Bambara groundnut is nutritionally valuable, especially due to its high protein content. Bambara groundnuts also supply – next to saturating carbohydrates – valuable fibres and minerals. Further, the crop is low in fat, which may be of special interest in weight management.

Bambara groundnut is particularly promising in agriculture due to its drought resistance, especially considering climate change and increasing scarcity of rain and water for irrigation.

The applicant, Bio Innovation Zimbabwe (BIZ), is a specialized research organization. Its mission is to create wealth among rural producers and provide consumers in Zimbabwe and external markets with high-quality products through the commercialization of underutilized species that are resilient to the effects of climate change.

This mission entails addressing constraints to commercialization along the entire value chain, targeting high-potential plant species based on sound consumer and market research. BIZ seeks to achieve multi-level impact – creating wealth for households, helping communities thrive, promoting conservation of natural resources at a landscape level, and helping to grow the national economy.

Bringing Bambara groundnut to markets in Europe as a traditional novel food will allow African farmers to produce the beans on a larger scale, increasing their incomes, which in turn will strengthen the local economy.

BIZ operates as an umbrella/hub organization for smallholder growers of Bambara groundnut, as well as aggregators/offtakers and processors. As such, specifications and processing procedures in the application dossier – while in alignment with GACPs and other certifications – are generic, modelled on those for other legume crops, and designed to match EU regulations.

Aspects that received specific attention in the assessment process include:

- Propagation, growth and harvesting conditions;
- Measures for production control and quality, and safety assurance:
  - Handling of unprocessed food and raw materials for further processing (mycotoxins, insects etc.);
  - Processing contaminants;
- Analytical information on at least five independently produced batches;
- Full description of all the analytical methods;
- Potential risk of allergic reactions;
- Potential for nutritional disadvantage.

The assessment is ongoing.

Source: Bio Innovation Zimbabwe (BIZ)

Figure 7 Bambara groundnut (*Vigna subterranea*)

Source: © BIZ

Foods for specific uses

Foods for specific uses, governed by Regulation (EU) 609/2013,[39] is another category of potential significance as it splits into three subcategories:

- Food for specific medical purposes (FSMP): Regulation (EU) 2016/128;[40]
- Total diet replacement for weight reduction: Directive 96/8/EU;[41]
- Foods for infants and young children: Regulation (EU) 2016/127[42] and Directive 2006/125/EU.[43]

FSMP is defined as '[F]ood specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolize or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone.'

[39] The full text of Regulation (EU) 609/2013: http://data.europa.eu/eli/reg/2013/609/2021-04-28

[40] Full text of regulation (EU) 2016/128, at http://data.europa.eu/eli/reg_del/2016/128/2021-07-15

[41] Full text of directive 96/8/EU, at http://data.europa.eu/eli/dir/1996/8/2007-06-20

[42] Full text of regulation (EU) 2016/127, at http://data.europa.eu/eli/reg_del/2016/127/2022-04-01

[43] Full text of directive 2006/125/EU, at http://data.europa.eu/eli/dir/2006/125/oj

Naturally occurring foodstuffs used in their natural state, without undergoing any special processing or formulation, are not considered FSMP, which is only intended for the diseased. Usage under medical supervision is a key element in classifying a product as FSMP. With the available EC[44] and EFSA[45] guidance and the fact that both the EC and EFSA might be involved in the appropriate classification of a product as FSMP, opportunities to market a product as FSMP have become more limited.

It will be difficult to find arguments supporting the classification of a product as FSMP if food supplements with a similar composition/dosage can be found on the EU market. In any case, a number of conditions must be met for a product to qualify for this category (see Figure 1).

Figure 8 FSMP checklist

FSMP is food	✓
FSMP is specifically formulated or processed	✓
The target group of FSMP are patients with a specific (defined) disease	✓
FSMP needs to be taken under medical supervision	✓
Possibility of the dietary management of the disease is given	✓
(Realistic) modification of the normal diet is not possible	✓
Efficacy and suitability is proven by scientific data	✓

Source: Prepared by the authors of this guide

Food supplement ingredients and products

In the EU, food (dietary) supplements are regulated by Directive 2002/46/EC as amended[46] and defined as 'foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities' whereby nutrients may be vitamins or minerals. Allowable health claims associated with aforementioned 'nutrients or other substances with a nutritional or physiological effect' are governed by regulation (EC) 1924/2006 as amended,[47] articles 13.1, 13.5 and 14, and pertain specifically to:

- Role of a nutrient or other substance in growth, development, and the functions of the body;
- Psychological and behavioural functions;
- Slimming, weight control, reduction of hunger, increase of satiety, reduction of energy available from the diet;
- Reduction of disease risk;
- Children's development and health.

[44] EC guidance, at https://food.ec.europa.eu/safety/labelling-and-nutrition/specific-groups/food-special-medical-purposes_en

[45] Scientific and technical guidance on foods for special medical purposes, at https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6544

[46] See http://data.europa.eu/eli/dir/2002/46/oj

[47] See http://data.europa.eu/eli/reg/2006/1924/2014-12-13

The regulation also tasks EFSA with the assessment of the scientific substantiation and authorization of such health claims.[48] However, most health claims related to botanicals have either been rejected as insufficiently substantiated or placed 'on hold', i.e. remain unassessed.[49] Most approved claims pertain to vitamins and minerals.

If the introduction of the traditional herbal registration (THR) category (see below) and, with it, the opportunity to make mild health claims based on traditional use, was intended to 'attract' botanicals from the food supplement category, then the motion has largely failed. Marketers have shown to prefer the more economical route of manufacturing according to food standards and either promote food supplements containing botanicals without claims, relying on consumers' informed choice, or formulate with vitamins and minerals to be able to use allowable claims for the entire formula.

While the THR directive has created a portfolio of quality herbal medicines, it has not achieved to push botanical food supplements of indiscernible quality off the market.

Medicinal ingredients and products

Finished HMPs require the applicant to obtain pre-marketing authorization through a product registration procedure. There are three main regulatory pathways for an HMP to gain market access in EU member states:

1. HMPs with a long tradition of medicinal use (at least 30 years, including 15 in the EU) may be registered as traditional herbal medicinal products (THMPs), also referred to as THRs, when an applicant submits sufficient levels of quality and safety evidence with efficacy evidence based on traditional use data.

2. Another product type is the well-established use herbal medicinal product (WEU-HMP). Marketing authorization requirements for WEU-HMPs are similar for evidence of quality, but evidence of efficacy and safety may be supported by published scientific literature.

3. Stand-alone or mixed applications are another possibility whereby safety and efficacy evidence are based on the applicant's own development or a combination of own studies and bibliographic data.

It is also possible to apply for a full marketing authorization (MA), which requires new clinical trial data on a company's specific HMP. Furthermore, there are procedures for obtaining marketing authorization for anthroposophical and homoeopathic HMPs. Figure 2 summarizes the category characteristics.

[48] More information on how EFSA assesses health claims can be found at https://www.efsa.europa.eu/en/topics/topic/health-claims

[49] The current list of 'on hold' assessments is available at https://www.efsa.europa.eu/sites/default/files/2021-06/questions-on-hold-botanical-claims.xlsx. Note that, until assessed, these claims can be used to market the supplement ingredients concerned.

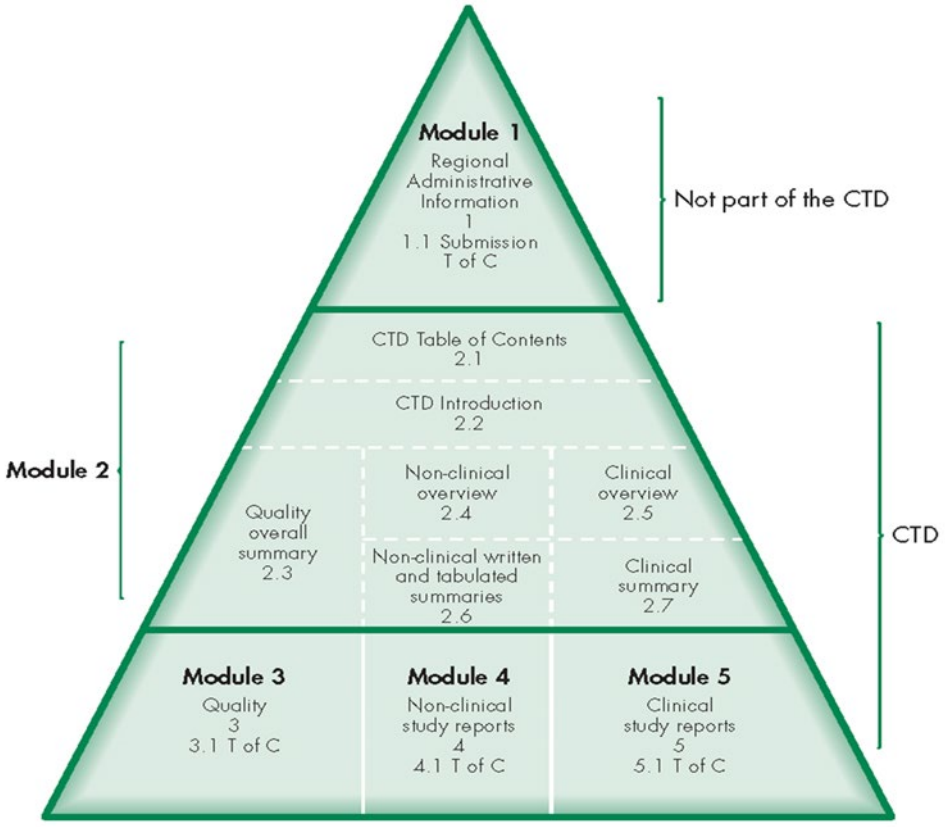
Figure 9 EU regulatory categories for herbal medicinal products

<table>
<tr><th colspan="2">Marketing authorization</th><th>Registration</th></tr>
<tr><td colspan="3">Patient information/labelling/advertising/pharmacovigilance</td></tr>
<tr><td colspan="3">Efficacy</td></tr>
<tr><td>New, product-specific evidence (clinical trials)</td><td>Bibliographic evidence</td><td>Traditional use evidence (or HMPC monograph)</td></tr>
<tr><td colspan="3">Safety</td></tr>
<tr><td>New, product-specific evidence (toxicological and safety studies)</td><td>Bibliographic evidence</td><td>Expert report (bibliographic)</td></tr>
<tr><td colspan="3">GACP/GMPs/quality assurance and control</td></tr>
<tr><td>New (full MA)</td><td>WEU-HMP</td><td>THMP/THR</td></tr>
<tr><td></td><td colspan="2">Community herbal monographs/community list</td></tr>
<tr><td></td><td></td><td>Directive 2004/24/EC</td></tr>
<tr><td colspan="3">Directive 2001/83/EC as amended</td></tr>
</table>

Source: This figure prepared by the authors of this guide

Commonalities shared between all three categories are requirements pertaining to standards for agriculture and collection, manufacturing and quality control, and the format in which applications for authorizations are to be submitted to the competent authorities. The latter is referred to as CTD, a standard designed to be used across Europe, Japan, the United States and other participating countries as part of a broader attempt to harmonize aspects of the world's drug regulations. Figure 3 presents the structure of CTD and the required information to be submitted therein.

Figure 10 CTD structure



Notes: Module 1 holds administrative data: the application form, expert reports, summary of product characteristics, patient information leaflet, packaging, GACP and GMP compliance, pharmacovigilance, and requirements. It is, however, not strictly part of the CTD as its format is governed by national competent authorities. Module 2 contains bibliographic or expert evidence for traditional use or proof of efficacy, and bibliographic reviews and/or expert report of safety data and a summary of quality and production data. Module 3 is the pharmaceutical part of the dossier and presents quality data for APIs and the finished product. Modules 4 and 5 contain non-clinical and clinical study reports or traditional use evidence, respectively.[50]

Source: Brendler, T., Phillips, L. D. and Spiess, S. (2009). A practical guide to licensing herbal medicinal products. London: Pharmaceutical Press.

[50] For more information, see https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-2_en#volume-2b---presentation-and-content-of-the-dossier

Box 4 Case study: Market access for an herbal medicinal product

First TCM THR approved by Dutch competent authorities

In 2012, the Dutch Medicines Evaluation Board (MEB) granted SU BioMedicine B.V. from the Netherlands a registration for Diao Xin Xue Kang, capsules for oral use as a traditional herbal medicinal product (THMP). These capsules contain 100 mg of an extract of dried rhizomes of *Dioscorea nipponica Makino*, equivalent to 5-6.67 g of dried plant material. The drug to extract ratio is 50.0–66.7:1.

Diao Xin Xue Kang is used for the relief of headache and muscular pains and muscle cramps in the neck, back and legs. This use is based on traditional use only and not on demonstrated clinical efficacy. The registration of these capsules is based exclusively on the longstanding use of *D. nipponica* root as a THMP in both China and Europe.

The application of Diao Xin Xue Kang capsules was discussed in multiple MEB meetings. Initially, it was concluded that a full assessment of the pre-clinical safety data could not performed because the complete study reports of the available repeated dose toxicity, genotoxicity and reproduction toxicity studies were not provided. Additional safety data were provided and the MEB decided that the pre-clinical safety data were insufficient because genotoxicity tests did not comply with existing guidelines.

Furthermore, it was concluded that the submitted pharmacovigilance data did not prove that the use of Diao Xin Xue Kang is safe due to strong limitations of the provided data. Based on new data provided by the applicant, it was concluded that the submitted clinical safety data were insufficient, because extrapolation of the data provided, concerning the use in patients and the safety as acquired in China, to the European population was inadequate.

The applicant was asked to substantiate the extrapolation of safety data obtained in the Chinese population to the Western population and to provide more information on the extent of use in Europe. Eventually, the MEB decided that, on the basis of the data submitted, a registration could be granted if the safety of the product is monitored with a pharmacovigilance system and the results of a genotoxicity test conducted in accordance with existing EU guidelines are submitted before the renewal of the registration.

At the time of assessment and registration, no preparations of *D. nipponica* were registered as a medicinal product in the EU but, in China and Russia, extracts of *D. nipponica* had been on the market for more than 30 years. The data supplied by the applicant thus substantiated 30 years of medicinal use of *D. nipponica*, including at least 15 years in the European Community.

The herb was first recorded in 1959 and, in 1977, a monograph of *D. nipponica* was included in the Pharmacopoeia of the People's Republic of China (PPRC). Diao Xin Xue Kang capsules have been marketed in China since 1970. Over the past 30 years, more than 100 million people have used the product. A product containing an extract of *D. nipponica* entered the Russian market in 1975. For the justification of traditional use in the EU, reference was made to European herbal handbooks, sales figures and documented use in France, Belgium, the Netherlands, and the UK.

Release specifications of the herbal substance comprised general characteristics, identification by microscope and thin-layer chromatography (TLC), foreign matter, residual solvent, microbiological quality, toxic metals, radioactivity, pesticides and marker content. Stability studies have been conducted with three production scale batches in the final container closure system. The data support the storage conditions and shelf life. A detailed description of the manufacturing process (extraction, drying, blending), including batch size, manufacturing formula, process conditions, in-process controls and flow diagram, was provided.

Release specifications for the extract comprised appearance, identification by TLC fingerprint, marker content, loss on drying, residual solvent, pesticides, heavy metals, aflatoxins and microbiological purity. Identity was tested in accordance with the monograph of the PPRC. Other parameters were tested in accordance with European Pharmacopoeia (PhEur).

Stability data were presented of three production-scale batches tested under real time and accelerated conditions. The stability data provided showed no incompatibilities between the herbal preparation and the container. All specifications were met at all time points. The marker content remained stable, and no changes were observed in the phytochemical fingerprint profile.

Diao Xin Xue Kang capsules are manufactured by Chengdu Diao Pharmaceutical Group Co. in Chengdu, Sichuan, People's Republic of China. The manufacturer was inspected by the Dutch Inspectorate, and EU GMP compliance was confirmed. Batch release of the finished medicinal product for the EU is performed by Tjoapack B.V. (Emmen, Netherlands), a company that is GMP-certified by the Dutch Inspectorate for batch releases in the EU.

The finished product specification includes tests for appearance, uniformity of mass, loss on drying, disintegration time, identification (chemical test and TLC), marker content and microbiological purity. Analytical data of three production scale batches were provided, demonstrating compliance with the specification.

Stability studies were performed in accordance with the relevant International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines. Limit values were identical to these of the release specifications (within the acceptable tolerance interval for the marker of 95%-105% related to t0). Analytical procedures were identical to those used for the testing of release specifications.

Expert reports written by nonclinical substantiated the safety of Diao Xin Xue Kang capsules. The expert reports included an overview of available safety data from literature. Based on experimental details provided it was not possible to ascertain if the data assessed in the review would comply with today's regulatory safety testing requirements with regards to design, conduct and analysis. However, preclinical data submitted did not indicate safety concerns. Because the longstanding use of the product is satisfactorily demonstrated, the lack of a complete standard pre-clinical safety package is considered acceptable and in compliance with the Guideline on non-clinical documentation for herbal medicinal products in applications for simplified registration.

The clinical data provided (241 clinical studies including more than 16,000 patients) could only be considered as supportive because the studies were not in compliance with existing EU guidelines. As the studies were performed in China, it was not clear to what extent the data can be extrapolated to the European population. However, the applicant demonstrated that extracts of *D. nipponica* have long history of safe use in China and in Russia.

Diao Xin Xue Kang capsules to date is the only product, the composition and indication of which originate in a traditional medicinal paradigm outside Western herbalism, to be registered as a THR in Europe.

Key learning

- Traditional use evidence must demonstrate significant consumption within and outside the EU for the desired indication and dosage form;
- Evidence for safety must comply with modern evaluation standards;
- Evidence for clinical efficacy has a supportive role only;
- Pharmacovigilance data must be applicable to the target demographic;
- GACP must be demonstrated;
- Processing and manufacture must be GMP certified;
- Batch release must occur within the EU;
- All quality requirements pertaining to pharmaceutical manufacturing must be met.

Source: CBG MEB (2012) Public Assessment Report: Diao Xin Xue Kang, capsules for oral use SU BioMedicine B.V., The Netherlands RVG 102142, NL-PAR, at https://db.cbg-meb.nl/pars/h102142.pdf

The marketing authorization procedure evaluates efficacy, safety and pharmaceutical quality of a medicinal product. The necessary documentation can be submitted to the regulatory authorities by the pharmaceutical company that intends to place the medicinal product on the market or a designated representative.[51]

Under the centralized authorization procedure, a pharmaceutical company or its representative submits a single application to EMA. After assessment by EMA, the EC issues a legally binding decision allowing the marketing authorization holder to market the medicine throughout the EU per single marketing authorization.[52]

Alternatively, a pharmaceutical company may apply for marketing authorization in several EU member states via the mutual recognition procedure (a marketing authorization granted in one member state to be recognized in other member states) or by decentralized procedure (a new HMP to be simultaneously authorized in several member states).

Further, all member states maintain their own national authorization procedures. A THR is generally only granted by national procedure, even though some member states allow for the mutual recognition procedure to be applied.

[51] For more information, see: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-2_en#volume-2a---procedures-for-marketing-authorisation

[52] Includes all EU member states, Norway, Iceland and Liechtenstein

In summary, European regulations governing market access for herbal medicinal products are strict and aligned with standards applicable to other pharmaceutical products. The traditional use category, while providing an opportunity for less well-studied APIs with strong traditional use evidence, is effectively limited to APIs with a tradition within the EU.

Full marketing authorization

The MA category is for new products or APIs with ingredient/product-specific evidence for safety and efficacy. Botanical ingredients or products with no history of use in the EU must be tested and documented with the same rigour as conventional medicinal products or APIs.

Unfortunately, many traditional herbal ingredients and products from paradigms other than Western herbalism that were not early introductions, e.g. by colonial powers, entrepreneurs or diaspora, and are thus not 'grandfathered' in according to EU traditional use criteria, fall into this category. For strictly medicinal botanicals without evidence for substantial use in the food category, this may well be the only regulatory category for EU market access.

Well-established use marketing authorization

The well-established use (WEU) category is effectively for 'me-too' products that reference bibliographic evidence for efficacy and safety but come without proprietary clinical data. Provision of product-specific pre-clinical or clinical trials is not required if API(s) have been in well-established medicinal use within the EC for at least 10 years, which includes recognized efficacy and an acceptable level of safety.

Traditional herbal registration

The traditional herbal registration (THR) category replaces the requirement of sufficient clinical efficacy and safety evidence with that of long-standing traditional use, specifically, for at least 30 years worldwide and 15 years within the EU. Evidence for use must be continuous, dosage forms must correspond, and the product and health claims associated with it must be suitable for over the counter and unsupervised use. However, what constitutes sufficient evidence for traditional use is interpreted differently under national rule and is thus not fully harmonized.

Community herbal monographs/community list

EMA has, over the last 15 years compiled close to 200 monographs and public statements for herbal medicinal products that fall into the WEU-HMP and/or THR categories.

A European Union herbal monograph (formerly known as a community herbal monograph)[53] reflects the scientific opinion of the HMPC on safety and efficacy data concerning the medicinal use of an herbal substance and its preparations. This opinion is based on evaluation of all available information, including non-clinical and clinical data and documented long-standing use and experience in the community.

EU monographs may cover well-established use (marketing authorization) and traditional use (simplified registration). A final monograph can be referenced in a marketing authorization application (well-established use) or a traditional herbal registration application (traditional use part) provided that the API and associated health claims correspond with the listed preparations, dosage forms and claim language, respectively.

In contrast, EU list entries are legally binding to applicants and competent authorities alike. An applicant is not required to provide safety and traditional use evidence as part of a licence application; nor may competent authorities request additional data for the assessment if API and related health claims comply with the information contained in the EU list entry.

[53] EU herbal monographs are available at https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Herbal/field_ema_herb_outcome/european-union-herbal-monograph-254; and community list entries are available at https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Herbal/field_ema_herb_outcome/european-union-list-entry-256

Anthroposophical and homoeopathic HMPs

Homoeopathic and anthroposophical medicinal products are subject to the same application procedures as herbal medicinal products (Article 8 in Directive 2001/83/EC) regarding manufacturing procedures, technical quality of the product and all other requirements. A standard full MA, a simplified registration procedure (Article 14 and 15 in Directive 2001/83/EC) and a national marketing authorization based on special national rules (Article 16.2 in Directive 2001/83/EC) allow for alternative documentation of efficacy.

Box 5 Case study: Market access for an herbal food supplement in the US

Traditional medicine from a third country: Sceletium (*Mesembryanthemum tortuosum* L.) aerial parts

This case study investigates and compares how a Southern African herbal medicine with great potential as an anxiolytic and mild antidepressant – *Mesembryanthemum tortuosum* L. [syn. *Sceletium tortuosum* (L.) N.E.Br.] aerial parts – fares internationally in today's regulatory environment. The plant is a succulent commonly found in the dry western parts of South Africa. It is a traditional medicinal plant used for relieving abdominal pain and hunger and to enhance mood.

More recently, it has attracted attention for its potential in the treatment of depression and anxiety, promote well-being and provide stress relief. Potential mechanisms for its observed clinical effects have been described and the main active constituents have been identified as mesembrine alkaloids and some of their individual properties have been investigated.

Many herbal ingredients from indigenous cultures and traditional paradigms of medicine have made a successful career in developed markets as foods, food supplements, cosmetics or medicines. Historically, it was the explorers, settlers and traders, who freely dispersed the ingredients of their traditional apothecaries. This trend has slowed, primarily due to increasingly stringent regulations affecting developed markets. In the days of ethical product development, governed by the principles of the Nagoya protocol, patenting to protect such investment has become controversial.

While access-benefit-sharing (ABS) agreements protect traditional knowledge at its source, it has become increasingly difficult to protect proprietary (manufacturing) knowledge in the marketplace. This dilemma is – to a varying degree – exacerbated by national regulations. Regulatory barriers and 'loopholes' form a highly heterogeneous landscape of opportunity, ranging from relatively open to almost entirely closed systems. Consequently, one and the same product may have to be force-fitted into different national regulatory categories, or the best regulatory intentions may prevent it from reaching the consumer altogether because the cost associated with market entry becomes prohibitive.

For instance, Europe's regulatory landscape creates a conundrum for ingredients such as sceletium. In the food (and food supplement) category, it would be considered 'novel'; however, despite it being regulated as a food in its country of origin, competent authorities may likely not consider it suitable due to its predominant history as a traditional herbal medicine. At the same time, it has not been present in the EU marketplace for at least 15 years, nor would it be considered suitable for over-the-counter products; thus, it fails to qualify as a THMP. It has no flavour, fragrant or cosmetic uses. This leaves only one category for legal market access, through MA.

Drug development, in turn, requires considerable investment and bears substantial risks to such investment. Consequently, the ingredient, while interesting, unique and potentially beneficial in a therapeutic setting, has no commercial potential. Indeed, there are no legal products containing sceletium in the European marketplace to date.

In the US, on the other hand, while neither the botanical drug route nor the new drug application route appear to be affordable or practical for the marketing of sceletium ingredients and products, sceletium as an ingredient that is regulated as a conventional food in its country of origin may not require notification as a new dietary ingredient to be used in dietary supplement products. Alternatively, to be used as an ingredient of a conventional food or supplement product, it must be generally recognized as safe (GRAS), either through evaluation by the FDA or an independent conclusion of GRAS status. Although components of a dietary supplement product do not need to be GRAS for their intended use, GRAS substances should generally be acceptable for use in dietary supplement products.

In February 2011, independent conclusion of GRAS status was confirmed for a very specific extract of *M. tortuosum* and supplement products containing the extract appeared in the US market in soon after.

Source: Brendler et al. (2021)

Figure 11 Mesembryanthemum tortuosum

Source: © Thomas Brendler

Quality assurance

For quality assurance of MAP materials, growing, harvesting and post-harvest primary processing should occur according to suitable good agricultural and collection practice (GACP) guidelines.[54] Secondary processing should occur according to suitable good manufacturing practice (GMP) guidelines.[55]

Sources: Left: WHO GACP guidelines. Centre: WHO GMP guidelines. Right: ISO 9001:2015 guidance for SMEs

[54] See EMA GACPs, at https://www.ema.europa.eu/en/good-agricultural-collection-practice-starting-materials-herbal-origin

[55] See WHO GMPs, at https://apps.who.int/iris/bitstream/handle/10665/43672/9789241547161_eng.pdf

Depending on the regulatory classification of the finished herbal product, certain quality assurance standards may be mandatory or voluntary. However, even if a standard is not required by regulation, the prospective customer may still require it of their qualified suppliers. Customers may likely require ingredient suppliers to adhere to various quality and safety standards of the International Organization for Standardization (ISO) such as:

- ISO 9001:2015 Quality management systems – Requirements[56]
- ISO 22000:2018 Food safety management systems – Requirements

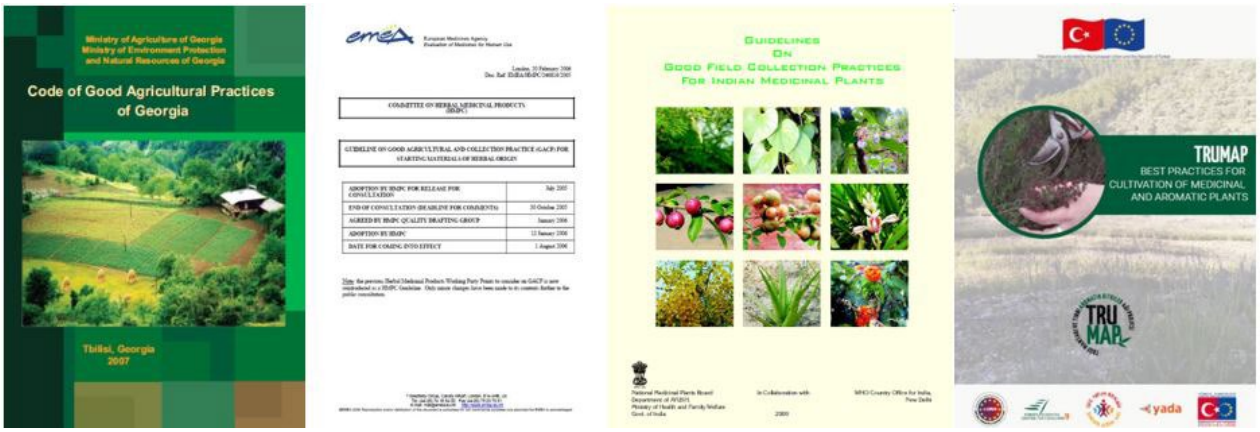
Box 6 Tip: Quality certificates

After implementation of quality assurance and quality management standards, have an independent, third-party, accredited inspection and certification organization audit your operation for conformance to the standards. Your prospective customers will request copies.

Make it easy for prospective customers to find and download relevant certification documents from your website. Currently valid certificates are essential for vendor qualification purposes.

Source: Authors of this report

Good agricultural and collection practices



Sources: Left: Code of Good Agricultural Practices of Georgia, Ministry of Agriculture of Georgia. Centre left: Guideline on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin, European Medicines Agency. Centre right: Guidelines on Good Field Collection Practices for Indian Medicinal Plants, National Medicinal Plants Board, Government of India. Right: Best Practices for Cultivation of Medicinal and Aromatic Plants, European Union and the Republic of Turkey.

To preserve quality and prevent contamination in herbal materials, best practices for hygienic herb harvesting and post-harvest primary processing steps are outlined in good agricultural and collection practice (GACP) guidelines for production of MAPs.

For herbal materials used as active ingredients of registered HMPs, GACP implementation is a mandatory regulatory requirement. For botanical materials used as components of food or food supplement products, GACP implementation is voluntary, yet advisable. Additionally, the World Health Organization (WHO) has published Good Herbal Processing Practice (GHPP) guidelines,[57] which:

- Elaborate on post-harvest processing procedures outlined within GACP guidelines;
- Supplement GMP guidelines on processing procedures for production and manufacture of herbal preparations, such as extracts.

[56] See ISO 9001 guidance for SMEs, at https://www.iso.org/publication/PUB100406.html

[57] See WHO GHPPs in Annex 1, at http://apps.who.int/iris/bitstream/handle/10665/272452/9789241210195-eng.pdf

Publicly available to the MAP producer and exporter are general international GACP guidelines, such as those published by WHO.[58] Based on the WHO guidelines, many countries have developed their own country-specific GACPs, such as those of the Indian National Medicinal Plants Board, developed in collaboration with the WHO Country Office for India.[59]

For export of herbal material that will be used in Europe as an active ingredient of an herbal medicinal product (HMP), evidence of crop production in conformance with the *European Medicines Agency Guideline on GACPs for Starting Materials of Herbal Origin* is a regulatory requirement for the applicant. The quality of herbal material must also be in conformance with European pharmacopoeial quality specifications.

WHO also developed a model species-specific GACP for the anti-malarial herbal drug *Artemisia annua*.[60] One of the objectives was to provide a model monograph to serve as the basis for countries to develop species-specific GACPs for medicinal plants of national importance. Appendix I of this guide lists selected publicly available GACP guidelines of different types – international, national (country-specific), trade-sector-specific and species-specific – along with links for document download.

Sources: Left: Good Practices for Saffron Production in Kashmir Practical Manual, Sher-e-Kashmir University of Agricultural Sciences and Technology of Kashmir, Centre left: *Matricaria chamomilla* L. – A GACP monograph, Department of Plant Resources Nepal. Centre right: Manuel des bonnes pratiques de collecte du romarin *Rosmarinus officinalis*, Haut Commissariat aux Eaux et Forêts et à la Lutte Contre la Désertification (Maroc). Right: WHO monograph on good agricultural and collection practices (GACP) for *Artemisia annua* L.

Good manufacturing practices

Good manufacturing practices (GMPs) are part of a quality system covering the manufacture and testing of APIs (e.g. an herbal drug extract that will be used in a licenced or registered medicine), cosmetic products, food products, food supplement products and medicinal products. GMPs are guidelines that outline the aspects of production and testing that can impact the quality of a product.

EU legislation requires that manufacturers of cosmetic, food and medicinal products must follow certain GMP procedures. Food supplements are subject to food GMP, hygienic and safety rules. In the US, however, cosmetic GMPs are guidelines rather than rules and there are somewhat different GMP rules for food and food supplements. Table 5 lists different levels of GMP in the US along with links for downloading the rules. The rest of this section of the guide elaborates on GMP regulations in the EU.

[58] See WHO GACPs, at https://apps.who.int/iris/handle/10665/42783

[59] See the National Medicinal Plants Board website to download GACP documents, at https://nmpb.nic.in/

[60] See WHO GACPs for *Artemisia annua,* at https://apps.who.int/iris/handle/10665/43509

Table 5 US GMPs: Cosmetics, foods, food supplements and drugs

Type of product	Code of Federal Regulations	Which GMP?
Cosmetic	guidance only	Cosmetic Good Manufacturing Practices[61]
Food	21 CFR Part 110	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food[62]
Dietary supplement	21 CFR Part 111	Current Good Manufacturing Practice in Manufacturing, Packaging, Labelling, or Holding Operations for Dietary Supplements[63]
Food and/or dietary supplement	21 CFR Part 117	Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food[64]
Drug	21 CFR Part 210	Current Good Manufacturing Practice in Manufacturing Processing, Packing, or Holding of Drugs[65]
	21 CFR Part 211	Current Good Manufacturing Practice for Finished Pharmaceuticals[66]

Source: United States Food and Drug Administration (FDA)

EU GMPs for cosmetics

The manufacture of cosmetic products for marketing within the EU must comply with GMP with a view to ensuring the functioning of the internal market and a high level of protection of human health.[67] Compliance with GMP is presumed by the competent authority where the product is marketed if the manufacture is occurring in accordance with relevant harmonized standards, such as, specifically:

- ISO 22716:2007 Cosmetics – Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices[68]

When a cosmetic product is placed on the EU market, the manufacturer's responsible person must also prepare a product information file and retain it for period of 10 years (readily accessible in electronic or other format at the address indicated on the finished product label) past the date on which the last batch was placed on the market. Among other content requirements, the file must contain a description of the method of manufacturing and a statement on compliance with GMP, as well as data on any animal testing performed by the product manufacturer or ingredient suppliers, including any animal testing performed to meet the legislative or regulatory requirements of third countries.

[61] See https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-cosmetic-good-manufacturing-practices

[62] See https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-110

[63] See https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-111

[64] See https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117

[65] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.1

[66] See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211

[67] See Consolidated text: Regulation (EC) No 1223/2009 on cosmetic products (Text with EEA relevance), at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20220301

[68] ISO 22716:2007(en) Cosmetics – GMP available to purchase, at https://www.iso.org/standard/36437.html

EU GMPs for foods

EU food safety policy includes standards for ensuring food hygiene, plant health and control of contamination from external substances, such as pesticides.[69] The scope includes both traditional and novel foods as well as food supplements. There are general rules regarding:

- 'Farm to fork' strategy for a fair, healthy and environmentally friendly food system;
- Methods of sampling and analysis for the control of levels of certain elements in foodstuffs;
- Specific rules on organic food production, labelling and control.

While the European Commission (EC) regulation on food safety established the European Food Safety Authority (EFSA) and food safety procedures, GMP is not part of the regulation.[70] Food GMP rules and audits of facilities for compliance are handled in Europe by national authorities.

Of most relevance to GMP for manufacture of herbal food products in the EU are:

- EC regulation on the hygiene of foodstuffs,[71] which covers the principles of hazard analysis and critical control points (HACCP) and the application of good hygiene practice;
- EU regulation on GMP for materials and articles intended to come into contact with food.[72]

EU GMPs for food supplements

In the EU, food supplement products are regulated as foods.[73] Therefore, food regulations are applicable. A non-profit organization, Food Supplements Europe, has published an elaborated guide on GMP for manufacturers of food supplements.[74]

EU GMPs for herbal medicinal active substances

Pre-marketing authorization is required for placement of herbal medicinal products on to the EU market. The manufacturing authorization holder is required to comply with the principles and guidelines of GMP for medicinal products and to use only active substances that have been manufactured in accordance with GMP for active substances and distributed in accordance with good distribution practices for active substances. Therefore, the authorization holder must verify the GMP and good distribution practice compliance by the manufacturer of the active substance by conducting audits at the manufacturing and distribution sites.[75]

This means that the manufacturer and exporter of an herbal active substance that will be used as an active ingredient of an authorized HMP in the EU must manufacture the ingredient in compliance with EU GMPs and be subject to external audits.

EU guidelines to GMP of HMPs are publicly available to download in Annex 7 of Volume 4 of *The rules governing medicinal products in the European Union*.[76]

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[69] See European Union food safety policy information, at https://eur-lex.europa.eu/summary/chapter/30.html?expand=3010,301005,301001#arrow_301001

[70] See Consolidated text: Regulation (EC) No 178/2002 on general principles and requirements of food law, at https://eur-lex.europa.eu/eli/reg/2002/178/2022-07-01

[71] See Consolidated text: Regulation (EC) No 852/2004 on the hygiene of foodstuffs, at https://eur-lex.europa.eu/eli/reg/2004/852/2021-03-24

[72] See Consolidated text: Commission Regulation (EC) No 2023/2006 on GMP for food contact materials and articles, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R2023-20080417

[73] See EFSA Food Supplements information, at https://www.efsa.europa.eu/en/topics/topic/food-supplements

[74] See FSE guide on GMP for food supplements, at https://foodsupplementseurope.org/publications-guidelines/

[75] See Article 46 of Consolidated text: Directive 2001/83/EC on the Community code relating to medicinal products for human use, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02001L0083-20220101

[76] See EC Volume 4 of *The rules governing medicinal products in the European Union*, at https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-4_en

Quality specifications

Box 7 Tip: Buyer/seller quality agreements

To support quality assurance: 'Agreements between producers and buyers of medicinal plants/herbal substances with regard to quality such as content of active principle, macroscopical and olfactory properties, limit values for microbial contamination, chemical residues and heavy metals etc., must be based on recognized regional and/or national specifications and should be laid down in written form.'

Source: European Medicines Agency (EMA) GACPs

When an herbal substance is intended for use as an active ingredient of an HMP, a quality specification must be established corresponding to a monograph published in the PhEur or of a monograph published in a national pharmacopoeia of an EU member state.

The EMA guideline on quality of herbal medicinal products states:[77] 'If a monograph for an herbal substance exists in the PhEur or another Pharmacopoeia referred to in Annex I of Directive 2001/83/EC or in Annex II of Regulation (EU) 2019/6, as amended, the herbal substance must be in accordance with this monograph. If no monograph for the herbal substance is given in a Pharmacopoeia referred to in Annex I of Directive 2001/83/EC or in Annex II of Regulation (EU) 2019/6, as amended, a comprehensive specification for the herbal substance must be developed which should be set out in the same way as the monographs on herbal drugs in the PhEur.'

However, if an herbal substance will be used as a component of a food or food supplement product, quality specifications may be established on the basis of various publicly available standards such as:

- Codex Alimentarius International Food Standards;[78]
- Combined Compendium of Food Additive Specifications, Joint FAO/WHO Expert Committee on Food Additives (JECFA);[79]
- European Spice Association (ESA) Quality Minima Document;[80]
- ISO Food Technology Standards, ICS (International Classification for Standards) 67.140 (Tea. Coffee. Cocoa), 67.200 (Edible oils and fats. Oilseeds), and 67.220 (Spices and condiments. Food additives);[81]
- United Nations Economic Commission for Europe (UNECE) agricultural quality standards.[82]

The image below shows selected publicly available guidance documents on the quality of herbs, both governmental (mandatory) and trade association (voluntary).

[77] See EMA guidelines on quality of herbal medicinal products, at https://www.ema.europa.eu/en/quality-herbal-medicinal-products-traditional-herbal-medicinal-products#current-effective-version-section

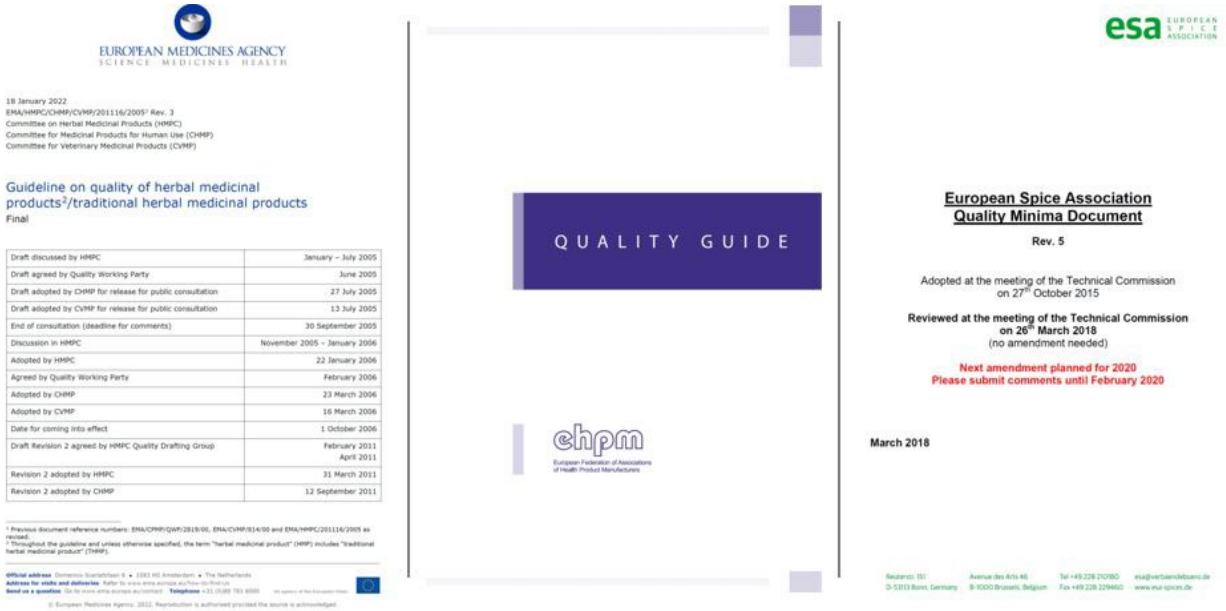
[78] See Codex Alimentarius International Food Standards, at https://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/

[79] See JECFA 'Combined Compendium of Food Additive Specifications' online edition, at https://www.fao.org/3/a0691e/a0691e00.htm

[80] See ESA Quality Minima Document, at https://www.esa-spices.org/index-esa.html/publications-esa

[81] See ISO (ICS 67) Food Technology Standards, at https://www.iso.org/ics/67/x/

[82] See UNECE Agricultural Quality Standards, at https://unece.org/trade/working-party-agricultural-quality-standards-wp7



Sources: Left: European Medicines Agency; Centre: European Federation of Associations of Health Product Manufacturers (EHPM); Right: European Spice Association (ESA)

Box 8 Tip: Selling the same ingredient in different export markets

A successful producer, exporter and marketer of herbal materials will likely develop business with customers in several different export markets, each with different quality requirements for market access. The same herbal ingredient may require very different analyses and accompanying documentation for access to the European market versus other destinations. Therefore, it is important to understand any differences in official quality standards and the test methods that are used in the foreign market to determine acceptable quality.

Source: Authors of this guide

Box 9 Tip: Quality specifications

Buyers situated in countries that do not have a national pharmacopoeia may base their quality specification requirements on a pharmacopeial monograph of another country.

For example, Canada does not have a national pharmacopoeia. In its *Quality of Natural Health Products Guide*, the Natural and Non-prescription Natural Health Products Directorate lists the following pharmacopoeias and international standards as acceptable in their entirety: United States Pharmacopeia; British Pharmacopoeia; European Pharmacopoeia; French Pharmacopoeia; Pharmacopoeia Internationalis; Japanese Pharmacopoeia; and the Food Chemicals Codex.

'It is expected that if a monograph is published in one of these pharmacopoeias, the pharmacopoeial monograph specifications should be considered as minimum specifications used for testing of the medicinal ingredient and finished product.'

Source: Section 1.5.4 (Acceptable pharmacopoeias) of the NNHPD *Quality of Natural Health Products Guide*: https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/quality-guide.html

Sources: European Pharmacopoeia (PhEur X 2020), Pharmacopoeia of the People's Republic of China (PPRC X 2015), State Pharmacopoeia of the Russian Federation (PhRus XIV 2018), United States Pharmacopoeia (USP 43 2020)

Using liquorice root as an example to illustrate differences in quality requirements of different markets, Table 6 compares the significantly different quality specifications established for liquorice root in the national pharmacopoeias of four major markets for liquorice: European Pharmacopoeia (PhEur),[83] Pharmacopoeia of the People's Republic of China (PPRC),[84] State Pharmacopoeia of the Russian Federation (PhRus)[85] and United States Pharmacopoeia (USP).[86]

The European Pharmacopoeia defines liquorice root as the 'dried, unpeeled or peeled, whole or cut root and stolons of *Glycyrrhiza glabra* L. and/or of *Glycyrrhiza inflata* Bat. and/or *Glycyrrhiza uralensis* Fisch.'

Figure 12 Glycyrrhiza glabra

Source: © Thomas Brendler

[83] Information on the European Pharmacopoeia and how to subscribe, at https://www.edqm.eu/en/european-pharmacopoeia

[84] Information on the Chinese Pharmacopoeia, at https://www.chp.org.cn/gjyjwyw/index.jhtml

[85] Monographs of the State Pharmacopoeia of the Russian Federation can be downloaded at https://femb.ru/record/pharmacopea14

[86] Information on the United States Pharmacopoeia and National Formulary and how to subscribe, at https://www.uspnf.com/purchase-usp-nf

Table 6 Comparison of liquorice pharmacopoeial quality standards

	PhEur	PPRC	PhRus	USP
Content	NLT 4.0% of 18β-glycyrrhizic acid	NLT 2.0% of glycyrrhizic acid and NLT 0.50% of liquiritin	NLT 6% of glycyrrhizic acid	NLT 2.5% of glycyrrhizic acid
Alcohol-soluble extractives	No requirement	No requirement	No requirement	NLT 25.0%
Identification tests	Macroscopic, microscopic and TLC	Macroscopic, microscopic and TLC	Macroscopic, microscopic and TLC	Macroscopic, microscopic and TLC
Loss on drying	NMT 10.0%	No requirement	No requirement	NMT 12.0%
Water	No requirement	NMT 12.0%	NMT 14.0%	No requirement
Total ash	Unpeeled: NMT 10%; Peeled: NMT 6.0%	NMT 7.0%	NMT 8%	NMT 7.0%
Acid-insoluble ash	Unpeeled: NMT 2.0% Peeled: NMT 0.5%	NMT 2.0%	Unpeeled: NMT 2.5% Peeled: NMT 1%	NMT 2.0%
Foreign matter	NMT 2% m/m. Pyrrolizidine alkaloids: No prescribed limits: 'Patient exposure to PAs from medicinal products should be as low as possible and must not exceed the maximum daily intake agreed by the competent authority.'	No requirement	Unpeeled: NMT 1% organic impurities; NMT 1% mineral impurities; NMT 4% flabby roots and stem remnants; Peeled: NMT 0.5% organic impurities; NMT 0.5% mineral impurities; NMT 15% of roots with adhering cork, NMT 20% of roots dark brown on surface but light yellow in the fracture.	NMT 2.0%
Microbiological quality	Complies with PhEur General Chapter 5.1.8	Complies with PPRC General Chapter 1107 –Microbiological Acceptance Criteria	Complies with PhRus General Chapter Microbiological Purity	Complies with USP General Chapter 2023
Aflatoxin B_1	NMT 2 µg/kg	No requirement	No requirement	No requirement
Ochratoxin A	NMT 20 µg per kg	No requirement	No requirement	No requirement
Heavy metals	Cadmium: NMT 1.0 ppm; lead: NMT 5.0 ppm; mercury: NMT 0.1 ppm	Arsenic: NMT 2 mg/kg; cadmium: NMT 0.3 mg/kg; copper: NMT 20 mg/kg; lead: NMT 5 mg/kg; mercury: NMT 0.2 mg/kg	Arsenic: NMT 0.5 mg/kg; cadmium: NMT 1.0 mg/kg; lead: NMT 6.0 mg/kg; mercury: NMT 0.1 mg/kg	Arsenic (inorganic): NMT 2 µg/g; cadmium: NMT 0.5 µg/g; lead: NMT 5 µg/g; mercury (total): NMT 1 µg/g; methylmercury (as Hg): NMT 0.2 µg/g
Pesticide residues	Complies with PhEur General Chapter 2.8.13 limits	Total hexachloro-cyclohexane (sum of α-BHC, β-BHC, γ-BHC, δ-BHC): NMT 0.2 mg/kg; Total chlorophenothane (sum of p,p'-DDT, o,p-'DDT, p,p'-DDE, p,p'-DDD): NMT 0.2 mg/kg; PCNB: NMT 0.1 mg/kg	Complies with PhRus General Chapter limits	Complies with USP General Chapter ⟨561⟩ limits

	PhEur	PPRC	PhRus	USP
Radioactive contamination	No prescribed limits: 'In some specific circumstances, the risk of radioactive contamination is to be considered'	No requirement	Cesium-137 (Cs-137): NMT 400 Becquerel (Bq) per kg; Strontium-90 (Sr-90): NMT 200 Bq/kg	No requirement

Sources: European Pharmacopoeia (PhEur X 2020), Pharmacopoeia of the People's Republic of China (PPRC X 2015), State Pharmacopoeia of the Russian Federation (PhRus XIV 2018), United States Pharmacopoeia (USP 2022)

Herbal ingredients used in food or food supplement products

While quality specifications for herbs used in HMPs must be established on the basis of official pharmacopoeial standards, there is no requirement or template for the content of quality specifications for herbal ingredients that will be used in food or food supplement products. All food ingredients, including herbal, must test in compliance with the regulations that establish maximum allowable limits for known contaminants (which are provided in this guide); the content of an herbal food substance specification is a matter to be agreed upon between the buyer and seller.

There are, however, publicly available voluntary standards that can be used by companies as the basis of written quality specifications, made available by intergovernmental organizations such as the Food and Agriculture Organization of the United Nations (FAO) and WHO,[87, 88] non-governmental organizations such as ISO[89] and trade associations situated in the EU.[90, 91] One trade association, the European Federation of Associations of Health Product Manufacturers (EHPM), provides extensive guidance on quality specifications for herbal food supplement components and products.[92]

It is possible that an EU buyer may require a quality specification conforming to an international standard of FAO or ISO or to a voluntary standard outlined by a European trade association. Table 7 provides a non-exhaustive list of selected publicly available specifications for selected herbal materials for use in food products.

[87] Access FAO-WHO Codex Alimatarius Standards at https://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/

[88] Access FAO Combined Compendium of Food Additive Specifications at https://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/

[89] See list of ISO standards for spices, culinary herbs and condiments at https://www.iso.org/committee/47912/x/catalogue/p/1/u/0/w/0/d/0

[90] See ESA Quality Minima Document at https://www.esa-spices.org/index-esa.html/publications-esa

[91] See THIE Compendium of Guidelines at https://thie-online.eu/publications.html

[92] See EHPM Quality Standards at https://ehpm.org/ehpm-standards/

Table 7 Publicly available quality specifications for selected herbal food ingredients

Name of herb	CA	ESA	ISO	JECFA	THIE
Acacia (*Acacia senegal*) stem and branch gum				X	
Allspice (*Pimenta dioica*) fruit, whole or ground		X	X		
Aniseed (*Pimpinella anisum*) fruit		X	X		
Bezoin, Siam (*Styrax tonkinensis*) balsamic resin				X	
Bilberry (*Vaccinium myrtillus*) fruit, quick frozen	X				
Basil, Camphor (*Ocimum kilimandscharicum*)	X				
Basil, Holy (*Ocimum tenuiflorum*, *Ocimum sanctum*) leaf	X				
Basil, Sweet (*Ocimum basilicum*) leaf	X	X	X		
Blackcurrant (*Ribes nigrum*) fruit extract				X	
Capsicum (*Capsicum annuum*, *C. frutescens* and sub-species) fruit		X	X		
Caraway (*Carum carvi*) fruit		X	X		
Cardamom (*Elettaria cardamomum*) seed, whole capsule		X	X		
Cardamom, Large (*Amomum subulatum*), capsules and seeds			X		
Carob (*Ceratonia siliqua*) bean gum				X	
Cassia (*Cassia tora* and *C. obtusifolia*) seed gum				X	
Castor (*Ricinus communis*) seed oil				X	
Celery (*Apium graveolens*) fruit		X	X		
Chamomile (*Matricaria chamomilla*) flower					X
Cherry, Sour/Tart (*Prunus cerasus*) fruit, dried			X		
Cinnamon tree bark: Chinese-type (*Cinnamomum cassia*), Indonesian-type (*C. burmanii*), Sri Lankan-type (*C. zeylanicum*), and Vietnamese-type (*C. loureirii*)		X	X		
Clove (*Syzygium aromaticum*) flower bud, whole or ground	X	X	X		
Coriander (*Coriandrum sativum*) fruit, whole or ground		X	X		
Cumin (*Cuminum cyminum*) fruit	X	X	X		
Dammar (*Agathis* spp., *Hopea* spp., *Shorea* spp.) tree gum				X	
Fennel, Bitter (*Foeniculum vulgare* var. *vulgare*) fruit		X	X		
Fennel, Sweet (*Foeniculum vulgare* var. *panmorium*)		X	X		X
Fenugreek (*Trigonella foenum-graecum*) seed		X	X		
Galangal (*Alpinia galanga*, *A. officinarum*, *Kaempferia galangal*)		X			
Garlic (*Allium sativum*) bulb, dehydrated	X	X	X		
Ginger (*Zingiber officinale*) rhizome	X	X	X		
Ginseng, American (*Panax quinquefolius*), Asian (*P. ginseng*)	X				
Guaiac (*Guajacum officinale* or *G. sanctum*) wood resin				X	
Guar (*Cyamopsis tetragonolobus*) seed gum				X	
Gum ghatti (*Anogeissus latifolia*)				X	
Honeybush (*Cyclopia* spp.) herb					X
Juniper (*Juniperus communis*) berry		X	X		
Karaya (*Sterculia urens*) stem and branch gum				X	
Kava (*Piper methysticum*) peeled rhizomes, basal stems, roots	X				
Konjac (*Amorphophallus* spp.) tuber flour				X	
Laurel (*Laurus nobilis*) leaf, whole or ground		X	X		

Name of herb	CA	ESA	ISO	JECFA	THIE
Lemon balm (*Melissa officinalis*) leaf					X
Lemongrass (*Cymbopogon* spp.) leaf		X			X
Lemon verbena (*Aloysia citriodora*) herb					X
Linden (*Tilia cordata*, *T. platyphyllos*) flower					X
Liquorice (*Glycyrrhiza glabra*) root					X
Mace (*Myristica fragrans*) aril, whole or in pieces		X	X		
Mulberry (*Morus alba*) fruit, dried			X		
Nettle (*Urtica* spp.) herb					X
Nutmeg (*Myristica fragrans*) kernel		X	X		
Oregano (*Origanum vulgare*) leaf	X	X	X		
Oregano, Mexican (*Lippia* spp.) leaf and flowering top	X				
Paprika (*Capsicum annuum*) fruit powder, and extracts			X	X	
Parsley (*Petroselinum crispum*) leaf		X	X		
Pepper, Black, Green, White (*Piper nigrum*) fruit	X	X	X		
Peppermint (*Mentha* × *piperita*) leaf					X
Pink pepper (*Schinus* spp.) fruit		X			
Quillaia (*Quillaja saponaria*) bark extract				X	
Rooibos (*Aspalathus linearis*) herb					X
Rosehip, Dog (*Rosa canina*) fruit			X		X
Roselle (*Hibiscus sabdariffa*) flower					X
Rosemary (*Rosmarinus officinalis*) leaf		X	X		
Saffron (*Crocus sativus*) pistil, stigma		X	X	X	
Sage (*Salvia officinalis*) leaf		X	X		X
Savory, Summer (*Satureja hortensis*), sprigs and leaves		X	X		
Savory, Winter (*Satureja montana*), sprigs and leaves		X	X		
Spearmint (*Mentha spicata*) leaf		X	X		X
Star anise (*Illicium verum*) fruit		X	X		
Sumac (*Rhus coriaria*) fruit powder			X		
Sweet marjoram (*Origanum majorana*) herb			X		
Tagetes (*Tagetes erecta*) petal extract				X	
Tara (*Caesalpinia spinosa*) seed gum				X	
Tarragon (*Artemisia dracunculus*) leaf		X	X		
Tea, Black, Green, White (*Camellia sinensis*) shoots			X		
Thyme (*Thymus vulgaris*) leaf, rubbed		X	X		
Thyme, Wild (*Thymus* spp.) leaf and flower	X				
Tragacanth (*Astragalus gummifer*) stem and branch gum				X	
Turmeric (*Curcuma longa*) rhizome		X	X		
Yacon (*Smallanthus sonchifolius*) tuberous root	X				

Sources: FAO-WHO Codex Alimentarius International Food Standards, at https://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/; ESA Quality Minima Document, at https://www.esa-spices.org/index-esa.html/publications-esa; ISO International Food Products Standards, at https://www.iso.org/committee/47858.html; JECFA Combined Compendium of Food Additive Specifications, at https://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/; THIE Compendium of Guidelines for Herbal and Fruit Infusions, at https://thie-online.eu/publications.html

To illustrate the range of food grade standards available for herbal materials, Table 8 compares quality specifications for spearmint (*Mentha spicata*) leaf, available from ESA, ISO and THIE, against those of the French Pharmacopoeia (PhFr).

Table 8 Comparison of spearmint leaf food quality standards

	PhFr	ESA	ISO	THIE
Content	NLT 10 ml/kg of essential oil	NLT 5 ml/kg of essential oil	NLT 5 ml/kg of essential oil	NLT 6 ml/kg of essential oil
Identification tests	Macroscopic, microscopic and TLC	Organoleptic. No specified methods	*Organoleptic. Colour*: dull green or greyish green; *Odour*: strong, characteristic, free from earthy or decaying vegetable odour; *Taste*: strong, characteristic, sweet	Macroscopic, Organoleptic
Water	NMT 11.0%	NMT 13.0%	NMT 13.0%	NMT 13.0%
Total ash	NMT 10.0%	NMT 12.0%	NMT 12.0%	No specified limit
Acid-insoluble ash	N/A	NMT 2.5%	NMT 2.5%	NMT 2.5%
Foreign matter	*Foreign organs*: NMT 5.0% stems. *Foreign elements*: NMT 2.0%.	N/A	NMT 1% mint leaves of other species; Practically free from dead insects, rodent contamination visible to the naked eye	*Foreign plant material and non-plant material which do not present a health risk*: NMT 2.0%
Microbiological quality	Complies with General Chapter 5.1.8	The product shall be free from microorganisms at such levels which may represent a hazard to health; Specific requirements to be agreed between buyer and seller	No specified limits	Aerobic Plate Count ≤ 10^8/g Moulds ≤ 10^6/g E. coli ≤ 10^4/g Salmonella absent in 125 g
Mycotoxins	NMT 2 µg/kg of aflatoxin B_1	Must comply with national and/or EU legislation	No specified limits	NMT 2 µg/kg of aflatoxin B_1 - NMT 4 µg/kg aflatoxins B_1, B_2, G_1 and G_2 (as sum)
Heavy metals	Cadmium: NMT 1.0 ppm; lead: NMT 5.0 ppm; mercury: NMT 0.1 ppm.	Must comply with national and/or EU legislation	No specified limits	Complies with regulations (EC) 396/2005 and (EC) 1881/2006
Pesticide residues	Complies with General Chapter 2.8.13 limits	Application and residue limits must comply with existing EU and/or national legislation	No specified limits	Complies with Regulation (EC) No 396/2005

Sources: Pharmacopée française, 11th edition, at https://ansm.sante.fr/documents/reference/pharmacopee/la-pharmacopee-francaise; ESA Quality Minima Document, at https://www.esa-spices.org/index-esa.html/publications-esa; ISO International Food Products Standards, at https://www.iso.org/committee/47858.html; THIE Compendium of Guidelines for Herbal and Fruit Infusions, at https://thie-online.eu/publications.html

Herbal ingredients with EU quality scheme certification

Companies that aim to export an herbal material to Europe may be interested to know if the same species is also produced in Europe according to the EU quality scheme. A few herbs are labelled and marketed with certifications according to the EU quality scheme concerning geographical indications, which establish intellectual property rights for products whose qualities are specifically linked to the area of production.

According to the European Commission, 'Recognized as intellectual property, geographical indications play an increasingly important role in trade negotiations between the EU and other countries.'[93]

Although a niche market, EU quality scheme certified herbal materials and products must be produced according to a defined quality specification. Regionally in Europe, some companies may manufacture finished products using these certified materials, but mainly for local markets. Table 9 provides a list of some herbs with geographical indication specifications in Europe.

Table 9 Selected herbs with EU quality scheme certification

Name of herb	Name of geographic indication	Country
Caraway (*Carum carvi*) fruit	Český kmín (Czech Caraway)	Czechia
Chamomile (*Matricaria chamomilla*) flower	Alföldi kamillavirágzat (Wild Alföld Chamomile)	Hungary
	Chamomilla Bohemica (Bohemian Chamomile)	Czechia
Liquorice (*Glycyrrhiza glabra* var. *typica* 'Cordara') root and rhizome	Liquirizia di Calabria (Calabrian Liquorice)	Italy
Saffron (*Crocus sativus*) style and stigma	Azafrán de la Mancha (Mancha Saffron)	Spain
	Κρόκος Κοζάνης (Krokos Saffron)	Greece
	Zafferano dell'Aquila (Aquila Saffron)	Italy
	Zafferano di San Gimignano (San Gimignano Saffron)	Italy
	Zafferano di Sardegna (Sardinia Saffron)	Italy

Source: EU Quality Schemes, at https://ec.europa.eu/info/food-farming-fisheries/food-safety-and-quality/certification/quality-labels_en

[93] See https://agriculture.ec.europa.eu/farming/geographical-indications-and-quality-schemes/geographical-indications-and-quality-schemes-explained_en

Figure 13 Matricaria recutica

Source: © Thomas Brendler

Herbal ingredients used in medicinal products

Active ingredients of HMPs must be specified in compliance with a quality monograph of the PhEur or, in the absence of a PhEur monograph, of a monograph of the national pharmacopoeia or codex of a member state.

For non-pharmacopeial herbal substances, 'The specification should be established on the basis of recent scientific data and should be set out in the same way as PhEur monographs.'[94]

In such cases, it can also be justified to use a pharmacopoeial monograph of a non-member state as the basis of a quality specification, for example of the British Pharmacopoeia, Pharmacopoeia Helvetica (PhHelv) or the United States Pharmacopoeia. The European Pharmacopoeia Commission, under the European Directorate for the Quality of Medicines (EDQM), is responsible for the elaboration and maintenance of the PhEur.[95]

In its guidelines on specifications for HMPs, EMA states: 'A specification is defined as a list of tests, references to analytical or biological procedures, and appropriate acceptance criteria, which are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which an herbal substance, herbal preparation or HMP should conform to be considered acceptable for its intended use. "Conformance to specification" means that the herbal substance/preparation and/or HMP, when tested according to the listed analytical procedures, will meet the listed acceptance criteria. Specifications are legally binding quality standards that are proposed and justified by the manufacturer/marketing authorization holder and approved by regulatory authorities.'[96]

[94] See EMA Guideline on specifications for herbal substances, herbal preparations and HMPs: https://www.ema.europa.eu/en/specifications-test-procedures-acceptance-criteria-herbal-substances-herbal-preparations-herbal#current-effective-version-section

[95] See information on the European Pharmacopoeia Commission: https://www.edqm.eu/en/the-european-pharmacopoeia-commission

[96] See EMA Guideline on specifications for herbal substances, herbal preparations and HMPs at https://www.ema.europa.eu/en/specifications-test-procedures-acceptance-criteria-herbal-substances-herbal-preparations-herbal#current-effective-version-section

EMA's Committee on Herbal Medicinal Products (HMPC) is responsible for producing the EU herbal monographs, which form the basis of the required product labelling information for applicants obtaining marketing authorization of individual HMPs. EMA's EU herbal monographs provide companies with the information that must appear on their product labelling.

The existence of an EU herbal monograph may be viewed as an indication of the economic importance of the herb in the EU marketplace. At the time this guide was prepared, there were 167 EU herbal monographs. Furthermore, each EU herbal monograph provides information on the required quality standard if the herb will be used as an active ingredient of a registered HMP.

Relevant to exporters, the finished HMP marketing authorization holders are prospective buyers of these herbs in their specified qualities. Table 35 in Appendix II of this guide provides a list of herbs with EU herbal monographs and the pharmacopoeial quality standard that is specified in each EMA monograph.

Limits established for adulterants and contaminants

Before beginning export trade to prospective customers in Europe, it is important to be aware of the regulatory limits and official controls or measures that have been established for a range of potential contaminants or adulterants of herbal materials entering the EU.

Prospective customers may require batch-specific analytical report documentation that shows conformance with European limits. This includes maximum allowable limits established for content of foreign alkaloids (nicotine, pyrrolizidine, tropane), fumigants (ethylene oxide, methyl bromide, propylene oxide), heavy metals, microbial pathogens, mycotoxins, pesticide residues, polycyclic aromatic hydrocarbons and radioactive contamination.

Box 10 Tip: Temporary official controls that impact entry into the EU

Assume that your consignment may be sampled and analysed for the presence of certain known contaminants, which may vary depending on the herbal material and country of origin.

Additionally, from time to time, testing results from member states are notified through the European Commission Rapid Alert System for Food and Feed, which may result in an EC regulation that temporarily increases official controls and emergency measures governing the entry of certain goods from certain third countries.

Prior to shipping, your trade partner in the EU should inform you of any temporary regulations in force that would require an exporter to attach, along with shipping documents for the consignment, the results of sampling and analysis and an official certificate stating that the results comply with the relevant EU regulation(s).

Source: Commission Implementing Regulation on the temporary increase of official controls and emergency measures governing the entry into the EU of certain goods from certain third countries. Available at https://eur-lex.europa.eu/eli/reg_impl/2021/2246/oj

Heavy metals

If an operation is exporting MAP materials to buyers in Europe of herbal food or herbal medicinal ingredients, it is important to be aware that the maximum allowable limits for certain elemental impurities (heavy metals content) are different for each sector. The heavy metals limits for herbal food ingredients, spices and food supplements are established under European Commission regulations.[97] The limits for herbal drugs and herbal drug preparations are established by the European Directorate for the Quality of Medicines (EDQM) in the PhEur.[98]

[97] See Consolidated text: Commission Regulation (EC) No 1881/2006: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1881-20220503

[98] Information on the European Pharmacopoeia and how to subscribe: https://www.edqm.eu/en/european-pharmacopoeia

Table 10 shows the limits of relevance established within the European Economic Area (EEA).

Table 10 European heavy metals limits: Herbal drugs, foods and supplements

Category	Arsenic	Cadmium	Lead	Mercury
Herbal drugs and herbal drug extracts (PhEur)	No general limit. Kelp: NMT 90 ppm; Carrageenan: NMT 3.0 ppm	NMT 1.0 ppm	NMT 5.0 ppm	NMT 0.1 ppm
Dried spices: barks			NMT 2.0 ppm	
Dried spices: buds and flower pistils			NMT 1.0 ppm	
Dried spices: fruits			NMT 0.60 ppm	
Dried spices: roots and rhizomes			NMT 1.50 ppm	
Dried spices: seeds			NMT 0.90 ppm	
Food supplements		NMT 1.0 ppm	NMT 3.0 ppm	NMT 0.10 ppm
Food supplements consisting mainly of seaweed		NMT 3.0 ppm		
Fresh leafy herbs		NMT 0.20 ppm		
Fresh turmeric (*Curcuma longa*) and ginger (*Zingiber officinale*)			NMT 0.80 ppm	
Linseed (*Linum usitatissimum*)		NMT 0.50 ppm		
Wild fungi		NMT 0.50 ppm	NMT 0.80 ppm	

Sources: European Pharmacopoeia (PhEur X 2020), European Directorate for the Quality of Medicines (EDQM) and Consolidated text: Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (text with EEA relevance)

Microbial pathogens

The EC regulations on microbiological criteria for foodstuffs do not include limits for culinary herbs, spices, seasonings or non-medicinal beverage teas.[99] Various trade associations, however, have published microbiological quality guidelines, such as the Tea & Herbal Infusions Europe (THIE).[100] Furthermore, no EU regulations specify microbial limits for herbs that are used in food supplement products. The trade association Food Supplements Europe, in its guidance document, recommends that microbial limits for herbal ingredients used in food supplements should follow the specifications established by PhEur for herbal drugs and herbal drug extracts.[101]

Microbiological quality of herbal drugs and herbal drug extracts that are used as active substances of HMPs are legally binding. Table 11 provides a summary of PhEur limits for different categories of herbal ingredients.

[99] See Consolidated text: Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02005R2073-20200308

[100] See THIE recommendation microbiological specifications: https://thie-online.eu/publications.html

[101] See FSE quality of botanical preparations guidance: https://foodsupplementseurope.org/publications-guidelines/

Table 11 Summary of PhEur microbial limits

Category	Limits
Herbal tea preparations to be prepared with boiling water (infusions or decoctions)	
Total aerobic microbial count (TAMC)	Acceptance criterion: 10^7 cfu/g. Maximum acceptable count: 50 000 000 cfu/g
Total combined yeasts/moulds count (TYMC)	Acceptance criterion: 10^5 cfu/g. Maximum acceptable count: 500 000 cfu/g
Escherichia coli	Acceptance criterion: 10^3 cfu/g
Salmonella	Absence (25 g)
Herbal extracts and/or herbal drugs, where the method of processing (e.g. extraction) or, in the case of herbal drugs, of microbial reduction treatment, reduces the levels of organisms to below those stated for this category	
TAMC	Acceptance criterion: 10^4 cfu/g or cfu/ml. Maximum acceptable count: 50 000 cfu/g or cfu/ml
TYMC	Acceptance criterion: 10^2 cfu/g or cfu/ml. Maximum acceptable count: 500 cfu/g or cfu/ml
Bile-tolerant gram-negative bacteria	Acceptance criterion: 10^2 cfu/g or cfu/ml
Escherichia coli	Absence (1 g or 1 ml)
Salmonella	Absence (25 g or 25 ml)
Herbal extracts and/or herbal drugs, where it can be demonstrated that the method of processing (e.g. extraction with low-strength ethanol or water that is not boiling, or low-temperature concentration) or, in the case of herbal drugs, of pre-treatment, would not reduce the level of organisms sufficiently to reach the criteria required under B	
TAMC	Acceptance criterion: 10^5 cfu/g or cfu/ml. Maximum acceptable count: 500 000 cfu/g or cfu/ml
TYMC	Acceptance criterion: 10^4 cfu/g or cfu/ml. Maximum acceptable count: 50 000 cfu/g or cfu/ml
Bile-tolerant gram-negative bacteria	Acceptance criterion: 10^4 cfu/g or cfu/ml
Escherichia coli	Absence (1 g or 1 ml)
Salmonella	Absence (25 g or 25 ml)

Source: European Directorate for the Quality of Medicines (EDQM) European Pharmacopoeia (PhEur) 10th edition.

Mycotoxins

According to both EDQM and EMA, herbal drugs that are subject to contamination by aflatoxins or ochratoxin A must have specifications with limits established and must tested by a validated method.[102, 103] Aflatoxins are naturally occurring mycotoxins produced mainly by *Aspergillus flavus* and *Aspergillus parasiticus*. In the EEA, maximum allowable limits for certain mycotoxin contaminants have also been established in regulations applicable to certain herbal food ingredients and food supplements.[104]

Table 12 provides the limits established for certain herbal foods, food supplements and herbal medicinal products. Other mycotoxins such as ergot alkaloids and *Fusarium* toxins have limits established for cereals and grains but not for herbal food or herbal medicine materials.

[102] See EMA 2022 guideline on quality of herbal medicinal products: https://www.ema.europa.eu/en/quality-herbal-medicinal-products-traditional-herbal-medicinal-products

[103] See EMA 2022 guideline on specifications: test procedures and acceptance criteria: https://www.ema.europa.eu/en/specifications-test-procedures-acceptance-criteria-herbal-substances-herbal-preparations-herbal

[104] See Consolidated text of Commission regulation (EC) 1881/2006, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1881-20220503#E0052

Table 12 European mycotoxin limits: Herbal drugs, foods and supplements

Category	aflatoxin B_1	aflatoxins B_1, B_2, G_1 and G_2	ochratoxin A
Capsicum spp., as a spice, (dried fruits thereof, whole or ground, including chillies, chilli powder, cayenne and paprika)	NMT 5.0 µg/kg	NMT 10.0 µg/kg	NMT 20 µg/kg
Fig (*Ficus carica*), dried	NMT 6.0 µg/kg	NMT 10.0 µg/kg	
Herbal drugs and herbal drug extracts (PhEur)	NMT 2 µg/kg	The competent authority may also require NMT 4 µg/kg	No general limit. Liquorice PhEur NMT 20 µg/kg, liquorice extract NMT 80 µg/kg
Liquorice root, ingredient for herbal infusion (as foodstuff)			NMT 20 µg/kg
Liquorice extract for use in food, in particular beverages and confectionary			NMT 80 µg/kg
Oilseeds intended for direct human consumption or use as an ingredient in foodstuffs, e.g. hemp (*Cannabis sativa*) and linseed (*Linum usitatissimum*)	NMT 2.0 µg/kg	NMT 4.0 µg/kg	
Spices: The following species: *Piper* spp. (fruits thereof, including white and black pepper); *Myristica fragrans* (nutmeg); *Zingiber officinale* (ginger); *Curcuma longa* (turmeric)	NMT 5.0 µg/kg	NMT 10.0 µg/kg	NMT 15 µg/kg
Spices: Mixtures of spices containing one or more of the abovementioned spices	NMT 5.0 µg/kg	NMT 10.0 µg/kg	NMT 15 µg/kg

Sources: European Pharmacopoeia (PhEur X 2020), European Directorate for the Quality of Medicines (EDQM) and Consolidated text: Commission regulation (EC) 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (text with EEA relevance).

Nicotine

MAPs imported from some origins have been found to be contaminated with measurable levels of nicotine. Nicotine is the main alkaloid in tobacco (*Nicotiana tabacum*) leaf and other *Nicotiana* species. Contamination of imported MAPs may be the result of crops produced in regions where tobacco is produced, or contamination during drying, storage or transport.[105]

For example, peppermint (*Mentha* × *piperita*) plants have been found to uptake significant levels of nicotine from contaminated soils as well as via fumigation with exhaled cigarette smoke. Maximum residue levels for nicotine on certain MAPs, established with relevance in the EEA,[106] are summarized in Table 13.

[105] See EFSA opinion on nicotine detected in tea, herbal infusions, spices, rosehips and fresh herbs, at https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2098

[106] See Consolidated text: Regulation (EC) No 396/2005: https://eur-lex.europa.eu/eli/reg/2011/812/oj

Table 13 European maximum residue levels for nicotine (mg/kg) for selected MAPs

MAP name, plant part, form	maximum residue level (mg/kg)
Black current (*Ribes nigrum*) fruit with stems (fresh or frozen)	NMT 0.3 mg/kg
Cranberry (*Vaccinium macrocarpon*) fruit (fresh or frozen)	NMT 0.3 mg/kg
European elder (*Sambucus nigra*) berry (fresh or frozen)	NMT 0.3 mg/kg
Fungi, wild (fresh)	NMT 0.04 mg/kg
Herbs (dried), for use in herbal tea infusions, e.g. American ginseng (*Panax quinquefolius*), Asian ginseng (*Panax ginseng*) root, German chamomile (*Matricaria chamomilla*) flower, jasmine (*Jasminum officinale*, *J. sambac*) flower, linden (*Tilia cordata*, *T. platyphyllos*, *T. tomentosa*) flower, Roman chamomile (*Chamaemelum nobile*) flower, rooibos (*Aspalathus linearis*) herb, roselle (*Hibiscus sabdariffa*) flower, rose (*Rosa* spp.) petal, strawberry (*Fragaria* x *ananassa*) leaf, valerian (*Valeriana officinalis*) root, yerba maté (*Ilex paraguariensis*) leaf), and others.	NMT 0.5 mg/kg
Herbs (fresh), e.g. basil (*Ocimum basilicum*) leaf, parsley (*Petroselinum crispum*) leaf, rosemary (*Rosmarinus officinalis*) leaf, sage (*Salvia officinalis*) leaf, tarragon (*Artemisia dracunculus*) leaf, thyme (*Thymus vulgaris*) herb, and others.	NMT 0.4 mg/kg
Rosehips (*Rosa canina*, *R. majalis*, *R. rugosa*) (fresh or frozen)	NMT 0.3 mg/kg
Spices (dried arils, barks, buds, roots, stigma), e.g. caper (*Capparis spinosa*) bud, Ceylon cinnamon (*Cinnamomum verum*) bark, clove (*Syzygium aromaticum*) flower bud, ginger (*Zingiber officinale*) rhizome, horseradish (*Armoracia rusticana*) root, liquorice (*Glycyrrhiza glabra*) root, mace (*Myristica fragrans*) aril, saffron (*Crocus sativus*) stigma, turmeric (*Curcuma longa*) rhizome, and others.	NMT 4 mg/kg
Spices (dried fruits, seeds and seedlike fruits), e.g. allspice (*Pimenta dioica*) fruit, aniseed (*Pimpinella anisum*) fruit, black caraway (*Elwendia persica*) fruit, caraway (*Carum carvi*) fruit, cardamom (*Elettaria cardamomum*) seed, coriander (*Coriandrum sativum*) fruit, cumin (*Cuminum cyminum*) seed, fennel (*Foeniculum vulgare*) fruit, fenugreek (*Trigonella foenum-graecum*) seed, juniper (*Juniperus communis*) berry, long pepper, nutmeg (*Myristica fragrans*) kernel, peppercorn (*Piper nigrum*) fruit, Sichuan pepper (*Zanthoxylum* spp.) fruit, tamarind (*Tamarindus indica*) fruit, vanilla (*Vanilla planifolia*) pod, and others.	NMT 0.3 mg/kg
Tea (*Camellia sinensis*), leaf, bud, stalk, whether or not fermented (dried)	NMT 0.6 mg/kg

Source: Consolidated text: Regulation (EC) 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02005R0396-20220516

Pesticide residues

The maximum allowable limits for pesticide residue contamination differ depending on whether the herbal material will be used as a food (or food supplement) or as a component of an HMP.

PhEur defines pesticide residues in herbal drugs as: '… any substance or mixture of substances intended for preventing, destroying or controlling any pest, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of herbal drugs. The item includes substances intended for use as growth-regulators, defoliants or desiccants and any substance applied to crops, either before or after harvest, to protect the commodity from deterioration during storage and transport.'

Appendix III provides the PhEur list of pesticides with the maximum residue limits that are in force for all herbal drugs used in medicinal products in the EU.[107] PhEur also provides a method for calculating the maximum residue limits of other pesticides that are not listed but whose presence is suspected. Furthermore, the PhEur maximum residue limits are harmonized with those of the USP.

[107] See Table 2.8.13.-1 in the European Pharmacopoeia General Chapter 2.8.13 Pesticide Residues, at https://pheur.edqm.eu/home

Herbal materials for use in foods or food supplements are subject to regulation (EC) 396/2005 of the European Parliament and the Council on Maximum Residue Levels of Pesticides, which provides species-specific maximum residue levels: '… the upper legal level of a concentration for a pesticide residue in or on food or feed set in accordance with this regulation, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers.'[108]

When used as food, approved pesticides and the established maximum residue levels will vary by plant species and plant part. For example, for food use, residues and the maximum residue levels permitted on chamomile (*Matricaria chamomilla*) flower are different from those permitted on dog rose (*Rosa canina*) hips. However, if the chamomile or dog rosehips will be used as active ingredients of registered HMPs, the materials are subject to the maximum residue levels established in the PhEur, which are the same for all herbal drugs and herbal drug preparations, regardless of species or plant part.

Polycyclic aromatic hydrocarbons

Polycyclic aromatic hydrocarbons (PAHs) are impurities arising from extraneous sources. PAHs are created when substances such as coal, oil, gas and organic waste are burned incompletely. As per EMA: 'This can arise due to contamination by environmental sources, as the lipophilic properties of these compounds allow their adsorption onto atmospheric particles and direct deposition in sediments, soils and plants, or during the post-harvest processing.'[109]

In the EEA, maximum allowable limits for PAHs have been established in regulations applicable to certain herbal food ingredients and food supplements.[110] Table 14 shows the limits of relevance established within the EEA.

For HMPs, EMA discusses controls for PAH contamination in both the guideline on quality of herbal medicinal products [111] and guideline on specifications: test procedures and acceptance criteria for herbal substances.[112] EMA guidance is general, stating that the 'potential for PAH contamination should be considered and controls applied, as needed, using suitable validated methods.'

Certain EMA monographs, for example the 'Community herbal monograph on *Ilex paraguariensis* St Hilaire, folium', include the statement: 'The content of polycyclic aromatic hydrocarbons (PAH) should be adequately controlled',[113] which means that companies trading in this herb, or marketing HMPs containing this herb, should establish controls and maximum allowable limits in their quality specifications.

[108] See Consolidated text of regulation (EC) 396/2005, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02005R0396-20220214

[109] See EMA reflection paper on polycyclic aromatic hydrocarbons in herbal medicinal products, at https://www.ema.europa.eu/en/polycyclic-aromatic-hydrocarbons-herbal-medicinal-productstraditional-herbal-medicinal-products#current-version-section

[110] See Consolidated text of Commission regulation (EC) 1881/2006, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1881-20220503#E0052

[111] See EMA 2022 guideline on quality of herbal medicinal products, at https://www.ema.europa.eu/en/quality-herbal-medicinal-products-traditional-herbal-medicinal-products

[112] See EMA 2022 guideline on specifications: test procedures and acceptance criteria, at https://www.ema.europa.eu/en/specifications-test-procedures-acceptance-criteria-herbal-substances-herbal-preparations-herbal

[113] See EMA Community herbal monograph for *Mate folium*, at https://www.ema.europa.eu/en/medicines/herbal/mate-folium

Table 14 European polycyclic aromatic hydrocarbon limits: Herbal foods and supplements

Food category	Maximum levels (µg/kg)	
	Benzo(a)pyrene	Sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene
Cocoa (*Theobroma cacao*) beans and derived products (excluding cocoa butter)	5.0 µg/kg fat	30.0 µg/kg fat
Cocoa fibre and products derived from cocoa fibre, intended for use as an ingredient in food	3.0	15.0
Coconut (*Cocos nucifera*) oil intended for direct human consumption or use as an ingredient in food	2.0	20.0
Dried herbs	10.0	50.0
Food supplements containing botanicals and their preparations	10.0	50.0
Dried spices with the exception of cardamon (*Elettaria cardamomum*) and smoked *Capsicum* spp.	10.0	50.0

Source: Consolidated text: Commission regulation (EC) 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (text with EEA relevance)

Table 15 provides a summary of available resources to help the producer and exporter to understand and navigate the European regulatory landscape concerning PAH contamination of herbs and herbal products.

Table 15 Publicly available resources on PAH contamination of herbal materials

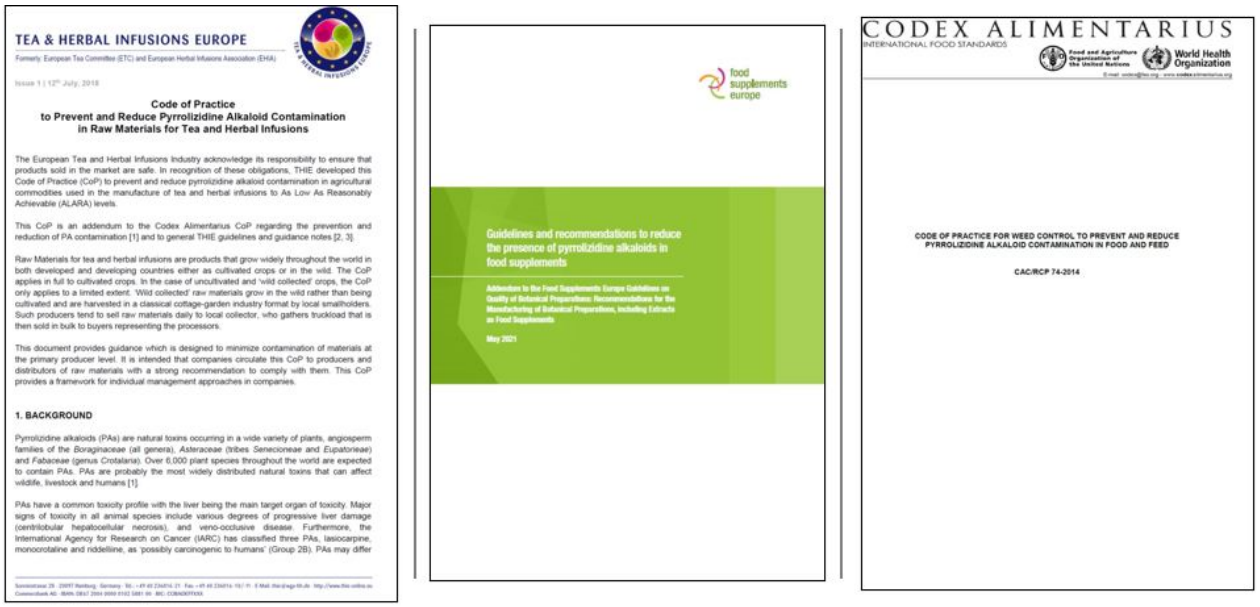
Year	Name of resource	Source
2009	Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes[114]	Codex Alimentarius Commission, Food and Agriculture Organization of the United Nations (FAO) and WHO
2016	Reflection paper on Polycyclic Aromatic Hydrocarbons in herbal medicinal products/traditional herbal medicinal products[115]	Committee on Herbal Medicinal Products of the European Medicines Agency

Sources: Listed in the table with URL internet addresses provided for publicly available downloadable documents

[114] https://www.fao.org/fao-who-codexalimentarius/codex-texts/codes-of-practice/en/

[115] https://www.ema.europa.eu/en/polycyclic-aromatic-hydrocarbons-herbal-medicinal-productstraditional-herbal-medicinal-products

Pyrrolizidine alkaloids



Sources: Left: Tea & Herbal Infusions Europe (THIE). Centre: Food Supplements Europe. Right: Codex Alimentarius Commission, FAO and WHO

As per PhEur: 'Pyrrolizidine alkaloids (PAs) are nitrogen-containing compounds that occur naturally in plants. Several hundred structurally distinct PAs have been found in several thousand different plant species. Many of these plants are common weeds, which can contaminate raw plant materials used for the production of medicinal products. This results in contamination of raw plant materials by PAs, usually at very low levels.'[116]

The European Medicines Agency provided guidance in 2021 on the use of HMPs containing toxic, unsaturated PAs.[117] The guidance suggested that a daily intake (oral or cutaneous) for an adult, equivalent to 1.0 µg of PAs, can serve as a maximum limit.

Concerning PA limits in food and food supplement products, European Commission regulation 2020/240 established maximum levels of PAs in certain foodstuffs, including non-medicinal teas, herbal tea infusions and herbal food supplements. Table 16 shows the maximum levels established for herbal foodstuffs in units of micrograms (µg) per kilogram (kg).

[116] See PhEur General Chapter 2.8.26. Contaminant Pyrrolizidine Alkaloids, at https://pheur.edqm.eu/home

[117] See EMA guidance on the use of HMPs containing Pas, at https://www.ema.europa.eu/en/use-herbal-medicinal-products-containing-toxic-unsaturated-pyrrolizidine-alkaloids-pas

Table 16 European pyrrolizidine alkaloid limits: Herbal foods and supplements

Foodstuffs in Section 8 of the annex to regulation (EC) 1881/2006		Maximum level (*1) (µg/kg)
8.4.	**Pyrrolizidine alkaloids**	
8.4.1.	Herbal infusions (dried product) (*2) (*3) with the exception of the herbal infusions referred to in 8.4.2. and 8.4.4.	200
8.4.2.	Herbal infusions of rooibos (*Aspalathus linearis*), anise (*Pimpinella anisum*), lemon balm (*Melissa officinalis*), chamomile (*Matricaria chamomilla*), thyme (*Thymus* species), peppermint (*Mentha* × *piperita*), lemon verbena (*Aloysia citrodora*) (dried product) and mixtures exclusively composed of these dried herbs (*2) (*3) with the exception of the herbal infusions referred to in 8.4.4.	400
8.4.3.	Tea (*Camellia sinensis*) and flavoured tea (*4)(*Camellia sinensis*) (dried product) (*3) with the exception of the tea and flavoured tea referred to in 8.4.4.	150
8.4.4.	Tea (*Camellia sinensis*), flavoured tea (*4)(*Camellia sinensis*) and herbal infusions for infants and young children (dried product)	75
8.4.5.	Tea (*Camellia sinensis)*, flavoured tea (*4)(*Camellia sinensis*) and herbal infusions for infants and young children (liquid)	1,0
8.4.6.	Food supplements containing herbal ingredients including extracts (*2) with the exception of the food supplements referred to in 8.4.7.	400
8.4.7.	Pollen based food supplements. Pollen and pollen products	500
8.4.8.	Borage leaves (fresh, frozen) placed on the market for the final consumer (*2)	750
8.4.9.	Dried herbs with the exception of the dried herbs referred to in 8.4.10. (*2)	400
8.4.10.	Borage (*Borago officinalis*), lovage (*Levisticum officinale*), marjoram (*Origanum majorana*) and oregano (*Origanum onites* or *Origanum vulgare*) (dried) and mixtures exclusively composed of these dried herbs (*2)	1 000
8.4.11.	Cumin (*Cuminum cyminum*) seeds (seed spice)	400

(*1) The maximum level refers to the lower bound sum of 21 specified PAs plus an additional 14 PAs known to co-elute with one or more of the identified 21 PAs

(*2) Without prejudice to more restrictive national rules in certain member states on placing on the market of PA-containing plants.

(*3) The terms 'herbal infusions (dried product)' and 'tea (*Camellia sinensis*) (dried product)' refer to:

– Herbal infusions (dried product) from flowers, leaves and herbs, roots and any other parts of the plant (in sachets or in bulk)/tea (*Camellia sinensis*) (dried product) from dried leaves, stalks and flowers (in sachets or in bulk) used for the preparation of herbal infusion (liquid product)/tea (liquid product);

– Instant herbal teas/teas. In the case of powdered tea extracts, a concentration factor of 4 has to be applied.

(*4) Flavoured tea is tea with flavourings and certain food ingredients with flavouring properties, as defined in regulation (EC) 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (OJ L 354, 31.12.2008, p. 34).

Table 17 provides a summary of available resources to help the producer and exporter to understand and navigate the European regulatory landscape concerning PA contamination of herbs and herbal products.

Table 17 Publicly available resources: Mitigation of PA contamination and requirements

Year	Name of resource	Source
2011	Scientific opinion on pyrrolizidine alkaloids in food and feed[118]	European Food Safety Authority (EFSA) Journal
2013	Pyrrolizidine alkaloids in herbal teas and teas[119]	German Federal Institute for Risk Assessment (BfR)
2014	Code of practice for weed control to prevent and reduce pyrrolizidine alkaloid contamination in food and feed[120]	Codex Alimentarius Commission (CAC)
2016	Code of practice to prevent and reduce pyrrolizidine alkaloid contaminations of medicinal products of plant origin[121]	German Medicines Manufacturers' Association (BAH) and German Pharmaceutical Industry Association (BPI)
2016	Public statement on contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids[122]	Committee on Herbal Medicinal Products (HMPC) of the European Medicines Agency
2017	Risks for human health related to the presence of pyrrolizidine alkaloids in honey, tea, herbal infusions and food supplements[123]	European Food Safety Authority (EFSA) Journal
2018	Code of Practice to Prevent and Reduce Pyrrolizidine Alkaloid Contamination in Raw Materials for Tea and Herbal Infusions[124]	Tea & Herbal Infusions Europe (THIE)
2019	Code of Practice zur Vermeidung und Verringerung der Kontamination von Lebensmitteln mit Pyrrolizidinalkaloiden[125]	Lebensmittelverband Deutschland
2020	Code of Practice zur Vermeidung und Verringerung der Kontamination pflanzlicher Nahrungsergän-zungsmittel mit Pyrrolizidinalkaloiden[126]	Lebensmittelverband Deutschland
2020	Commission regulation (EU) 2020/2040 of 11 December 2020 amending regulation (EC) 1881/2006 as regards maximum levels of pyrrolizidine alkaloids in certain foodstuffs (text with EEA relevance)[127]	Official Journal of the European Union
2021	European Pharmacopoeia Commission new general chapter Contaminant pyrrolizidine alkaloids (PhEur 2.8.26)[128]	European Directorate for the Quality of Medicines (EDQM)
2021	Guidelines and recommendations to reduce the presence of pyrrolizidine alkaloids in food supplements[129]	Food Supplements Europe
2021	Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination of herbal medicinal products with PAs[130]	Committee on Herbal Medicinal Products (HMPC) of the European Medicines Agency

Sources: Listed in the table with URL internet addresses provided for publicly available downloadable documents.

[118] See https://www.efsa.europa.eu/en/efsajournal/pub/2406

[119] See https://www.bfr.bund.de/cm/349/pyrrolizidine-alkaloids-in-herbal-teas-and-teas.pdf

[120] See https://www.fao.org/fao-who-codexalimentarius/codex-texts/codes-of-practice/en/

[121] See https://www.journals.elsevier.com/journal-of-applied-research-on-medicinal-and-aromatic-plants/news/code-of-practice-to-prevent-and-reduce-pyrrolizidine-alkaloi

[122] See https://www.ema.europa.eu/en/contamination-herbal-medicinal-productstraditional-herbal-medicinal-products-pyrrolizidine-alkaloids

[123] See https://www.efsa.europa.eu/en/efsajournal/pub/4908

[124] See https://thie-online.eu/publications.html

[125] See https://www.lebensmittelverband.de/de/lebensmittel/sicherheit/unerwuenschte-stoffe-kontaminanten/pyrrolizidinalkaloide-pa

[126] See https://www.lebensmittelverband.de/de/lebensmittel/sicherheit/unerwuenschte-stoffe-kontaminanten/pyrrolizidinalkaloide-pa

[127] See https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R2040

[128] See https://pheur.edqm.eu/home

[129] See https://foodsupplementseurope.org/publications-guidelines/

[130] See https://www.ema.europa.eu/en/use-herbal-medicinal-products-containing-toxic-unsaturated-pyrrolizidine-alkaloids-pas

Tropane alkaloids

Sources: Left: Forschungsinstitut für biologischen Landbau (FiBL); Centre: FAO and WHO; Right: FAO and WHO

According to the European Food Safety Authority (EFSA), tropane alkaloids (TAs) are secondary metabolites that naturally occur in plants of several families, including Brassicaceae, Solanaceae (e.g. mandrake, henbane, deadly nightshade, jimson weed) and Erythroxylaceae, including coca (*Erythroxylum coca*). Seeds of TA-producing plants, such as *Datura stramonium*, can be found as impurities in agricultural crops.

In 2022, the European Commission published a regulation on the maximum levels of TAs (atropine and scopolamine) in non-medicinal herbal tea infusions (dried and liquid).[131] Table 18 shows the maximum levels established for infusions in units of micrograms (µg) per kilogram (kg).

Table 18 European tropane alkaloid limits: Herbal tea infusions

Foodstuffs		Maximum level (µg/kg) (sum of atropine and scopolamine)
8.2	**Tropane alkaloids**	
8.2.7.	Herbal infusions (dried product) with the exception of the herbal infusions referred to in 8.2.8.	25 as from 1 September 2022
8.2.8.	Herbal infusions (dried product) of anise (*Pimpinella anisum*) seeds	50 as from 1 September 2022
8.2.9.	Herbal infusions (liquid)	0.20 as from 1 September 2022

Source: EUR-Lex official website of the European Union for access to EU law, at https://eur-lex.europa.eu/homepage.html

[131] See Consolidated text of Commission regulation (EC) 1881/2006, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1881-20220503

Table 19 provides a summary of available resources to help the producer and exporter to understand and navigate the European regulatory landscape concerning TA contamination of herbs and herbal products.

Table 19 Publicly available resources: Mitigation of TA contamination and requirements

Year	Name of resource	Source
2013	Scientific Opinion on Tropane alkaloids in food and feed[132]	European Food Safety Authority (EFSA) Journal
2016	Tropane alkaloids – Prevention of contamination in organic crops[133]	FibL
2020	Report of the Joint FAO/WHO Expert Meeting on Tropane Alkaloids[134]	FAO and WHO
2020	Guidance document on physical Datura stramonium seed contamination[135]	FAO and WHO
2022	Consolidated text: Commission regulation (EC) 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (text with EEA relevance)[136]	European Union Law
2022	Assessment of the Conclusions of the Joint FAO/WHO Expert Meeting on Tropane Alkaloids[137]	European Food Safety Authority (EFSA) Journal

Sources: Listed in the table with URL internet addresses provided in footnotes for publicly available downloadable documents.

Radioactive contamination

WHO's *Quality control methods for herbal materials* discusses the potential contamination of medicinal plants with airborne radioactive materials following a nuclear accident. In such cases, WHO recommends that the activity concentration and type of radioactive contamination can be measured by the radiation monitoring laboratories of most WHO member states."[138]

The former European Council regulation on imports of agricultural products, ratified following the 1986 accident at the Chernobyl nuclear power station in Ukraine, expired in March 2020.[139] Neither EMA nor EDQM prescribe limits for contamination of herbal substances. EDQM advises that, in some circumstances, the risk of radioactive contamination is to be considered in herbal drugs. EMA recommends that a test for radioactivity should be included in herbal drug specifications if there is reason for concern.[140]

However, if a producer or supplier of MAPs is exporting to customers situated in the Russian Federation or in some republics of the former Soviet Union, pharmacopoeial limits and testing requirements for herbal drug materials are still in force. The state pharmacopoeias of Belarus, Kazakhstan, Russian Federation and Ukraine include limits for radioactive contamination in herbal drugs. Table 20 provides the radionuclide limits applicable to all herbal drugs of the Russian pharmacopoeia.

[132] See https://www.efsa.europa.eu/en/efsajournal/pub/3386

[133] See https://www.fibl.org/en/shop-en/1711-tropane-alkaloids

[134] See https://www.fao.org/documents/card/en/c/cb1857en

[135] See https://www.fao.org/food-safety/news/news-details/fr/c/1363024/

[136] See https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1881-20220503

[137] See https://www.efsa.europa.eu/en/efsajournal/pub/7229

[138] WHO Quality control methods for herbal materials, at https://apps.who.int/iris/handle/10665/44479

[139] See Consolidated text of (expired) Council regulation (EC) 733/2008, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008R0733-20091107

[140] See EMA Guidance of quality of herbal medicinal products, at https://www.ema.europa.eu/en/quality-herbal-medicinal-products-traditional-herbal-medicinal-products

Table 20 Pharmacopoeial maximum level of radionuclide activity: Herbal drugs

Radionuclide	Maximum permissible level, becquerel (Bq) per kilogram (kg)
Cesium-137 (Cs-137)	NMT 400 Bq/kg
Strontium-90 (Sr-90)	NMT 200 Bq/kg

Source: General Chapter, Determination of the radionuclide content in herbal drugs and herbal drug preparations (in Russian), State Pharmacopoeia of the Russian Federation (PhRus XIV 2018), at https://femb.ru/record/pharmacopea14

Residues of fumigants and ionizing radiation

Fumigants such as ethylene oxide, methyl bromide and propylene oxide, as well as ionizing radiation have been used in some countries for microbial decontamination of herbs and spices. It is important for the producer and exporter of MAPs to the European Economic Area to be aware of limitations or restrictions and, furthermore, that validated methods exist that can detect if an herbal substance has been fumigated or irradiated.

Residues of fumigants

For herbal medicinal products, the European Pharmacopoeia requires that, if a decontaminating treatment has been used, '… it is necessary to demonstrate that the constituents of the herbal drug are not affected and that no harmful residues remain. The use of ethylene oxide (EtO) is prohibited for the decontamination of herbal drugs.'[141]

The use of EtO for the decontamination of herbal substances has been prohibited in the European Union since 31 December 1989 for reasons including genotoxicity, harm to workers and the formation of toxic reaction products such as ethylene chlorohydrin [2-chloroethanol] and ethylene glycol. The use of methyl bromide is also being phased out worldwide in accordance with the Montreal Protocol 1992 because it is an ozone-depleting substance.[142]

A potential pitfall for exporters to the EU is that, from time to time, based on reports of contaminated shipments, the European Commission will adopt an implementing regulation on a temporary increase of official controls and emergency measures governing the entry of certain goods from certain third countries.[143]

For example, due to the reported contamination risk by EtO, this regulation came into force in December 2021 for shipments from India of certain goods including guar gum (*Cyamopsis tetragonolobus*), food supplements containing botanicals and several spices, e.g. cinnamon (*Cinnamomum* spp.) bark. Until further notice, consignments of those products must be accompanied by an official certificate stating that all results of sampling and analysis show compliance with the regulation on maximum residue levels of EtO for consignments of food and feed.

[141] See general monograph Herbal Drugs of the European Pharmacopoeia, at https://pheur.edqm.eu/home

[142] See EMA reflection paper on the use of fumigants, at https://www.ema.europa.eu/en/use-fumigants

[143] See Commission Implementing Regulation (EU) 2021/2246, at https://eur-lex.europa.eu/eli/reg_impl/2021/2246/oj

Box 11 Tip: EtO residues in herbal drugs vs food additives in the EU

The use of EtO is prohibited for the decontamination of herbal drugs that are intended for use in medicinal products in the EU. The European Pharmacopoeia provides no tolerance for residues of EtO (European Pharmacopoeia Commission, 2022).

EtO may not be used for sterilizing purposes in food additives. No residue above 0.1 mg/kg, irrespective of its origin, of EtO (sum of EtO and 2-chloro-ethanol expressed as EtO*) shall be present in food additives. (European Commission, 2022)

i.e. ethylene oxide + 0,55 2-chloroethanol

Sources: European Commission. Commission Regulation (EU) 2022/1396 of 11 August 2022 amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to regulation (EC) 1333/2008 of the European Parliament and of the Council as regards the presence of ethylene oxide in food additives (text with EEA relevance). Official Journal of the European Union. 12.8.2022, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R1396; and the European Pharmacopoeia Commission. European Pharmacopoeia, 11th edition (PhEur 11.0). Strasbourg, France: European Directorate for the Quality of Medicine (EDQM).

By comparison, in the United States, while the use of EtO is disallowed for the treatment of herbal dietary supplement ingredients and products and disallowed for use on any certified organic herbal materials, the Environmental Protection Agency (EPA) has established tolerances for residues of EtO and the EtO reaction product, 2-chloroethanol, on certain herbs and spices that are used in conventional food products and that are not certified organic (see Table 21).

Table 21 EPA tolerances for residues of EtO and 2-chloroethanol in herbal food

Botanical	EtO ppm	2-chloroethanol ppm
Crop Group 25: Herb Group: e.g. calendula (*Calendula officinalis*) flower, chamomile (*Matricaria chamomilla*) flower, lemon balm (*Melissa officinalis*) leaf, mulberry (*Morus alba*) leaf, peppermint (*Mentha × piperita*) leaf and others	7	940
Crop Group 26: Spice Group: e.g. ajowan (*Trachyspermum ammi*) fruit, asafoetida (*Ferula asafoetida*) oleo-gum-resin, black cumin (*Nigella sativa*) seed, coriander (*Coriandrum sativum*) fruit, cumin (*Cuminum cyminum*) seed, saffron (*Crocus sativus*) stigma and others		
Liquorice (*Glycyrrhiza glabra, G. inflata, G. uralensis*) root		
Sesame (*Sesamum indicum* L., Pedaliaceae) seed		
Walnut (*Juglans regia* L., Juglandaceae)	50	–

Source: United States Code of Federal Regulations Title 40, Part 180 (40 CFR §180) Tolerances and exemptions for pesticide chemical residues in food, at https://www.govinfo.gov/app/details/CFR-2021-title40-vol26/CFR-2021-title40-vol26-sec180-41/context

Residues of irradiation

Different considerations and regulations in Europe govern the use of ionizing radiation on herbal food substances and herbal medicinal substances.

For HMPs, the European Medicines Agency states: 'Irradiation is restricted or not permitted in a number of European member states and, when allowed, it should only be used when there is a reasonable need, and no other methods can be applied.' EMA recommends a complete evaluation and testing if a company suspects that irradiation was carried out on an herbal substance or HMP.[144] For herbal food substances, an EU directive permits treatment of dried aromatic herbs, spices and vegetable seasonings with ionizing radiation.[145]

[144] See EMA reflection paper on microbiological aspects of HMPs, at https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-microbiological-aspects-herbal-medicinal-products-traditional-herbal-medicinal_en.pdf

[145] See Directive 1999/3/EC of the European Parliament and of the Council of 22 February 1999, at https://eur-lex.europa.eu/eli/dir/1999/3/oj

However, irradiation remains unpopular in Europe and products containing irradiated ingredients are required to be labelled with the words 'irradiated' or 'treated with ionizing radiation'. On the contrary, certified organic herbs and spices are very popular and ionizing radiation is not permitted for use on certified organic products.

By comparison, US Food and Drug Administration (FDA) regulations permit the use of irradiation only under specific conditions, for certain food colours and food flavours, with limitations and labelling requirements (e.g. radiation disclosure statement).[146] Irradiation may be used to treat culinary herbs and spices or vegetable seasonings, but only when they are used as ingredients in small amounts solely for flavouring or aroma of other products and not ingested on their own. Furthermore, turmeric (*Curcuma longa*) rhizome and paprika (*Capsicum annuum*) fruit may also be irradiated when they are to be used as colour additives.

Table 22 compares the limitations established in the EU and the US for maximum radiation dosages.

Table 22 Comparison of EU and US maximum ionizing radiation doses: Herbal foods

	Category of foodstuff	Limitations
EU	Dried aromatic herbs, spices and vegetable seasonings.	Maximum overall average absorbed radiation dose: 10 kilogray (kGy)
US	'For microbial disinfection of the following dry or dehydrated aromatic vegetable substances when used as ingredients in small amounts solely for flavouring or aroma: culinary herbs, seeds, spices, vegetable seasonings that are used to impart flavour but that are not either represented as, or appear to be, a vegetable that is eaten for its own sake, and blends of these aromatic vegetable substances. Turmeric and paprika may also be irradiated when they are to be used as colour additives. The blends may contain sodium chloride and minor amounts of dry food ingredients ordinarily used in such blends.'	Not to exceed 30 kGy = 3 megarad (Mrad)

Sources: Directive 1999/3/EC of the European Parliament and of the Council of 22 February 1999 (on the establishment of a community list of foods and food ingredients treated with ionizing radiation); and US FDA regulation 21CFR §179.26 (Ionizing radiation for the treatment of food)

Labelling

Herbal ingredients

As a general rule, labels accompanying bulk shipments of botanical raw materials into the EU should include the following basic information:

- Common name of the botanical material;
- Latin name of the botanical material;
- Commodity HS code;
- Net weight;
- Lot marking with the marking preceded by the letter 'L';
- Country of origin or place of provenance;
- Name and address of the exporter;
- If certified (e.g. Organic, Biodynamic, Fair for Life, Fairtrade or FairWild), information on the certification and certifying control body.

Additional labelling, certificates, or documents are required to accompany the shipment for particular categories of materials, such as:

[146] See US FDA regulation 21CFR §179.26 (Ionizing radiation for the treatment of food), at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=179.26

- Certain plants, plant products and other objects listed in Annex XI and XII of Regulation (EU) 2019/2072 entering the EU must have a phytosanitary certificate;[147]
- Certified organic herbal materials;[148] all organic products imported into the EU must have the appropriate electronic certificate of inspection (e-COI). These are administered through the Trade Control and Expert System (TRACES);[149]
- Foodstuffs treated with ionizing radiation;[150]
- New (novel) foods and food ingredients.[151]

Herbal finished products

Labelling requirements and the claim statements that may be made will vary significantly in Europe depending on whether the herbal product is a cosmetic, food, food supplement or medicine. Table 23 provides information on the various labelling requirements.

Table 23 Labelling requirements: Cosmetic, food, food supplement, medicinal product

Type of product	What are the labelling requirements?
Cosmetic	Regulation (EC) 1223/2009 on cosmetic products; see Chapter VI Consumer Information Article 19 Labelling.[152]
Food	Regulation (EU) 1169/2011 on the provision of food information to consumers; see Articles 21, 22, 23, 26, 30, 49 and 50[153]
Food supplement	Directive 2002/46/EC on the approximation of the laws of the member states relating to food supplements; see Articles 6, 7 and 8[154]
Medicinal	Directive 2001/83/EC on the community code relating to medicinal products for human use; see Articles 54-65[155]
	Directive 2004/24/EC amending, on traditional herbal medicinal products, Directive 2001/83/EC on the community code relating to medicinal products for human use; see Article 16g[156]
	European Medicines Agency guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products[157]
	EC and EMA guideline on excipients in the labelling and package leaflet of medicinal products for human use[158]
Organic product of any type	Regulation (EU) 2018/848 on organic production and labelling of organic products[159]

Sources: EUR-Lex access to European law, at https://eur-lex.europa.eu/homepage.html; and European Medicines Agency, at https://www.ema.europa.eu/en

[147] Consolidated text: Commission Implementing Regulation (EU) 2019/2072, protective measures against pests of plants, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02019R2072-20220411

[148] EU rules on producing and labelling organic products, at https://eur-lex.europa.eu/EN/legal-content/summary/eu-rules-on-producing-and-labelling-organic-products-from-2022.html

[149] European Commission information on importing organic produce, at https://ec.europa.eu/info/food-farming-fisheries/farming/organic-farming/trade_en

[150] Information on labelling and packaging of irradiated foods and food ingredients, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=legissum:l21117

[151] Information on labelling of new (novel) foods and food ingredients, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=legissum:l21119

[152] See https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20220301

[153] See https://eur-lex.europa.eu/eli/reg/2011/1169/2018-01-01

[154] See https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02002L0046-20210330

[155] See https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02001L0083-20220101

[156] See https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32004L0024

[157] See https://www.ema.europa.eu/en/declaration-herbal-substances-herbal-preparations-herbal-medicinal-productstraditional-herbal

[158] See https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/reference-guidelines/excipients-labelling

[159] See https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02018R0848-20220101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Chapter 4
Sustainable production and trade

In the 21st century, the international trade in medicinal and aromatic plants occurs in a context of:

- International conventions, such as the Convention on Biological Diversity (CBD) and the Convention on International Trade in Endangered Species (CITES);
- Conservation status assessments carried out by governmental Red List authorities and non-governmental organizations, such as IUCN Red List assessments;
- Directives and regulations concerning biodiversity conservation, fair labour practices, social responsibility, labelling and traceability;
- The emergence of voluntary standards for demonstrating economic, environmental and social sustainability in the MAP supply chain.

International conventions

Sources: Left: UNCTAD (2014): The Convention on Biological Diversity and the Nagoya Protocol: Intellectual Property Implications. A Handbook on the Interface between Global Access and Benefit Sharing Rules and Intellectual Property. Available at https://unctad.org/webflyer/convention-biodiversity-and-nagoya-protocol-intellectual-property-implications. Centre left: UEBT (2020): Tool on Access & Benefit Sharing (ABS), at https://uebt.org/resource-pages/uebt-online-tool-on-access-and-benefit-sharing. Centre right: Timoshyna, A. et al. (2019): CITES and voluntary certification for wild medicinal and aromatic plants. TRAFFIC Bulletin Vol. 31 No. 2, at https://www.traffic.org/site/assets/files/12507/cites-wild-maps.pdf Right: Schippmann, U. (2020): Plant # Annotations in the CITES Appendices: An Illustrated Manual, Version 3.0, CoP 18 Bonn: Bundesamt für Naturschutz (BfN), at https://cites.org/sites/default/files/eng/com/pc/25/Inf/E-PC25-Inf-09.pdf

Convention on Biological Diversity of the United Nations

The Convention on Biological Diversity (CBD) entered into force on 29 December 1993. Its three main objectives are:[160]

- Conservation of biological diversity;
- Sustainable use of the components of biological diversity;
- Fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

'The *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity* is a supplementary agreement to the Convention on Biological Diversity.' The protocol was adopted in October 2010 in Nagoya, Japan and

[160] Information on the CBD, at https://www.cbd.int/intro/

entered into force on 12 October 2014, 90 days after the deposit of the 50th instrument of ratification. Its objective is the fair and equitable sharing of benefits arising from the use of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity. Table 24 provides links to publicly available guidance information on requirements of the Nagoya Protocol.

Table 24 Publicly available resources on the Nagoya Protocol

Year	Name of resource	Source
2011	The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Text and Annex)[161]	Secretariat of the Convention on Biological Diversity (CBD)
2012	An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing[162]	International Union for Conservation of Nature (IUCN)
2014	Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union Text with EEA relevance[163]	EUR-Lex Access to European Union Law
2014	The Convention on Biodiversity and the Nagoya Protocol: Intellectual Property Implications - A Handbook on the Interface between Global Access and Benefit Sharing Rules and Intellectual Property[164]	United Nations Conference on Trade and Development (UNCTAD)
2017	Frequently Asked Questions on the Nagoya Protocol on ABS[165]	Union for Ethical BioTrade (UEBT)

Sources: Listed in the table with URL internet addresses provided in the footnotes for publicly available downloadable documents

Convention on International Trade in Endangered Species of the United Nations

CITES (Convention on International Trade in Endangered Species of Wild Fauna and Flora) is an international agreement between governments. It aims to ensure that international trade in wild animals and plants does not threaten the survival of the species. Of the approximately 32,800 plant species listed in CITES appendices, around 1,280 are medicinal and aromatic plants (MAPs).[166] Of these 1,280 species, most international trade involves about 47 CITES-listed MAP species.

- **Appendix I** includes species threatened with extinction. Trade in specimens of these species is permitted only in exceptional circumstances;
- **Appendix II** includes species not necessarily threatened with extinction, but in which trade must be controlled to avoid utilization incompatible with their survival;
- **Appendix III** contains species that are protected in at least one country that has asked other CITES Parties for assistance in controlling the trade.

Import and export trade data for these monitored species can be accessed at the online CITES Trade Database, which was developed and is maintained by the UN Environment Programme World Conservation Monitoring Centre (UNEP-WCMC) on behalf of the CITES Secretariat.[167] Directly linked to the CITES Trade

[161] See https://www.cbd.int/abs/

[162] See https://portals.iucn.org/library/node/10258

[163] See https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0511

[164] See https://unctad.org/webflyer/convention-biodiversity-and-nagoya-protocol-intellectual-property-implications

[165] See https://uebt.org/resource-pages/faq-nagoya-protocol-abs

[166] See CITES medicinal and aromatic plants information, at https://cites.org/eng/prog/medplants

[167] Access CITES Trade Database at https://trade.cites.org/

Database is the CITES Wildlife TradeView, an interactive online tool for exploring and visualizing CITES trade data.[168]

As per the European Directorate-General for Environment: 'Due to the European Single Market and the absence of systematic border controls within the EU, the provisions of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) have to be implemented uniformly in all EU Member States. CITES is implemented in the EU through a set of Regulations known as the EU Wildlife Trade Regulations.'[169]

Some governments have regulations that link their CITES reporting obligations with the trade and use of herbal substances that are included their national pharmacopoeia. For example, Republic of Korea has two official compendia, the Korean Pharmacopoeia (KP) and Korean Herbal Pharmacopoeia (KHP). The Korean Pharmaceutical Affairs Act requires pharmaceutical companies to obtain approval from the Ministry of Food and Drug Safety of Korea in cases where herbal raw materials and/or finished products that contain CITES-listed species are exported, imported, carried or re-exported. Table 25 shows CITES-listed species with monographs appearing in the KP or KHP.

Table 25 Example from South Korea: CITES-listed MAP species in trade

Korean common name (Chinese)	Description	CITES
노회 (蘆薈)	Aloe KHP is the dried juice-like fluid, obtained from leaves of *Aloe barbadensis* Linne, *Aloe ferox* Miller, *Aloe africana* Miller or *Aloe spicata* Baker (Liliaceae) and mixed-bred species.	II
침향 (沈香)	Aquilariae Lignum KHP is the infiltrated wood with the resin of Aquilaria agallocha Roxburgh (Thymeleaceae).	II
목향 (木香)	Aucklandiae Radix KHP is the root of *Aucklandia lappa* Decne. with peeling off the rough skin (Compositae).	I
백급 (白芨)	Bletillae Rhizoma KHP is the rhizome of *Bletilla striata* (Thunberg) Reichenbach fil. (Orchidaceae).	II
구척 (狗脊)	Cibotii Rhizoma KP is the rhizome of *Cibotium barometz* J. Smith (Dicksoniaceae).	II
육종용 (肉蓯蓉)	Cistanchis Herba KHP is the fleshy stem of *Cistanche deserticola* Y. C. Ma (Orobanchaceae) and other species of the same genus.	II
산자고 (山慈菇)	Cremastrae Tuber KHP is the pseudobulb of *Cremastra appendiculata* (D. Don) Makino, *Pleione bulbocodioides* Rolfe or *Pleione yunnanensis* Rolfe (Orchidaceae).	II
강향 (降香)	Dalbergiae Odoriferae Lignum KHP is the duramen of the stem and root of *Dalbergia odorifera* T. Chen (Leguminosae).	II
석곡 (石斛)	Dendrobii Caulis KHP is the stem of *Dendrobium nobile* Lindley, *Dendrobium loddigesii* Rolfe., *Dendrobium fimbriatum* Hook. var. *oculatum* Hook., *Dendrobium chrysanthum* Wall. ex Lindley or *Dendrobium candidum* Wall. ex Lindley (Orchidaceae).	II
적전 (赤箭)	Gastrodiae Herba KHP is the aerial part of *Gastrodia elata* Blume (Orchidaceae).	II
천마 (天麻)	Gastrodiae Rhizoma KP is the steamed and dried rhizome of *Gastrodia elata* Blume (Orchidaceae).	II
인삼 (人蔘)	Ginseng Radix KP is the root, or the removed thin roots and cork layers of *Panax ginseng* C.A.Meyer (Araliaceae).	II (Russia only)
미삼 (尾蔘)	Ginseng Radix Palva KHP is thin roots of *Panax ginseng* C. A. Meyer (Araliaceae).	

[168] Access CITES Wildlife TradeView online tool at https://tradeview.cites.org/

[169] See European Directorate-General for Environment for information on CITES, at https://ec.europa.eu/environment/cites/legislation_en.htm

Korean common name (Chinese)	Description	CITES
홍삼 (紅蔘)	Ginseng Radix Rubra KP is the steamed roots of *Panax ginseng* C. A. Meyer (Araliaceae).	
감송향 (甘松香)	Nardostachyos Radix et Rhizoma KHP is the rhizome and root of *Nardostachys chinensis* Batal or *Nardostachys jatamansi* DC. (Valerianaceae).	II
호황련 (胡黃蓮)	Picrorhizae Rhizoma KHP is the rhizome of *Picrorhiza kurroa* Bentham or Picrorhiza scrophulariiflora Pennell (Scrophulariae).	II
인도사목(印度蛇木)	Rauwolfia Radix KHP is the root of *Rauwolfia serpentina* Bentham (Apocynaceae).	II
자단향 (紫檀香)	Santalini Lignum Rubrum KHP is the duramen of *Pterocarpus santalinus* Linné (Leguminosae).	II

Source: Republic of Korea Medicinal Plants Listings in CITES, at https://cites.org/sites/default/files/eng/cop/18/inf/E-CoP18-Inf-048.pdf

European Union regulations

EC (proposed) directive on corporate sustainability due diligence

In February 2022, the EC adopted a proposal for a directive on corporate sustainability due diligence,[170,171] which will impact EU and non-EU companies engaged in the MAP import-export trade. According to the EC: 'The proposal aims to foster sustainable and responsible corporate behaviour throughout global value chains. Companies play a key role in building a sustainable economy and society. They will be required to identify and, where necessary, prevent, end or mitigate adverse impacts of their activities on human rights, such as child labour and exploitation of workers, and on the environment, for example pollution and biodiversity loss.'

The new due diligence rules will apply to the following companies and sectors:

- **EU companies**:
  - Group 1: All EU limited liability companies of substantial size and economic power (with 500+ employees and more than €150 million in net turnover worldwide);
  - Group 2: Other limited liability companies operating in defined high-impact sectors that do not meet both Group 1 thresholds but have more than 250 employees and a net turnover of €40 million worldwide and more. For these companies, rules will start to apply two years later than for Group 1.
- **Non-EU companies** active in the EU with turnover threshold aligned with Groups 1 and 2, generated in the EU.

EC regulation concerning traceability and labelling of genetically modified organisms

Regulation (EC) 1830/2003[172] puts in place rules to ensure products containing GMOs and food and animal feed derived from them can be traced at all stages of the production and distribution chain. The rules cover labelling, monitoring environmental and health risks, and the ability to withdraw products where necessary.

[170] EC press release (23 Feb 2022) 'Just and sustainable economy: Commission lays down rules for companies to respect human rights and environment in global value chains', at https://ec.europa.eu/commission/presscorner/detail/en/ip_22_1145

[171] Proposal for a Directive of the European Parliament and of the Council on Corporate Sustainability Due Diligence, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0071

[172] Consolidated text: Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003R1830-20190726

Three requirements are relevant to exporters of GMO ingredients:

1. Inform trade buyers in writing that a product contains GMOs (or provide a 'declaration of use' for products intended for food or animal feed);
2. Communicate the unique identifiers assigned to each GMO under the regulation;
3. For food and feed, identify each ingredient produced from GMOs, if an ingredients list exists.

EU regulation on organic production and labelling of organic products

Regulation (EC) 889/2008 lays down detailed rules with regard to organic production, labelling and control.[173] Control rules cover requirements for plant products and seaweeds, which have relevance for non-EU companies that export organic herbal materials to customers in the EU, including:

- Certified organic operator responsibilities;
- Annual inspections by accredited control authorities;
- Documentation and accounts;
- Access to facilities.

Per EU rules on producing and labelling organic products,[174] a product may be imported from a non-EU country to be sold in the EU as an organic product if certain conditions are met. It must:

- Comply with the production and control rules of the non-EU country that are recognized under an international agreement as being equivalent to those in the EU;
- Have a certificate issued by the relevant control authorities or control bodies in non-EU countries confirming that the product complies with EU standards.

All organic products imported into the EU must have the appropriate electronic certificate of inspection (e-COI). These are administered through the Trade Control and Expert System (TRACES).[175]

- Equivalent countries: Certificates are issued by the control bodies designated by the countries' national authorities;
- All other countries: Certificates are issued by the control bodies designated by the EU.

[173] Specific rules on organic production, labelling and control, at https://eur-lex.europa.eu/EN/legal-content/summary/specific-rules-on-organic-production-labelling-and-control.html

[174] EU rules on producing and labelling organic products (from 2022), at https://eur-lex.europa.eu/EN/legal-content/summary/eu-rules-on-producing-and-labelling-organic-products-from-2022.html

[175] EC information on importing organic produce, at https://ec.europa.eu/info/food-farming-fisheries/farming/organic-farming/trade_en

Voluntary sustainability standards

Sources: Left: UEBT (2020) Ethical BioTrade Standard, at https://uebt.org/setting-the-standard; Centre left: EcoCert (2022) Fair for Life Standard, at https://www.fairforlife.org/pmws/indexDOM.php?client_id=fairforlife&page_id=root_2_3&lang_iso639=en; Centre right: FLO (2012) Fairtrade Standard for Herbs and Herbal Teas for Hired Labour and Traders, at https://www.fairtrade.net/standard/hl-herbs; Right: FWF (2010): FairWild Standard, at https://www.fairwild.org/documents

A range of credible international voluntary sustainability standards (VSS) are relevant to the production and trade of MAPs and the value-added ingredients made from MAP raw materials.

These standards are rulebooks in the form of principles, criteria and performance indicators with control points that can be implemented by the MAP producer operation and are used by accredited independent third-party auditors for the purpose of assessing the operation's conformance with the standard. Successful audits lead to issuance of certification documents to the operation by the inspection and certification control body.

Each VSS may differ in scope or focus. Some buyers may specify procurement of MAP ingredients carrying certification against two or more standards.

Brands using MAP ingredients in their products are increasingly specifying supply chain visibility with access to documentary evidence of ethical production and trade, protection of nature and reduction of carbon and water footprints.

The production, trade and use of certified ingredients supports certain sustainable development goals (SDGs), which strengthens environmental, social and governance (ESG) and CSR profiles of all operations in the MAP value chain, from the producer operations to the processors and traders to the finished product manufacturers and marketers.

This section of the guide summarizes information on selected VSS that may be relevant for the MAP sector and are visible on the labels of popular products in the European and American markets, including:

- Ethical BioTrade Standard (Union for Ethical BioTrade);
- Fair for Life Standard (EcoCert);
- Fairtrade Standard for Herbs and Herbal Teas for Hired Labour and Traders (Fairtrade International);
- FairWild Standard (FairWild Foundation);
- International Demeter Biodynamic Standard (Biodynamic Federation Demeter International).

The listing of any particular MAP producer operation or exporter in this section is meant only for the purpose of illustrating the types of operations involved in the export trade of MAPs that carry one or more certifications showing conformance with an international VSS. The listings are not comprehensive and are not to be construed as an endorsement of any particular company.

Box 12 Tip: Value added by VSS certifications

Implementation of VSS may not only fill in some of the gaps in GACP guidelines and sustainable agriculture regulations, respectively, but also provide the value-addition of certifications that demonstrate conformance with credible international standards, bolstering the economic viability of the MAP production operation.

Implementation of VSS can also contribute to assuring conformance to pharmacopoeial quality standards, production and process control system requirements, and regulations on documentation, safety, country-of-origin labelling and traceability.

Source: Authors of this report

Ethical BioTrade standard

Founded in 2007, the Union for Ethical BioTrade (UEBT), with its secretariat based in Amsterdam, the Netherlands, is a non-profit association that promotes 'sourcing with respect'. UEBT is the standards setting organization responsible for the Ethical BioTrade Standard.[176]

According to UEBT: 'We work to regenerate nature and secure a better future for people through ethical sourcing of ingredients from biodiversity. We aim to contribute to a world in which all people and biodiversity thrive. We set good practices for how companies and their suppliers source specialty ingredients for the beauty, food, natural pharmaceuticals, flavours and fragrances, herbs and spices sectors, among others. UEBT is internationally recognized for its work with companies on ethical sourcing of ingredients from biodiversity.'

Table 26 provides some examples of UEBT-certified operations that produce MAP ingredients for domestic consumption and for export.

Table 26 Selected UEBT-certified MAP ingredients and producer operations

Company	Country	Certified MAPs
Agrifaso S.A.R.L.	Burkina Faso	Ginger (*Zingiber officinale)* rhizome, roselle (*Hibiscus sabdariffa*), shea (*Vitellaria paradoxa*) nut butter
Les Arômes du Maroc	Morocco	Bitter orange (*Citrus aurantium*) extracts and oils
Mexialoe Laboratorios S.A.	Mexico	*Aloe vera* gel and powder
Natura Industria	Brazil	Açaí (*Euterpe oleracea*) fruit and pulp, *Mentha arvensis* leaf, *Schinus terebinthifolii* leaf and many others.
P.T. Cassia Co-op	Indonesia	Cinnamon (*Cinnamomum* spp.) tree bark
Ravina S.A.R.L.	Madagascar	*Centella asiatica* leaf

Source: UEBT Certificate holders, at https://uebt.org/certificate-holders

[176] Download the UEBT Ethical BioTrade Standard, at https://uebt.org/setting-the-standard

Fair for Life standard

The Fair for Life standard[177] is a certification programme for fair trade in agriculture, manufacturing and trade, created in 2006 by the Swiss Bio-Foundation in cooperation with the IMO Group, then taken over by the Ecocert Group in 2014.

According to EcoCert Group: 'Fair for Life promotes an approach of fair trade that allows all producers and workers who are at a socio-economic disadvantage to access a wider range of social and economic benefits. Fair trade is part of a broader context of sustainable development within a region that safeguards and supports the local social fabric, particularly in rural settings. These principles hold true equally well in the Global South as the Global North and apply throughout the whole supply chain covering producers, traders, manufacturers and brand holders.'

Table 27 Selected Fair for Life certified MAP ingredients and producer operations

Company	Country	Certified MAPs
Birlik Tütün Pamuk Gıda Mad. Tic. Ve San. A.Ş.	Turkey	Fennel (*Foeniculum vulgare*) fruit
Castor Products Company	India	Castor (*Ricinus communis*) seed oil cold pressed, sesame (*Sesamum indicum*) seed oil cold pressed, moringa (*Moringa oleifera*) seed oil cold pressed, moringa leaves dried, neem (*Azadirachta indica*) seed oil cold pressed
Cultivator Natural Products Pvt. Ltd	India	*Aloe vera*, amla (*Phyllanthus emblica*) fruit, castor (*Ricinus communis*) seed, chamomile (*Matricaria chamomilla*) flower, chia (*Salvia hispanica*) seed, eucalyptus (*Eucalyptus globulus*) leaf, ginger (*Zingiber officinale*) rhizome, henna (*Lawsonia inermis*) leaf, holy basil (*Ocimum sanctum*) leaf, indigo (*Indigofera tinctoria*) leaf, neem (*Azadirachta indica*), roselle (*Hibiscus sabdariffa*) flower, senna (*Senna alexendrina*) leaflet, shatavari (*Asparagus racemosus*) root, sidr (*Ziziphus jujuba*) leaf, turmeric (*Curcuma longa*) rhizome
EcoSo Dynamics cc	Namibia	Devil's claw (*Harpagophytum procumbens*) root tuber, roselle (*Hibiscus sabdariffa*) flower
Herb Artizan Pvt. Ltd	India	Black pepper (*Piper nigrum*) fruit, cardamom (*Elettaria cardamomum*) seed, cinnamon (*Cinnamomum* spp.) tree bark, clove (*Syzygium aromaticum*) flower bud, ginger (*Zingiber officinale*) rhizome, turmeric (*Curcuma longa*) rhizome, west Indian lemongrass (*Cymbopogon citratus*) leaf
JV 'Licoroots' LLC	Uzbekistan	Liquorice (*Glycyrrhiza glabra*) root
Naturnorm Organik Tarım Ürünleri San. ve Tic. Ltd Şti.	Turkey	Fennel (*Foeniculum vulgare*) fruit
Nomade Palize	Iran, Islamic Republic of	Damask rose (*Rosa* x *damascene*) buds and petals, saffron (*Crocus sativus*) stigma
Uttarkannada District Co-Operative Organic Farmers Federation Limited	India	Black pepper (*Piper nigrum*) fruit, cardamom (*Elettaria cardamomum*) seed, cinnamon (*Cinnamomum* spp.) tree bark, clove (*Syzygium aromaticum*) flower bud, ginger (*Zingiber officinale*) rhizome, turmeric (*Curcuma longa*) rhizome, west Indian lemongrass (*Cymbopogon citratus*) leaf
Vanamoolika Herbals and Research Pvt. Ltd	India	Black pepper (*Piper nigrum*) fruit, clove (*Syzygium aromaticum*) flower bud, ginger (*Zingiber officinale*) rhizome, moringa (*Moringa oleifera*) leaf, turmeric (*Curcuma longa*) rhizome
Vina Samex JSC	Viet Nam	Chinese-type cinnamon (*Cinnamomum cassia*) bark, star anise (*Illicium verum*) fruit

Source: Fair for Life certified products, at https://www.fairforlife.org/pmws/indexDOM.php?client_id=fairforlife&page_id=certprod&lang_iso639=en

[177] Fair for Life: Standard & material, at https://www.fairforlife.org/pmws/indexDOM.php?client_id=fairforlife&page_id=root_2_3&lang_iso639=en

Fairtrade standard for herbs, herbal teas and spices

Founded in 1997, Fairtrade International (FLO) is a non-profit association of 22 member organizations – three producer networks and 19 national Fairtrade organizations. FLO standards of relevance to the production and trade of MAP ingredients and products include:[178]

- Fairtrade Standard for Herbs and Herbal Teas for Hired Labour and Traders;
- Fairtrade Standard for Herbs, Herbal Teas and Spices for Small Producer Organizations and Traders;
- Fairtrade Standard for Tea, applies to Hired Labour Organizations and Traders;
- Fairtrade Standard for Tea, applies to Small-scale Producer Organizations and Traders.

Table 28 Selected FLO Fairtrade certified MAP ingredients and producer operations

Company	Country	Certified MAPs
Arghavan Dasht e Paeezan	Iran, Islamic Republic of	Saffron (*Crocus sativus*) stigma
Cherideo-Purbat Tea Estate	India	Moringa (*Moringa oleifera*) leaf, tea (*Camellia sinensis*) leaf
Cooperativa Agrofrutífera dos Produtores de Urucará	Brazil	Guaraná (*Paullinia cupana*) seed
Dustkul Bogi	Uzbekistan	Almond (*Prunus dulcis* var. *dulcis*) flower, apricot (*Prunus armeniaca*) seed, basil (*Ocimum basilicum*) leaf, black mulberry (*Morus nigra*) leaf, blackberry (*Rubus fruticosus*) leaf, blackcurrant (*Ribes nigrum*) leaf, caper (*Capparis spinosa*) fruit, caraway (*Carum carvi*) fruit, celery (*Apium graveolens*) fruit/leaf, cumin (*Cuminum cyminum*) seed, dill (*Anethum graveolens*), German chamomile (*Matricaria chamomilla*) flower, juniper (*Juniperus communis*) berry, mint (*Mentha* species), Morello sour cherry (*Prunus cerasus*) stem, parsley (*Petroselinum crispum*) leaf, pomegranate (*Punica granatum*) flower, raspberry (*Rubus idaeus*) leaf, rosehip (*Rosa* species), thyme (*Thymus* species) herb, walnut (*Juglans regia*) leaf, white mulberry (*Morus alba*) leaf, wild strawberry (*Fragaria vesca*) leaf
Fairtrade Support Network Zimbabwe	Zimbabwe	Roselle (*Hibiscus sabdariffa*) flower
Heiveld Co-operative Ltd	South Africa	Rooibos (*Aspalathus linearis*) herb
La Campiña Peru S.A.C.	Peru	Ginger (*Zingiber officinale*) rhizome, turmeric (*Curcuma longa*) rhizome
Ottoman for Trading & Manufacturing, Royal Herbs S.A.E	Egypt	Aniseed (*Pimpinella anisum*) fruit, basil (*Ocimum basilicum*) leaf, black cumin (*Nigella sativa*) seed, calendula (*Calendula officinalis*) flower, caraway (*Carum carvi*) fruit, coriander (*Coriandrum sativum*) fruit, cumin (*Cuminum cyminum*), dill (*Anethum graveolens*), fennel (*Foeniculum vulgare*) fruit, fenugreek (*Trigonella foenum-graecum*) seed, German chamomile (*Matricaria chamomilla*) flower, lemon balm (*Melissa officinalis*) leaf, liquorice (*Glycyrrhiza glabra*) root, marjoram (*Origanum majorana*) leaf, mint (*Mentha* spp.) leaf, parsley (*Petroselinum crispum*) leaf, roselle (*Hibiscus sabdariffa*) flower, rosemary (*Rosmarinus officinalis*) leaf, thyme (*Thymus* spp.) herb, west Indian lemongrass (*Cymbopogon citratus*) leaf.

Source: FLOCERT database, at https://www.flocert.net/about-flocert/customer-search/

[178] FLO Fairtrade standards, at https://www.fairtrade.net/standard/fairtrade-standards

FairWild standard

The FairWild Standard 2.0 is the result of two precursor standards, the International Standard for Wild Collection of Medicinal and Aromatic Plants (ISSC-MAP) and FairWild Standard 1.0, that were developed between 2001 to 2006 through processes involving governmental organizations (BfN of Germany and SIPPO of Switzerland), nature conservation non-governmental organizations (e.g. IUCN, TRAFFIC and WWF), MAP producer groups and communities, traders and finished product brands.

In 2008, the FairWild Foundation was registered in Switzerland and the two initiatives merged. The FairWild Foundation's mission is 'to enable transformation of resource management and business practices to be ecologically, socially and economically sustainable throughout the supply chain of wild-collected products. [It aims] to provide a worldwide framework for implementing a sustainable, fair and value-added management and trading system for wild-collected natural ingredients and products thereof.'

Table 29 Selected FairWild certified MAP ingredients and producer operations

Company	Country	Certified MAPs
Azia Gold t.o.o.	Kazakhstan	Liquorice (*Glycyrrhiza uralensis*) root and rhizome, raspberry (*Rubus idaeus*) leaf
Başaran Organics, with Nimeks Organics	Uzbekistan	Liquorice (*Glycyrrhiza glabra*) root and rhizome
B'Ayoba	Zimbabwe	Baobab (*Adansonia digitata*) dried fruits, powder, seed, fibre, pulp on seed, oil, seed meal, seed cake
Geoflower Ltd	Georgia	Blackberry (*Rubus fruticosus*) leaf, dog rose (*Rosa canina*) hip, European elder (*Sambucus nigra*) flower, linden (*Tilia* spp.) flower/leaf, liquorice (*Glycyrrhiza glabra*) root and rhizome, stinging nettle (*Urtica dioica*) leaf, wild apple (*Malus sylvestris*) fruit
Herbes del Moli	Spain	Liquorice (*Glycyrrhiza glabra*) root and rhizome
Himalayan Bio Trade Pvt. Ltd	Nepal	Jatamansi (*Nardostachys jatamansi*) root and rhizome, kutki (*Neopicrorhiza scrophulariiflora*) root and rhizome
Kobac General Trading	Somalia	Frankincense (*Boswellia* spp.) gum resin, essential oil, hydrosol, myrrh (*Commiphora myrrha*) gum resin, essential oil, hydrosol
Nelixia	El Salvador and Honduras	American storax (*Liquidambar styraciflua*) trunk balsam, balsam of Peru (*Myroxylon balsamum* var. *pereirae*) resin
neo botanika	Somaliland, Somalia	Frankincense (*Boswellia* spp.) gum resin, essential oil, hydrosol, myrrh (*Commiphora myrrha*) gum resin, essential oil, hydrosol
ORGIIS	Burkina Faso and Ghana	Baobab (*Adansonia digitata*) fruit powder and oil
Pingwu Shuijing TCM Cooperative	China	Southern schisandra (*Schisandra sphenanthera*) fruit

Source: FairWild species and ingredients, at https://www.fairwild.org/species-ingredients

International Demeter Biodynamic standard

Established in 1924, biodynamics is the world's oldest system of organic growing. According to the Biodynamic Federation Demeter International, the International Demeter Biodynamic standard [179] is the strictest standard for organic agriculture worldwide. Principles of the biodynamic approach are:

- Regeneration – sustainability is not enough;
- Integrating well-being of nature and human beings – we are part of the picture;
- Creating a living context within which human beings, animals and plants can thrive and develop;
- Include animals in a way that respects their well-being, while producing nutrient dense food, nourishing the soil and protecting wildlife;
- Agriculture is contextual – of its ecology, landscape and culture;
- Ecological responsibility – caring for resources, including packaging and transport impacts;
- Social responsibility – support community development and a cooperative approach throughout the supply chain.

Table 30 Selected Demeter certified MAP ingredients and producer operations

Company	Country	Certified MAPs
Ambootia Homesteads & Mullootar Homesteads Darjeeling Organic Tea Estates Pvt. Ltd	India	Ginger (*Zingiber officinale*) rhizome, jasmine (Jasminum spp.) flower, rose (Rosa spp.) flower, tea (*Camellia sinensis*) leaf, turmeric (Curcuma longa) rhizome
Cherideo Purbat Tea Estate (Darjeeling Organic Tea Estates Pvt. Ltd)	India	Ginger (*Zingiber officinale*) rhizome, lemongrass (*Cymbopogon* spp.) leaf, tea (*Camellia sinensis*) leaf, turmeric (*Curcuma longa*) rhizome
Dr Madihi's Farm Chenar Farm	Iran, Islamic Republic of	Rose (*Rosa* spp.) flower, saffron (*Crocus sativus*) stigma
Jaycee Organics LLP	India	Amla (*Phyllanthus emblica*), ashwagandha (*Withania somniferum*) root, guduchi (*Tinospora cordifolia*) stem, holy basil (Ocimum sanctum) leaf,
La Campiña Peru S.A.C.	Peru	Ginger (*Zingiber officinale*) rhizome, turmeric (*Curcuma longa*) rhizome
Matebrás Indústria do Mate Ltda ME	Brazil	Yerba maté (*Ilex paraguariensis*) leaf
Zanj Spice LTD ZOSG	Tanzania	Bird's eye chili (*Capsicum annuum*) fruit, black pepper (*Piper nigrum*) fruit, Ceylon cinnamon (*Cinnamomum verum*) bark, mace (*Myristica fragrans*) aril, nutmeg (*Myristica fragrans*) kernel, vanilla (*Vanilla planifolia*) fruit

Source: Demeter database, at https://database.demeter.net/welcome

[179] Access the International Demeter Biodynamic Standard at https://demeter.net/certification/standard/


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Chapter 5
Export marketing

Main markets for MAP ingredients

Using selected representative World Customs Organization four-digit HS codes[180] in the UN's COMTRADE database,[181] HS 0910, 1211, 1301, 1302 and 3301, it can be shown that the main import markets – collectively accounting for about half of global trade value – are the US, some European countries (Germany, France, the Netherlands and the United Kingdom), China (mainland and Hong Kong SAR), Japan and India. Table 31 summarizes these general data.

Table 31 Main markets for selected MAP headings in 2021

Heading	Definition	Top five importers
0910	Ginger, saffron, turmeric, thyme, bay leaves, curry and other spices.	The reported global import trade value of MAPs imported under HS 0910 amounted to about $2.7 billion. The main importers were the US, accounting for 16.4%, the Netherlands 9.0%, Germany 8.3%, United Kingdom 6.0% and Japan 5.8%, These five importers accounted for 45.5% of the global trade value of HS 0910.
1211	Plants and parts of plants (including seeds and fruits), of a kind used primarily in perfumery, in pharmacy or for insecticidal, fungicidal or similar purposes, fresh, chilled, frozen or dried, whether or not cut, crushed or powdered.	The reported global import trade value of MAPs imported under HS 1211 amounted to about $3.2 billion. The main importers were the US, accounting for 15.3%, Germany 12.7%, Japan 8.1%, Hong Kong SAR 6.6% and China 6.2%. These five importers accounted for nearly half of the global trade value of HS 1211.
1301	Lac; natural gums, resins, gum-resins and oleoresins (e.g. balsams).	The reported global import trade value of MAP natural gums and resins imported under HS code 1301 amounted to about $0.784 billion, of which India accounted for 24%, the US 14%, France 10.2%, China 8.4% and Germany 6.3%. These five importers accounted for about 63% of the global trade value of HS 1301.
1302	Vegetable saps and extracts; pectic substances, pectinates and pectates; agar-agar and other mucilages and thickeners, whether or not modified, derived from vegetable products	The reported global import trade value of MAP extracts imported under HS 1302 amounted to about $6.7 billion, of which the US accounted for about 25.8%, Germany about 9.7%, China about 6.0%, France about 5.3% and Japan about 4.7%. These five importers accounted for over half of global trade value of HS 1302.
3301	Essential oils (terpeneless or not), including concretes and absolutes; resinoids; extracted oleoresins; concentrates of essential oils in fats, in fixed oils, in waxes or the like, obtained by enfleurage or maceration; terpenic by-products of the deterpenation of essential oils; aqueous distillates and aqueous solutions of essential oils.	The reported global import trade value of MAP essential oils and resinoids imported under HS 3301 amounted to about $4.92 billion, of which the US accounted for about 24%, France 9.4%, Germany 8.1%, China 6.9% and the United Kingdom 6.0%. These five importers accounted for over half of global trade value of HS 3301.

Source: United Nations Statistics Division COMTRADE database

[180] World Customs Organization (WCO) HS Nomenclature 2022 edition, at http://www.wcoomd.org/en/topics/nomenclature/instrument-and-tools/hs-nomenclature-2022-edition/hs-nomenclature-2022-edition.aspx

[181] COMTRADE database, at https://comtrade.un.org/data/

Main MAP ingredients imported into the European Union

When a MAP producer operation is considering which crops to produce or to scale up for export to the EU market, a competitive landscape analysis can be helpful. The analysis should identify which crops are already produced at a commercial scale in the destination market; those which are being imported on a large scale; and from which countries they come.

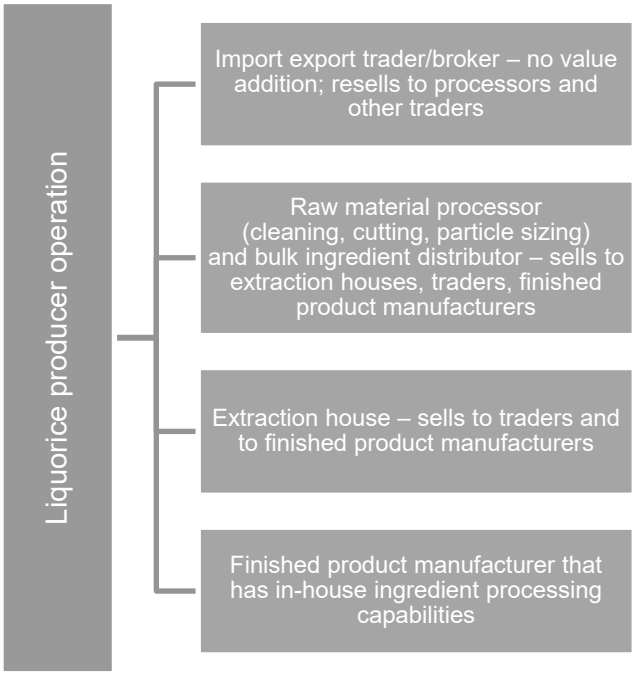
Appendix IV provides a list of selected MAP crops that are produced at a commercial scale in the EU. Appendix V shows selected MAP ingredients that are imported into the EU along with the top five supplier countries in order of predominance.

Distribution channels

Depending on the size of the operation and its capabilities, the herbal raw material producer – whether a farm or wild collection operation (or both) – may carry out value-addition (e.g. extraction) in-house. Alternatively, they may sell their raw materials to other companies in-country for value-addition prior to export or export the raw materials or extracts directly to foreign customers.

Using liquorice (*Glycyrrhiza* spp.) as an example, Figure 4 illustrates possible distribution channels for the producer exporting to Europe.

Figure 14 Possible distribution channels for liquorice root exported to Europe



Source: This figure prepared by the authors of this guide.

Marketing and branding strategies for SMEs

The SME producer and exporter of MAP ingredients should seek to understand their relative size and position in the global market and then target the appropriate customers, preferably those who are aligned on values – this is especially true if the SME is focused on sustainable (organic and fair certified) MAP ingredients.

If an SME's annual offering is a few tonnes of MAP materials, the target customer(s) will likely be different than if the annual offering were tens or hundreds of tonnes. If the SME is offering crude unprocessed MAP raw materials (for further processing), the target customers will also likely be different than if the SME has value-adding ingredient processing capabilities. In the latter case, the SME may be able to target finished product manufacturing companies and bypass the need to sell primarily to MAP processing and ingredient distribution companies.

SMEs should attend (or exhibit at) the relevant international trade shows to assess prospective buyer companies with which to align. Likewise, the SME producer/exporter should determine whether to target other SME import-export trading companies situated in the export destination country; larger processing and ingredient distribution companies; or finished product brands that have their own ingredient processing and packaging capabilities. It is difficult to cater to all levels (traders, processors and finished product manufacturers).

Some MAP ingredient producers and exporters make a strategic decision to establish an exclusive sales and marketing representative in each distinct foreign market, for example, its brand of ingredients is marketed through an exclusive distributor situated in the EU and another exclusive distributor situated in the US, and so on. It may be too costly for an SME to establish its own sales and marketing offices and warehousing in the destination markets. Larger MAP ingredient producers and exporters, however, often have their own sales offices and warehousing in the EU and the US, among other markets.

When the SME has successfully passed the range of audits and has been issued all of the certifications and verifications that buyers request or require, it should make it easy for prospective buyers to find and download all of the documents necessary for the buyer's quality unit to carry out their new vendor qualification process. The quality and sustainability status of the SME is amplified by presence of the documents on the websites of the independent inspection and certification organizations and standard-setting organizations. This visibility can be leveraged in the SME's own marketing strategy.

Using one Indian company to illustrate this point, Table 32 shows some of the certifications that the company holds along with the links to the external organizations' online databases or directories that also display the company's profile and/or a downloadable certificate document. Buyers often first search these databases to identify interesting prospective suppliers.

Table 32 One company's leveraging of quality and sustainability certifications

Certification	Where to find it?
BRCGS Global Food Safety Standard. Scope: processing of herbs and botanicals, nutraceutical products, medicinal herbs, Ayurvedic herbs, food supplement and packed in flexible packaging	Listing in BRCGS Directory of certified operations[182]
European Organic Standard	Organic certificate in EcoCert online certifications database[183]
Fair for Life – Social and Fair-Trade Certification	Company profile in the Fair for Life certified operators online database[184]
FairWild registered trading company	Company listing in FairWild Foundation website[185]
Halal certification	Company listing in Halal India online certification tracking system[186]
Kosher certification	Certificate in the Star-K website[187]
United States Department of Agriculture (USDA) National Organic Program (NOP)	Organic operation profile in the USDA Organic Integrity online database[188]

Sources: URL internet addresses to the certification and standards organizations provided in the footnotes

ITC, as part of its SME Trade Academy, offers a course that introduces the ways export marketing forms a vital component of the export development process. Small enterprises need to craft their messages appropriately to be perceived in the way they want by their customers. This is achieved by adopting a strategy based on the export marketing process and by adhering to certain key principles.

The ITC course, Setting up an Export Marketing Strategy, is available online at https://learning.intracen.org/course/info.php?id=147.

Meeting prospective buyers

Appendix VI provides details on the most relevant trade shows in Europe for producers, suppliers and exporters to meet prospective buyers at different levels, including processors of MAP raw materials (e.g. powdering, granulation, tea-bag-cutting), manufacturers of herbal extracts (dry, liquid, soft), plant juices, essential oils and fatty oils, and finished product brands that may process some of their own ingredients.

Trade shows to consider for setting targeted face-to-face meetings with prospective buyers of sustainably produced MAP raw materials, extracts and oils include BioFach Germany (biggest international organic trade show), CPhI (Convention on Pharmaceutical Ingredients) Worldwide, Fi (Food Ingredients)/Hi (Health Ingredients)/Ni (Natural Ingredients) Europe and VitaFoods Europe. Each of these trade shows has a different focus but there is some overlap of attendees and exhibitors depending on the sub-sector, e.g. whether marketing organic spices for food, organic essential or fatty oils for cosmetics, or organic medicinal plants and standardized extracts for pharmaceutical use.

[182] See https://directory.brcgs.com/site/1814721

[183] See https://certificat.ecocert.com/client.php?source=recherche&id=76BDC608-CFF5-4694-9B39-BF64E948DED3

[184] See https://www.fairforlife.org/pmws/indexDOM.php?client_id=fairforlife&page_id=certified&lang_iso639=en&company_id=1056

[185] See https://www.fairwild.org/all-fairwild-participants/cultivator-natural-products

[186] See http://halalindia.org/display.htm

[187] See https://www.star-k.org/listings/star-k#c

[188] See https://organic.ams.usda.gov/Integrity/CP/OPP.aspx?cid=89&nopid=4920002980&ret=%252fIntegrity%252fDefault.aspx&retName=Home

Price developments and factors influencing price

Price quotes for a seemingly same or similar herbal material may vary substantially depending on many factors, including whether they are:

- Unprocessed (crude botanical raw material in whole form or pieces) or processed (e.g. cleaned and cut to a specified particle size, length and density);
- Untreated or treated for insect pests (e.g. using carbon dioxide) and microbiological contamination (e.g. using thermal methods, such as steam or dry heat, infrared or ozone);
- Untested or already analysed at an accredited laboratory with certificate of analysis document showing conformity with customer's quality specification;
- Conventional or produced and traded in conformance with one or more sustainability standards (e.g. Demeter Biodynamic, EcoCert Fair for Life, EU Organic, FLO Fairtrade, FWF FairWild, UEBT Ethical BioTrade, UEBT & Rainforest Alliance Herbs & Spices Programme, WFEN Wildlife Friendly);
- Food quality (e.g. Codex, FCC or ISO specification) or medicinal quality (e.g. PhEur monograph specification).
- A spot buy or part of annual contracted quantity, basis of quote (e.g. EXW, FOB or CIF), terms of payment, currency and the level of overall annual trade between the buyer and seller (all items);
- Affected by currency fluctuations.

Using the endemic South African MAP rooibos (*Aspalathus linearis*) herb as an example, Table 33 illustrates the Fairtrade (FLO) price structure. This price structure, however, does not include differences in quality grades of rooibos that could affect pricing. South Africa's Department of Agriculture has defined, in regulation, standards on the quality and the requirements for packing, marking and labelling of rooibos and rooibos mixtures for export.[189]

Table 33 Fairtrade price structure for rooibos (*Aspalathus linearis*) herb from South Africa

Standards	Producer type	Price level (INCOTERMS)	Currency	Fairtrade minimum price	Fairtrade premium
Conventional and Fairtrade	Hired labour	EXW	ZAR	13/kg	12/kg
Conventional and Fairtrade	Hired labour	FOB	ZAR	18/kg	12/kg
Conventional and Fairtrade	Small producer organization	EXW	ZAR	20/kg	5/kg
Conventional and Fairtrade	Small producer organization	FOB	ZAR	25/kg	5/kg
Organic and Fairtrade	Hired labour	EXW	ZAR	18/kg	12/kg
Organic and Fairtrade	Hired labour	FOB	ZAR	12/kg	12/kg
Organic and Fairtrade	Small producer organization	EXW	ZAR	25/kg	5/kg
Organic and Fairtrade	Small producer organization	FOB	ZAR	30/kg	5/kg

Source: FLO Fairtrade Minimum Price and Premium Information, at https://www.fairtrade.net/standard/minimum-price-info

[189] Standards and requirements regarding control of the export of rooibos and rooibos mixtures, at https://sarooibos.co.za/wp/wp-content/uploads/2016/01/ROOIBOS-20142.pdf

Main importer buyers

Appendix VII provides a list of selected importer buyers in Europe, the US, China and India that process, handle and trade certain herbal ingredients that have been produced in conformance with the requirements of one or more of the voluntary sustainability standards that are important in the EU market. These include Demeter Biodynamic, Fair for Life, Fairtrade, FairWild, Organic, Rainforest Alliance, UEBT and UTZ.

While most of the listed companies also handle conventional non-certified herbal ingredients, the market continues to grow for ingredients with supply chain visibility and documentary evidence of production and trade occurring according to credible standards for economic, environmental and social sustainability.

Market access to the UK after Brexit

On the matter of the United Kingdom leaving the European Union, effective 31 January 2020, the UK Food Standards Agency, the UK Medicines and Healthcare products Regulatory Agency and EMA issued guidance on the consequent effects on regulations governing market access. At the end of the transition period, EU legislation that had applied since 31 December 2020 was kept in the UK and is referred to as 'retained EU law'. Any EU laws that came into effect before 31 December 2020 but applied from 1 January 2021 or later do not apply in the UK. Further, any amendments to EU legislation that have been made since 1 January 2021 do not apply in the UK.

One area of divergence is novel foods. Novel foods that have been authorized by the EU since 1 January 2021 cannot be used as ingredients in foods intended for the UK market until also authorized by the UK Food Standards Agency.

Further, divergence impacts food supplements, e.g. the UK now maintains its own list of permissible vitamins and minerals, issues its own authorizations for GMOs and flavouring substances, and sets its own maximum permitted levels of pesticides and other contaminants in food.

Divergence is also starting to occur in food labelling and claims. Consequently, it will become increasingly difficult to retain a uniform label on a product that is marketed across both the EU and the UK. Manufacturers are advised to carefully check UK government-issued guidance before exporting ingredients, their derivatives or finished products thereof that are permissible in the EU to the UK.

Exporters of MAP ingredients and products should consider the UK as a distinctly separate market from the European Single Market. Exporters should also consider different export marketing strategies for other major importing countries, such as the US, China and India.

Appendices

Appendix I Publicly available GACP guidelines

Table 34 Selected GACPs: International, national, trade, species-specific

Source of monograph	Title
International – General	
Food and Agriculture Organization of the United Nations (FAO)	Good Agricultural and Collection Practices for Medicinal Plants. Illustrated Booklet for Farmers and Collectors[190]
Food and Agriculture Organization of the United Nations (FAO)	Trainer's Manual on Good Agricultural and Collection Practices (GACP) for Medicinal Plants[191]
World Health Organization (WHO)	WHO Guidelines on Good Agricultural and Collection Practices (GACP) for medicinal plants[192]
National – General	
Centre Tecnològic Forestal de Catalunya	Buenas prácticas agrícolas de plantas aromáticas y medicinales[193]
China National Medical Products Administration (NMPA)	Good Agricultural Practice (GAP) for Chinese Crude Drugs[194]
European Medicines Agency (EMA)	Guideline on Good Agricultural and Collection Practice for starting materials of herbal origin[195]
EU and Republic of Turkey TRUMAP (Black Truffles and Medicinal & Aromatic Plants Network Project)	TRUMAP Best Practices for Cultivation of Medicinal and Aromatic Plants[196]
Government of Georgia Ministry of Agriculture	Code of Good Agricultural Practices of Georgia[197]
Government of Guatemala Instituto de Ciencia y Tecnología Agrícolas (ICTA)	Manual básico de buenas prácticas agrícolas en la producción de plantas medicinales y aromáticas[198]
Government of India National Medicinal Plants Board (NMPB)	Good Agricultural Practices for Medicinal Plants[199]
Government of India NMPB	Good Agricultural Practices Standard for Medicinal Plants - Requirements[200]
Government of India NMPB	Good Field Collection Practices Standard for Medicinal Plants - Requirements[201]
Government of India NMPB	Guidelines on Good Field Collection Practices for Indian Medicinal Plants[202]

[190] https://coin.fao.org/coin-static/cms/media/8/13069087097420/trainers_manual_on_gacp_for_medicinal_plants1_latest.pdf
[191] http://biolaya.com/wp-content/uploads/Trainers-Manual-on-GACP-for-Medicinal-plants.pdf
[192] http://apps.who.int/iris/bitstream/handle/10665/42783/9241546271.pdf?sequence=1
[193] https://apsb.ctfc.cat/docs/ficha%20BUENAS%20PRACTICAS%20PAM.pdf
[194] http://english.nmpa.gov.cn/2022-03/17/c_772359.htm
[195] https://www.ema.europa.eu/en/good-agricultural-collection-practice-starting-materials-herbal-origin
[196] http://trumap.ctfc.cat/?page_id=14&lang=en
[197] http://extwprlegs1.fao.org/docs/pdf/geo190208.pdf
[198] https://www.icta.gob.gt/publicaciones/Plantas medicinales/Plantas medicinales y aromaticas.pdf
[199] https://nmpb.nic.in/
[200] https://nmpb.nic.in/
[201] https://nmpb.nic.in/
[202] https://nmpb.nic.in/

Source of monograph	Title
Government of Kenya Bureau of Standards (KEBS)	KS ARS 952:2016 – African Traditional Medicine – Requirements on good agricultural and collection practices (GACP) for medicinal plants[203]
Morocco - Haut-Commissariat aux Eaux et Forêts et à la Lutte Contre Désertification (HCEFLCD)	Guide des bonnes pratiques de collecte des plantes aromatiques et médicinales du Maroc[204]
Trade – Sector-specific	
American Herbal Products Association (AHPA)	Good Agricultural & Collection Practices and Good Manufacturing Practices (GACP-GMP) for botanical materials[205]
American Spice Trade Association (ASTA)	General Guidelines for Good Agricultural Practices for Spices[206]
European Herb Growers Association (EUROPAM)	Guidelines for Good Agricultural and Wild Collection Practice (GACP) of Medicinal and Aromatic Plants[207]
European Herb Growers Association (EUROPAM)	A Practical Implementation Guide to Good Agricultural and Wild Collection Practices (GACP)[208]
International Organization of Spice Trade Associations (IOSTA)	General Guidelines for Good Agricultural Practices on Spices & Culinary Herbs[209]
Tea & Herbal Infusions Europe (THIE)	Guidelines for Good Agricultural and Hygiene Practices for Raw Materials used for Herbal and Fruit Infusions (GAHP)[210]
Species-specific	
Indian Council of Agricultural Research (ICAR) Directorate of Medicinal & Aromatic Plants Research (DMAPR)	Good Agricultural Practices for *Aloe vera*[211]
ICAR-Directorate of Medicinal & Aromatic Plants Research	Good Agricultural Practices for Ashwagandha (*Withania somnifera*)[212]
ICAR-Directorate of Medicinal & Aromatic Plants Research	Good Agricultural Practices for Isabgol (*Plantago ovata*)[213]
ICAR-Directorate of Medicinal & Aromatic Plants Research	Good Agricultural Practices for Madhunashini (*Gymnema sylvestre*)[214]
ICAR-Directorate of Medicinal & Aromatic Plants Research	Good Agricultural Practices for Patchouli, Geranium and Lemongrass[215]
ICAR-Directorate of Medicinal & Aromatic Plants Research	Good Agricultural Practices for Safed musli (*Chlorophytum borivilianum*)[216]

[203] https://webstore.kebs.org/index.php?route=product/product&path=7&product_id=16916

[204] https://www.fellah-trade.com/ressources/pdf/GBPC-Francais.pdf

[205] https://ahpa.gomembers.com/AHPAResources/GoodAgriculturalandCollectionPractices.aspx

[206] https://www.astaspice.org/food-safety-technical-guidance/best-practices-and-guidance/good-agricultural-practices-guide-gap-guide/

[207] https://www.europam.net/documents/

[208] https://www.europam.net/documents/

[209] https://www.esa-spices.org/index-esa.html/publications-esa

[210] https://thie-online.eu/publications.html

[211] https://dmapr.icar.gov.in/Publications/E-book on Bulletins.html

[212] https://dmapr.icar.gov.in/Publications/E-book on Bulletins.html

[213] https://dmapr.icar.gov.in/Publications/E-book on Bulletins.html

[214] https://dmapr.icar.gov.in/Publications/E-book on Bulletins.html

[215] https://dmapr.icar.gov.in/Publications/E-book on Bulletins.html

[216] https://dmapr.icar.gov.in/Publications/E-book on Bulletins.html

Source of monograph	Title
ICAR-Directorate of Medicinal & Aromatic Plants Research	Good Agricultural Practices for Senna (*Cassia angustifolia*)[217]
ICAR-Directorate of Medicinal & Aromatic Plants Research	Good Agricultural Practices for Shatavari (*Asparagus racemosus*)[218]
ISO 21983:2019	Guidelines for the harvesting, transportation, separation of stigma, drying and storage of saffron before packing[219]
Morocco – HCEFLCD	Manuel des bonnes pratiques de collecte de l'origan (*Origanum compactum*)[220]
Morocco – HCEFLCD	Manuel des bonnes pratiques de collecte du romarin (*Rosmarinus officinalis*)[221]
Morocco – HCEFLCD	Manuel des bonnes pratiques de collecte du thym (*Thymus satureioides*)[222]
Namibia Network of the Cosmetics Industry (NANCi)	Good Agricultural and Collection Practice Plus (GACP+) Standard for Devil's Claw in Namibia[223]
Nepal Department of Plant Resources	*Asparagus racemosus* Willd – A GACP monograph[224]
Nepal Department of Plant Resources	*Diploknema butyracea* (Roxb.) H. J. Lam – A GACP monograph[225]
Nepal Department of Plant Resources	Good Agricultural and Collection Practices (GACP) of *Cinnamomum tamala*
Nepal Department of Plant Resources	Good Agricultural and Collection Practices (GACP) of *Zanthoxylum armatum*
Nepal Department of Plant Resources	*Mentha arvensis* L. – A GACP monograph[226]
Nepal Department of Plant Resources	*Matricaria chamomilla* L. – A GACP monograph[227]
Nepal Department of Plant Resources	Quality Standard, GACP of *Rauvolfia serpentina* (L.) Benth. Ex Kurz.[228]
Nepal Department of Plant Resources	Quality Standard, GACP of *Valeriana jatamansi* Jones

[217] https://dmapr.icar.gov.in/Publications/E-book on Bulletins.html

[218] https://dmapr.icar.gov.in/Publications/E-book on Bulletins.html

[219] https://www.iso.org/standard/72280.html?browse=tc

[220] https://www.fellah-trade.com/ressources/pdf/MBPC_Origan_Francais.pdf

[221] https://www.fellah-trade.com/ressources/pdf/MBPC_Romarin_Francais.pdf

[222] https://www.fellah-trade.com/ressources/pdf/MBPC_Thym_Francais.pdf

[223] https://nanci.biz/gacp-standard-for-devils-claw-in-namibia/

[224] https://dpr.gov.np/en/%e0%a4%85%e0%a4%b8%e0%a4%b2-%e0%a4%96%e0%a5%87%e0%a4%a4%e0%a4%bf-%e0%a4%a4%e0%a4%a5%e0%a4%be-%e0%a4%b8%e0%a4%82%e0%a4%95%e0%a4%b2%e0%a4%a8-%e0%a4%85%e0%a4%ad%e0%a5%8d%e0%a4%af%e0%a4%be%e0%a4%b8-2/

[225] https://dpr.gov.np/en/%e0%a4%85%e0%a4%b8%e0%a4%b2-%e0%a4%96%e0%a5%87%e0%a4%a4%e0%a5%80-%e0%a4%a4%e0%a4%a5%e0%a4%be-%e0%a4%b8%e0%a4%82%e0%a4%95%e0%a4%b2%e0%a4%a8-%e0%a4%85%e0%a4%ad%e0%a5%8d%e0%a4%af%e0%a4%be%e0%a4%b8-4/

[226] https://dpr.gov.np/en/%e0%a4%85%e0%a4%b8%e0%a4%b2-%e0%a4%96%e0%a5%87%e0%a4%a4%e0%a5%80-%e0%a4%a4%e0%a4%a5%e0%a4%be-%e0%a4%b8%e0%a4%82%e0%a4%95%e0%a4%b2%e0%a4%a8-%e0%a4%85%e0%a4%ad%e0%a5%8d%e0%a4%af%e0%a4%be%e0%a4%b8-3/

[227] https://dpr.gov.np/en/%e0%a4%85%e0%a4%b8%e0%a4%b2-%e0%a4%96%e0%a5%87%e0%a4%a4%e0%a5%80-%e0%a4%a4%e0%a4%a5%e0%a4%be-%e0%a4%b8%e0%a4%82%e0%a4%95%e0%a4%b2%e0%a4%a8-%e0%a4%85%e0%a4%ad%e0%a5%8d%e0%a4%af%e0%a4%be%e0%a4%b8-2/

[228] https://www.researchgate.net/publication/316586480_Quality_Standards_Good_Agricultural_and_Collection_Practice_GACP_of_Rauvolfia_serpentina_L_Benth_Ex_Kurz

Source of monograph	Title
Normas Técnicas Peruanas	NTP 011.032:2009 (revisada el 2019) Buenas Prácticas Agrícolas para el cultivo de camu arbustivo (*Myrciaria dubia* H.B.K. McVaugh)[229]
Normas Técnicas Peruanas	NTP 151.402:2018 Buenas prácticas agrícolas para el cultivo de Sacha Inchi (*Plukenetia volubilis* Linneo)[230]
Sher-e-Kashmir University of Agricultural Sciences and Technology of Kashmir	Good Practices for Saffron Production in Kashmir Practical Manual[231]
Thai Agricultural Standard	TAS 3501-2015 Good Agricultural Practices for Ginger[232]

[229] https://www.inacal.gob.pe/cid/categoria/normas-tecnicas-peruanas

[230] https://www.inacal.gob.pe/cid/categoria/normas-tecnicas-peruanas

[231] http://diragrijmu.nic.in/saffron/saffron-manual.pdf

[232] https://www.acfs.go.th/standard/download/eng/GAP-GINGER-ENG.pdf

Appendix II Selected herbs with EU herbal monographs and specified quality

Table 35 Selected herbs with EU herbal monographs and specified quality

Common name	Botanical name	Specified quality standard
Agnus castus fruit	*Vitex agnus-castus* L.	PhEur monograph (ref.: 01/2015: 2147)
Agrimony herb	*Agrimonia eupatoria* L.	PhEur monograph (ref.: 01/2011:1587)
Aloes leaves dried juice	*Aloe barbadensis* Mill. and Aloe various species	PhEur monograph (ref.: 0257 and/or 0258)
Anise oil	*Pimpinella anisum* L.	PhEur monograph (ref.: 01/2008:0804)
Aniseed fruit	*Pimpinella anisum* L.	PhEur monograph (ref.: 01/2012:0262)
Arctic root	*Rhodiola rosea* L.	Detailed specification for the herbal substance shall be given by references to bibliographic sources in absence of a PhEur monograph
Arnica flower	*Arnica montana* L.	PhEur monograph (ref.: 04/2008, 1391)
Artichoke leaf	*Cynara cardunculus* L. (syn. *C. scolymus* L.)	PhEur monograph (ref.: 1866)
Ash leaf	*Fraxinus excelsior* L., *F. angustifolia* Vahl	PhEur monograph (ref.: 07/2012:1600)
Bearberry leaf	Arctostaphylos uva-ursi (L.) Spreng.	PhEur monograph (ref.: 1054)
Bilberry fruit, dried	*Vaccinium myrtillus* L.	PhEur monograph (ref.: 1588)
Bilberry fruit, fresh	*Vaccinium myrtillus* L.	PhEur monograph (ref.: 1602)
Birch leaf	*Betula pendula* Roth/*B. pubescens* Ehrh.	PhEur monograph (ref.: 04/2013:1174)
Black cohosh rhizome	*Cimicifuga racemosa* (L.) Nutt.	PhEur monograph (ref.: 2069)
Blackcurrant leaf	*Ribes nigrum* L.	PhEur monograph (ref.: 2528)
Bladderwrack thallus	*Fucus vesiculosus* L.	PhEur monograph (ref.: 01/2008:1426)
Bogbean leaf	*Menyanthes trifoliata* L.	PhEur monograph (ref:: 1605)
Boldo leaf	*Peumus boldus* Molina	PhEur monograph (ref.: 1396)
Burdock root	*Arctium lappa* L.	Deutscher Arzneimittel-Codex (DAC) monograph
Butcher's-broom rhizome	*Ruscus aculeatus* L.	PhEur monograph (ref.: 1847)
Calendula flower	*Calendula officinalis* L.	PhEur monograph (ref.: 01/2011:1297)
California poppy herb	*Eschscholzia californica* Cham.	In absence of a PhEur monograph, a national pharmacopoeia or national codex currently used officially in a Member State
Capsicum fruit	*Capsicum annuum* L. var. *minimum* (Miller) Heiser	PhEur monograph (ref.: 1859)
Caraway fruit	*Carum carvi* L.	PhEur monograph (ref.: 1080).
Caraway oil	*Carum carvi* L.	PhEur monograph (ref.: 1817)
Cascara bark	*Rhamnus purshianus* D.C.	PhEur monograph (ref.: 0105)
Castor oil	*Ricinus communis* L.	PhEur monograph (Ricini oleum virginale (ref.: 0051) or Ricini oleum raffinatum (ref.: 2367))
Centaury herb	*Centaurium erythraea* Rafn. s.l.	PhEur monograph (ref.: 1301)
Chamomile (Matricaria) flower	*Matricaria recutita* L.	PhEur monographs (ref.: 0404) and (ref.: 1544)

Common name	Botanical name	Specified quality standard
Chamomile (Matricaria) oil	*Matricaria recutita* L.	PhEur monograph (ref.: 1836)
Chamomile flower, Roman	*Chamaemelum nobile* (L.) All.	PhEur monograph (ref.: 01/2008:0380)
Chicory root	*Cichorium intybus* L.	Detailed specification for the herbal substance shall be given by references to bibliographic sources in absence of a PhEur monograph
Cinnamon bark	*Cinnamomum verum* J. S. Presl	PhEur monograph (ref.: 04/2011:0387)
Cinnamon bark oil	*Cinnamomum verum* J. S. Presl	PhEur monograph (ref.: 04/2011:1501)
Clove oil	Syzygium aromaticum (L.) Merr. et L.M. Perry	PhEur monograph (ref.: 01/2008:1091)
Cola seed	*Cola nitida* (Vent.) Schott et Endl./*Cola acuminata* (P. Beauv.) Schott et Endl.	PhEur monograph (ref.: 01/2008:1504)
Comfrey root	*Symphytum officinale* L.	Detailed specification for the herbal substance shall be given by references to bibliographic sources in absence of a PhEur monograph
Coneflower herb, Purple (fresh)	*Echinacea purpurea* (L.) Moench	Detailed specifications for the herbal substance by references to bibliographic sources in absence of a PhEur monograph, a national pharmacopoeia or national codex currently used officially in a member state.
Coneflower root, Narrow-leaved	*Echinacea angustifolia* DC.	PhEur monograph (ref.: 01/2008:1821)
Coneflower root, Pale	*Echinacea pallida* (Nutt.) Nutt.	PhEur monograph (ref.: 1822)
Coneflower root, Purple	*Echinacea purpurea* (L.) Moench.	PhEur monograph (ref.: 1824)
Couch grass rhizome	*Agropyron repens* (L.) P. Beauv.	PhEur monograph (ref.: 01/2008:1306)
Cranberry fruit	*Vaccinium macrocarpon* Aiton	USP-NF monograph
Dandelion leaf	*Taraxacum officinale* Weber ex Wigg.	PhEur monograph on herbal drugs
Dandelion root	*Taraxacum officinale* F.H. Wigg.	PhEur monograph (ref.: 1852)
Dandelion root with herb	*Taraxacum officinale* Weber ex Wigg.	PhEur monograph (ref.: 1851)
Devil's claw root	*Harpagophytum procumbens* DC.; *Harpagophytum zeyheri* Decne	PhEur monograph (ref.: 1095)
Dittany of Crete herb	*Origanum dictamnus* L.	Detailed specifications for the herbal substance by references to bibliographic sources in absence of a PhEur monograph, a national pharmacopoeia or national codex currently used officially in a member state
Elder flower	*Sambucus nigra* L.	PhEur monograph (ref.: 1217)
Eleutherococcus rhizome	*Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim.	PhEur monograph (ref.: 01/2008:1419)
Eucalyptus leaf	*Eucalyptus globulus* Labill.	PhEur monograph (ref.: 01/2008:1320)
Eucalyptus oil	*Eucalyptus globulus* Labill.; *E. polybractea* R.T. Baker; *E. smithii* R.T. Baker.	PhEur monograph (ref.: 07/2012:0390)
European goldenrod herb	*Solidago virgaurea* L.	PhEur monograph (ref.: 01/2006:1893)
Evening primrose oil	*Oenothera biennis* L.; *O. lamarckiana* L.	PhEur monograph (ref.: 01/2010:2104)

Common name	Botanical name	Specified quality standard
Fennel fruit oil, bitter	*Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*	PhEur monograph (ref.: 01/2005:0824)
Fennel fruit, bitter	*Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*	PhEur monograph (ref.: 01/2005:0824)
Fennel fruit, sweet	*Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung.	PhEur monograph (ref.: 01/2005:0825)
Fenugreek seed	*Trigonella foenum-graecum* L.	PhEur monograph (ref.: 01/2008:1323)
Feverfew herb	*Tanacetum parthenium* (L.) Schultz Bip.	PhEur monograph (ref.: 1516)
Frangula bark	*Rhamnus frangula* L.	PhEur monograph (ref.: 0025; 1214)
Fumitory herb	*Fumaria officinalis* L.	PhEur monograph (ref.: 07/2010:1869)
Garlic bulb	*Allium sativum* L.	PhEur monograph (ref.: 1216)
Gentian root	*Gentiana lutea* L.	PhEur monograph (ref.: 0392)
Ginger rhizome	*Zingiber officinale* Roscoe	PhEur monograph (ref.: 07/2008:1522)
Ginkgo leaf	*Ginkgo biloba* L.	Raw material complies with PhEur monograph 01/2011:1828. The herbal preparation complies with PhEur monograph 'Ginkgo dry extract, refined and quantified' 04/2008:1827
Ginseng root	*Panax ginseng* C. A. Mey.	PhEur monograph (ref.: 7.0/1523)
Grapevine leaf	*Vitis vinifera* L.	Pharmacopée française monograph
Green bean pod	*Phaseolus vulgaris* L.	DAC monograph
Green tea leaf	*Camellia sinensis* (L.) Kuntze	Pharmacopée française monograph
Guarana seed	*Paullinia cupana* Kunth	Pharmacopée française monograph
Gumweed herb	*Grindelia robusta* Nutt., *G. squarrosa* (Pursh) Dunal, *G. humilis* Hook. et Arn., *G. camporum* Greene	Pharmacopée française monograph
Hamamelis bark	*Hamamelis virginiana* L.	PhEur monograph (ref.: 2532)
Hamamelis distillate	*Hamamelis virginiana* L.	USP monograph 'Witch Hazel'
Hamamelis leaf	*Hamamelis virginiana* L.	PhEur monograph (ref.: 04/2008:0909)
Hawthorn leaf and flower	*Crataegus monogyna* Jacq. (Lindm.), *C. laevigata* (Poir.) DC. or their hybrids; *C. pentagyna* Waldst. et Kit. ex Willd.; *C. azarolus* L.	PhEur monograph (ref.: 1432)
Hedge mustard herb	*Sisymbrium officinale* (L.) Scop.	Pharmacopée française monograph
Hop strobile	*Humulus lupulus* L.	PhEur monograph (ref.: 1/2011:1222)
Horse-chestnut bark	*Aesculus hippocastanum* L.	Detailed specification for the herbal substance shall be given by references to bibliographic sources in absence of a PhEur monograph
Horse-chestnut seed	*Aesculus hippocastanum* L.	Raw material complies with PhEur monograph (ref.: 1830). The herbal preparation complies with PhEur monograph (ref.: 1829)
Horsetail herb	*Equisetum arvense* L.	PhEur monograph (ref.: 1825)
Iceland moss thallus	*Cetraria islandica* (L.) Acharius s.l.	PhEur monograph (ref.: 07/2010:1439)
Ironwort	*Sideritis scardica* Griseb.; *S. clandestina* (Bory & Chaub.) Hayek; *S. raeseri* Boiss. and Heldr.; *Sideritis syriaca* L.	Detailed specifications for the herbal substance shall be given by references to bibliographic sources in absence of a PhEur monograph, a national pharmacopoeia or national codex currently used officially in a member state

Common name	Botanical name	Specified quality standard
Ispaghula husk	*Plantago ovata* Forssk.	PhEur monograph (ref.: 01/2008:1334)
Ispaghula seed	*Plantago ovata* Forssk.	PhEur monograph (ref.: 01/2008:1333)
Ivy leaf	*Hedera helix* L.	PhEur monograph (ref.: 2148)
Java tea leaf	*Orthosiphon aristatus* (Blume) Miq. var. *aristatus*	PhEur monograph (ref.: 1229)
Juniper cone berry	*Juniperus communis* L.	PhEur monograph (ref.: 01/2008:1532)
Juniper oil	*Juniperus communis* L.	PhEur monograph (ref.: 1/2008:1832)
Knotgrass herb	*Polygonum aviculare* L.	PhEur monograph (ref.: 1885)
Lavender flower	*Lavandula angustifolia* Mill.	PhEur monograph (ref.: 01/2008:1534)
Lavender oil	*Lavandula angustifolia* Mill.	PhEur monograph (ref.: 07/2010:1338)
Lemon verbena leaf	*Aloysia citriodora* Paláu	PhEur monograph (ref.: 1834)
Linden (Lime) flower	*Tilia cordata* Miller, *T. platyphyllos* Scop., *T.* x *vulgaris* Heyne	PhEur monograph (ref.: 01/2008:0957)
Linseed	*Linum usitatissimum* L.	PhEur monograph (ref.: 0095)
Liquorice root	*Glycyrrhiza glabra* L.; *G. inflata* Bat.; *G. uralensis* Fisch.	PhEur monograph (ref.: 01/2010: 0277)
Lovage root	*Levisticum officinale* W.D.J. Koch	PhEur monograph (ref.: 01/2013:1233)
Marjoram herb	*Origanum majorana* L.	Farmakopea Polska monograph
Mallow flower	*Malva sylvestris* L.	PhEur monograph (ref.: 1541)
Mallow leaf	*Malva sylvestris* L.; *Malva neglecta* Wallr.	PhEur monograph (ref.: 2391)
Marigold flower	*Calendula officinalis* L.	PhEur monograph (ref.: 01/2011:1297)
Marshmallow root	*Althaea officinalis* L.	Raw material complies with PhEur monograph (ref.: 1126). Prepared in accordance with the pharmacopoeial monographs for Sirupus althaeae in Österreichisches Arzneibuch 1981, Československý lékopis 1954, Farmakopea Polska 1970 and 2002 or with the monograph Eibischsirup in Deutscher Arzneimittel-Codex 1979
Mastic resin	*Pistacia lentiscus* L.	PhEur monograph (ref.: 1876)
Maté leaf	*Ilex paraguariensis* A. St.-Hil.,	DAC or Pharmacopée française
Meadowsweet flower	*Filipendula ulmaria* (L.) Maxim.	Detailed specification for the herbal substance shall be given by references to bibliographic sources in absence of a PhEur monograph
Meadowsweet herb	*Filipendula ulmaria* (L.) Maxim.	PhEur monograph (ref.: 01/2008:1868)
Melilot herb	*Melilotus officinalis* (L.) Lam.	Raw material complies with PhEur monograph (ref.: 2120). Preparation method described in Farmakopea Polska IV, 1970.
Melissa leaf	*Melissa officinalis* L.	PhEur monograph (ref.: 01/2011:1447)
Milk thistle fruit	*Silybum marianum* L. Gaertn.	PhEur monograph (ref.: 1860)
Motherwort herb	*Leonurus cardiaca* L.	PhEur monograph (ref.: 01/2008:1833)
Mouse-ear hawkweed	*Hieracium pilosella* L.	Pharmacopée française monograph
Mullein flower	*Verbascum thapsus* L.; *V. densiflorum* Bertol.; *V. phlomoides* L.	PhEur monograph (ref.: 1853)
Nettle herb	*Urtica dioica* L.; *Urtica urens* L.	Hagers Handbuch monograph

Common name	Botanical name	Specified quality standard
Nettle leaf	*Urtica dioica* L.; *Urtica urens* L.	PhEur monograph (ref.: 01/2008:1897)
Nettle root	*Urtica dioica* L.; *Urtica urens* L.	Deutsches Arzneibuch (DAB) monograph
Oak bark	*Quercus robur* L.; *Q.* (Matt.) Liebl.; *Q. pubescens* Willd.	PhEur monograph (ref.: 01/2008:1887).
Oat fruit	*Avena sativa* L.	USP monograph
Oat herb	*Avena sativa* L.	Detailed specification for the herbal substance shall be given by references to bibliographic sources in absence of a PhEur monograph
Olive leaf	*Olea europaea* L.	PhEur monograph (ref.: 1878)
Passionflower herb	*Passiflora incarnata* L.	PhEur monograph (ref.: 01/2005:1364)
Pelargonium root	*Pelargonium sidoides* DC; *P. reniforme* Curt.	PhEur monograph (ref.: 2264)
Peppermint leaf	*Mentha* x *piperita* L.	PhEur monograph (ref.: 07/2017:0406)
Peppermint oil	*Mentha* x *piperita* L.	PhEur monograph (ref.: 0405)
Polypody rhizome	*Polypodium vulgare* L.	Detailed specification for the herbal substance shall be given by references to bibliographic sources in absence of a PhEur monograph
Primula flower	*Primula veris* L.; *Primula elatior* (L.) Hill	DAC monograph
Primula root	*Primula veris* L.; *Primula elatior* (L.) Hill	PhEur monograph (ref.: 01/2008:1364)
Psyllium seed	*Plantago afra* L.; *Plantago indica* L.	PhEur monograph (ref.: 01/2008:0858)
Pumpkin seed	*Cucurbita pepo* L.	DAB monograph
Pygeum bark	*Prunus africana* (Hook f.) Kalkm.	PhEur monograph (ref.: 1886)
Raspberry leaf	*Rubus idaeus* L.	PhEur monograph (ref.: 04/2020:2950)
Restharrow root	*Ononis spinosa* L.	PhEur monograph (ref.: 01/2008:1879)
Rhubarb root	*Rheum palmatum* L.; *Rheum officinale* Baillon	PhEur monograph (ref.: 0291)
Ribwort plantain leaf	*Plantago lanceolata* L.	PhEur monograph (ref.: 01/2008:1884)
Rose flower	*Rosa centifolia* L.; *Rosa gallica* L.; *Rosa damascena* Mill.	Pharmacopée française monograph
Rosemary leaf	*Rosmarinus officinalis* L.	PhEur monograph (ref.: 01/2008:1560)
Rosemary oil	*Rosmarinus officinalis* L.	PhEur monograph (ref.: 01/2008:1846)
Rupturewort herb	*Herniaria glabra* L.; *Herniaria hirsuta* L.; *Herniaria incana* Lam.	Österreichisches Arzneibuch (ÖAB) monograph
Sage leaf	*Salvia officinalis* L.	PhEur monograph (ref.: 1370)
Sandy everlasting flower	*Helichrysum arenarium* (L.) Moench	Farmakopea Polska monograph
Saw palmetto fruit	*Serenoa repens* (W. Bartram) Small	PhEur monograph (ref.: 1848)
Senna leaflet	*Cassia senna* L.; *Cassia angustifolia* Vahl	PhEur monograph (ref.: 0206)
Senna pods	*Cassia senna* L.; *Cassia angustifolia* Vahl	PhEur monograph (ref.: 0207 and/or 0208)
Shepherds purse	*Capsella bursa-pastoris* (L.) Medik.	Pharmacopée française monograph
Soya-bean lecithin	*Glycine max* (L.) Merr.	Detailed specifications for the herbal substance by references to bibliographic sources in absence of a PhEur monograph, a national pharmacopoeia or national codex currently used officially in a member state

Common name	Botanical name	Specified quality standard
Soya-bean oil, refined	*Glycine max* (L.) Merr.	PhEur monograph (ref.: 1473)
St. John's wort herb	*Hypericum perforatum* L.	Raw material complies with PhEur monograph (ref.: 01/2008:1438). The herbal preparations comply with PhEur monograph (ref.: 07/2008:1874)
Tea-tree oil	*Melaleuca alternifolia* (Maiden and Betche) Cheel	PhEur monograph (ref.: 01/2008:1837)
Thyme herb	*Thymus vulgaris* L.; *Thymus zygis* L.	PhEur monograph (ref.: 04/2009:0865)
Thyme oil	*Thymus vulgaris* L.; *Thymus zygis* L.	PhEur monograph (ref.: 1374)
Tormentil rhizome	*Potentilla erecta* (L.) Raeusch.	Raw material complies with PhEur monograph (ref.: 01/2008:1478). The tincture complies with PhEur monograph (ref.: 01/2008:1895).
Turmeric rhizome	*Curcuma longa* L.	PhEur monograph (ref.: 2543)
Turmeric rhizome, Javanese	*Curcuma xanthorrhiza* Roxb. (*C. xanthorrhiza* D. Dietrich).	PhEur monograph (ref.: 01/2008:1441)
Valerian essential oil	*Valeriana officinalis* L.	DAB monograph
Valerian root	*Valeriana officinalis* L.	PhEur monograph (ref.: 0453)
Walnut leaf	*Juglans regia* L.	Detailed specification for the herbal substance shall be given by references to bibliographic sources in absence of a PhEur monograph
White horehound herb	*Marrubium vulgare* L.	PhEur monograph (ref.: 01/2008:1835)
Wild pansy herb with flower	*Viola tricolor* L.; *Viola arvensis* Murray (Gaud); *Viola vulgaris* Koch (Oborny)	PhEur monograph (ref.: 01/2008:1855)
Wild strawberry leaf	*Fragaria vesca* L.; *Fragaria moschata* Weston; *Fragaria viridis* Weston; *Fragaria* x *ananassa* (Weston) Duchesne ex Rozier	ÖAB monograph
Willow bark	*Salix* [various species including *S. purpurea* L.; *S. daphnoides* Vill.; *S. fragilis* L.]	PhEur monograph (ref.: 1583)
Willow herb	*Epilobium angustifolium* L. and/or *Epilobium parviflorum* Schreb.	Detailed specification for the herbal substance shall be given by references to bibliographic sources in absence of a PhEur monograph
Woody nightshade stem	Solanum dulcamara L.	Detailed specification for the herbal substance shall be given by references to bibliographic sources in absence of a PhEur monograph
Wormwood	*Artemisia absinthium* L.	PhEur monograph (ref.: 1380)
Yarrow herb	*Achillea millefolium* L.	PhEur monograph (ref.: 1382)
Yarrow flower	*Achillea millefolium* L.	Pharmacopoeia Helvetica (PhHelv) monograph

Source: European Medicines Agency European Union monographs, at https://www.ema.europa.eu/en/search/search

Appendix III Maximum residue levels for pesticides in herbal drugs

European Pharmacopoeia General Chapter 2.8.13 provides maximum residue levels for pesticides in herbal drugs. These limits are in legal force for herbal drugs and herbal drug preparations marketed in the EU.

Table 36 PhEur pesticide maximum residue levels established for herbal drugs

Substance	Limit (mg/kg)
Acephate	0.1
Alachlor	0.05
Aldrin and dieldrin (sum of)	0.05
Azinphos-ethyl	0.1
Azinphos-methyl	1
Bromophos-ethyl	0.05
Bromophos-methyl	0.05
Brompropylate	3
Chlordane (sum of *cis*-, *trans* - and oxychlordane)	0.05
Chlorfenvinphos	0.5
Chlorpyriphos-ethyl	0.2
Chlorpyriphos-methyl	0.1
Chlorthal-dimethyl	0.01
Cyfluthrin (sum of)	0.1
λ-Cyhalothrin	1
Cypermethrin and isomers (sum of)	1
DDT (sum of *o,p′*-DDE, *p,p′*-DDE, *o,p′*-DDT, *p,p′*-DDT, *o,p′*-TDE and *p,p′*-TDE)	1
Deltamethrin	0.5
Diazinon	0.5
Dichlofluanid	0.1
Dichlorvos	1
Dicofol	0.5
Dimethoate and omethoate (sum of)	0.1
Dithiocarbamates (expressed as CS2)	2
Endosulfan (sum of isomers and endosulfan sulfate)	3
Endrin	0.05
Ethion	2
Etrimphos	0.05
Fenchlorophos (sum of fenchlorophos and fenchlorophos-oxon)	0.1
Fenitrothion	0.5
Fenpropathrin	0.03
Fensulfothion (sum of fensulfothion, fensulfothion-oxon, fensulfothion-oxonsulfon and fensulfothion-sulfon)	0.05

Substance	Limit (mg/kg)
Fenthion (sum of fenthion, fenthion-oxon, fenthion-oxon-sulfon, fenthion-oxon-sulfoxid, fenthion-sulfon and fenthion-sulfoxid)	0.05
Fenvalerate	1.5
Flucytrinate	0.05
τ-Fluvalinate	0.05
Fonophos	0.05
Heptachlor (sum of heptachlor, *cis*-heptachlorepoxide and *trans*-heptachlorepoxide)	0.05
Hexachlorbenzene	0.1
Hexachlorocyclohexane (sum of isomers α-, β-, δ- and ε)	0.3
Lindan (γ-hexachlorocyclohexane)	0.6
Malathion and malaoxon (sum of)	1
Mecarbam	0.05
Methacriphos	0.05
Methamidophos	0.05
Methidathion	0.2
Methoxychlor	0.05
Mirex	0.01
Monocrotophos	0.1
Parathion-ethyl and paraoxon-ethyl (sum of)	0.5
Parathion-methyl and paraoxon-methyl (sum of)	0.2
Pendimethalin	0.5
Pentachloranisol	0.01
Permethrin and isomers (sum of)	1
Phosalone	0.1
Phosmet	0.05
Piperonyl butoxide	3
Pirimiphos-ethyl	0.05
Pirimiphos-methyl (sum of pirimiphos-methyl and *N*-desethyl-pirimiphos-methyl)	4
Procymidone	0.1
Profenophos	0.1
Prothiophos	0.05
Pyrethrum (sum of cinerin I, cinerin II, jasmolin I, jasmolin II, pyrethrin I and pyrethrin II)	3
Quinalphos	0.05
Quintozene (sum of quintozene, pentachloraniline and methyl penthachlorphenyl sulfide)	1
S-421	0.02
Tecnazene	0.05
Tetradifon	0.3
Vinclozolin	0.4

Source: European Pharmacopoeia, European Directorate for the Quality of Medicines (EDQM), at https://pheur.edqm.eu/home

Appendix IV MAP crops produced at commercial scale in the EU

Legend for Table 37: AT, Austria; BE, Belgium; BG, Bulgaria; CY, Cyprus; CZ, Czechia; DE, Germany; DK, Denmark; EE, Estonia; ES, Spain; FI Finland; FR, France; GR, Greece; HR, Croatia; HU, Hungary; IE, Ireland; IT, Italy; LT, Lithuania; LU, Luxembourg; LV, Latvia; MT, Malta; NL, the Netherlands; PL, Poland; PT, Portugal; RO, Romania; SE, Sweden; SI, Slovenia; SK, Slovakia

Table 37 Selected MAP crops produced at commercial scale in the EU

MAP	AT	BE	BG	CY	CZ	DE	DK	EE	ES	FI	FR	GR	HR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK
Agrimony (*Agrimonia eupatoria*)				X		X								X	X	X							X				
Angelica (*Angelica archangelica*)		X		X	X	X		X			X			X	X	X					X	X					X
Aniseed (*Pimpinella anisum*)	X		X	X		X			X				X	X		X								X			
Arnica (*Arnica* spp.)						X			X	X				X		X	X				X	X					
Artichoke (*Cynara cardunculus*)	X					X			X		X				X	X						X	X	X			
Basil (*Ocimum basilicum*)			X	X		X			X		X		X	X		X						X	X				
Bay (*Laurus nobilis*)				X		X			X		X		X	X		X							X				
Bilberry (*Vaccinium myrtillus*)			X		X					X	X				X	X	X					X		X	X		
Bitter fennel (*Foeniculum vulgare* subsp *vulgare* var. *vulgare*)	X		X			X							X	X													
Black chokeberry (*Aronia melanocarpa*)						X																X					
Blackcurrant (*Ribes nigrum*)	X					X			X		X			X	X	X						X		X			
Borage (*Borago officinalis*)				X		X			X		X			X		X						X	X				

MAP	AT	BE	BG	CY	CZ	DE	DK	EE	ES	FI	FR	GR	HR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK
Calendula (*Calendula officinalis*)	X		X	X		X		X	X	X	X		X	X	X	X			X		X	X	X	X			
Cannabis (*Cannabis sativa*)	X					X	X			X			X								X	X					
Caraway (*Carum carvi*)	X	X			X	X			X	X				X		X	X		X		X	X		X			
Carob (*Ceratonia siliqua*)				X					X				X			X							X				
Chamomile, German (*Matricaria chamomilla*)	X		X	X	X	X		X	X		X		X	X	X	X			X		X	X					
Chamomile, Roman (*Chamaemelum nobile*)		X				X					X					X						X					
Chaste tree (*Vitex agnus-castus*)						X			X							X											
Cherry, Sour (*Prunus cerasus*)			X											X		X								X			
Chicory (*Cichorium intybus*)		X				X					X					X					X	X					
Coriander (*Coriandrum sativum*)	X		X			X			X		X		X	X		X						X					
Cornflower (*Centaurea cyanus*)	X					X		X			X			X		X							X				
Dandelion (*Taraxacum officinale*)			X			X					X			X	X	X					X	X					
Digitalis spp.						X								X							X	X		X			
Dill (*Anethum graveolens*)	X			X		X			X	X	X		X	X	X	X					X	X					
Echinacea angustifolia						X										X											
Echinacea pallida						X										X											
Echinacea purpurea			X			X			X	X	X			X	X	X					X	X	X	X			

MAP	AT	BE	BG	CY	CZ	DE	DK	EE	ES	FI	FR	GR	HR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK
Elecampane (*Inula helenium*)			X			X									X	X						X					
English lavender (*Lavandula angustifolia*)			X			X			X		X					X											
English plantain (*Plantago lanceolata*)					X	X				X	X				X	X					X	X					
Eucalyptus (*Eucalyptus globulus*)						X			X		X					X							X				
European elder (*Sambucus nigra*)	X			X		X	X				X			X	X	X						X					
European goldenrod (*Solidago virgaurea*)						X				X	X			X	X	X						X					
European vervain (*Verbena officinalis*)				X		X					X				X	X											
Feverfew (*Tanacetum parthenium*)	X					X				X	X				X	X					X						
Gentian (*Gentiana lutea*)	X					X			X		X		X		X	X					X			X			
Ginkgo biloba						X					X				X	X											
Hop (Humulus lupulus)	X			X	X	X					X				X	X											
Horse chestnut (*Aesculus hippocastanum*)			X			X					X											X		X			
Horseradish (*Armoracia rusticana*)						X	X			X				X		X									X		
Horsetail (*Equisetum arvense*)						X					X				X	X						X					
Hyssop (*Hyssopus officinalis*)	X			X		X			X		X		X	X	X	X					X		X	X			
Ironwort (*Sideritis* spp.)			X	X								X															

MAP	AT	BE	BG	CY	CZ	DE	DK	EE	ES	FI	FR	GR	HR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK
Juniper (*Juniperus communis*)						X			X		X				X	X											
Lemon balm (*Melissa officinalis*)	X		X	X		X			X	X	X		X	X	X	X					X	X	X	X			
Lemon verbena (*Aloysia citrodora*)	X			X					X		X					X							X				
Linden (*Tilia* spp.)			X			X					X			X	X							X		X			
Liquorice (*Glycyrrhiza glabra*)									X							X											
Lovage (*Levisticum officinale*)	X					X					X			X		X			X		X	X	X				
Marshmallow (*Althaea officinalis*)			X		X	X		X			X		X	X	X	X						X					
Milk thistle (*Silybum marianum*)	X	X	X		X	X					X			X		X					X	X		X			
Motherwort (*Leonurus cardiaca*)				X		X								X	X	X			X			X		X			
Mugwort (*Artemisia vulgaris*)						X								X		X											
Mullein (*Verbascum* spp.)				X		X					X			X	X												
Oregano (*Origanum vulgare*)			X			X			X		X		X	X		X							X				
Parsley (*Petroselinum crispum*)	X			X		X			X		X				X	X					X		X		X		
Passionflower (*Passiflora incarnata*)											X					X											
Peppermint (*Mentha* x *piperita*)			X	X		X			X		X		X	X	X	X					X	X	X	X			
Poppy, California						X					X					X											

MAP	AT	BE	BG	CY	CZ	DE	DK	EE	ES	FI	FR	GR	HR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK
(*Eschscholzia californica*)																											
Poppy, Field (*Papaver rhoeas*)						X					X					X											
Poppy, Opium (*Papaver somniferum*)	X				X	X			X		X		X	X							X	X					
Red clover (*Trifolium pratense*)	X		X			X									X	X								X			
Rhodiola rosea			X			X													X						X		
Rose, Damask (*Rosa x damascena*)			X	X		X					X																
Rosehip, Dog (*Rosa canina*)			X			X					X			X		X											
Rosemary (*Salvia rosmarinus*)	X			X		X			X		X		X	X		X							X				
Saffron (*Crocus sativus*)				X					X		X	X		X		X											
Sage (*Salvia officinalis*)	X		X			X			X		X		X			X							X				
Sage, Clary (*Salvia sclarea*)			X			X			X		X		X	X		X											
Savory, Summer (*Satureja hortensis*)			X			X			X		X			X		X						X	X				
Savory. Winter (*Satureja montana*)									X		X			X		X							X				
Sea buckthorn (*Hippophae rhamnoides*)						X								X										X			
Spearmint (*Mentha spicata*)				X		X			X		X			X		X							X	X			
St John's wort (*Hypericum perforatum*)	X		X			X	X			X	X		X		X	X	X		X		X	X	X				
Stinging nettle (*Urtica dioica*)	X		X			X				X	X			X	X	X						X					
Sweet marjoram	X		X	X		x			X		X		X	X		X						X	X				

MAP	AT	BE	BG	CY	CZ	DE	DK	EE	ES	FI	FR	GR	HR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK
(*Origanum majorana*)																											
Sweet violet (*Viola odorata*)						X					X				X	X					X						
Tarragon, French (*Artemisia dracunculus*)	X			X		X			X	X	X			X		X					X		X			X	
Thyme (*Thymus vulgaris*)	X			X		X			X		X		X	X	X	X						X	X	X			
Thyme, Wild (*Thymus serpyllum*)			X			X					X		X	X													
Valerian (*Valeriana officinalis*)		X	X	X	X	X	X				X		X		X	X			X		X	X					
Willow (*Salix* spp)						X					X				X												
Wormwood (*Artemisia absinthium*)				X		X					X				X	X										X	
Yarrow (*Achillea millefolium*)	X					X					X			X	X	X											
Yellow sweetclover (*Melilotus officinalis*)	X					X					X					X			X								

Source: Brinckmann, J.A., Kathe, W., Berkhoudt, K., Harter, D.E.V. and Schippmann, U. (2022). A new global estimation of medicinal and aromatic plant species in commercial cultivation and their conservation status. *Economic Botany, at* https://link.springer.com/article/10.1007/s12231-022-09554-7

Appendix V MAP ingredients imported into the EU

Table 38 MAP ingredients imported into the EU in 2021 and top suppliers

HS Code	Description	Trade value ($)	Net weight (kg)	Top five suppliers ($)
3301	Essential oils, aqueous distillates, resinoids and extracted oleoresins, e.g. of aniseed (*Pimpinella anisum*), cinnamon (*Cinnamomum* spp., eucalyptus (*Eucalyptus* spp.), mint (*Mentha* spp.) and many others	$1,243,229,239	49,169,198	US, India, China, Brazil, Argentina
081040	Bilberry (*Vaccinium myrtillus*), highbush blueberry (*V. corymbosum*), cranberry (*V. macrocarpon*), lingonberry (*V. vitis-idaea*), other *Vaccinium* spp., fresh	$814,566,417	130,627,797	Peru, Morocco, South Africa, Chile, Serbia
081190	Bilberry (*Vaccinium myrtillus*), lowbush blueberry (*V. angustifolium, V. myrtilloides*), other *Vaccinium* spp., sour (tart) cherry (*Prunus cerasus*), frozen	$672,982,715	311,492,818	Ukraine, Peru, Canada, Serbia, Belarus
0902	Tea (*Camellia sinensis*) leaf	$624,630,624	127,436,853	Sri Lanka, China, India, UK (re-export), Kenya, Argentina
121190	Other medicinal plants n.e.c. in heading 1211, e.g. basil (*Ocimum* spp.), leaf, chamomile (*Matricaria chamomilla*) flower, liquorice (*Glycyrrhiza* spp.) root, peppermint (*Mentha* × *piperita*) leaf, psyllium (*Plantago ovata*) husk or seed, sage (*Salvia officinalis*) leaf, senna (*Senna alexandrina*) leaf or pod.	$613,630,548	120,989,077	India, US, Switzerland, Egypt, Morocco
130219	Other herbal extracts n.e.c. in heading 1302,1, e.g. centella (*Centella asiatica*) herb extract, ginkgo (*Ginkgo biloba*) leaf extract, ginseng (*Panax* spp.) root extract, vanilla (*Vanilla* spp.), fruit extracted oleoresin	$586,256,684	71,816,455	China, US, India, Switzerland, Madagascar
0904	*Capsicum* spp., *Pimenta* spp. and/or *Piper* spp. fruits	$577,249,150	185,097,440	China, Viet Nam, Brazil, India, Indonesia
120400	Linseed (*Linum usitatissimum*)	$505,969,651	660,002,045	Kazakhstan, Russian Federation, Canada, UK, Ukraine
0905	Vanilla (*Vanilla planifolia*, *V. tahitensis*) fruit	$301,656,540	1,552,891	Madagascar, Indonesia, Uganda, Papua New Guinea, French Polynesia
091011 091012	Ginger (*Zingiber officinale*) rhizome	$257,756,539	123,863,413	China, Peru, Brazil, Nigeria, Thailand
130232	Guar (*Cyamopsis tetragonolobus*) seed and/or carob (*Ceratonia siliqua*) seed mucilage or thickener	$147,169,687	52,218,154	India, Switzerland, Turkey, US, Morocco
130190	Other natural gums, resins, oleo-gum-resins n.e.c. in heading 1301, e.g. asafoetida (*Ferula asafoetida*) gum, copaiba (*Copaifera* spp.) resin, frankincense (*Boswellia* spp.) gum resin, myrrh (*Commiphora* spp.) gum resin, tragacanth (*Astragalus gummifer*) gum	$106,048,769	37,261,352	Brazil, Somalia, India, Iran, Argentina

HS Code	Description	Trade value ($)	Net weight (kg)	Top five suppliers ($)
091099	Other spices, n.e.c., e.g. bay (*Laurus nobilis*) leaf, fenugreek (*Trigonella foenum-graecum*) seed, thyme (*Thymus vulgaris)* herb, wild thyme (*Thymus serpyllum*) herb	$84,922,942	20,620,736	Turkey, India, Thailand, Egypt, Brazil
130120	Acacia (*Acacia senegal*) gum	$84,323,862	55,019,219	Sudan, Chad, UK (re-export), US (re-export), Nigeria, Mali, Senegal
0906	Cinnamon (*Cinnamomum* spp.) bark	$79,143,924	15,451,272	Indonesia, Viet Nam, Sri Lanka, Madagascar, China
1210	Hop (*Humulus lupulus*) strobile	$77,688,021	3,429,743	US, UK, Australia, New Zealand, Switzerland
090961 090962	Aniseed (*Pimpinella anisum*), caraway (*Carum carvi*), fennel (*Foeniculum vulgare*), juniper (*Juniperus communis*), star anise (*Illicium verum*) fruit	$63,041,317	15,728,751	Egypt, Serbia, China, Viet Nam, Turkey
090831 090832	Cardamom (*Elettaria cardamomum*)	$50,170,496	2,641,975	Guatemala, India, Tanzania, Honduras, UK (re-export), US (re-export), China
090931 090932	Cumin (*Cuminum cyminum*) seed	$42,640,090	12,918,459	India, Turkey, Syria, Egypt, Viet Nam
091020	Saffron (*Crocus sativus*) stigma	$42,012,819	Not reported	Iran, Afghanistan, Uzbekistan, UK (re-export), India, Switzerland (re-export), US (re-export), Morocco
091030	Turmeric (*Curcuma* spp.) rhizome	$39,646,789	18,383,651	India, Peru, Costa Rica, UK (re-export), Madagascar, China
090811 090812	Nutmeg (*Myristica fragrans*) kernel	$36,453,155	4,362,327	Indonesia, Sri Lanka, Grenada, Viet Nam, India
091091	Other spices, mixtures of two or more	$33,367,709	6,758,372	India, UK (re-export), Pakistan, Sri Lanka, China, Lebanon
130212	Liquorice root (*Glycyrrhiza* spp.) extract	$31,458,577	Not declared	Iran, China, Turkmenistan, US, Israel
130231	Agar (*Gelidium* spp.) algae polysaccharides	$30,090,878	1,760,917	China, Morocco, Chile, Indonesia, US
130213	Hop (*Humulus lupulus*) strobile extract	$28,472,089	1,230,285	US, UK, China, Australia, Switzerland
0814	Peels of *Citrus* genus (e.g. orange peel used in herbal tea), dried	$20,626,310	13,794,011	Peru, Argentina, Mexico, Ghana, Paraguay
0903	Yerba maté (*Ilex paraguariensis*) leaf	$18,937,227	5,505,296	Brazil, Argentina, Paraguay, Syria (re-export), Uruguay, Ecuador
090821 090822	Mace (*Myristica fragrans*) aril	$17,997,744	834,661	Indonesia, Sri Lanka, Viet Nam, Papua New Guinea, India
110620	Flour, meal, powder of dried roots/tubers, e.g. arrowroot (*Maranta arundinacea*), maca (*Lepidium meyenii*), manioc (*Manihot esculenta*), sago (*Metroxylon sagu*), taro (*Colocasia* spp.), yam (*Dioscorea* spp.), yautia (*Xanthosoma* spp.) and others	$16,501,146	9,959,046	Peru, Brazil, UK (re-export), Ghana, Rwanda, Côte d'Ivoire

HS Code	Description	Trade value ($)	Net weight (kg)	Top five suppliers ($)
090921 090922	Coriander (*Coriandrum sativum*) fruit	$16,125,112	29,181,412	Russian Federation, Ukraine, India, Morocco, Turkey
0907	Clove (*Syzygium aromaticum*) flower buds and stems	$15,706,949	2,509,271	Madagascar, Indonesia, Sri Lanka, Comoros, Tanzania
210130	Chicory (*Cichorium intybus*) root, roasted, and other coffee substitutes	$12,588,704	3,410,347	Switzerland, India, Ukraine, UK, Turkey
121120	Ginseng (*Panax* spp.) root	$12,547,148	384,447	China, Rep. of Korea, US, India (re-export), Brazil (re-export), UK (re-export), Canada, Hong Kong SAR
121294	Chicory (*Cichorium intybus*) root, not roasted	$1,307,627	1,657,994	Indian, China, Serbia, UK, Albania
130211	Opium poppy (*Papaver somniferum*) extract	$1,186,773	7,799	India
121150	Ephedra (*Ephedra* spp.) herb	$56,094	21,859	Mali, Morocco, Peru, Côte d'Ivoire, Senegal
130214	Ephedra (*Ephedra* spp.) herb extract	$22,745	558	US, China
121140	Opium poppy (*Papaver somniferum*) straw (husk)	$12,601	924	China
121130	Coca (*Erythroxylum coca*) leaf	$7,297	1,326	China, Peru, Ghana

Source: United Nations COMTRADE database, at https://comtrade.un.org/

Appendix VI Relevant trade shows in Europe

Table 39 lists and summarizes the relevant recurring trade shows in Europe for producers and exporters of MAP ingredients and products to attend or take part.

Table 39 Trade shows for producers and exporters of MAP ingredients and products

Event and contact	When	Where	About
BIOFACH[233]	Every year, usually in February	Exhibition Centre Nuremberg, Germany	In 2020, 3,448 exhibitors and 47,561 attendees; international trade fair featuring certified organic goods, mainly finished products, but also organic MAP ingredients
CP**H**I (Convention on Pharmaceutical Ingredients) **Worldwide**[234]	Every year, usually in October or November	Alternating European cities (Barcelona, Madrid, Milan, Frankfurt)	More than 1,150 exhibitors, including manufacturers and distributors of active pharmaceutical ingredients, excipients, fine chemicals, botanical and natural extracts
Fi Europe[235]	Every year, usually in December	Alternating European cities (Amsterdam, Frankfurt, Paris)	In 2021, more than 1,200 exhibitors and 20,000 attendees (online and in-person); features exhibitors that supply ingredients to the food and beverage sector, including zones for food ingredients, health ingredients and natural ingredients
Vitafoods Europe[236]	Every year, usually in May	Palexpo Exhibition Centre, Grand-Saconnex (Geneva), Switzerland	In 2021, 658 exhibitors and 22,703 attendees; features exhibitors from each part of the supply chain from botanical raw materials and processed ingredients to branded finished products, contract manufacturers and private label, services and equipment

[233] https://www.biofach.de/en

[234] https://www.cphi.com/europe/en/home.html

[235] https://www.figlobal.com/fieurope/en/home.html

[236] https://www.vitafoods.eu.com/en/home.html

Appendix VII Selected importers/buyers (Europe, China, India, US)

The tables in this appendix list selected buyers of sustainably produced herbal materials, including those mainly involved with the importing, processing and trading of:

- Herbal raw materials (whole, sliced, cut and sift, tea bag cut, granule, powder);
- Herbal extracts, plant juices and plant juice concentrates;
- Oils (essential oils, fatty oils), absolutes, concretes, hydrosols, oleoresins, resinoids.

The sustainability certification programmes in which each company participates are also listed (e.g. Demeter Biodynamic, Fair for Life, Fairtrade, FairWild, For Life, Organic, Rainforest Alliance, UEBT). This does is not mean, however, that all ingredients processed and marketed by the listed companies hold the same range of sustainability standards. Most companies also import, process and trade in some amount of lower cost, non-certified materials.

Table 40 concerns buyers situated in Europe; Table 41, China; Table 42, India; and Table 43, US.

Table 40 Selected buyers of sustainably produced herbal materials in Europe

Name and contact link	Location	Sustainability certifications
Herbal raw material processors and traders		
Amorós Nature S.L.	C/ Can Batalló, s/n, 17450 Hostalric, Girona SPAIN	Organic
C.E. Roeper GmbH	Hans-Duncker Straße 13, 21035 Hamburg GERMANY	Organic
Dani Organic Foods Ltd	Lakesview International Business Park, Claremont Way, Unit 11 Canterbury, Hersden CT3 4JZ UNITED KINGDOM	Fairtrade, Organic
Diana Food SAS – division of Symrise AG	Allee 35000, 7 All. Ermengarde d'Anjou, 35000 Rennes FRANCE	Fair for Life, Organic
Dixa AG	Stationsstrasse 39a, 9014 St Gallen SWITZERLAND	Organic
Dried Ingredients GmbH	Am Windhukkai 5, 20457 Hamburg GERMANY	Fairtrade, Organic, UTZ
Hälssen & Lyon GmbH	Pickhuben 9, 20457 Hamburg GERMANY	Fairtrade, Organic, Rainforest Alliance, UTZ
Heinrich Klenk GmbH & Co. KG	Aschenhof 35, D-97525 Schwebheim GERMANY	Organic
l'Herbier du Diois	F-26410 Châtillon-en-Diois FRANCE	Biodynamic, Fair for Life, Fairtrade, FairWild, For Life, Organic
HerbaNordPol – Gdańsk Sp. z o.o.	ul. Obrońców Westerplatte 28, 82-230 Nowy Staw POLAND	Organic
Herbissima	1090, Old Railway Way, ZA Les Écluses 84110 Vaison-la-Romaine, FRANCE	Fairtrade, Organic
High Quality Organics Europe	Leeuwenveldseweg 3B, 1382 LV Weesp, The NETHERLANDS	Organic
Kräuter Mix GmbH	Wiesentheider Straße 4, D-97355 Abtswind GERMANY	Organic, Rainforest Alliance, UTZ
Martin Bauer GmbH & Co. KG	Dutendorfer Straße 5-7, 91487 Vestenbergsgreuth GERMANY	Fair for Life, Fairtrade, FairWild, Organic, Rainforest Alliance, UEBT, UTZ

Name and contact link	Location	Sustainability certifications
Müggenburg Pflanzliche Rohstoffe GmbH & Co. KG	Tegelbarg 35, D-24576 Bad Bramstedt GERMANY	Organic
Natural Origins – division of Döhler Group	471 rue Louis Arnal, ZAC des Prés Secs 69380 Lozanne FRANCE	Fair for Life, For Life, Organic
Organic Flavour Co. BV – division of Euroherb bio	Turbinestraat 12, 3903 LW Veenendaal NETHERLANDS	Biodynamic, Fairtrade, Organic
Organic Herb Trading	Butts Way, Milverton, Somerset TA4 1ND UNITED KINGDOM	Biodynamic, Fair for Life, Fairtrade, FairWild, Organic
Ph. Seyfried Gewürzmühle GmbH & Co. KG	Lagerstrasse 11, D-68169 Mannheim GERMANY	Fairtrade, Organic
Pronatec AG	Stegackerstrasse 6, 8409 Winterthur SWITZERLAND	Biodynamic, Fair for Life, Fairtrade, Naturland Fair, For Life, Organic, Rainforest Alliance, UTZ
S.& P. Lendi Erboristi SA	Via Costa 17, CH-6986 Curio SWITZERLAND	Fairtrade, FairWild, Naturland Fair, Organic
Suanfarma	Avenida Prat de la Riba s/n CP 08708 Pallejá, Barcelona SPAIN	Organic
Waldland Naturstoffe GmbH	Oberwaltenreith 10, 3533 Friedersbach AUSTRIA	Organic
Worlée Naturprodukte GmbH	Grusonstrasse 26, 22113 Hamburg GERMANY	Fairtrade, FairWild, Organic, Rainforest Alliance, UEBT, UTZ,
Herbal extract manufacturers		
Anklam Extrakt GmbH	Johann-Friedrich-Böttger Straße 4 17389 Anklam GERMANY	(some) Organic
Blue Sky Botanics	Castle Farm, Upton Bishop, Ross-on-Wye HR9 7UW UNITED KINGDOM	Fairtrade, FairWild, Organic
Estratti Piante Officinali SrL	Via Stadera, 19, 20141 Milan ITALY	(some) Organic
Euromed – division of Dermapharm AG	Carrer Rec de Dalt, 21-23, 08100 Mollet del Vallès, Barcelona SPAIN	(some) Organic, Rainforest Alliance
Flavex Naturextrakte GmbH	Nordstraße 7, D-66780 Rehlingen GERMANY	Organic, Rainforest Alliance
Finzelberg GmbH & Co. KG – division of Martin Bauer	Koblenzer Straße 48-56, 56626 Andernach GERMANY	(some) Organic
Indena SpA	Viale Ortles, 12 20139 Milan, ITALY	(some) Organic, Ecocert Validated
Iprona SpA	Via Industria 1/6, 39011 Lana (BZ), South Tyrol ITALY	(some) Organic
Laboratoires Expanscience	1 place des Saisons 92048 Paris La Défense Cedex FRANCE	(some) Fair for Life, FairWild, Organic
Möller Pharma GmbH & Co. Herstellungs- und Vertriebs KG	Lise-Meitner Straße 2, D 45659 Recklinghausen GERMANY	(some) Organic
Naturex – division of Givaudan	250 rue Pierre Bayle BP 81218, 84140 Avignon FRANCE	(some) Organic
Phytoneering Extract Solutions GmbH – division of Blonorica SE	Kerschensteinerstraße 11-15, 92318 Neumarkt GERMANY	(some) Organic
Plantex	ZAC de la Noue Rousseau, 6 rue d'Alembert, 91240 Saint Michel sur Orge FRANCE	Organic
Plantextrakt GmbH & Co. KG – division of Martin Bauer	Dutendorfer Straße 5, 91487 Vestenbergsgreuth GERMANY	(some) Fairtrade, Organic

Name and contact link	Location	Sustainability certifications
Select Botanical S.L.	c/ Bori i Fontestà. 49, 08017 Barcelona SPAIN	Organic
Oils, absolutes, concretes, hydrosols, oleoresins, resinoids		
Albert Vieille SAS – division of Givaudan	629 route de Grasse, BP217, 06227 Vallauris Cedex FRANCE	Fair for Life, Organic
Arxfarm d.o.o.	Turopolje 7, 8310 Šentjernej SLOVENIA	(some) FairWild, Organic
Bontoux SAS	583 route du Col de Peyruergue, Quartier Aguzon, 26170 Saint-Auban-sur-l'Ouvèze FRANCE	For Life, Organic
Henry Lamotte Oils GmbH	Merkurstrasse 47, 28197 Bremen GERMANY	Fair for Life, Organic
H. Reynaud & Fils	La Cheminade, 26570 Montbrun-les-Bains FRANCE	Organic
Laboratoire HELPAC SAS	ZI CHAPPES 43390 Auzon FRANCE	Fair for Life, Organic
Laboratoire Monique Remy (LMR) Naturals – division of International Flavors & Fragrances Inc.	Parc Industriel des Bois de Grasse Grasse, 06130 FRANCE	FairWild, For Life, Organic
SanaBio GmbH	Geschwister-Scholl Straße 143A, D-39218 Schönebeck GERMANY	Organic
Symrise AG	Mühlenfeldstraße 1, 37603 Holzminden GERMANY	UEBT, UTZ

Table 41 Selected buyers of sustainably produced herbal materials in China

Name and contact link	Location	Sustainability certifications
Herbal raw material processors and traders		
Chengdu TowerD Import & Export Trading Co. Ltd	No.1, 2/F, Unit 3, Building 33, No. 36, Section 2, Jinhua Road, Jinjiang District, Chengdu, Sichuan	Organic
China Meheco Corporation	No. 18, Guangming Zhongjie, Dongcheng District, Beijing 100061	Organic, UEBT & Rainforest Alliance Herbs & Spices Programme
Ever Pharm Ltd	408-342 Zhongzeyayuan, Tongzhou District, Beijing 101121	Organic, UEBT & Rainforest Alliance Herbs & Spices Programme
Ginger Food (Zhangzhou) Co. Ltd	40 Qiaodong Road, Fengtian Town, Nanjing County, Zhangzhou 363612	Fairtrade, Organic
Huisong Pharmaceuticals	236 N Jianguo Road 15F, Hangzhou, Zhejiang 310003	Organic
Hunan Tea Group Co. Ltd	Xiangcha High Technology Industrial Park, No. 19, LongYuan First Road, Furong District, Changsha 410002	Fairtrade, Organic
Naturz Organics (Dalian) Co. Ltd	Room 3203A, World Trade Centre 25 Tongxing Street, Zhongshan District, Dalian 116001 Liaoning	Organic
Nutraline Co. Ltd	Rm.212, Building 1, M5 Canal No. 1, No. 9 Yunheyuan Rd, Tongzhou District, Beijing 101199	Organic
Zhejiang Tea Group Co. Ltd	218 Ti Yu Chang Road, Hangzhou 310041	Fairtrade, Organic, UEBT & Rainforest Alliance Herbs & Spices Programme

Name and contact link	Location	Sustainability certifications
Herbal extract manufacturers		
Cactus Botanics (Shanghai) Co. Ltd	Room 6, Floor 11, No. 560 Zhang Yang Road, Pudong New District, Shanghai City 200122	Organic
Ever Pharm Ltd	408-342 Zhongzeyayuan, Tongzhou District, Beijing 101121	Organic, UEBT & Rainforest Alliance Herbs & Spices Programme
Huisong Pharmaceuticals	236 N. Jianguo Road 15F, Hangzhou, Zhejiang 310003	Organic
Guilin Layn Natural Ingredients Corp.	19 South Renmin Road, Lingui, Guilin City, Guangxi Zhuang Autonomous Region	Organic
Martin Bauer Plant Extracts (China) Co. Ltd	568 19th Street, Hangzhou Economic Development Area (HEDA), Hangzhou, 310018	(some) Fairtrade, Organic
Shanghai Tianyuan Plant Product Co. Ltd	18 Hexiang Road, Baihe Town, Qingpu District, Shanghai 201615	Organic, Panda-friendly
Shaanxi Jiahe Pharmaceutical Co. Ltd	7 Binhe Rd, Agricultural Hi-tech Industries Demonstration Zone, Yangling, 712100 Shaanxi	Organic
StarHealth Botanical Technology Corporation	2nd Floor, Bldg.1, No. 18 Longqing Street, Beijing Economic-Technological Development Area, Beijing	(some) Fair for Life, Organic, Rainforest Alliance

Table 42 Selected buyers of sustainably produced herbal materials in India

Name and contact link	Location	Sustainability certifications
Herbal raw material processors and traders		
Creation Biotech	Ganga Nagar Colony, Behind Swasti Hospital, Badaun Road, Bareilly, 243001 Uttar Pradesh	Fair for Life, Organic
Cultivator Natural Products Pvt. Ltd	Plot 24 to 31 and 25 to 30, Khasra No. 135/1, Sonamukhi Nagar, Sangaria Fanta, Jodhpur, 342013 Rajasthan	Fair for Life, FairWild, Organic
Dani Foods India	Survey 30/2 P 3, Near Sadguru Cold, Goras Road, Village Lakhupara, TA Mahuva, Bhavnagar, 364290 Gujarat	Organic
Geo-Fresh Organic	Khali Char Rasta, Near Bank of Baroda, Sidhpur, 384151 Gujarat	Fairtrade, Organic
Herb Artizan Pvt. Ltd	Plot 5B, Veerasandra Industrial Area, 19th KM Stone, Hosur Road, Electronics City Post, Bangalore, 560100 Karnataka	Fair for Life, Organic
J. V. Gokal & Co. Pvt. Ltd	Falta Special Economic Zone, Sector II, 24 Parganas, Kolkata, 743504 West Bengal	Fairtrade, Organic, Rainforest Alliance
Phalada Agro Research Foundation Pvt. Ltd	92/5 Kannalli, Seegehalli Cross, Magadi Main Road, Bangalore, 562130 Karnataka	Demeter Biodynamic, Fairtrade, Fair for Life, Naturland Fair and Forest Garden Programme, Organic
PlantRich Agri Tech Pvt. Ltd	Mini Industrial Estate, Manarcadu PO, Kottayam, 686019 Kerala	Fairtrade, Organic
Umalaxmi Organics Pvt. Ltd	701-702, Siddhartha Complex, Alkapuri, Baroda, 390007 Gujarat	Organic

Name and contact link	Location	Sustainability certifications
Herbal extract manufacturers		
Ayush Herbs Pvt. Ltd	25, Phase I, Industrial Area, Nagrota Bagwan, Kangra, 176047 Himachal Pradesh	Organic
Indfrag Biosciences Pvt. Ltd	S. 102/3, Kundumaranapalli Village, 12th Km., Kelamangalam Road, Hosur, 635113 Tamil Nadu	(some) Fairtrade
Natural Remedies Pvt. Ltd	Plot 5B, Veerasandra Industrial Area, 19th Km. Stone, Hosur Road, Bangalore, 560100 Karnataka	Organic
Umalaxmi Organics Pvt. Ltd	701-702, Siddhartha Complex, Alkapuri, Baroda, 390007 Gujarat	Organic
Vidya Herbs Pvt. Ltd	#N3-3, Vidya Building, 24th Main, JP Nagar 1st Phase, Bengaluru, 560078 Karnataka	(some) Fairtrade, Organic
Oils, absolutes, concretes, hydrosols, oleoresins, resinoids		
Aromatic and Allied Chemicals	B-8/9/10 Industrial Estate, C.B. Ganj Bareilly, 243502 Uttar Pradesh	Organic
Castor Products Company	Plot 204, Ward 12/C Gandhidham, Kutch, 370201 Gujarat	Fair for Life, Organic
Katyani Exports	BT-1/94, Mangolpuri Industrial Area, Phase 1, Near Safal Dairy, 110083 New Delhi	Organic
Manorama Industries Ltd	2474 Birkoni, Near Parswani Road, Mahasamund, Raipur, 493445 Chhattisgarh	Fairtrade, Organic
Natural & Essential Oils Pvt. Ltd	74/2B, Manandavadi Road, HD Kote Rd, Sriramapura, Mysuru, 570008 Karnataka	For Life, Organic
Nature in Bottle	Kh. No-13/21, Khampur, G.T. Karnal Road, Delhi, 110036 Delhi	Organic
Vidya Herbs Pvt. Ltd	#N3-3, 'Vidya Building', 24th Main, JP Nagar 1st Phase, Bengaluru, 560078 Karnataka	(some) Fairtrade, Organic

Table 43 Selected buyers of sustainably produced herbal materials in the US

Name and contact link	Location	Sustainability certifications
Herbal raw material processors and traders		
Aromatics Inc.	230 Center St., Basin City, Washington 99343	Organic, UEBT & Rainforest Alliance Herbs & Spices Programme
High Quality Organics Inc.	12101 Moya Blvd, Reno, Nevada 89506	Organic
Martin Bauer Inc.	400 Plaza Drive 3rd Floor, Secaucus, New Jersey 07094	(some) Fairtrade, FairWild, Organic
Mountain Rose Herbs	PO Box 50220, Eugene, Oregon 97405	Fair for Life, Organic
Mueggenburg Farms Inc.	12623 SW Green Drive, Culver, Oregon 97734	Organic

Name and contact link	Location	Sustainability certifications
Nuherbs Co.	14722 Wicks Blvd, San Leandro, California 94577	Organic
Penn Herb Co. Ltd	10601 Decatur Road, Suite 200, Philadelphia, Pennsylvania 19154	Organic
Pharmachem Laboratories LLC – division of Ashland	265 Harrison Avenue, Kearny, New Jersey 07032	(some) Fair for Life, Organic
Pure Ground Ingredients	2535 Business Parkway, Minden, Nevada 89423	Fairtrade, FairWild, Organic
Starwest Botanicals LLC	161 Main Ave, Sacramento, California 95838	Organic
Tradin Organics USA LLC	100 Enterprise Way, Suite B 101, Scotts Valley, California 95066	(some) Fairtrade, Organic
Whole Herb Company – division of Berjé Inc.	19800 8th Street East, Sonoma, California 95476	Organic
Herbal extracts		
Applied Food Sciences Inc.	8708 S. Congress Ave, Austin, Texas 78745	Organic
Carrubba Inc.	70 Research Dr., Milford, Connecticut 06460	Organic
Doehler North America	400 High Point Road SE, Cartersville, Georgia 30120	Organic
Firmenich Inc.	411 E. Gano Ave, Saint Louis, Missouri 63147	(some) Fairtrade, Organic
RFI Ingredients LLC	2100 W Midway Blvd, Broomfield, Colorado 80020	(some) Fair for Life, Organic
Sensient Flavors LLC	25 E. Main Street, Amboy, Illinois 61310	(some) Fairtrade, Organic
WILD Flavors and Specialty Ingredients (USA) Inc. – division of ADM	1261 Pacific Avenue, Erlanger, Kentucky 41018	Organic
Virginia Dare Extract Co. Inc.	900 Federal Boulevard, Carteret, New Jersey 07008	(some) Fairtrade, Organic
Oils, absolutes, concretes, hydrosols, oleoresins, resinoids		
Berjé Inc.	700 Blair Rd, Carteret, New Jersey 07008	Organic
Bio-Botanica Inc.	75 Commerce Drive, Hauppauge, New York 11788	(some) Organic
Jedwards International Inc.	141 Campanelli Drive, Braintree, Massachusetts 02184	Fairtrade, Fair for Life, Organic
Liberty Natural Products Inc.	20949 S. Harris Road, Oregon City, Oregon 97045	Organic
The Lebermuth Company Inc.	4004 Technology Drive, South Bend, Indiana 46628	Organic

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