

WILD PLANTS USING THE FOREST

CONSULTANT IN NATURAL
PRODUCTS

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FITOMÓN (PLANTS OF THE WORLD)

Consultancy Services for Natural Products Industry to comply with European regulations.

Legal strategy of marketing products based on plants.

Regulatory affairs, Product development, Training, Quality Assurance, Audits, R+D+I projects and Documentation.

<http://www.fitomon.com/>

<http://blog.fitomon.com/>

We help our customers to comply with legislation, to make the food authorizations, to follow HACCP, to prepare scientific and regulatory files to comply legislative issues in Europe relating with foods, food supplements and health: authorizations, product notifications, health claims, toxicological, ...

FITOMÓN / SERVICE DETAILS KEYWORDS

Functional Food (nutraceuticals)

Enriched (vitamins, minerals)

Natural Food additives

Ingredients

Organic substances

Soaps, detergents

Cosmetics

Biocides

Quality Control

Phytosanitary

Fertilizers

Crop production

LEST IT BE TOO LATE

How to adapt your products to market regulations to overcome entry barriers before it is too late.

Oftentimes, in a project we think about the legal marketing requirements at the end. This is a common mistake that sometimes couldn't have a solution.

It's not the first time I have ever met someone who has grown a plant or obtained an essential oil that finally couldn't put in the European market. Ex. *Artemisia annua*, Cannabis, etc..

It's so important to know if is possible market your plant or product.

We can find positive list of food plants in each European country.

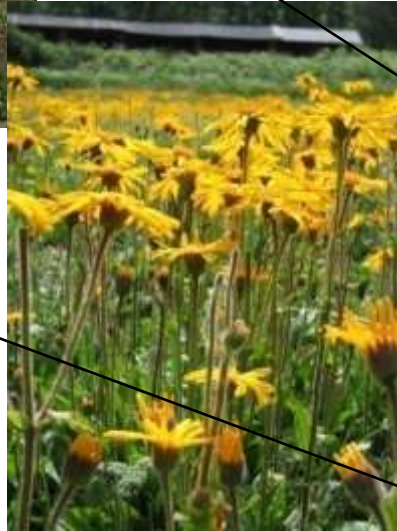
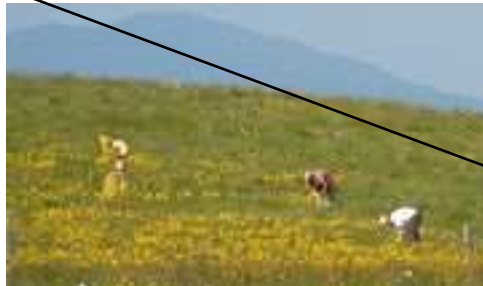
We have a common European list for feed, cosmetics or medicines.



RAW MATERIAL

Europe

EXTRACT FLOWERS *Arnica montana*





AUTHORIZATION

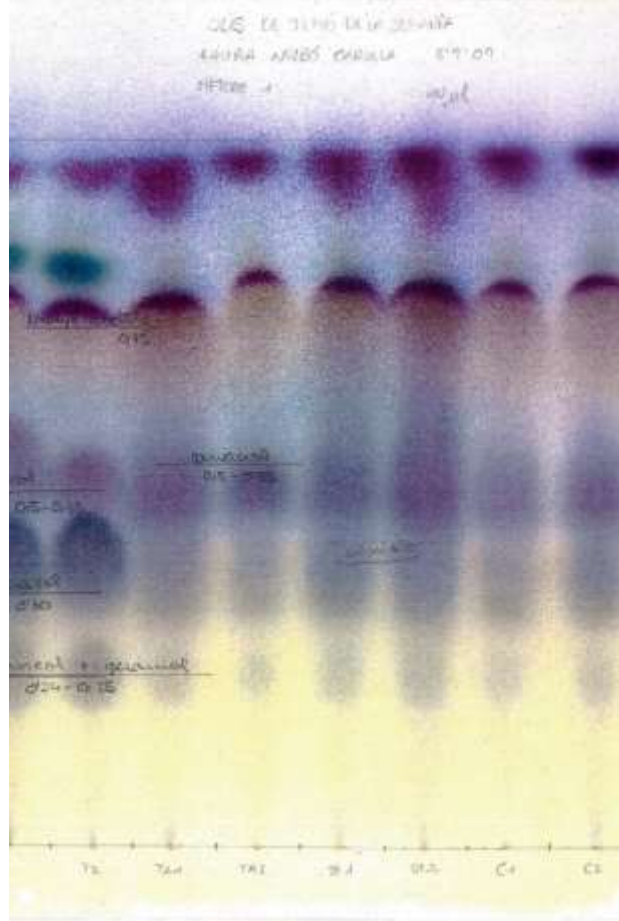
COMPANY

PRODUCTS

EUROPE

- Company.
Not needed.

- Products.
Not needed.



MEDICINAL RAW MATERIAL

Europe

London, 20 February 2006
Doc. Ref. EMEA/HMPC/246816/2005

**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

**GUIDELINE ON GOOD AGRICULTURAL AND COLLECTION PRACTICE (GACP) FOR
STARTING MATERIALS OF HERBAL ORIGIN**

ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	July 2005
END OF CONSULTATION (DEADLINE FOR COMMENTS)	30 October 2005
AGREED BY HMPC QUALITY DRAFTING GROUP	January 2006

GUIDELINE ON GOOD AGRICULTURAL AND COLLECTION PRACTICE GACP-MANDATORY

EMA

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003362.pdf

They are recommendations of compulsory compliance for raw materials for drugs.

They refer to everything that must be taken into account to collect and grow medicinal plants with quality criteria.





FOOD

Europe
No harmonization

BOTANICAL FOOD PRODUCTS

❖ Herbal food

- Tea and derivatives
- Infusions used in food
- Condiments and spices
- Refreshing drinks
- Syrups
- Liquors and wines
- Aromatic oils, vinegars, salt



❖ Herbal food and / or plant ingredients

- Food supplement
- Dietetics
- Additives in food and feed

**LEGAL: PURPOSE, DOSAGE, INGREDIENTS COMPOSITION,
AUTHORIZATION AND QUALITY REQUIREMENTS
MARKET: POINT OF SALE, LABELING, CLAIMS**

Food Supplement

**Tradicional herbal
medicine**

Thyme leaves. *Thymus vulgaris* L.

**Seasoning and spice
Infusion of use in
food**

**Additive, premix for
feed**

FOOD

Spice
(saffron)



Food supplement



AUTHORIZATION

COMPANY

PRODUCTS

EUROPE

- Company.

Mandatory. You must register the company, products and activity (manufacturing, distribution). Simultaneously start of activity.

Real Decreto 191/2011, Registro General Sanitario de Empresas Alimentarias y Alimentos.

- Products.

You don't need to do anything for most products, just comply with the standard: spices and seasonings, teas, aromatic salt...

It's mandatory to Notify food supplements and special foods. Simultaneously start of activity.

Real Decreto 1487/2009, Food supplements Capsules, tablets, ... + Mutual recognition.

Real Decreto 130/2018, relating to food supplements. List of ingredients.

PLANTS FOOD SUPPLEMENTS EUROPE

https://ec.europa.eu/food/safety/labelling_nutrition/supplements_en

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




NOVEL FOOD

Novel Food is defined as food that has not been consumed to a significant degree by humans in the EU prior to 1997, when the first Regulation on novel food came into force.

'Novel Food' can be newly developed, innovative food or food produced using new technologies and production processes as well as food traditionally eaten outside of the EU.

Commission and its priorities

Policies, information and services

English 

Search

European Commission > Food, farming, fisheries > Food > Food Safety > Novel food > Novel food catalogue > Search

EU Novel food catalogue

Novel Food ▾

Product Name

Quick Search

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z ALL

Abelmoschus esculentus

Abies alba

Abies balsamea

Abies pectinata

Acacia sp.

Acacia arabica

Acacia nilotica

Acacia rigidula

Acacia senegal

Acacia verek

Acanthopanax senticosus

Acca sellowiana

Acer saccharum

Acetyl L-carnitine

Achillea millefolium

Achras zapota

Actinidia arguta

Actinidia chinensis

Actinidia deliciosa

Artemisia annua


Common Names

EN: Sweet wormwood , NL: Zomeralsem, zoete alsem , ES: Ajenjo dulce o ajeno chino, FR: Armoise annuelle, DE: Einjähriger Beifuß

Common Names

Artemisia annua L. is a plant belonging to the Asteraceae family. All parts of this plant and their extracts are considered as novel food.

Status



What does it mean?

LABEL - REGLAMENT 1969 2011

Nombre - Marca

20 sobres de 2 g

Ingredientes:

Modo de empleo: Tomar

Peso neto: xx g

Lote : Consumir preferentemente antes de:

Conservar en un lugar fresco y seco.

Nombre de la empresa responsable – Dirección

Complemento alimenticio

Cantidad por dosis diaria

Los complementos alimenticios no deben utilizarse como sustitutos de una dieta equilibrada y variada ni de un estilo de vida sano.

No superar la dosis diaria recomendada.

Mantener fuera del alcance de los niños.

Name

Ingredients:

Instructions for use:

Net quantity: 51 g

Batch / Best before end

It should be stored in a cool, dry place and away from heat sources.

Company / Address

Food supplement

Amount recommended for daily consumption:

This product should not be used as a substitute for a varied and equilibrated diet nor a healthy lifestyle.

Do not exceed the recommended daily dose.

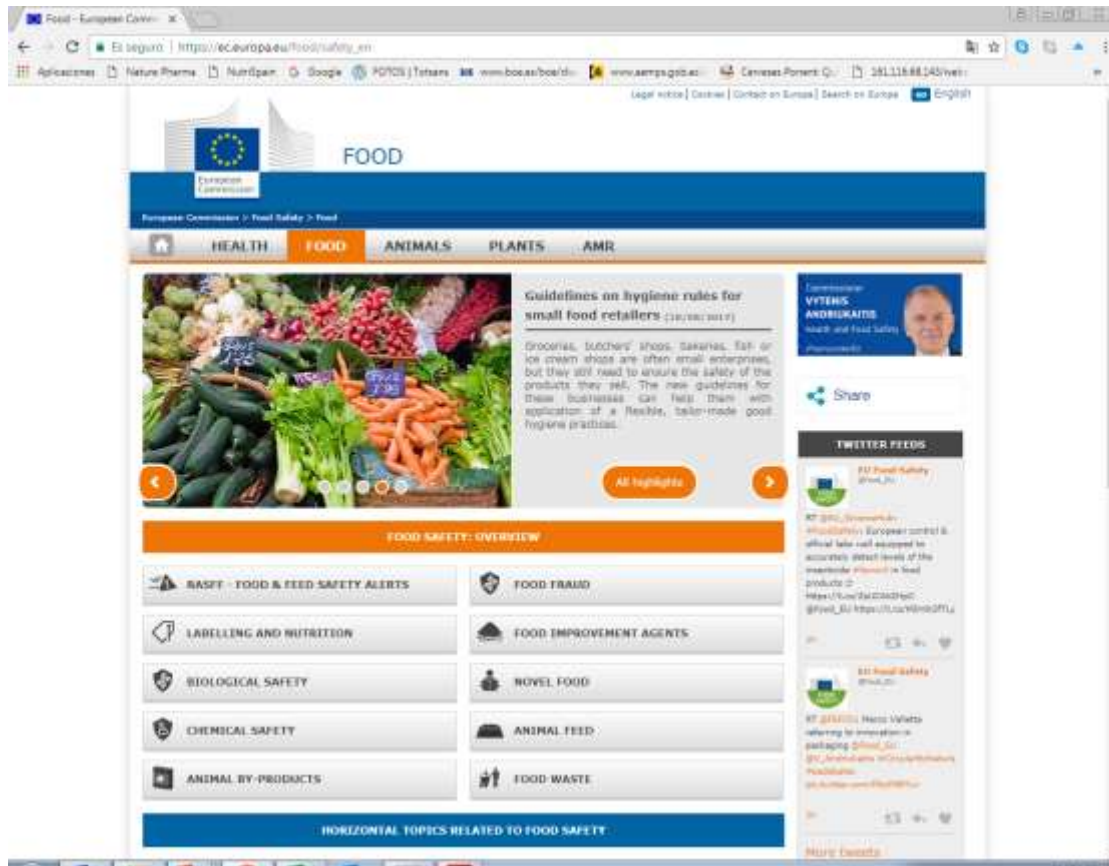
It should be stored out of the reach of young children.

The screenshot shows the EUR-Lex website interface. At the top, there's a navigation bar with links like 'Inicio', 'Diario Oficial', 'Derecho de la UE y otros documentos', 'Derecho nacional', 'Procedimientos legislativos', and 'Más'. Below this is a search bar with the text 'Búsqueda rápida: introduzca texto, un código CELEX o descripciones. Para encontrar la expresión exacta, pongala entre comillas.' and a 'BUSCAR' button. To the left, there's a sidebar with 'Enlaces directos' and 'Último DO publicado'. The main content area shows 'Buscar resultados por' with filters for 'Número de documento', 'Código CELEX', 'Año', 'Número', and 'Tipo'. Below this, there's a 'Publicación reciente' section with a list of documents, including 'Reglamento Delegado (UE) 2017/2168 de la Comisión' and 'Decisión (UE) 2017/2171 del Consejo'.

This screenshot shows the EUR-Lex website with a blue overlay on the right side. The overlay contains the EUR-Lex logo and a list of translations for the website's name in various languages. The list includes: BG (Достъп до правото на Европейския съюз), ES (El acceso al Derecho de la Unión Europea), CS (Přístup k právu Evropské unie), DA (Adgang til EU-lovgivningen), DE (Der Zugang zum EU-Recht), ET (Juurdepäas Euroopa Liidu õigusaktidele), EL (Πρόσβαση στο δίκαιο της Ευρωπαϊκής Ένωσης), EN (Access to European Union law), FR (Accès au droit de l'Union Européenne), GA (Rochtain ar dhlí an Aontais Eorpaigh), HR (Pristup zakonodavstvu Europske unije), IT (L'accesso al diritto dell'Unione europea), LV (Piekļuve Eiropas Savienības tiesību aktiem), LT (Prieiga prie Europos Sąjungos teisės), HU (Hozzáférés az európai unió joghoz), MT (Access ghal-ligi tal-Unjoni Ewropea), NL (De toegang tot het recht van de Europese Unie), PL (Dostęp do aktów prawnych Unii Europejskiej), PT (Acesso ao direito da União Europeia), RO (Accesul la dreptul Uniunii Europene), SK (Přístup k právu Európskej únie), SL (Dostop do prava EU), FI (Euroopan unionin oikeus ulottuvillasi), and SV (Ingång till EU-rätten).

LEGISLATION

<http://eur-lex.europa.eu/legal-content/en/all/?uri=celex%3a32011r1169>



SAFETY
https://ec.europa.eu/food/safety_en

General food law

Fitness check of the food chain

Food safety

Official controls and enforcement

Health and food Audits and analysis

Better training for safer food funding,

procurement & grants

Expert groups Committees

EU reference laboratories

Consultations and feedback

Food additives

Flavourings

Food Contact Materials

Health Claims

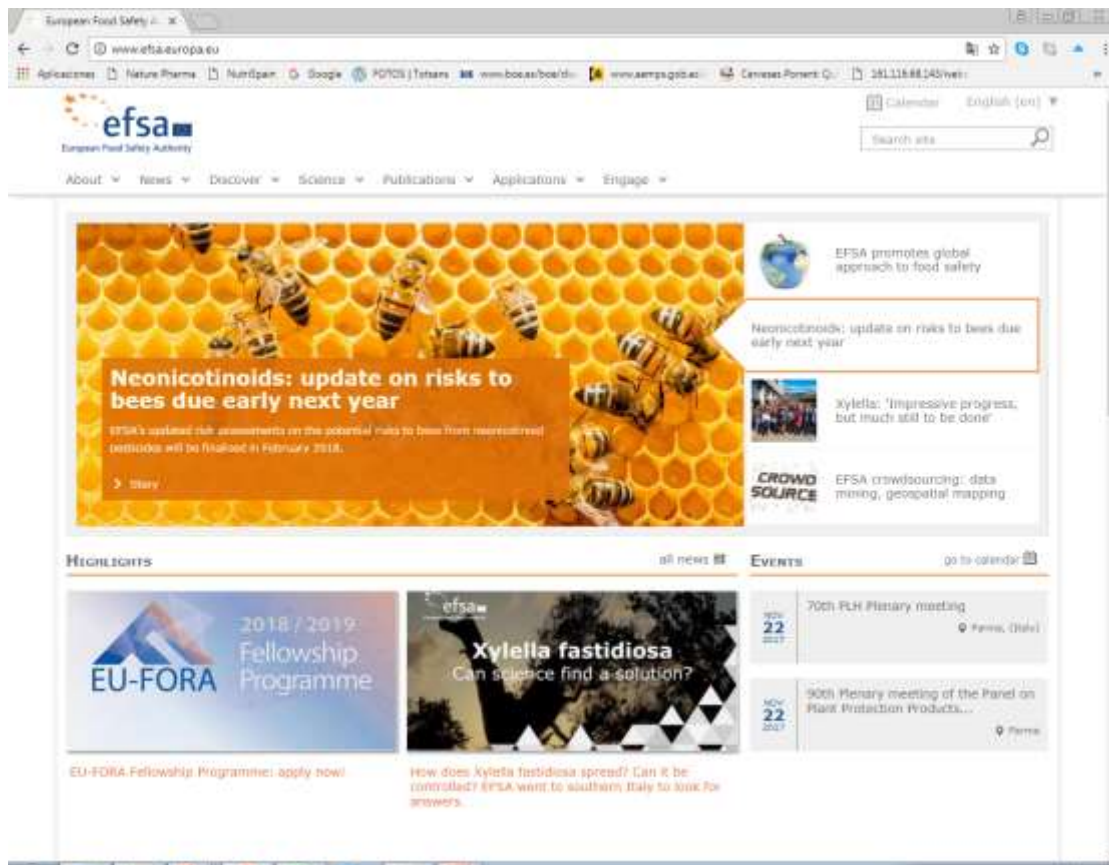
Health and food audit reports

Novel Foods

RASFF portal

GMO register

Register of national guides to good hygiene practice



EUROPEAN FOOD SAFETY
AUTHORITY
<http://www.efsa.europa.eu/>

[Animal feed](#)
[Animal health and welfare](#)
[Biological hazards](#)
[Chemical contaminants](#)
[Corporate](#)
[Cross-cutting science](#)
[Data](#)
[Food ingredients and packaging](#)
[GMO](#)
[Methodology](#)
[Nutrition](#)
[Pesticides](#)
[Plant health](#)
[Stakeholders](#)

SCIENTIFIC PUBLICATIONS

[Acrylamide](#)
[Antimicrobial Resistance](#)
[Bee health](#)
[Chemicals in food](#)
[GMO](#)
[Pesticides](#)
[Xylella](#)

Register of national guides to good hygiene practice Registre des guides nationaux de bonnes pratiques hygieniques Register für einzelstaatliche Leitlinien für die gute Hygiene Praxis

Welcome

[REGULATION \(EC\) No 853/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL](#) on the hygiene of foodstuffs of 29 April 2004, Chapter 1, Article 1 paragraph 1. states that "the guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles;" and Chapter III, Article 8 paragraph 4. requires that, "Member States shall forward to the Commission national guides complying with the requirements of paragraph 3. The Commission shall set up and run a registration system for such guides and make it available to Member States."

More information at: [Food Hygiene Legislation](#)

[REGULATION \(EC\) No 1831/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL](#) of 22 October 2003 laying down requirements for feed hygiene, Recital 6 states that "guides to good practice are a valuable instrument to help feed business operators at all levels of the feed chain comply with feed hygiene rules and with the application of HACCP principles;" Article 5(4) establish that "feed business operators may use the guides provided for in Chapter III to help them comply with their obligations under this Regulation" and Chapter III, Article 21(3) and (4) requires that "Member States shall transmit national guides to the Commission" and "the Commission shall set up and run a registration system for such guides and make it available to the Member States."

More information: [Animal Feed](#)

[Update the Register \(restricted\)](#)

Consult/Search the Register

Filter on country:

All countries ▼

Filter on issue:

All ▼

Filter on focus:

All ▼

Filter on year/edition:

All ▼

Guide Type:

All ▼

Filter on stage:

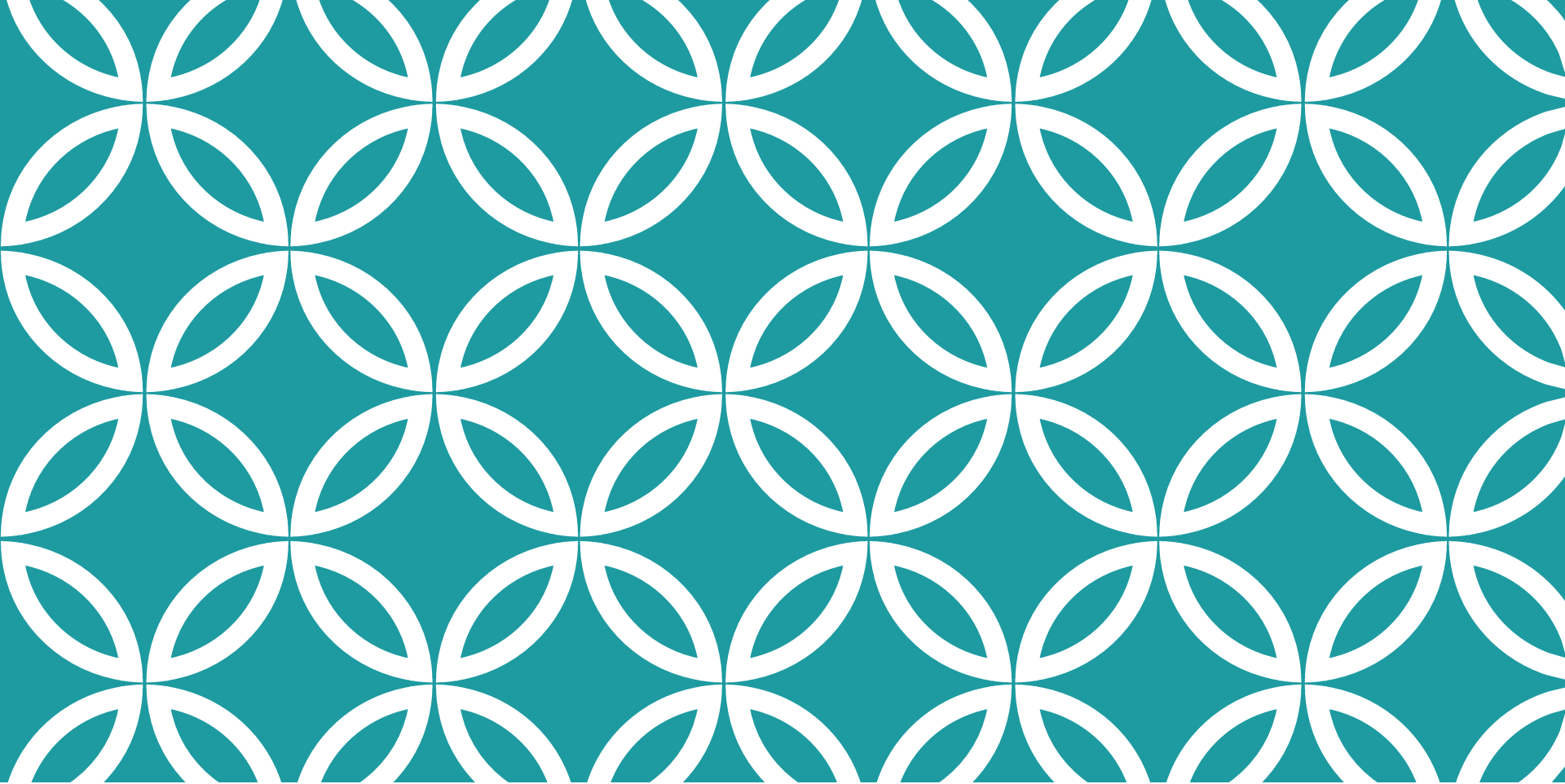
All ▼

Filter on product:

All ▼

Quality assurance systems. Food. HACCP

<https://webgate.ec.europa.eu/dyna/hygienelegislation/>



ANIMAL FEED

Europa

ANIMAL FEED

- Types: (the differentiation is not obvious)
 - raw Materials
 - compound feed including pet food
 - medicated feed
 - feed additives
 - techno-logical
 - organoleptic
 - nutritional
 - zootechnical
 - coccidiostatic and histomonostatic



[HTTPS://EC.EUROPA.EU/FOOD/SAFETY/ANIMAL-
FEED_EN](https://ec.europa.eu/food/safety/animal-feed_en)

Feed Hygiene
Feed Marketing
Feed Additives
Medicated Feed
Undesirable
Substances
Genetically Modified
Feed

Official Controls



https://ec.europa.eu/food/safety/animal-feed/feed-marketing/catalogue_en

FEED MATERIALS

European Union

Register of Feed Additives

pursuant to Regulation (EC) No 1831/2003

Annex I: List of additives

Health and
Food Safety

The information contained in this publication does not necessarily reflect the opinion or the position of the European Commission.

Neither the European Commission nor any person acting on its behalf is responsible for any use that might be made of the

REGISTER FEED ADDITIVES, 2020

http://ec.europa.eu/food/food/animalnutrition/feedadditives/comm_register_feed_additives_1831-03.pdf

FEEDMATERIALSREGISTER.EU

[Home](#) | [Presentation](#) | [Register](#) | [Notification Form](#) | [Search](#) | [Member area](#)

www.feedmaterialsregister.eu - © 2010
powered by [navalaroma](#)

FEED MATERIALS REGISTER

<http://www.feedmaterialsregister.eu/>

Biological hazard

Feed additives

Regulations and guidance

FAQ

Food contact materials

Food ingredients

GMO

Nutrition

Pesticides

About Applications
helpdesk

Feed additive applications: regulations and guidance

EU legislation and EFSA guidance documents detail how to compile dossiers for submission and the information and studies required for the evaluation. EFSA's guidance is updated regularly so applicants should check they are using the latest version before applying.

Regulatory framework(+)

Administrative guidance(+)

Scientific guidance(+)

Other guidance(+)

Additional resources(+)

See also

- [Authorisation: European Commission's Directorate-General for Health and Food Safety](#)
- [Samples and analytical methods: European Union Reference Laboratory](#)

Application toolbox



Track your application



Event calendar



Ask a question

EFSA FEED ADDITIVES

<http://www.efsa.europa.eu/en/applications/feedadditives/regulationsandguidance>



COSMETICS

Europe
Harmonization



AUTHORIZATION

COMPANY

PRODUCTS

EUROPE

- Company.

Mandatory. You must register the company, products and activity (manufacturing, distribution). Simultaneously start of activity.

- Products.

It's mandatory to Notify cosmetics to CPNP.

Commission and its priorities Policies, information and services

European Commission English EN Search

European Commission > Internal Market, Industry, Entrepreneurship and SMEs > Sectors > Cosmetics > CosIng > Search > Simple search

Internal Market, Industry, Entrepreneurship and SMEs

Single Market and Standards Industry Entrepreneurship and SMEs Access to finance for SMEs Sectors

CosIng

Search

Simple search Advanced search

Reference data

Regulations

Annexes

Functions

Abbreviations

User Manual

Cosmetics - links

News

Events

Contracts and grants

Public consultations

Publications

Search Results

NAME OF CAS/EC # Scope Version EC Regulation Status

artemisia annua All Active

Go

#	INCI Name/Substance Name	CAS No.	EC No.	Total 13 Restriction/ Annex/Ref #
1	ARTEMISIA ANNUA / LEAF STEM FOLIUS CARICA FRUIT GINSENG BUDRA LEAF EXTRACT			
2	ARTEMISIA ANNUA CALLUS EXTRACT			
3	ARTEMISIA ANNUA EXTRACT	84775-74-6	263-903-4	
4	ARTEMISIA ANNUA / HERB OIL	84775-74-6	263-903-4	
5	ARTEMISIA ANNUA LEAF EXTRACT	84775-74-6	263-903-4	
6	ARTEMISIA ANNUA LEAF STEM EXTRACT			

European harmonized standard, Reglamente 1223/2009.

Laboratory authorization in address country.

European product notification (CPNP).

COSING.

https://ec.europa.eu/growth/sectors/cosmetics/cosing_en

COSMETICS

http://ec.europa.eu/growth/sectors/cosmetics_en



HERBAL MEDICINES

Europe


MTP
WEU

PRODUCTION AND MANUFACTURING



Traceability





EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH

Search

Medicines ▾Human regulatory ▾Veterinary regulatory ▾Committees ▾News & events ▾Partners & networks ▾About us ▾

Human regulatory

OverviewResearch and developmentMarketing authorisationPost-authorisationHerbal products

EU monographs and list entriesRegulatory and scientific supportScientific guidelinesQ&A: Herbal medicinesProcedures

Herbal medicinal products

The Committee on Herbal Medicinal Products (HMPC) issues scientific opinions on herbal substances and preparations, along with information on recommended uses and safe conditions, on behalf of the European Medicines Agency (EMA). This gives companies and national competent authorities a clear reference point when preparing or assessing an application for marketing authorisation or registration of herbal medicinal products in European Union (EU) Member States.

In this section

Bringing herbal medicinal products to market within the EU	Establishing EU standards for national procedures
<ul style="list-style-type: none">Scientific guidelinesRegulatory and scientific support<ul style="list-style-type: none">Questions and answers	<ul style="list-style-type: none">EU monographs and list entries<ul style="list-style-type: none">Procedures for monograph and list establishment (including calls for scientific data and public consultations)

Bringing herbal medicinal products to market within the EU

Companies seeking to bring herbal medicinal products to the market in EU Member States should follow the

<https://www.ema.europa.eu/en/human-regulatory/herbal-medicinal-products>

EMEA

EU monographs and list entries

Regulatory and scientific support

Scientific guidelines

Q&A: Herbal medicines

Procedures

European Union monographs and list entries

Share

The **Committee on Herbal Medicinal Products (HMPC)** compiles and assesses scientific data on herbal substances, preparations and combinations with a focus on safety and efficacy.

This work supports the harmonisation of the European market: national competent authorities are able to refer to one unique set of information on a herbal substance or preparation when evaluating marketing applications.

European Union monographs

A European Union (EU) herbal monograph (formerly known as Community herbal monograph) contains the HMPC's scientific opinion on safety and efficacy data about a herbal substance and its preparations intended for medicinal use. The HMPC evaluates all available information, including non-clinical and clinical data, but also documented long-standing use and experience in the EU.

EU monographs provide all information necessary for the use of a medicinal product containing a specific herbal substance or preparation:

- what the herbal product is used for;
- who the herbal product is intended for;
- safety information such as information regarding undesirable effects and interactions with other medicines.

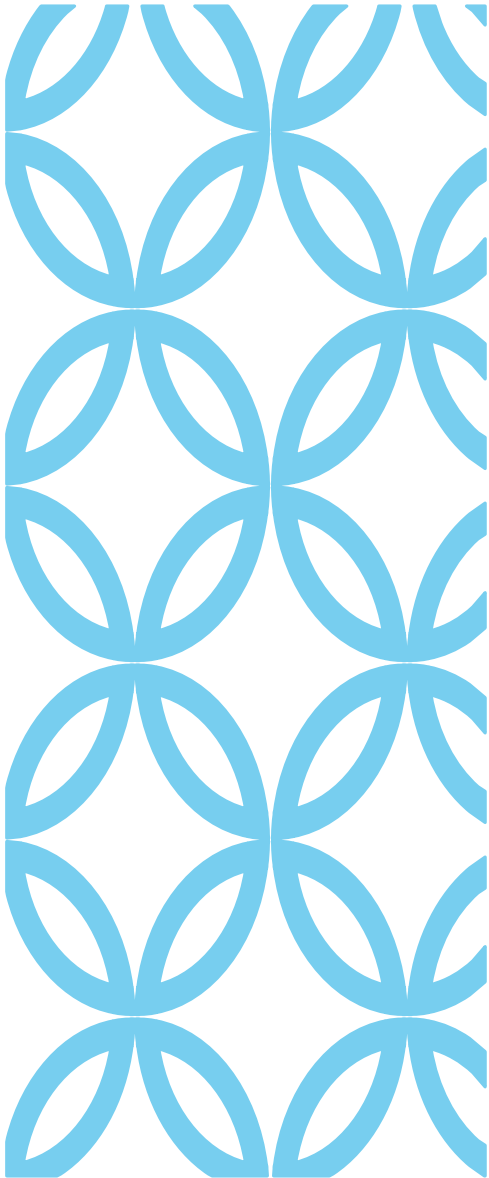
Monographs form the basis for the required individual medicinal product information such as the summary of product characteristics (SmPC) and the package leaflet. They are published together with other documents, including an assessment report containing reviews of all available data relevant for the medicinal use of the herbal substance or preparations.

EU monographs are divided into two sections:

Well-established use (marketing authorisation)	Traditional use (simplified registration)
Demonstrated with sufficient safety and efficacy data	Accepted on the basis of sufficient safety data and plausible efficacy

Others:
ESCOP. *European Scientific Cooperative on Phytotherapy*
WHO (1999, 2002, 2007 i 2009)
PHARMACOPOEIA

EMEA MONOGRAPHS OF MEDICINAL PLANTS



- To know what product I want, or I have. Is it a food or a food supplement?
- Is my plant in a food positive list in Europe?
- Where and how I can sell it.
- How to comply with legal requirements.

TO TAKE HOME

MOLTES GRÀCIES PER L'ATENCIÓ

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