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

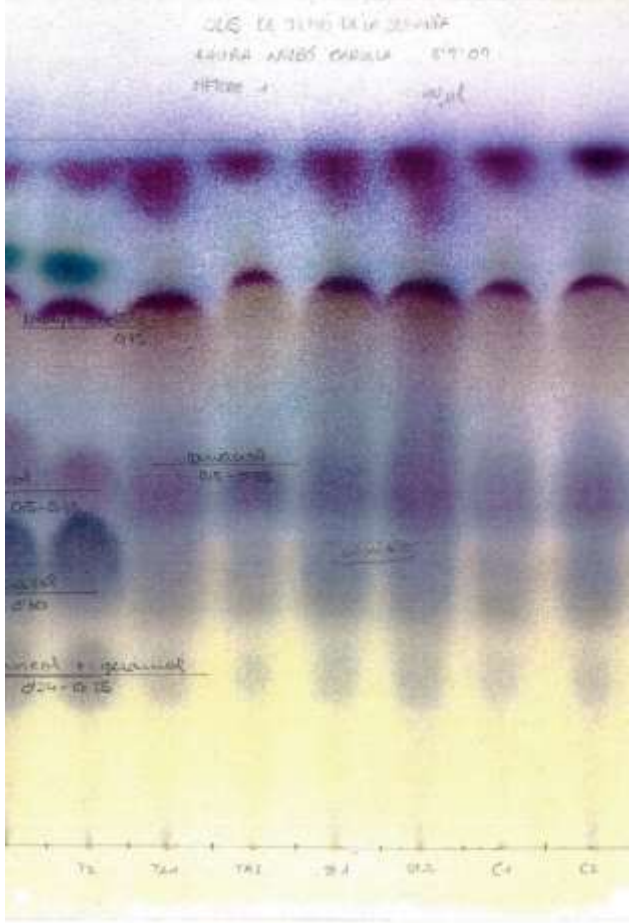
EUROPE

- Company.

Not needed.

- Products.

Not needed.



MEDICINAL RAW MATERIAL

Europe

European Medicines Agency
Evaluation of Medicines for Human Use

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

EMEA

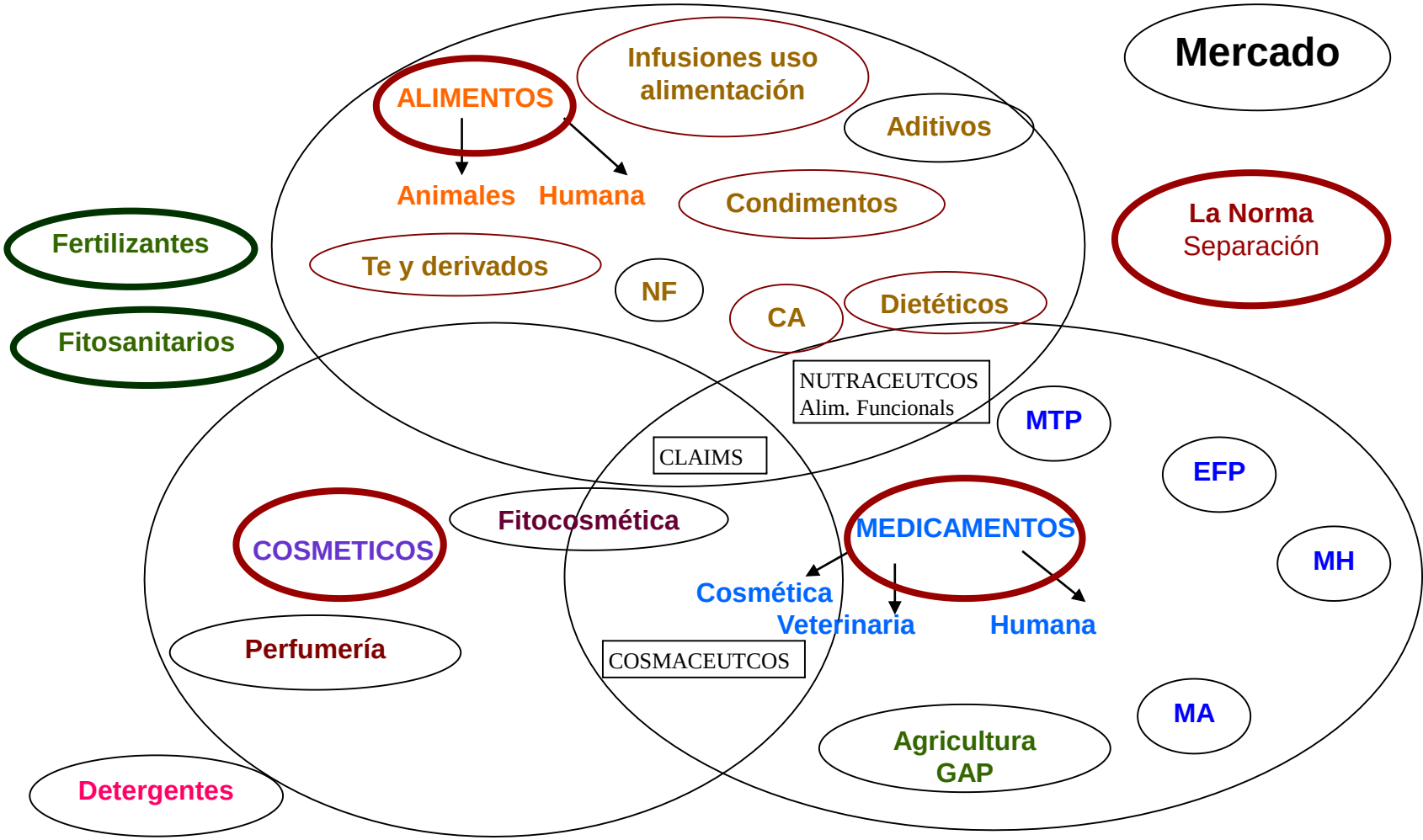
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003362.pdf

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.

Products based on botanicals

Market ≠ Standards



http://blog.fitomon.com/

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

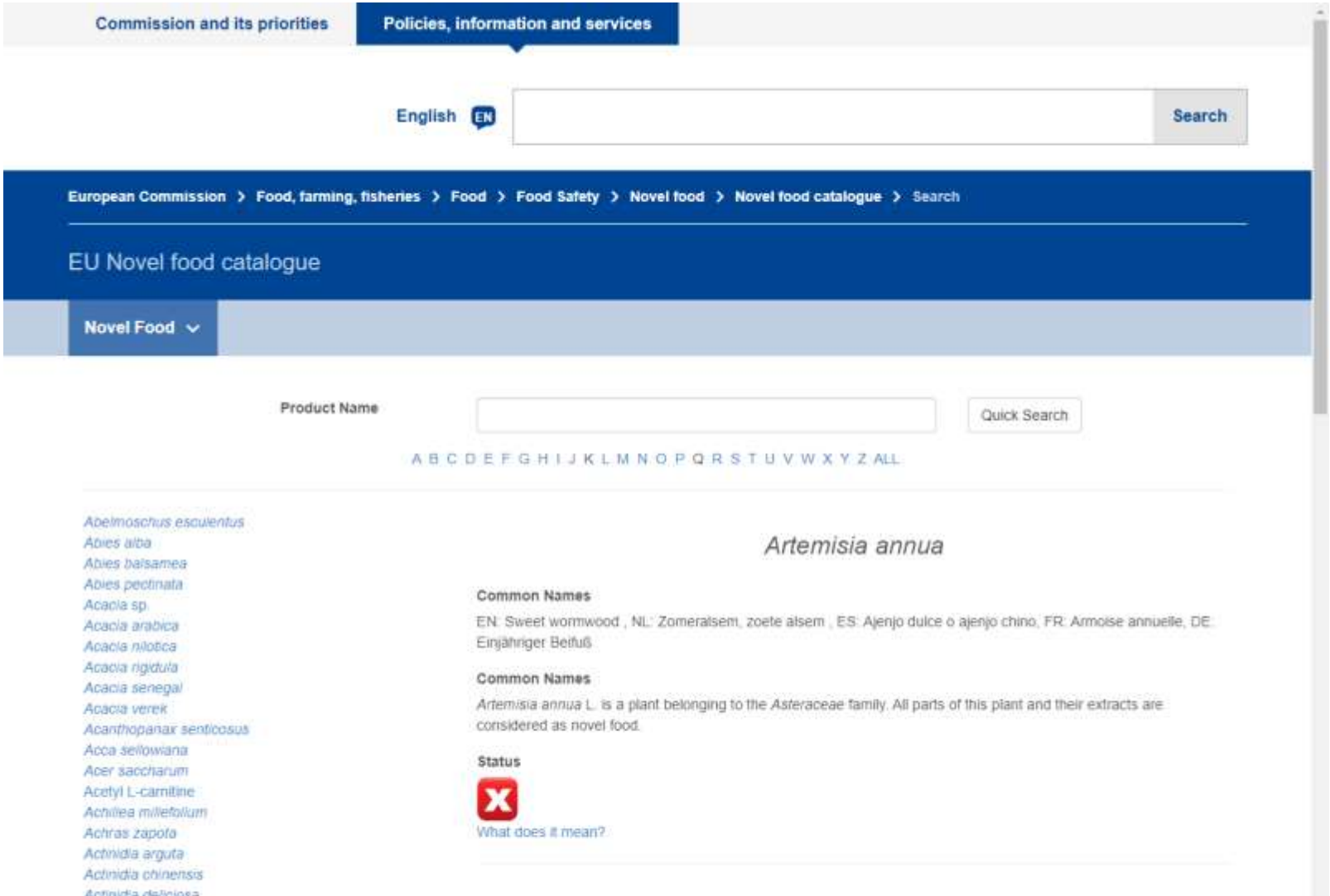
https://ec.europa.eu/food/safety/labelling_nutrition/supplements_en

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.



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

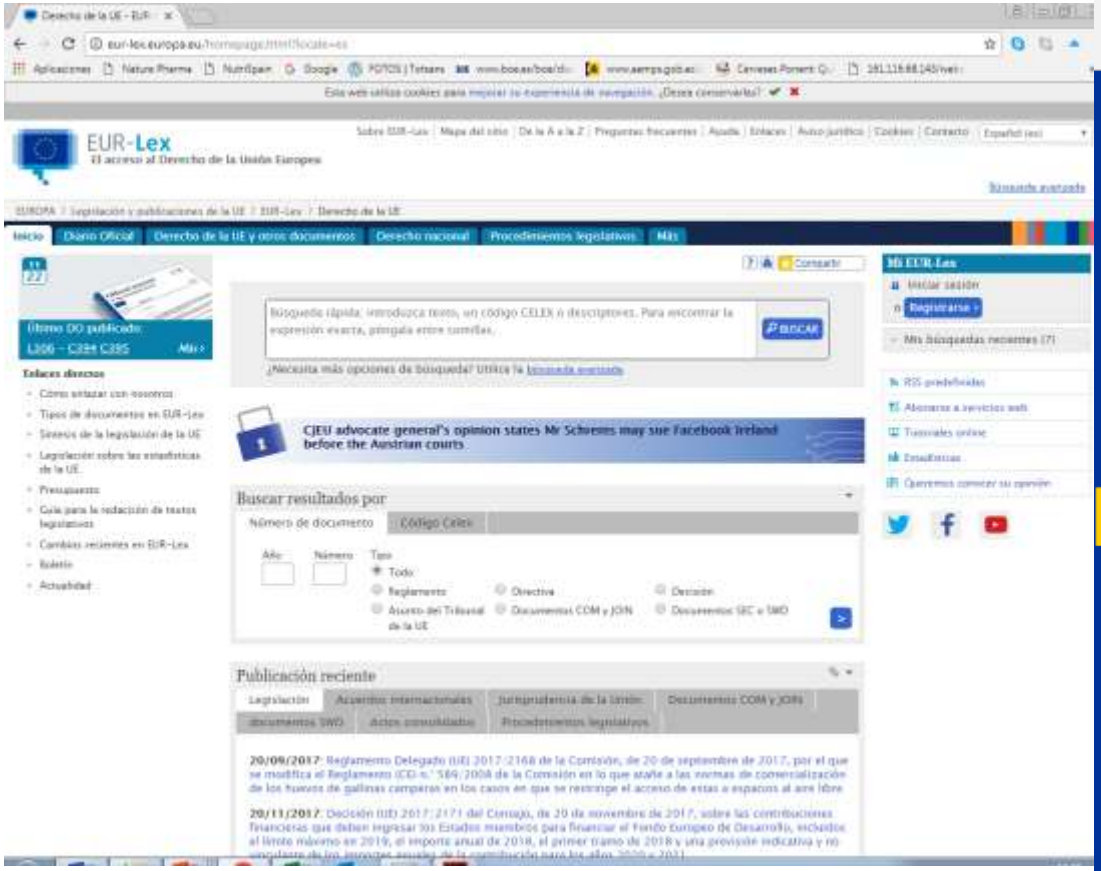
Food supplement

Amount recommended for daily consumption:

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

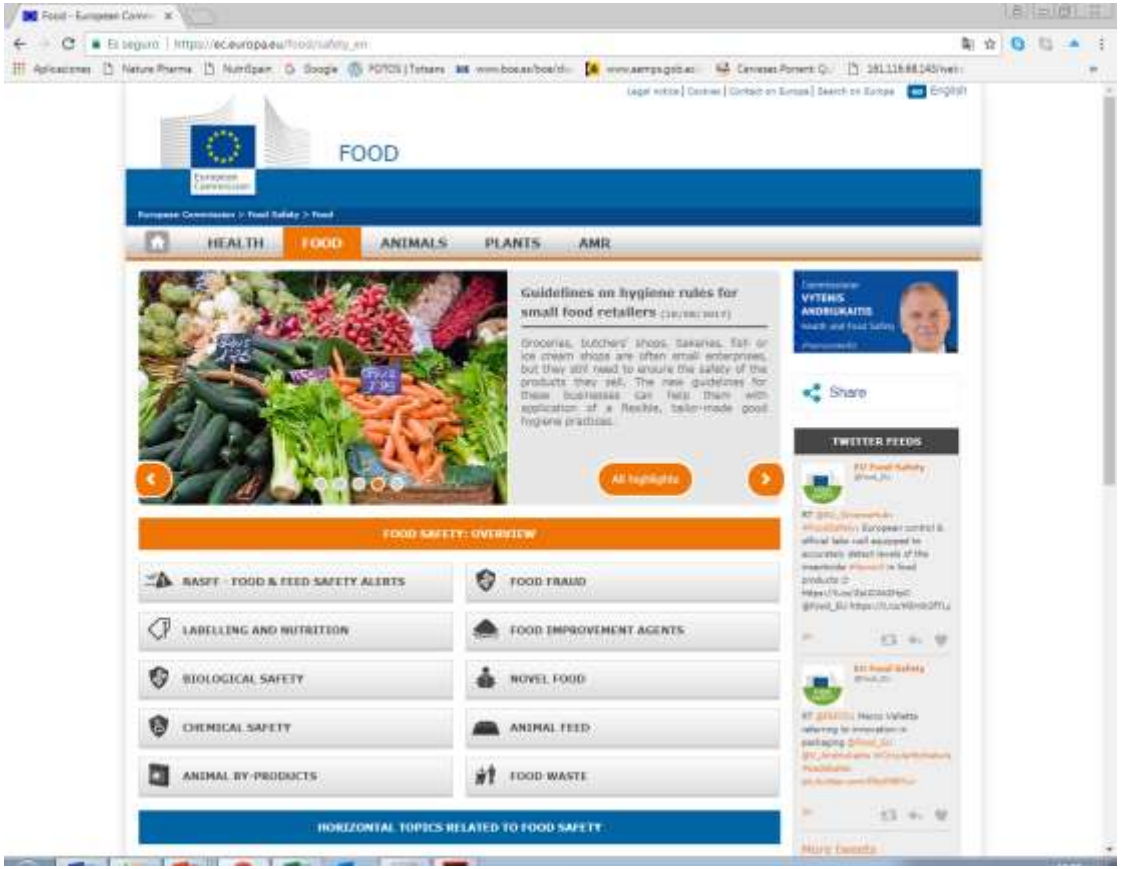
Do not exceed the recommended daily dose.

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



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

CIENTIFIC PUBLICATIONS

Acrylamide

Antimicrobial Resistance

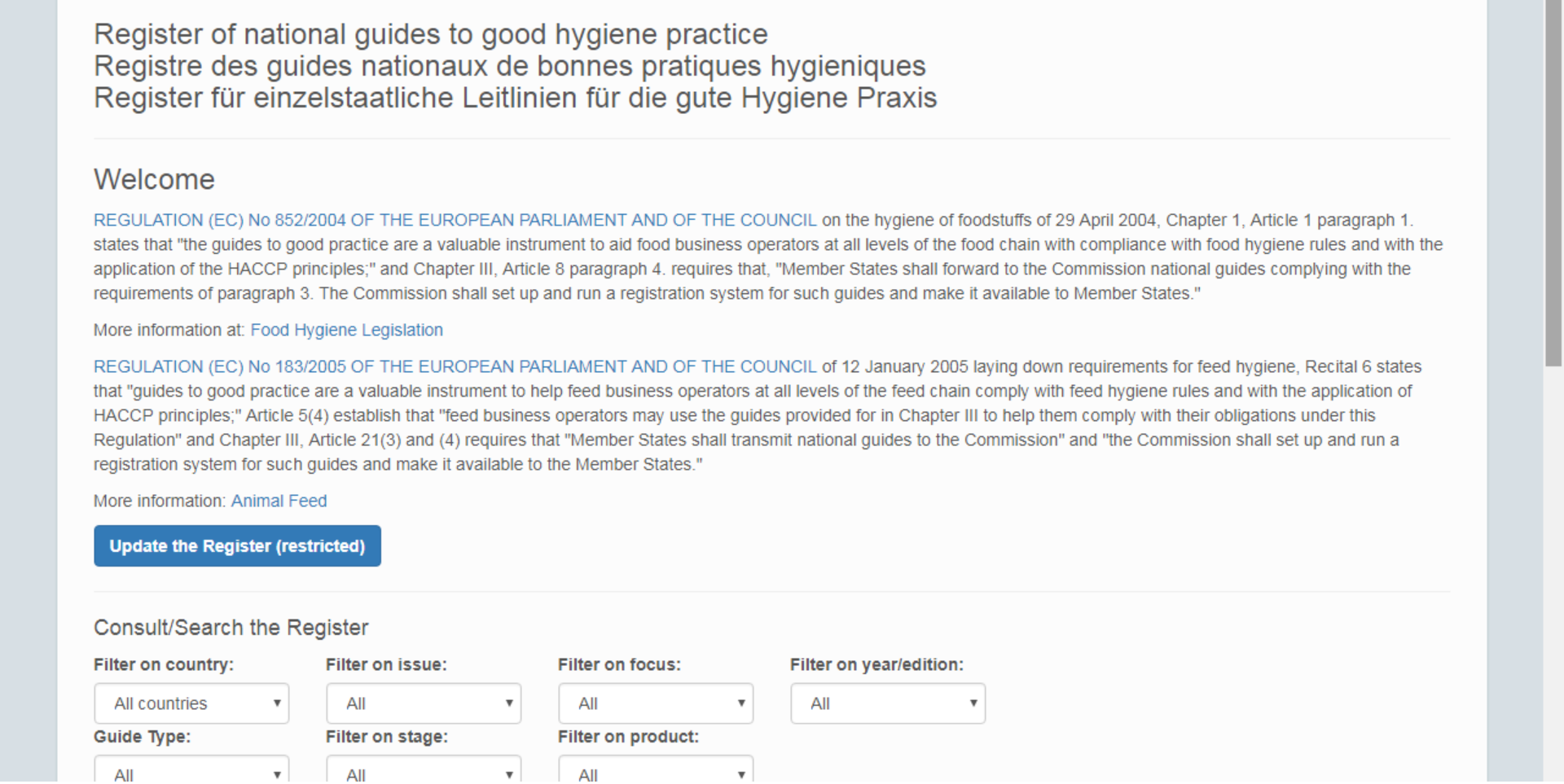
Bee health

Chemicals in food

GMO

Pesticides

Xylella



Quality assurance systems. Food. HAPPC

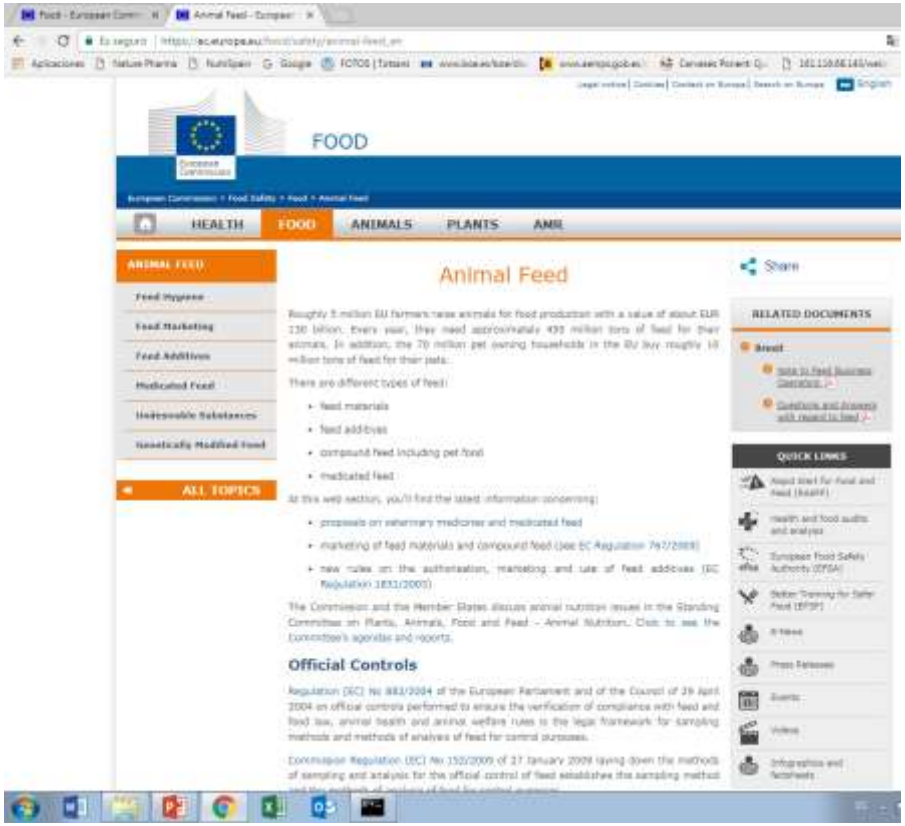
https://webgate.ec.europa.eu/dyna/hygienelegislation/

ANIMAL FEED

Europa

ANIMAL FEED

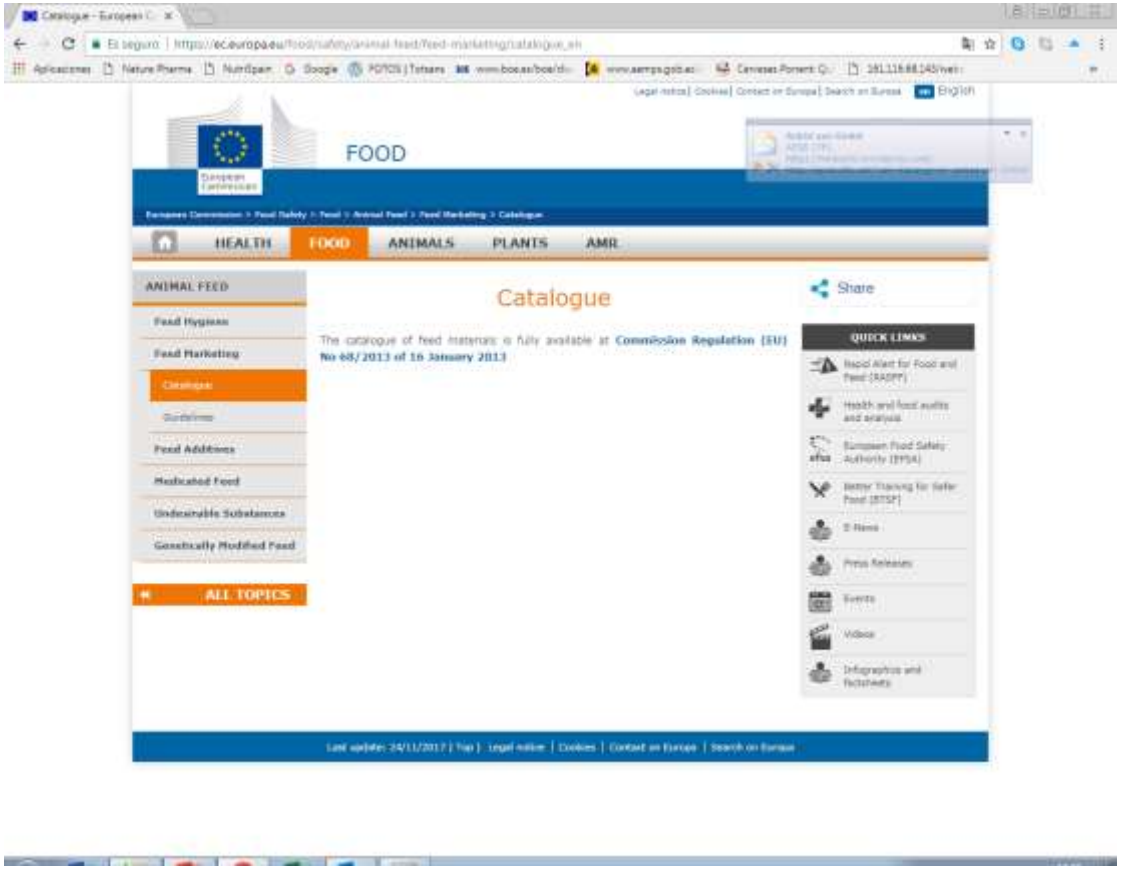
- Types: (the differentiation is not obvious)
  - raw Materials
  - compound feed including pet food
  - medicated feed
  - feed additives
    - techno-logical
    - organoleptic
    - nutritional
    - zootechnical
    - coccidiostatic and histomonostatic



HTTPS://EC.EUROPA.EU/FOOD/SAFETY/ANIMAL-FEED_EN

[Feed Hygiene](#)
[Feed Marketing](#)
[Feed Additives](#)
[Medicated Feed](#)
[Undesirable Substances](#)
[Genetically Modified Feed](#)

Official Controls



FEED MATERIALS

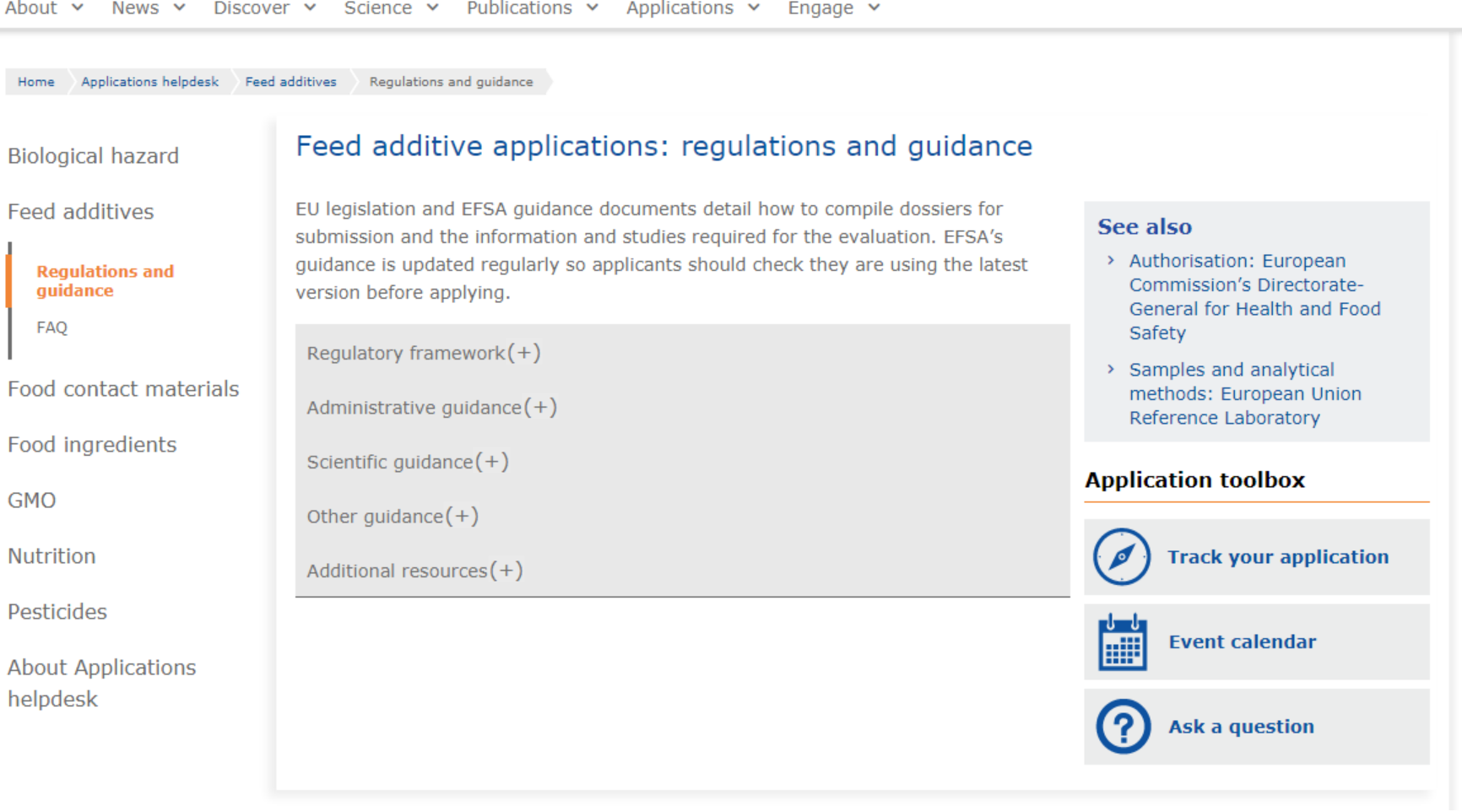
https://ec.europa.eu/food/safety/animal-feed/feed-marketing/catalogue_en

REGISTER FEED ADDITIVES, 2020

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

FEED MATERIALS REGISTER

http://www.feedmaterialsregister.eu/



EFSA FEED ADDITIVES

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

COSMETICS

Europe
Harmonization

AUTHORIZATION

COMPANY

PRODUCTS

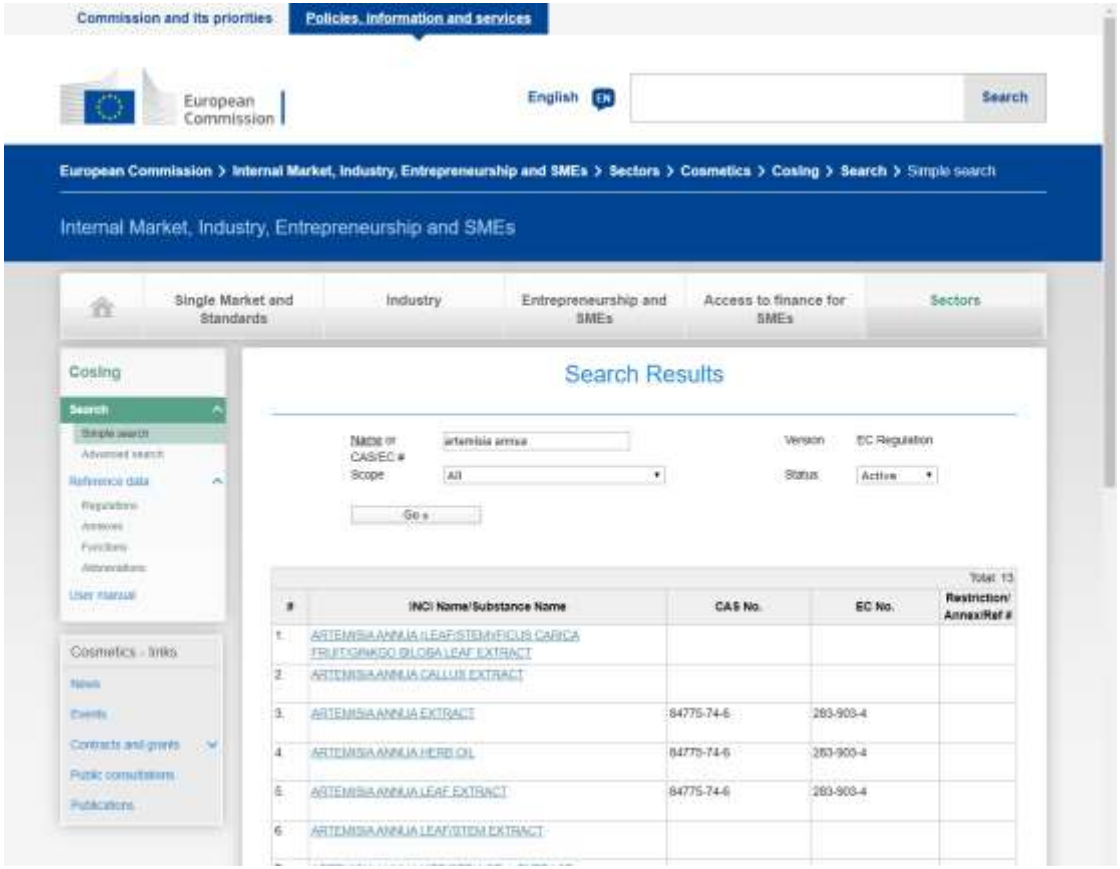
EUROPE

- 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.



COSMETICS

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

European harmonized standard, Reglament 1223/2009.

Laboratory authorization in address country.

European product notification (CPNP).

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

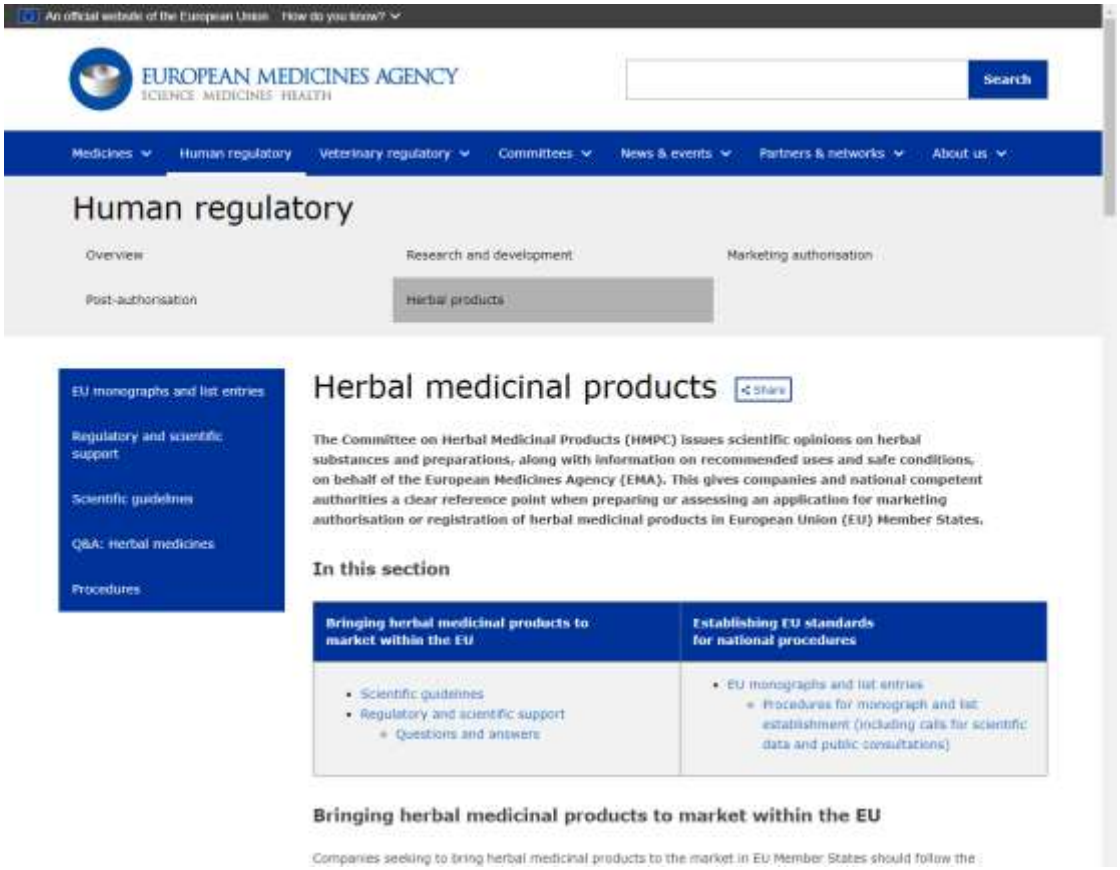
HERBAL MEDICINES

Europe

MTP
WEU

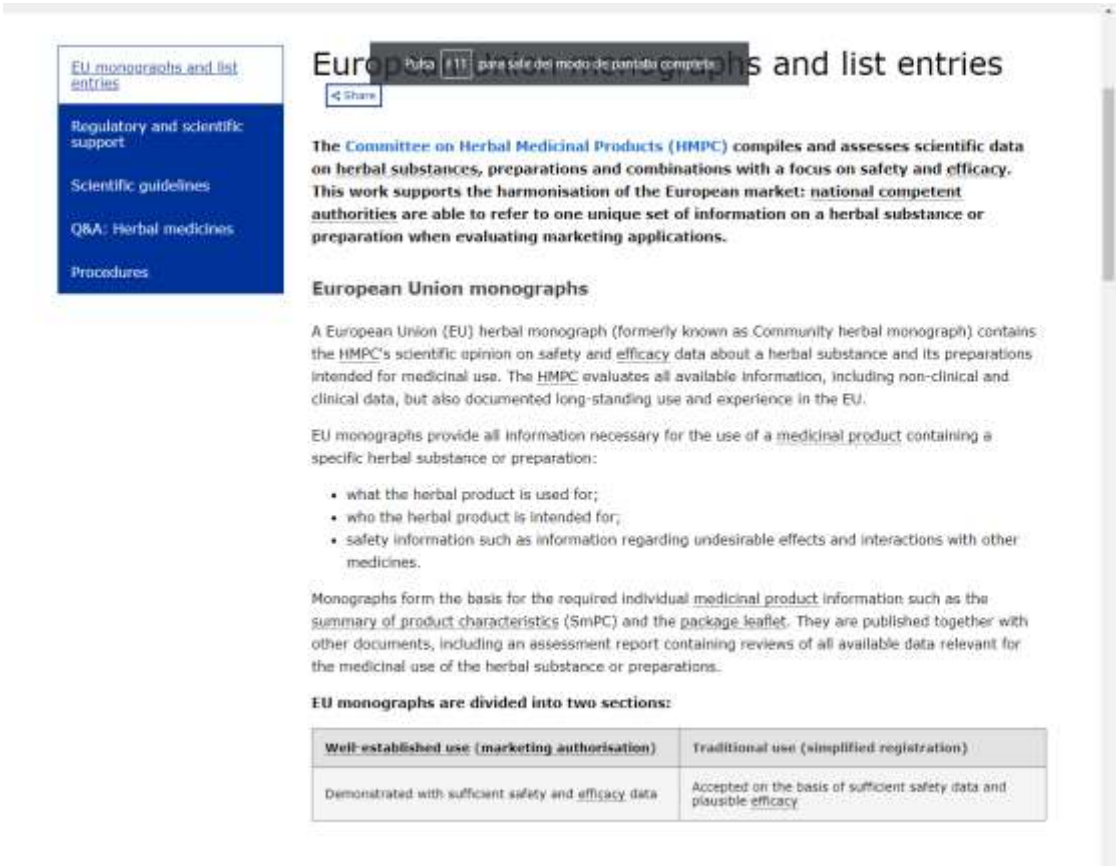
PRODUCTION AND MANUFACTURING

Traceability



EMEA

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



EMEA MONOGRAPHS OF MEDICINAL PLANTS

Others:

ESCOP. *European Scientific Cooperative on Phytotherapy*

WHO (1999, 2002, 2007 i 2009)

PHARMACOPOEIA

TO TAKE HOME

- 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.

MOLTES GRÀCIES PER L'ATENCIÓ

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