Euro News – Latest Restrictions & New Opportunities for Food Supplements

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Last restrictions & new opportunities for food supplements

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Nutrition & Health Products

Regulatory Strategy

Scientific & Toxicological Expertise

International Expertise

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The primary industries covered are: borderline products, nutrition products, medical devices, herbal medicines, pharmaceuticals, medical foods, cosmetics and more.

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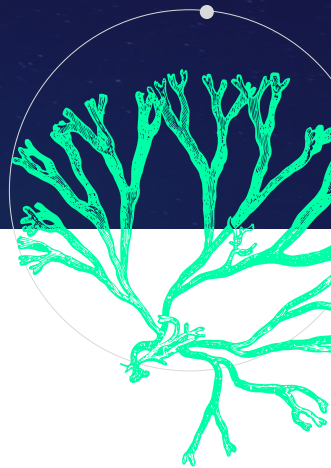
- Regulatory Context for food supplements in EU
- Last restrictions and opportunities for ingredients
- Quality / Safety/ Efficacy in EU + UK : Last updates

Regulatory context



Food supplements are regulated at an EU and national level

DIRECTIVE 2002/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 10 June 2002

on the approximation of the laws of the Member States relating to food supplements

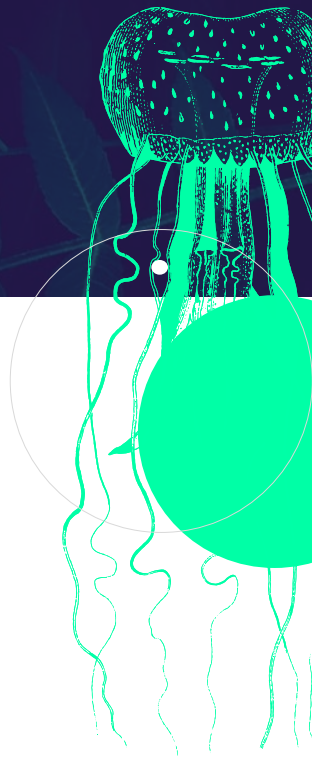
What is harmonized at an EU level

- Definition
- Specific rules for labelling, general warnings
- Positive lists for vitamins and minerals and authorized forms

What is regulated at a national level

- Botanicals and other substances lists,
- Maximum daily doses for vitamins and minerals,
- Marketing procedures
- Specific restrictions and warnings on ingredients

Food supplements are defined in article 2 of Directive 2002/46/EC



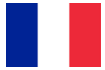
'food supplements' means foodstuffs the purpose of which is to supplement the normal diet, and which are:

1. Concentrated sources of nutrients (vitamins/minerals)
2. Active ingredients
3. Nutritional or physiological effect
4. Dosage form

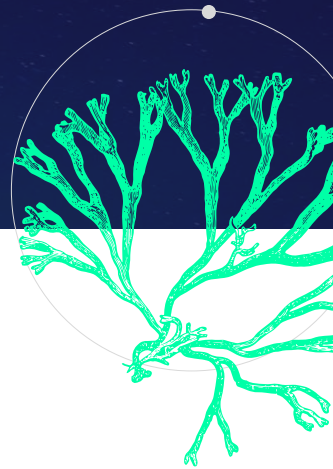
Marketing procedure differs between EU countries

- Some member states require Food Supplement products to be notified prior marketing in that country
- **Mutual Procedure:** mutual recognition procedure might be possible in some cases - it's a marketing authorization granted in one Member State that can be recognized in other EU countries

Examples for different member states :

	Country	Procedure	Cost	Timeline
	France	Notification Online	Free	2 months
	Italy	Notification Online	160,20 €	3 months
	Belgium	Notification Online	180 €	1 month
	Germany	Notification Online	Free	None
	Netherlands	No Marketing authorization mandatory for food supplement		

Last opportunities and restrictions : ingredients



Nutrients

- Annex I and II of Directive 2002/46/EC
- Addition of new forms
- Maximum limits not harmonized

New: Regulation (EU) 2021/418 of 9 March 2021 amending Directive 2002/46/EC as regards **nicotinamide riboside chloride** and **magnesium citrate malate** used in the manufacture of food supplements and as regards the **units of measurement used for copper**

No Harmonization of maximum level: creation of a working group at European level with representatives of Member States (on upper limits)

- Maximum levels have been increased in several Member States
- New maximum limits for children in some Member States (Denmark, France…)

Opportunities for botanicals / Substances

Botanicals / Substances

No exhaustive list of plants/Substances in the EU

- Case-by-case assessment by MS

Harmonized lists:

- Novel Food Catalog and Union list of Novel Food ingredients

- Novel Food regulations and national regulations
- Partial harmonization for botanicals: FR / IT / BE: joint work with Belfrit list
  Other lists: German / Croatian / Maltese list…
- Main positive list for substances in Italy
- Mutual recognition principles

Drug status: national lists of medicinal plants, European Union herbal monograph or other monographs

Regulation 1925/2006 – impact of the new restrictions under art. 8?

Procedure of Article 8 of Regulation 1925/2006: SUBSTANCES WHOSE USE IN FOODS IS PROHIBITED, RESTRICTED OR UNDER COMMUNITY SCRUTINY

The European Commission, on its own initiative or based on information provided by Member States or following an assessment by EFSA, may take the decision to include a given substance in a list of substances whose use in food is prohibited, restricted or subject to control.

How?

When the addition of a substance to foods would result in the ingestion of amounts of this substance **greatly exceeding those reasonably expected to be ingested under normal conditions of consumption** and/or would otherwise **represent a potential risk to consumers.**

Regulation 1925/2006 – impact of the new restrictions under art. 8?

Article 8 regulation 1925/2006

Regulation 1925/2006

EC can request a safety assessment from EFSA for a substance under the procedure of article 8

EFSA/EC

Scientific assessment by EFSA

EC decision to classify the substance in the Annex III of Regulation 1925/2006: **prohibited substances (Part A), substances subject to restrictions (part B), substances under community control (Part C)**

Context

More and more requests for evaluation of substances or ingredients containing a substance through this process

At the initiative of Member States

Major impact for food supplements

3 substances already included in Annex III several years ago: ephedra herb, Yohimbe bark, trans fatty acid

ANNEX III

SUBSTANCES WHOSE USE IN FOODS IS PROHIBITED, RESTRICTED OR UNDER COMMUNITY SCRUTINY

Part A — Prohibited substances

Ephedra herb and its preparations originating from *Ephedra* species

Yohimbe bark and its preparations originating from Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille)

PART B

Restricted substances

Restricted substance	Conditions of use	Additional requirements
Trans fat other than trans fat naturally occurring in fat of animal origin	*Maximum 2 grams per 100 grams of fat* in food intended for the final consumer and food intended for supply to retail	Food business operators supplying other food business operators with food not intended for the final consumer or not intended for supply to retail, shall ensure that supplied food business operators are provided with information on the amount of trans fat, other than trans fat naturally occurring in fat of animal origin, where that amount exceeds 2 grams per 100 grams of fat.

Part C — Substances under Community scrutiny

Current situation

EFSA scientific assessments

- Hydroxyanthracene derivatives,
- Green tea catechins,
- monacolins in red yeast rice

In progress :

- Alpha lipoic acid (2021)

European Commission

Text published in March 2021

- Hydroxyanthracene derivatives

Draft regulation in progress :

- Green tea catechins,
- monacolins in red yeast rice

Discussion at MS level

Procedure according to article 8 of reg 1925/2006 not yet requested by EC :

- Fennel and estragole
- Garcinia Cambodgia

Hydroxyanthracene derivatives

- REGULATION (EU) 2021/468 of 18 March 2021 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards botanical species containing hydroxyanthracene derivative - **Applicable in April 2021.**
- Part A: prohibited substances
  - ‘aloe-emodin and all preparations in which this substance is present’;
  - ‘emodin and all preparations in which this substance is present’;
  - ‘preparations from the leaf of Aloe species containing hydroxyanthracene derivatives’;
  - ‘danthron and all preparations in which this substance is present’.
- Part C: under community control
  - ‘preparations from the root or rhizome of Rheum palmatum L., Rheum officinale Baillon and their hybrids containing hydroxyanthracene derivatives’;
  - ‘preparations from the leaf or fruit of Cassia senna L. containing hydroxyanthracene derivatives’;
  - ‘preparations from the bark of Rhamnus frangula L., Rhamnus purshiana DC. containing hydroxyanthracene derivatives’.

Possible new restrictions or bans on additives used as food supplement excipients?

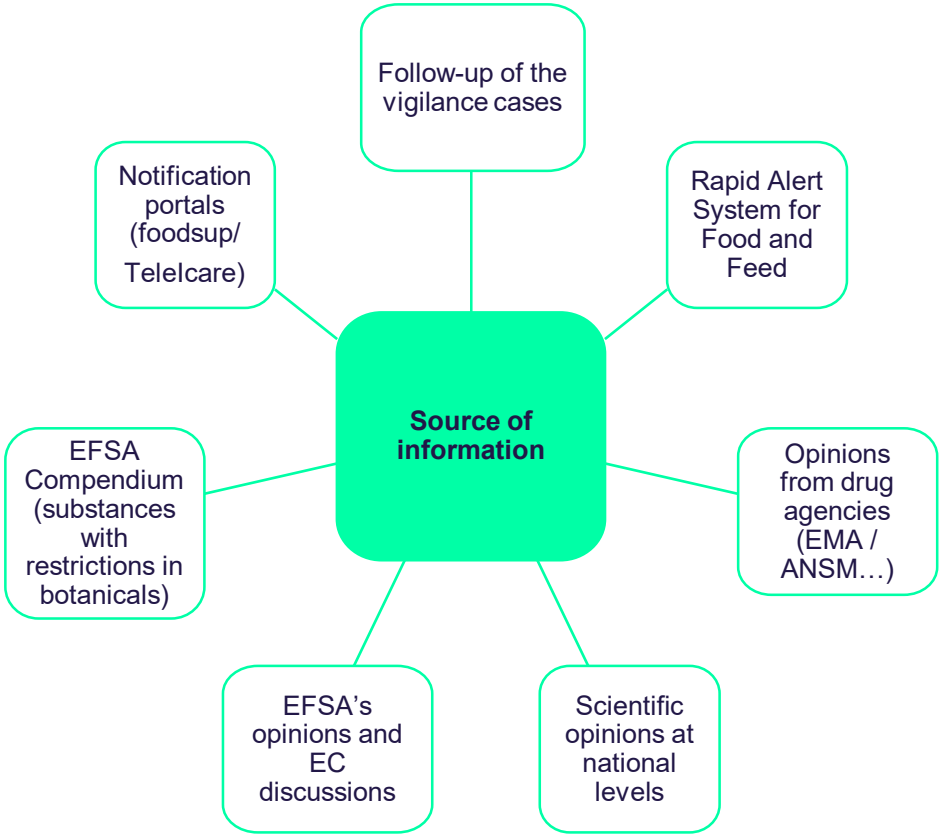
- REGULATION (EC) No 1333/2008 of 16 December 2008 on food additives
  - ANNEX II Union list of food additives approved for use in foods and conditions of use in food categories
- **Specifications** for food additives must comply with REGULATION (EU) No 231/2012 of 9 March 2012
- Under EU legislation from 2008, the safety of all food additives authorised for use in the EU prior to 20 January 2009 must be re-evaluated.
  - EFSA's expert Panel on Food Additives and Flavourings (FAF) carries out the re-evaluation of authorised food additives.

!

Titanium dioxide (E171)

- Forbidden in France since 2 years
- Last review from EFSA : negative opinion
- In progress: Amending Regulation 1333/2008 draft includes:
  - Ban of use in all food categories (including food supplements)
  - Transitional period of 6 months for the withdrawal from food products.
  - Industry must stop putting any food containing titanium dioxide from July 2022 (depending on date of publication)
  - A period of sale of stocks of food supplements placed on the EU/EEA market before date of application of the ban to remain on the market until their date of minimum durability or expiry

How to anticipate new restrictions in Europe?



Other hot topics in EU / UK

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Last updates on quality and safety restrictions

- **Contaminants : Pyrrolizidinic alcaloids**
  - new max limits by 2022
  - Food supplements containing herbal ingredients including extracts: 400 µg/kg (Without prejudice to more restrictive national rules in certain Member States)
  - Pollen based food supplements: 500 µg/kg

- **Pesticides : ETO banned from Europe since 2011**
  - **Ethylene oxide** : More and more food supplements concerned (HPMC capsules from Vietnam and Korea are contaminated - from Suheung Europe GmbH, which is based in Germany and distributes its capsules in EU)
  - **National authorities** : Risk assessment is required to identify the raw materials subject to this contamination, recall from market, corrective action plan to provide to the authorities (change of raw materials, change of suppliers, control at reception, control on the finished products)

- **New restrictions for substances** : new analysis are requested with official or internal methods (ISO norms / EP / Belgian list of recognized methods / etc)

What's up about pending health claims ?

- **Claim Regulation - REFIT (Regulatory Fitness and Performance programme - EC - may 2020)**
  - Inconsistency : harmonization for claims but no harmonization for positive lists of botanicals in EU
  - Harmonized positive lists of botanicals could simplify the access to the market
  - Keep national rules for the distinction between a food and a drug (products cannot be sold as drug and food in the same market – if the product is considered as a drug it cannot be a food – PAY ATTENTION TO THE DAILY DOSE to be lower than the THERAPEUTICAL DOSE)
  - Discrepancy in the recognition of "traditional use" data for claims made on foods and Traditional Herbal Medicinal Products.
  - Safety of botanicals should be reinforced
  - The setting of nutrient profiles needs to be further considered
- **At the national level, several countries are still waiting for a better harmonization too**
- Waiting for assessment on pending claims → HC should be substantiated by the industrials
  - Position confirmed by a recent Case law on claims (EUCJ): it is up to the industrials to justify the consumer are not mislead
- More sanctions for the use of unauthorized claims and therapeutical claims than before (national positions are published : Fr/Be…)
  - Therapeutical claims on communication media lead to a drug status (by presentation) even if the product has no therapeutical action

- BREXIT means UK is considered a 3rd country
- UK has retained EU Regulations through the **Nutrition (Amendment) (EU Exit) Regulation 2019** with the main changes being:
  - Labelling to include UK Food Business Operator (FBO) name and address
  - New health and nutrition claims to be assessed by Food Standards Agency rather than efsa
  - Regulated food products (i.e., novel foods) will require dual submission in the UK and EU
  - Mutual recognition no longer applies

- All existing EU authorisations (health and nutrition claims, novel foods etc) continue to be applicable in the UK

- Deadline for food supplements to be compliant is 30 September 2022 (hard stop)

Things to consider

- 2 FBOs required (1 for EU and 1 for UK). Set up a new business in the UK or partner with an importer/distributor or 3rd party (RNI)
- Update labelling to include new UK FBO name and address
- If regulated food product (e.g., novel food) is currently being assessed by EFSA, a new application is needed for the UK
- New health claim approvals in EU or UK are applicable to those regions only
- EU law still applicable in Northern Ireland

Current topics of interest in the UK for nutrition products

- Probiotic term
  - The UK Working Group on Probiotics has been established to provide a forum for the discussion and preparation of an agreed approach to take to the UK authorities to support the use of the term ‘probiotic’ on foods.
  - This paper urges the UK authorities to reconsider its guidance on use of the term, in light of the new consumer research demonstrating a strong consumer need for change.

- Plastic taxes
  - A new Plastic Packaging Tax will take effect from 1 April 2022 and will encourage the use of recycled rather than new plastic within plastic packaging.
  - Tax will apply to business from all industries including food which may use plastic in packaging.

- Allergen labelling
  - On 1 October 2021, the law on allergen labelling for pre-packed for direct sale (PPDS) foods will change. This means that any food business selling PPDS foods will have to include full ingredients on the product label with allergenic ingredients emphasized within that list.

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You ask you questions prior to the session, and RNI answers them!

Here are some questions that can be addressed:
- What are the primary strategic steps to introduce food supplements in foreign markets?
- What are the main regulatory red flags?
- What differences exist in food supplement labeling between EU, UK and USA?

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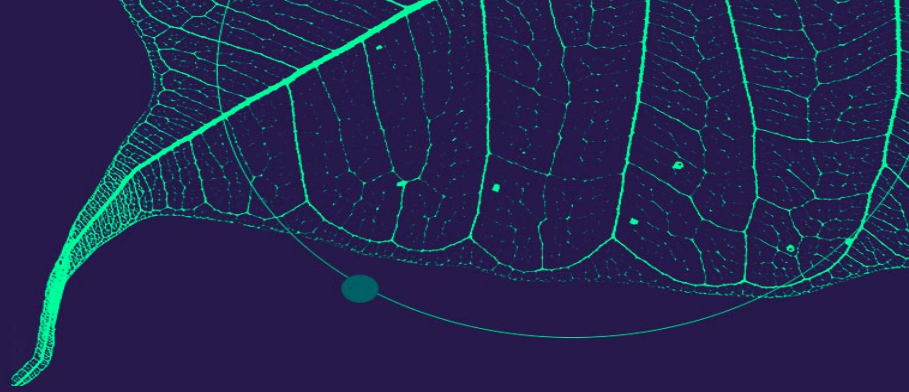

Thanks for your time

Any questions?
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