The International Conference on
Food Supplements

food supplements europe

The EU Perspective on Food Supplements Regulations

Martina Šímová
Chair Food Supplements Europe

20-21 November 2024, Copenhagen

CONTENT

The Food Supplements legal framework

Implementations issues at EU level

Caveats at national level

Article 8 process

Harmonisation of maximum levels for vitamins and minerals

Further harmonization?

Food Supplements Europe

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Our members

AK NEM
Arbeitskreis Nahrungsergänzungsmittel im Lebensmittelverband Deutschland e.V.

CRN UK
Council for Responsible Nutrition

TERVEYSTUOTETUKUT RY
Hälsoprodukttgrossisterna rf
Health Product Wholesalers in Finland

Afepadi
Asociación de las Empresas de Dietéticos y Complementos Alimenticios

SISTE

SANI
Food Supplements Industries Switzerland - FSIS

Gospodarska zbornica Slovenije
Chamber of Commerce and Industry of Slovenia

Nutraceutisk Industri
En del af DI Fødevarer

PRISA

Svensk Egenvård

ASSOERBE

Medaxes
Association for accessible medicines

Amway

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BASF
We create chemistry

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Science For A Better Life

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BRIGHT SCIENCE. BRIGHTER LIVING.

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Herbalife

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INSPIRED MOLECULAR SOLUTIONS

KERRY

Lonza

LR
HEALTH & BEAUTY

Nestlé
HealthScience

Perrigo

P&G Health

Pharma Nord

rb

SANOFI

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Our priority:
Science, Regulation and Policy

Food Supplement Legislation

Food Supplement Ingredients
- Botanicals
- Pre and Probiotics
- Other substances
- Vitamins & Minerals

- Facts about vitamins and minerals and other components with health effects

- Risk management approach to the setting of maximum levels of vitamins and minerals in supplements for adults and for children aged 4-14 years

Labelling & Nutrition
- Food Labelling
- Nutrition & Health Claims
- Tolerances

- Guidelines for the substantiation of beauty claims for food supplements
- The application of the nutrition & health claims regulation

- Setting of tolerances for nutrients values declared on a label

Safety & Quality
- Additives
- Contaminants
- Residues
- Food Hygiene
- Quality

- Guidelines and recommendations to reduce the presence of pyrrolizidine alkaloids in food supplements

- Food Supplements Europe Guide to Good Manufacturing Practice for Manufacturers of FS
- Quality of Botanical Preparations – Specific Recommendations for the Manufacturing of Botanical Preparations, Including Extracts as FS

Official controls
- Vitamin D

- Food Supplements Europe Guidelines relating to the manufacturing and imports of food supplements containing products of animal origin, with a particular focus on Vitamin D3

Novel Foods

- Guidance for food business operators on the verification of the status of a new food under the new Novel Foods regulation 2015/2283 (NFR)

Mutual Recognition

- Guidelines on how to apply the new Mutual Recognition Regulation (EU) 2019/515 to food supplements in the EU

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Food Supplements Regulatory Framework

FOOD SUPPLEMENTS ARE SUBJECT TO:

EU specific rules applicable to food supplements

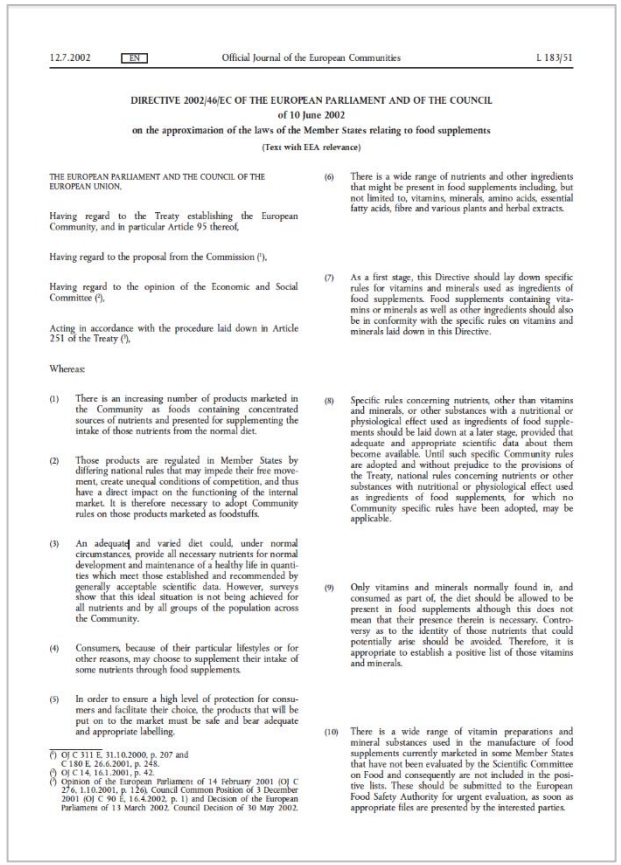
EU horizontal rules applicable to foods in general

- General Food Law
- Hygiene
- Official Controls
- Novel Foods
- Food Labelling
- Food Additives
- Food Fortification
- Contaminants
- Residues
- Extraction Solvents
- Irradiation

National specific rules of Member States

Mutual recognition

FOOD SUPPLEMENTS DIRECTIVE 2002/46/EEC



12.7.2002 EN Official Journal of the European Communities L 183/51

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
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social Committee (2),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (3),

Whereas:

(1) There is an increasing number of products marketed in the Community as foods containing concentrated sources of nutrients and presented for supplementing the intake of those nutrients from the normal diet.

(2) Those products are regulated in Member States by differing national rules that may impede their free movement, create unequal conditions of competition, and thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on those products marketed as foodstuffs.

(3) An adequate and varied diet could, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life in quantities which meet those established and recommended by generally acceptable scientific data. However, surveys show that this ideal situation is not being achieved for all nutrients and by all groups of the population across the Community.

(4) Consumers, because of their particular lifestyles or for other reasons, may choose to supplement their intake of some nutrients through food supplements.

(5) In order to ensure a high level of protection for consumers and facilitate their choice, the products that will be put on to the market must be safe and bear adequate and appropriate labelling.

(6) There is a wide range of nutrients and other ingredients that 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.

(7) As a first stage, this Directive should lay down specific rules for vitamins and minerals used as ingredients of food supplements. Food supplements containing vitamins or minerals as well as other ingredients should also be in conformity with the specific rules on vitamins and minerals laid down in this Directive.

(8) Specific rules concerning nutrients, other than vitamins and minerals, or other substances with a nutritional or physiological effect used as ingredients of food supplements should be laid down at a later stage, provided that adequate and appropriate scientific data about them become available. Until such specific Community rules are adopted and without prejudice to the provisions of the Treaty, national rules concerning nutrients or other substances with nutritional or physiological effect used as ingredients of food supplements, for which no Community specific rules have been adopted, may be applicable.

(9) Only vitamins and minerals normally found in, and consumed as part of, the diet should be allowed to be present in food supplements although this does not mean that their presence therein is necessary. Controversy as to the identity of those nutrients that could potentially arise should be avoided. Therefore, it is appropriate to establish a positive list of those vitamins and minerals.

(10) There is a wide range of vitamin preparations and mineral substances used in the manufacture of food supplements currently marketed in some Member States that have not been evaluated by the Scientific Committee on Food and consequently are not included in the positive lists. These should be submitted to the European Food Safety Authority for urgent evaluation, as soon as appropriate files are presented by the interested parties.

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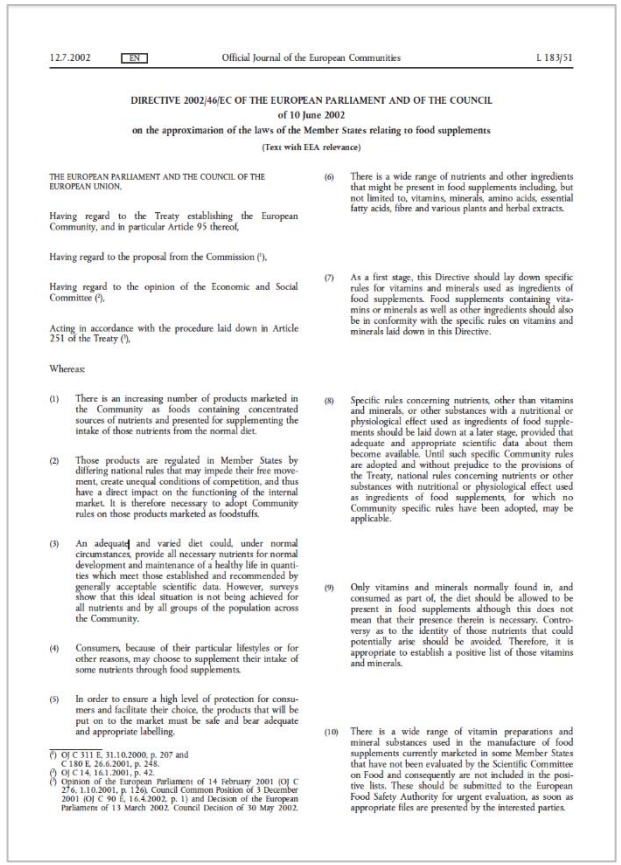
4 major achievements

→ Regulation under food law

→ Inclusion of other substances with a nutritional or physiological effect in the definition

<< 'food supplements' means **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** >>

FOOD SUPPLEMENTS DIRECTIVE 2002/46/EEC



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4 major achievements

→ Maximum levels to be set on the basis of safety

Article 5

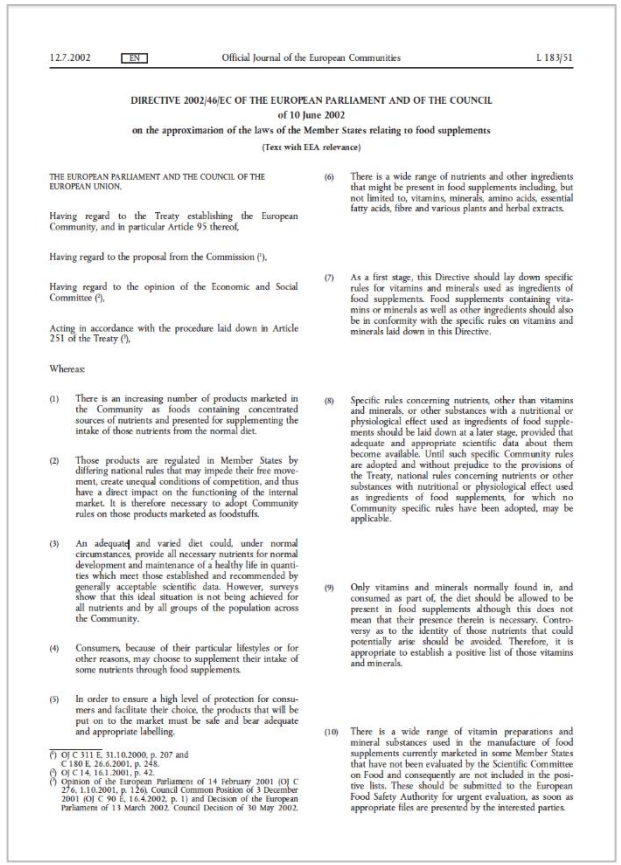
1. Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account:

   (a) **upper safe levels of vitamins and minerals established by scientific risk assessment** based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;

   (b) **intake of vitamins and minerals from other dietary sources**.

2. When the maximum levels referred to in paragraph 1 are set, **due account** should also be taken of reference intakes of vitamins and minerals for the population.

FOOD SUPPLEMENTS DIRECTIVE 2002/46/EEC



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4 major achievements

→ Notification instead of Registration

Most Member States introduced a notification system for food supplements

Mandatory notification in all EU Member States

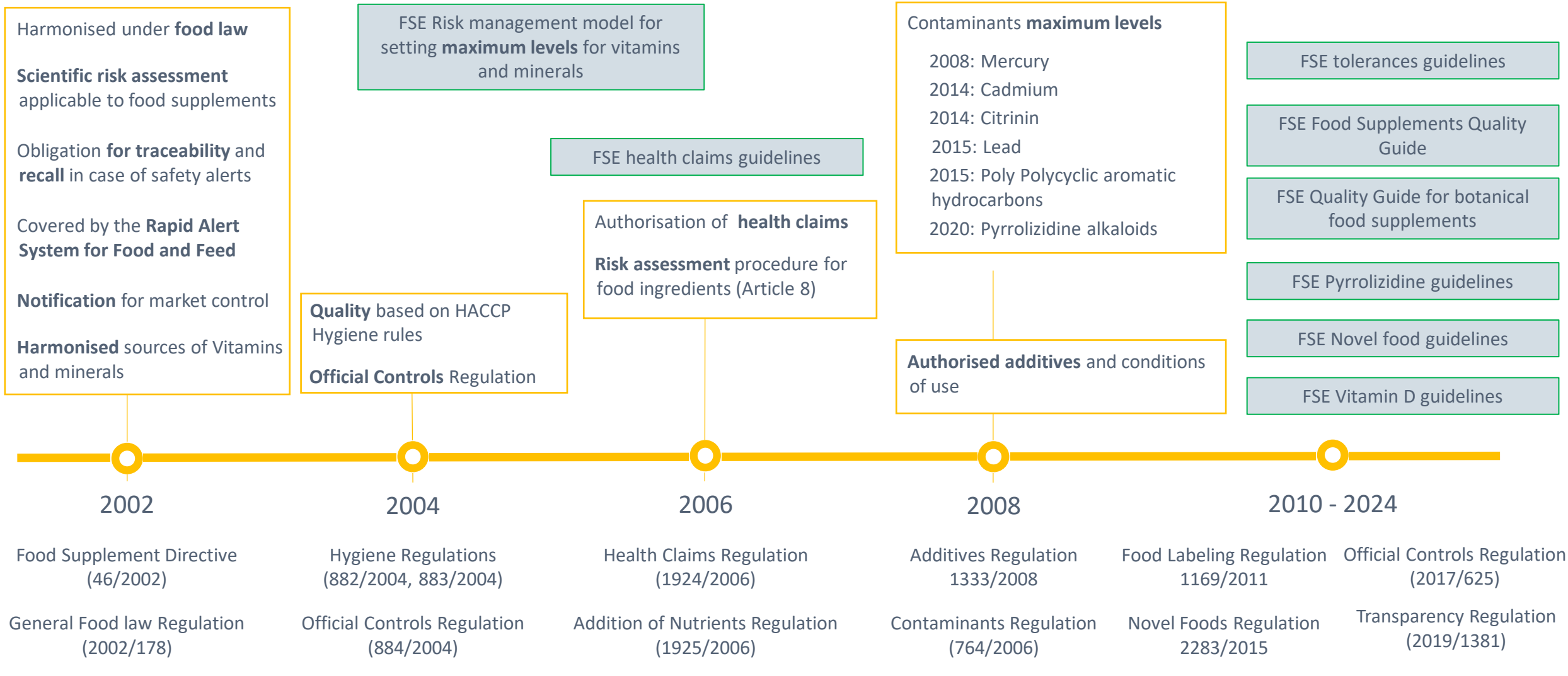
Except for:
- Austria
- the Netherlands,
- Slovenia,
- Sweden,

→ Post market control

Differences between Member States
- On paper vs electronically
- Level of information requested
- Costs involved

Notification is not a product registration
- Products can be launched on the market during the procedure

EXTENSIVE EU LEGISLATION ALSO APPLIES



EU IMPLEMENTATION ISSUES

EU Food Supplements Directive has established a legal framework for food supplements under EU food law that has enabled the development of a thriving and relatively stable food supplements market.

However, constant vigilance is required because of:

- EU implementation issues
- National development
- Article 8 procedure
- EU further harmonization

BE INFORMED AND BE PREPARED

EU implementation issues

EU IMPLEMENTATION ISSUES

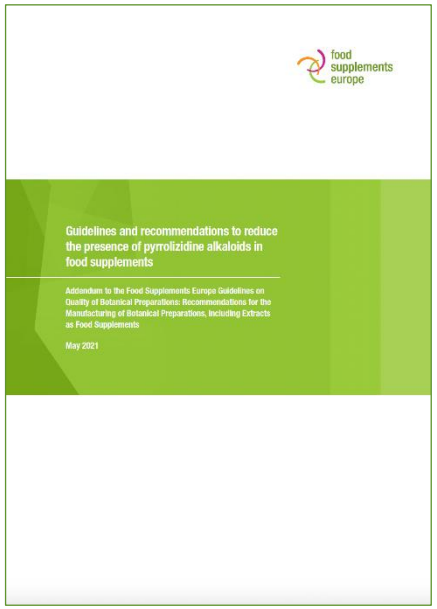
BE INFORMED AND BE PREPARED

Many EU decisions have no or insufficiently long transition periods

Examples:

- Ban of Aloe containing hydroxyanthracene derivatives
- Restriction of monacolins from red yeast rice
- Maximum permitted levels of pyrrolizidine alkaloids
- Ban of titanium dioxide as food additive

Guidelines and recommendations to reduce the presence of pyrrolizidine alkaloids in food supplements



EU IMPLEMENTATION ISSUES

BE INFORMED AND BE PREPARED

Unforeseen EFSA opinions can rapidly lead to restrictions

Examples:

Ban of Titanium Dioxide as food additive

Replacement of Quantum Satis by quantitative limits for food supplements

Alpha-lipoic acid may be completely banned

EU IMPLEMENTATION ISSUES

BE INFORMED AND BE PREPARED

EU discussions can lead to immediate restrictions

Examples:

Novel Food Status catalogue decisions on novel food status of longstanding ingredients

- e.g. curcuminoides
- e.g. pelargonium sidoides
- e.g. griffonia/5-HTP

Guidance for food business operators on the verification of the status of a new food under the new Novel Foods Regulation 2015/2283 (NFR)

Caveats at national level

INGREDIENTS USED IN FOOD AND FOOD SUPPLEMENTS

CAVEATS AT NATIONAL LEVEL

Botanicals and other substances must comply with EU legislation

- Novel Food
- Contaminants (e.g. pyrrolizidine alkaloids)
- Health claims

Compositional requirements exist at national level → Wide divergence across Member States

- Positive / negative lists
- Medicinal use
- Enforcement practice (e.g. term probiotic)

NATIONAL INITIATIVES

2024	**France**	ANSES advice on maximum levels proposed by government
	Netherlands	RIVM advice on further setting of maximum levels in The Netherlands
2021	**Germany**	BfR update advice on maximum levels
	Poland	Chief Sanitary Inspectorate established maximum levels
2019	**Switzerland**	New maximum levels based on a modified application of the BfR model
	Ireland	New maximum levels proposed
2018	**France**	French Control Authority (DGCCRF) has published new Guidance
	Sweden	Initiative to establish maximum levels (Swedish National Food Agency)
	Belgium	New legal maximum levels for food supplements and fortified foods
	Norway	Deletion of many maximum levels in view of a re-assessment
2017	**Germany**	BfR model update: New maximum levels proposed
	ECJ	Judgement in Case C-672/15
2014	**Denmark**	New proposed maximum levels for addition to foods

Article 8 Procedure

ARTICLE 8 PROCEDURE

Regulation (EC) 1925/2006:

Where a substance other than vitamins or minerals, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods under conditions that would result in the ingestion of amounts of this substance **greatly exceeding** those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent **a potential risk** to consumers.

(a) if a harmful effect on health has been identified:

Part A: Prohibition
Part B: Allowed under specific conditions

(b) if the possibility of harmful effects on health is identified but scientific uncertainty persists:

Part C.: Scrutiny (4 years)
Collection of data (24 months)
EFSA assessment

Decided:

- Ephedra
- Yohimbe
- Hydroxyanthracene derivatives
- Green tea catechins
- Monacolins from red yeast rice

In decision process:

- Alpha-Lipoic acid
- Other HAD containing plants

In the assessment process

- Fennel
- Hydroxycitric acid
- Berberine

ARTICLE 8 PROCEDURE

Already banned:

- Ephedra herb and its preparations originating from Ephedra species
- Yohimbe bark and its preparations (Pausinystalia yohimbe (K. Schum) Pierre ex Beille)
- Emodin, Aloe-emodin and danthron and all preparations in which these substances are present
- Preparations from the leaf of Aloe species containing hydroxyanthracene derivatives

Restricted:

- Green tea catechins
- Monacolins from Red Yeast Rice

Proposed to be banned:

- Rheum palmatum L.
- Rheum officinale Baill.
- Rhamnus purshiana Dc
- Rhamnus frangula L.
- Cassia senna L.
- Alpha-lipoic acid ?

Proposal up for vote, but uncertain because of the ruling of the CJEU of 13 November 2024

OUTCOME OF THE COURT CASES (COURT OF JUSTICE OF THE EU)

Requests to annul Regulation (EU) 2021/468 amending Annex III to Regulation (EC) 1925/2006 as regards botanical species containing hydroxyanthracene derivatives (HADs emodin, aloe-emodin and danthron and of preparations of Aloe containing HAD in food supplements).

- T-302/21 02/07/2021 Aboca and Others v Commission
- T-274/21 18/06/2021 Synadiet and Others v Commission
- T-271/21 18/06/2021 Ortis v Commission
- T-189/21 07/05/2021 Aloe Vera of Europe v Commission

Rulings published on 13 November 2024:

The CJEU annuls Regulation (EU) 2021/468 basically because Regulation 1925/2006 does not permit:

- to include ‘preparations’ in the Annex III, but only ‘substances’ and ‘ingredients’
- A blank prohibition because of insufficiency of data and failure to identify a level that is safe from the risk assessment

ARTICLE 8 PROCEDURE

In the assessment process

- Bitter and sweet fennel
- Hydroxycitric acid
- Berberine

Timeline

15 May 2025

From 12-05-2023 to 11-06-2023

Draft Protocol for the Scientific Opinion on the evaluation of th...

Public Consultation Finished

See details

2023

15-11-2022

Mandate Accepted

11-10-2022

Mandate Received

2022

HEADS OF AGENCIES REPORT: PROPOSED FOR ARTICLE 8 PROCEDURE

Proposed to be assessed

- Actaea racemosa
- Coumarin in plant preparations
- Curcumin in Curcuma spp.-preparations
- Hypericum perforatum
- Lepidium meyenii
- Melaleuca spp.-essential oils
- Ocimum tenuiflorum
- Piperine
- p-Synephrine in Citrus spp.-preparations
- Tribulus terrestri
- Tryptophan
- Withania somnifera

EC is consulting Member States and must decide if the criteria are met

Mandates to EFSA likely still this year

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Harmonisation of maximum levels of vitamins and minerals

EU HARMONISATION OF MAXIMUM LEVELS – EC TIMELINE

Information to the other Member States → 22 November 2023

Second meeting with the Member States → 30 April 2024

Third meeting with Member States → 2-3 June 2024

efsa → **June 2024 UL opinions**

Next meeting with the Member States → **19 November 2024**

Publication of the Call for Evidence → Early 2025 ?

Outreach to the stakeholders → March 2025 ?

Proposal + Impact assessment

Adoption by the Standing Committee

Scrutiny by the European Parliament

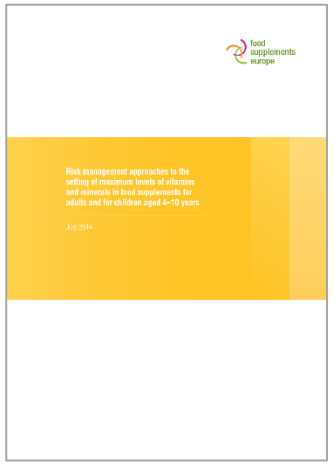
Publication in the Official Journal → 2026 ?

MAXIMUM LEVELS: THE FSE RISK MANAGEMENT MODEL

2005: ERNA Risk Management model

2008: FSTB 4:51–66,
DOI: 10.1616/1476-2137.14996.
2010: FSTB 7 (6) 77–101.
DOI: 10.1616/1476-2137.15997

2014: FSE Risk Management model



2020 Update

Based on FSAI data

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Further Harmonisation ?

2008 - EC REPORT ON FURTHER HARMONISATION

Further harmonisation is
not feasible

- Too many national differences
- Scientific and methodological difficulties to be overcome

Further harmonisation is
not necessary

- Full food law framework is applicable
  - Legislation covers many aspects
- Application of new legislation
  - Reg 1924/2006 Nutrition and Health Claims
  - Reg 1925/2006 Addition of Nutrients
  - Revision of Reg 258/1997 Novel foods
- Mutual Recognition

THE ISSUE OF HEALTH CLAIMS

Botanical Food Supplements (Regulation (EC) 1924/2006)

- Clinical trials needed but not available
- Justification by companies
- No single claim for botanicals accepted

Traditional Herbal Medicinal Products (Directive 2004/24/EC)

- No proof of efficacy needed
- EMA working on traditional herbal monographs

27 September 2010

EC decided to remove botanicals from the claims process and start a reflection on future rules

REFIT

August 2012: EC Option Paper for the Member States

- Option 1: ask EFSA to continue its assessments according to the same approach as all other claims
  - All claims assessed in the same way: No unfair competition
  - Specificity of botanicals not recognised: All claims rejected
  - Medicinal claims could continue: Without proof of efficacy
- Option 2: Address the specificities of botanicals via a change of the applicable legislation
  - This would enable tradition of use as a factor for health claims

May 2015: announcement of the better regulation initiative: REFIT

GENERAL CONCLUSIONS OF THE REFIT ASSESSMENT (2020)

- **Health claims** from the on-hold list have not been assessed
- **Legal uncertainty** persists
- **Polarized positions between stakeholders**
- The **safety of foods** containing plants is adequately addressed but there is an increasing demand to use the Article 8 process
- It is not coherent to have harmonized rules on claims while the use of botanicals is under national rules
- A **positive or negative list** of botanicals could improve the safety and smooth functioning of the market
- It could be appropriate to explore the notion of '**traditional use**' in the efficacy assessment together with the effects of the co-existence of THMP on the same plant substances

There are merits for further studying the potential EU harmonisation of plants, including the safety aspect

FURTHER EU HARMONISATION: EP RESOLUTION

Adopted by the European Parliament on 18.1.2024

- Solve the Borderline between food and medicine
- Establish an EU negative list of botanical substances used in foods and food supplements
- Resume the on hold claims assessment for botanicals

European Parliament

2019-2024

TEXTS ADOPTED

P9_TA(2024)0040

Implementation report on Regulation (EC) No 1924/2006 on nutrition and health claims made on foods

European Parliament resolution of 18 January 2024 on the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods (2023/2081(INI))

EU HARMONISATION: EP RESOLUTION

Commission reply

- Future steps will be guided by the priorities of the next Commission.
- Reminder of the conclusions of the REFIT evaluation:
  - It could be appropriate to explore the notion of 'traditional use'.
  - There are merits for further studying the potential EU harmonisation in the field of botanicals, including the safety aspect.
  - The safety of foods containing plants is adequately addressed by the EU legal framework for food, existing national rules and the use of the Article 8 procedure.
- To date, the Article 8 procedure has been used to restrict or prohibit the use of botanical substances for safety reasons, and it is currently ongoing for several substances.

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conclusions

CONCLUSIONS

The Food Supplements Directive established a sound regulatory framework for food supplements under food law in 2002.

However, the harmonisation is only partial and composition is largely regulated at national level.

It is important to keep up with national and EU developments to be forewarned and be able to adapt quickly.

The next step for harmonisation is maximum levels for vitamins and minerals. This may have a significant impact on products.

Whether further harmonisation will be initiated is unknown. Safety of botanicals is largely covered by the Article 8 process.

THANK YOU

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