

**T**his is a non-exhaustive list of the number of decrees published by the European members, the European Parliament, the Council and Commission Regulations relating to food supplements.

Each link of the chain from the early grower of the plants to the end-product must carefully check that its product fulfills the regulation and totally satisfy the safety needs.

### Plant names

Different countries, associations, working groups, etc... are working on the harmonization of plant and plant extracts in Europe, as for instance Synadiet, Be-sup, EHPM, etc... It works towards developing an appropriate regulatory framework throughout the EU for its members' products.

### Synonyms accepted for plant

The Plant List is a working list of all known plant species. It aims to be comprehensive for species of Vascular plant (flowering plants, conifers, ferns and their allies) and of Bryophytes (mosses and liverworts): see [www.theplantlist.org/](http://www.theplantlist.org/)

### Protection (Cites)

EC No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein

### Food supplements

#### Directive 2002/46/EC

This main directive of June 10, 2002 allowed the approximation of the laws of the Member States relating to food supplements and aims to ensure that they are safe and labeled in an appropriate manner. Labeling rules are governed by INCO regulation 1169/2011/EU. These products may carry nutrition and health claims in accordance with Regulation 1924/2006.

Plants and substances depend on national regulations. In France:

- plants - order of June 24, 2014
- authorized substances: order of September 26, 2016
- other French decrees: 2011/329 modifying 2006/352. The principle of mutual recognition is possible according to 2019/515/EU.

Regulation 609/2013 for foods intended for specific groups has repealed the legislation on foodstuffs intended for particular nutritional uses (DADAP: 2009/39/EC) since July 20, 2016, which has affected several categories: preparation for infants (2006/141/EC) and young chil-

dren (2006/125/EC), foods for special medical purposes (1999/21/EC) and total daily ration substitutes for weight control ( 96/8/EC) thus repealing these regulations.

### Organic

Since January 1, 2022, reference must be made to 2018/848/EC relating to organic production and the labeling of organic products and repealing regulation 834/2007/EC and regulation 2021/1165.

### Contaminants

#### General purposes

EC 1881/2006 of 19 December 2006 setting maximum levels for **certain contaminants** in foodstuffs

#### Toxins

EU 1259/2011 of 2 December 2011 amending Regulation EC 1881/2006 as regards maximum levels for dioxins, dioxin-like PCBs and non dioxin-like PCBs in foodstuff (2017/644/EU) – Mycotoxins : aflatoxin B1, total aflatoxins, Ochratoxin A, Patulin, Zearalenon, Fumonisin (401/2006/EC) – Nitrates (1882/2006) and most of other toxins are in 1881/2006. Regulation 2022/1370 is specifically focusing on maximum levels of Ochratoxin A.

#### Pyrrrolizidinic Alkaloids

EU 2020/2040 of 11 December 2020 amending Regulation (EC) No 1881/2006 as regards maximum levels of pyrrolizidine alkaloids in certain foodstuffs ; Food supplements containing herbal ingredients, including extracts, except for certain categories ≤400 ppb applicable from 1.7.2022 (Without prejudice to more restrictive national rules in certain Member States).

#### ETO (Ethylene oxide)

Since September 2020, numerous notifications concerning the presence of ethylene oxide (ETO) have been published in the RASFF food alert portal, firstly sesame seeds and then for our entire sector. Even if the finished product does not contain ETO, if the raw material used to manufacture the FP contains at a level that exceeds EU MRLs (EU 2015/868), then the product should be withdrawn from the market.

#### PAH

EU 2015/1933 of 27 October 2015 amending Regulation EC No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons. Usually:

- Benzo(a)pyrene ≤10 ppb
- Sum of Benzo(a)pyrene, Benz(a) anthracene, Benzo(b) fluoranthene and Chrysene) ≤50 ppb

#### Heavy Metals

EC 629/2008 of 2 July 2008 amending Regulation (EC) No 1881/2006 setting maximum levels for certain

contaminants in foodstuffs (especially heavy metals). The limits vary depending on the origin and the use.

However, we usually refer to :

- Total Heavy metals : usually 10 ppm
- Lead : usually 1 or 3 ppm
- Arsenic : usually 1.0 ppm, UE 2023/465 adds specific limits for some categories
- Cadmium : usually 1.0 ppm (3.0 seaweed der.)
- Mercury : usually 0.1 ppm

### Pesticides

EC 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC + EC No 149/2008. This list is much more strict than the EP, and even more than the USP.

[ec.europa.eu/food/plant/pesticides/eu-pesticides-database/](http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/) for active substances and pesticides MRLs

### Hydroxyanthracenic derivatives

(EU) No. 2021/4680 sets the maximum levels of HAD, in particular aloin, aloe-emodin, emodin. Certain plants are specifically concerned (publication by ANSES of a list of 39 plants).

### Other limits

#### Solvents and Residual solvents

Directive EU 2016/1855 of 19 October 2016 amending 2009/32/EC on extraction solvents used in the production of foodstuffs and food ingredients, amending EC 2009/32 of 23 April 2009 on extraction solvents used in the production of foodstuffs and food ingredients.

You may also refer in certain cases to Eur. Ph. 2.4.24 (methods) or 5.4 (limits).

### Other Quality specificities

#### Allergen

EU 1169/2011 of 25 October 2011 amending EC 1924/2006 and EC 1925/2006, and repealing 87/250/EEC, 90/496/EEC, 1999/10/EC, 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004



## ... the main decrees

### Bacteriology

Usually Eur. Ph. 5.1.8 (limits) and 2.6.12/2.6.31 (methods)

### GMO

EC 1829/2003 of 22 September 2003 on genetically modified food and feed and EC 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

### Food

Products comply with the Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety and with the Regulation (EC) No. 852/2004 on the hygiene of foodstuffs

### Packaging

Materials intended to come into contact with food as described in the Regulation (EC) No. 1935/2004 and 10/2011 and 1895/2005 and 2023/2006 and its amendments.

### Nano technology / material

Commission recommendation of 18 October 2011 on the definition of nanomaterial - 2011/696/EU (+2283/2015 + 1169/2011).

### non-irradiation

EC No. 1999/3 for the list of foods and food ingredients treated with ionizing radiation.

### Novel Food

Novel Food is defined as food that had not been consumed to a significant degree by humans in the EU before 15 May 1997, when the first Regulation on novel food came into force.

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

The Novel Food Catalogue is a non-exhaustive list and serves as orientation.

A plant may be not novel food when its extract is, because of its process or unknown uses.

EC 2002/46 of 10 June 2002, 2019/1381 of 06/09/2019 on Novel Food amending Regulation 1169/2011, 2017/2470/EC of 20/12/2017 establishing the Union list of novel foods.







### Substances

Substances are more and more concerned in Europe, although each country may still have its own considerations, and although the definition of a substance is not fully clear yet. France publishes its Order regarding the use of other substances in supplements. It confirms that the use of substances other than those listed in Annex I, which lays down specific conditions of use for four ingredients, may be used in supplements provided they are not novel.

French decree : « Arrêté du 26 septembre 2016 établissant la liste des substances à but nutritionnel ou physiologique autorisées dans les compléments alimentaires et les conditions de leur emploi »

The Natural Sign  
extraits de plantes standardisés objectivés

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| <br><b>140 MG</b><br>DAILY    | <br>CLINICAL<br>STUDIES                      |
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**SUITABLE FOR GUMMIES, GELS,**  
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**THE AUTHORIZED CURCUMA**

**FIRST EVER EFSA APPROVED NOVEL FOOD**  
**ACTIVE METABOLITE OF CURCUMINOIDS**

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Sabinsa has obtained **EFSA Novel Food approval** for its innovative turmeric extract **Curcumin C3 Reduct®** - 95% Tetrahydrocurcuminoids (THC), i.e. curcuminoid metabolites extracted from Curcuma longa. This may well be the first time a metabolite of a nutrient has been approved as a Novel Food.

**C3 Reduct® overcomes the limitation of the bioavailability of curcuminoids** in the most functional way since it allows the direct use of the active form of curcuminoids: its metabolites.