

**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, Federsalus, 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 10 June 2002 on the approximation of the laws of the Member States relating to food supplements Infants, young children, special medical purposes, total diet replacement - also refers for substances to EU 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing 92/52/EEC, 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009.

France: definition of "Compléments alimentaires"; plants and Substances, 2011/329 and 2006/352

#### Organic

EC 834/2007 and its implementing regulation of the European Commission 889/2008 gives the very strict rules for Organic products These regulations define rules at all stages of production, processing, labeling, control and import from third countries.

### 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 - aflatoxin B1, total aflatoxins, Ochratoxin A, Patulin, Zearaleonon, Fumonisin - and most of other toxins are in 1881/2006.

#### PAH

EU 2015/1933 of 27 October 2015 amending Regulation EC No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in cocoa fibre, banana chips, food supplements, dried herbs and dried spice. 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 (3 ppm in subsection 3.1.18)
- Arsenic : usually 1.0 ppm
- Cadmium : usually 1.0 ppm (3.0 for seaweed derivatives)
- 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 of 29 January 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto.

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

### 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

#### 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.

#### Nano technology / material

Commission recommendation of 18 October 2011 on the definition of nanomaterial - 2011/696/EU

#### 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.

EC 2002/46 of 10 June 2002,

#### 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.

NOR: ECFC1518714A on [legifrance.gouv.fr](http://legifrance.gouv.fr)

