**Food law and Food supplements legislation**

Food supplements are regulated in Greece by a piece of [national legislation which transposes Directive 2002/46/EC on food supplements](https://www.nomikosodigos.info/guide/legislation/622-enarmonisi-tis-ethnikis-nomothesias-me-tin-antistoihi-koinotiki-shetika-me-ta-sympliromata-diatrofis) (Government Gazette 395B/2004), as amended in 2011 by [Joint Ministerial Decision (JMD) 90235/2011](http://www.et.gr/idocs-nph/search/pdfViewerForm.html?args=5C7QrtC22wFYAFdDx4L2G3dtvSoClrL8dPiJFyS0CqR_zJjLAILKFuJInJ48_97uHrMts-zFzeyCiBSQOpYnTy36MacmUFCx2ppFvBej56Mmc8Qdb8ZfRJqZnsIAdk8Lv_e6czmhEembNmZCMxLMtUw9BrCDyWc2PJrmoQin_xmbPOgAiMi187PiJIzsNX-2) (Government Gazette 1984B/2011, page 3-4), in 2013 by [JMD 103499/2013](http://www.nomikosodigos.info/guide/legislation/742-ya-1003499-2013-sympliromata-diatrofis.html) (Government Gazette 2855B/2013) and in 2017 by [JMD Γ5α/53625/2017](https://www.e-nomothesia.gr/kat-ygeia/farmakeia/koine-upourgike-apophase-g5a-53625-2017.html) (Government Gazette 3328B/2017).

The [National Organization for Medicines](http://www.eof.gr/) (EOF) published a consolidated list of legislation applicable to food supplements.

The regulatory framework for food is based on the EU provisions. At national level, foodstuffs are regulated by the [Food and Beverage Code](http://www.gcsl.gr/index.asp?a_id=264&txt=y&show_sub=1) (Κ.Τ.Π.), as amended to comply with the EU regulations.

The [Hellenic Food Authority](http://www.efet.gr/) (EFET) has published the information concerning national and European legislation applicable to foodstuffs.

The [National Organization for Medicines](http://www.eof.gr/) (*EOF*), belonging to the [Ministry of Health](https://www.moh.gov.gr/), is responsible for food supplements and for the classification of products either as medicines or food supplements.

A manufacturer can apply for the classification of a product to the [National Organisation for Medicines](http://www.eof.gr/) *(EOF),* Division of Products Evaluation. The application should include information on the qualitative and quantitative composition of the product as well as on the suitability of the product for specific nutritional functions (by using literature sources). The cost for classification is EUR 150 + 2,4% per product (EOF Account, Bank of Greece, IBAN: GR 5301000 24 0000000000 263038), **not via e-paravolo**.

**Notification**

Every Food Supplement circulated in the Greek market must be notified to the National Organization for Medicines of Greece. The company responsible for placing a food supplement (or an FSMP) in the Greek market must be registered in the national online notification system GreFIS. This procedure is charge free.

A step by step guide (PDF) for this procedure (available only in Greek language) is provided in the following [link](http://www.eof.gr/assets/EGKYKLIOS_ELECTRONIC_SUBMISSION.pdf)

Α) For products manufactured in Greece or imported from another EU Member State which contain the allowed vitamins and minerals, the notification should be submitted using a simplified form.

The following information for a food supplement notification is required:

* Product name
* Name and address of the manufacturer and of the applicant
* Label in Greek and other foreign language (English, preferably)
* The full synthesis of the product (nutrients & excipients) quantitatively
* Proof of legal marketing in another EU country
* Proof of payment (EUR 300 + 2,4%) (EOF Account, Bank of Greece, IBAN: GR 5301000 24 0000000000 263038), **not via e-paravolo**.

B) Food supplements which are imported from countries outside the European Union or contain substances not included in the Annexes of the [Directive 2002/46/EC on food supplements](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002L0046&from=en), should submit a more detailed form to the [National Organization for Medicines](http://www.eof.gr/) *(EOF)*.

The following information for a food supplement notification is required:

* Product name
* Name and address of the manufacturer and of the applicant
* Qualitative and quantitative composition (official documentation from the manufacturer)
* Ingredients which are not listed in the food supplements legislation
* Label in Greek and other foreign language (if applicable)
* Nutrition information for the ingredients not listed in the legislation applicable to food supplements
* Specification of the raw materials
* Certificate of analysis of the final product
* Intended use and mechanism of action– if the active substance is not listed in the food supplements legislation
* Proof of legal marketing in another EU country
* Proof of payment (EUR 600 + 2,4%) (EOF Account, Bank of Greece, IBAN: GR 5301000 24 0000000000 263038), **not via e-paravolo**.

After the e-submission of the notification, a printed summary of the notification (generated through the printer thumb-icon of the database) must be signed and sent to [National Organization for Medicines](http://www.eof.gr/) *(EOF)* to the Department for Food supplements & Food for Special Medical Purposes (FSMPs) and Biocides, through the protocol, with a hard copy of the bank deposit attached, to the following address:

National Organization for Medicines

284 Mesogeion Av.,15562

Holargos, Athens, Greece

Tel center : +30 213 2040 200

Products fulfilling the notification process are assigned a notification number, which should be included in the labelling. In case it results from the assessment that the product does not meet the legal requirements, the [National Organization for Medicines](http://www.eof.gr/) *(EOF)* informs the applicant, who is supposed to comply within 60 days; otherwise sanctions will be imposed.

***Labelling***

Products should be labelled with the notification number assigned to them in the course of the notification procedure. Apart from that, there are no specific labelling provisions which differ from Community provisions.

A label sample and a check list are provided, for guidance, by the [National Organization for Medicines](http://www.eof.gr/) *(EOF).*

It is mandatory to add the notification reference number and date in every promotional material.

***Claims***

The legislation on claims complies with the EU provisions.

The [National Organization for Medicines](http://www.eof.gr/) *(EOF)* Circular 55220/22-7-2009 states that it is not allowed to use as a claim phrases like “approved by EOF” as this is considered as not legitimate and misleading.

***Vitamins and minerals***

The vitamins are minerals and their sources allowed to be used in food supplements are in line with the EU legislation.

***Vitamins and minerals***

**Maximum levels**

There are no official maximum levels, the products are assessed on a case-by-case basis by referring to generally accepted scientific data.

***Vitamins and minerals***

**Minimum levels**

Minimum levels are set at 15% of the Recommended Daily Intakes laid down in Annex III of the amendment of [2017](https://www.e-nomothesia.gr/kat-ygeia/farmakeia/koine-upourgike-apophase-g5a-53625-2017.html) of the regulation on food supplements.

**Margins of tolerances**

There are no official margins of tolerances. Levels for vitamins and minerals are assessed on a case-by-case basis considering the [DRV Finder](https://www.efsa.europa.eu/en/interactive-pages/drvs) generated by EFSA.

***Herbal substances***

There is no negative or positive list for herbal ingredients. The classification is made on a case-by-case basis.

***Other substances***

The use of other substances is allowed in food supplements. In the definition of food supplements, the legislation mentions a few groups that are allowed for use e.g. amino acids, proteins, antioxidant substances.

***Controls/Establishment of new food business operations***

**Notification of establishments**

Food supplements establishments should be authorized by the [National Agency for Medicines](http://www.eof.gr/) (*EOF).*

The requirements for operators manufacturing food supplements are listed in the [Decision no. 6206/2009](http://www.eof.gr/assets/ApofasiEOF_6206_2008_SYMPLHROMATA_DIATROFHS.pdf) (Government Gazette 199B/2009); [information](http://www.eof.gr/web/guest/various?p_p_id=62_INSTANCE_QbU6&p_p_lifecycle=0&p_p_state=maximized&p_p_mode=view&p_p_col_id=column-1&p_p_col_count=1&_62_INSTANCE_QbU6_struts_action=%2Fjournal_articles%2Fview&_62_INSTANCE_QbU6_groupId=12225&_62_INSTANCE_QbU6_articleId=30417&_62_INSTANCE_QbU6_version=1.0) on the different approvals needed e.g. Good Manufacturing Practice or packaging, is provided separately, by the [National Agency for Medicines](http://www.eof.gr/)*(EOF).* More information on that can be requested from the Division of Production and Distribution Control.

***Distribution***

As of 2013, food supplements can be sold in pharmacies and other stores for processed foodstuffs. According to the [National Organisation for Medicine](http://www.eof.gr/) *(EOF)* recommendations on implementing the [JMD Γ5α/53625/2017](https://www.e-nomothesia.gr/kat-ygeia/farmakeia/koine-upourgike-apophase-g5a-53625-2017.html) (Government Gazette 3328B/2017) amendment on food supplements, the product placement should be separated, marked “food supplements” and have a symbol in form of a plate (at least 15x25 cm) on which specific warnings are written.

***Taxes***

VAT on food supplements is 24%.

***Useful links/ Sources***

Ministry of Health <http://www.moh.gov.gr/>

National Organisation for Medicine *(EOF)* <http://www.eof.gr/>

Hellenic Food Authority *(EFET)* <http://www.efet.gr/>

General Chemical State Laboratory of Greece <https://www.aade.gr/gcsl>