MINISTERIO
DE CONSUMO

agencia española de seguridad alimentaria y nutrición

GUIDE TO THE SUBMISSION OF NOTIFICATION DOSSIERS FOR THE PLACING ON THE MARKET OF FOOD SUPPLEMENTS TO THE COMPETENT AUTHORITIES

This information is for information purposes, and in no case may it have any binding legal effect (Royal Decree 208/1996 of 9 February, which regulates the administrative information and citizen services, art. 4 b)

Contenido

INTRODUCTION

Food supplements, hereinafter FS, are food products consisting of concentrated sources of nutrients or other substances having a nutritional or physiological effect, in a simple or combined form.

A varied and balanced diet provides all the nutrients necessary for the normal development and maintenance of a healthy organism. However, because of their lifestyles or other different reasons, people may decide to increase their intake of some nutrients through FS, but these should never be used as a substitute for a healthy diet.

They are marketed in a dosage form, that is, capsules, pills, tablets, pills and other similar forms, powder sachets, liquid vials, dropper bottles and other similar forms of liquids and powders to be taken in small unit quantities, associated with a daily dose recommended by the manufacturer.

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 FS, to facilitate effective control of FS, provides for the possibility for Member States to require the person responsible for placing the products on the market to notify the competent authorities (“Comunicar” and “Comunicación” in Spanish legal terminology) of their placing on the market..

Spain decided to establish this obligation and this is regulated in Article 9 of Royal Decree 1487/2009, of 26 September, on FS.

The notification of the placing on the market of the FS will allow the start of the marketing of the product in Spain from the day of its presentation, without prejudice to the verification, control and inspection attributed to the Public Administrations. This is the administrative procedure by which food bussiness operators (FBO) bring their identification details and other requirements to the attention of the competent authorities.

This notice of placing on the market does not exclude the full responsibility of the FBO for compliance with the legislation applicable to it (See Annex I) and therefore product safety.

The notified products can be consulted in this website that includes, among other products, FS that have been communicated to the Spanish authorities and that are legally marketed in the Spanish market.

The purpose of this Guide is to provide complete and systematic information on this administrative procedure to FBO who have this obligation to the different competent authorities of our country, emphasising the documentation that needs to be provided to carry it out.

WHO?

The obligation to notificate the placing on the market of the FS, as well as the modification of data and the cessation of their placing on the market, falls on the person responsible for placing them on the Spanish market, that is, the FBO whose name and address in the European Union (EU) appears on the label under which the product is marketed in our country.

VERY IMPORTANT! Companies from outside the EU must have a representative or distributor in the EU who will be identified on the label of the product they market and the person responsible for this process to the Spanish administration.

WHEN?

Same day or prior to placing on the market.

WHERE?

The authorities receiving notifications concerning FS are different (the competent bodies of the Autonomous Communities -CCAA- or AESAN of the General State Administration) depending on the location of the head office of the person responsible for marketing the product in Spain:

VERY IMPORTANT! Only in case the address of the FBO responsible is in another Member State of the European Union, the notification shall be addressed to AESAN**.**

WHAT DOCUMENTATION IS NEEDED?

In Spain, it is mandatory to notificate:

- the first placing on the Spanish market of the products,
- any changes which might affect them (labelling, composition, undertaking responsible for marketing, etc.); and
- cessation of marketing.

To do this, it is necessary to send some documents to the competent authority:

- Notification form.
- Product label.
- Proof of payment of the fee (except in cases of notice of cessation)

And according to the composition of the product, the submission of other additional documentation:

- Document attesting to the prior marketing in another Member State and, if possible, the simple responsible translation thereof.
- Product label in another Member State.

1. NOTIFICATION FORM

Filled in and signed. The form is available on AESAN website.

2. LABEL

A label in Spanish shall be provided and shall comply with Regulation (EU) Nº 1169/2011 of the European Parliament and of the Council of 25 October 2011, on food information provided to the consumer and to include the MANDATORY FOOD INFORMATION referred to in Article 9 thereof.

Similarly, the label shall include:

- The labelling, presentation and advertising requirements set out in Articles 5 and 6 of Royal Decree 1487/2009, of 26 September.

- The indication of the lot on the label or packaging of the CA, in accordance with Royal Decree 1808/1991 of 13 December, which regulates the indications or marks that allow the identification of the lot to which a foodstuff belongs.

- Other additional mandatory information, as appropriate, in:

- Annex III to Regulation (EU) Nº 1169/2011.

- Annex V to Regulation (EC) Nº 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.

The label may contain VOLUNTARY INFORMATION in accordance with the requirements laid down, inter alia, in Regulation (EC) Nº 1924/2006 of the European Parliament and of the Council of 20 December 2006, concerning nutrition and health claims made on foods and their implementing legislation.

In general, the MANDATORY FOOD INFORMATION:

- Shall appear directly on the packaging or on a label attached thereto.
- To be marked prominently so that it is easily visible, clearly legible and, where appropriate, indelible.
- In no way shall it be concealed, obscured or separated by any other indication or image, or by any other material submitted.
- Will appear in Spanish.
- It shall be printed in characters using a font size equal to or greater than 1,2 mm. Where the maximum surface of the package is less than 80 cm2, the minimum size of the letter shall be 0.9 mm.

In order to avoid the presentation of labels with common deficiencies, Annex III lists the deficiencies most frequently identified in the review of the submitted CS files, which should be taken into account together with the other mandatory requirements

3. PROOF OF PAYMENT OF FEE

Proof of payment of the fee shall be attached, depending on the type of notification (first placing on the market or modification of data).

For dossiers submitted to AESAN: instructions and form.

4. DOCUMENT ATTESTING TO PREVIOUS MARKETING IN ANOTHER MEMBER STATE

The directly applicable legislation in Spain allows the marketing in our country of the ACs that incorporate:

- the vitamins and minerals listed in Annex I to Directive 2002/46/EC; or
- substances with a nutritional or physiological effect in the annex to Royal Decree 1487/2009, of 26 September.

- Substances harmonised at Community level (additives, flavourings, authorised novel foods, etc..)

FSs incorporating other types of substances may be placed on the market in Spain on the basis of the principle of mutual recognition, in accordance with Articles 34 and 36 of the Treaty on the Functioning of the EU.

To this end, proof of prior legal marketing in another Member State shall be required by:

- The document proving that the product has been notified to the competent authorities of that Member State, in those countries where, as in Spain, such processing is obligatory.
- Or, in the case that the country does not have such an obligation, some document that proves that such FS are legally present in the market. In this respect, the European Commission interprets as appropriate to demonstrate the effective marketing of a product in another Member State or in a country member of the EFTA and EEA AGREEMENT «any evidence, such as invoices or labels of products, catalogues with proof of a date, tax or sales documents, records, permits, notifications to or from the authorities, certificates, extracts from public records, etc. […]».

This same document is necessary in the event that the person responsible for marketing communicates a change of composition of a product that was being marketed in our country under the Principle of Mutual Recognition, together with the new label, to prove that it is being legally marketed with its new composition.

5. LABEL IN ANOTHER MEMBER STATE

In the event that the product is to be marketed in our country under the Mutual Recognition Principle, it will be necessary to provide the label under which the product is previously marketed in another Member State.

DIFFERENT FLAVOURS, PACKAGING SIZES OR GALENIC FORMS, HOW MANY DOSSIERS ARE NOTIFICATED?

When a product is offered on the market in different flavours or packaging sizes, the procedure is unique, including all formats under one file, or individualized for each format. In any case, the different labels with which a product of specific essential composition is presented on the market must be presented.

All flavours or packaging sizes of the same product are considered a single step and a single fee and, if any format is added to a product already reported, it is considered a minor modification of the original.

However, products with the same trade name and composition that differ in the galenic form with which they are presented (tablets, capsules, drops, etc.), shall be considered as separate files. Therefore, each galenic form of a supplement will earn the fee corresponding to the new product and must be accompanied by the rest of the documentation necessary for the first placing on the Spanish market.

ANNEX I - NON-EXHAUSTIVE LIST OF APPLICABLE LEGISLATION

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

Regulation (EU) Nº 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers

Regulation (EC) Nº 1924/2006 of the european parliament and of the council of 20 December 2006 on nutrition and health claims made on foods

Regulation (EC) Nº 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods

Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods,

Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods

Regulation (EC) Nº 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives

Real Decreto 1487/2009, de 26 de septiembre, relativo a los complementos alimenticios

Real Decreto 1334/1999, de 31 de julio, por el que se aprueba la Norma general de etiquetado, presentación y publicidad de los productos alimenticios

Real Decreto 1808/1991, de 13 de diciembre, por el que se regulan las menciones o marcas que permiten identificar el lote al que pertenece un producto alimenticio

Principios generales de flexibilidad en la redacción de declaraciones de propiedades saludables

ANNEX II - MORE FREQUENT DEFICIENCIES IN THE FS FILES AND THEIR LABELS

In order to avoid the presentation of labels with common weaknesses, the following recommendations are made in relation to the deficiencies most frequently identified in the review of submitted FS files, to be taken into account alongside other mandatory requirements:

- The company (corporate name and address) that appears on the label, must correspond to the company that makes the notification of the product and that appears in the corresponding section of the notification form. In the event that these are not coincident, it would be necessary to send documentation clarifying the relationship between the two.

- Mandatory label details must appear in Spanish.

- The correct legal name IN SPANISH for this type of product is «COMPLEMENTO ALIMENTICIO» and it is therefore the one that should appear on the label of these products and not similar terms such as «food supplement» or «food supplement».

- The lot must be indicated on the label or package. Where the indication of the lot appears on the packaging of the product, confirmation of the inclusion of the lot should be provided as a guarantee that the FBO is aware of this obligation.

- Where the product incorporates copper in its composition, the significant amount of copper per recommended daily dose shall be expressed in micrograms (µg), as this is the correct unit according to Annex I to Directive 2002/46/EC.

- The indication of the date of minimum duration shall be preceded by one of the following formulas established for that purpose in Spanish: «Best before ...» where the date includes the indication of the day; or «Best before the end of.....» in other cases.

- The designation of the functional class to which an additive belongs, which must appear before the specific name of the additive or, if applicable, its E number in the list of ingredients, shall be in accordance with those in the Spanish version of Annex I to Reglamento (CE) Nº 1333/2008.

- Health claims should be made only for the nutrient, substance, food or category of food for which they have been authorised and not for the FS containing them.

- The use of claims referring to general and non-specific benefits relating to good health in general or to health-related well-being may only be labelled if they are accompanied by a specific health claim authorized and related to the same.