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 FOR SPECIFIC POPULATION GROUPS TO THE COMPETENT AUTHORITIES. Unofficial translation of the Spanish Guide.

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)

Content

INTRODUCTION

Regulation 609/2013 of the European Parliament and of the Council, of 12 June, related to food intended for infants and young children, food for special medical purposes and total diet replacement for weight control, establishes the general composition and information requirements for the following food categories:

- infant formulas and follow-on formulas,
- processed cereal-based foods and baby food,
- food for special medical purposes and
- total diet replacement for weight control.

Community legislation, and in Spain, specifically, Royal Decree 1412/2018, of 3 December, in order to facilitate effective control of these products, establishes the obligation for the food business operator (FBO) responsible for placing the products on the market to notify the competent authorities ("Comunicar" and "Comunicación" in Spanish legal terminology) some of them:

- Infant formulas.
- Follow-on formulas that contains other ingredients than those listed in Annex II of Delegated Regulation (EU) 2016/127 of the Commission, of 25 September 2015.
- Follow-on formulas made from protein hydrolysates can be notify voluntarily before 22 February 2021 and compulsorily after that date.

- Food for special medical purposes.
- Total diet replacement for weight control can be notified voluntarily before 27 October 2022 and compulsorily after that date.

The notification of the placing on the market of the indicated products 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 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) and therefore product safety.

The notified products can be consulted in the website that includes, among other products, food for specific groups 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 these products, 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.

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.

The responsible FBO that has head office in Spain must be registered in the Spanish General Sanitary Registry of Food Companies under the sector “ready to eat food, food for specific groups, food supplements and other ingredients and food products” (Key 26). Companies with head office in another Member State of the European Union do not require this company registration in Spain.

WHEN?

Same day or prior to placing on the market.

WHERE?

The authorities receiving notifications concerning 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:

- When the person responsible has head office in Spain, the notification shall be addressed to the competent body of the Autonomous Community where he resides.
- When the address of the FBO responsible is in another Member State of the European Union, the notification shall be addressed to AESAN.

You can see this distribution of powers graphically in the following table:

Origin of the Product	Person responsible for the marketing	Competent Authority
European Union (EU)	With head office and Nº RGSEAA in Spain	CCAA
	Companies from another Member States Of EU (no head office in Spain)	AESAN
Outside EU	With head office and Nº RGSEAA in Spain	CCAA
	Companies from another Member States Of EU (no head office in Spain)	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).
- Any other information that, in a motivated way, the competent authority considers necessary to establish the conformity of the product with the applicable regulations.

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 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.

In addition, in accordance with Regulation (EU) Nº 609/2013 of the European Parliament and of the Council, of June 12 2013, regarding food intended for infants and young children, food for special medical purposes and total diet replacement for weight control must comply with the general composition and information requirements of these food categories, and also with the specific requirements developed in the respective Delegated Regulations:

- Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding.
- Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes.
- Commission Delegated Regulation (EU) 2017/1798 of 2 June 2017 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for total diet replacement for weight control.

In food for specific groups, the VOLUNTARY INFORMATION that can appear on the label is very limited compared to other food groups. In the case of infant formulas and food for special medical purposes, nutritional and health claims are prohibited, in accordance with the 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 the case of total diet replacement for weight control, all nutritional and health claims are prohibited except the «added fibre» nutritional claim, which may be used when the dietary fibre content of the product is not less than 10 g.

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.

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. ADDITIONAL INFORMATION

The competent authorities may require the food business operator responsible for placing it on the market to submit any other information that the competent authority, in a motivated way, considers necessary to establish the conformity of the product with the applicable regulations.

ANNEX I - NON-EXHAUSTIVE LIST OF APPLICABLE LEGISLATION

Regulation (EU) Nº 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 Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009

Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding

Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes

Commission Delegated Regulation (EU) 2017/1798 of 2 June 2017 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for total diet replacement for weight control

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 1412/2018, de 3 de diciembre, por el que se regula el procedimiento de comunicación de puesta en el mercado de los alimentos para grupos específicos de población.

dispone que el operador de la empresa alimentaria que introduzca en el mercado los preparados para lactantes y preparados de continuación, alimentos para usos médicos especiales y sustitutivos de la dieta completa para control de peso

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