Report of the Scientific Committee of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) on warnings in the labelling of certain substances to be used in food supplements-5

Section of Food Safety and Nutrition
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Abstract

The Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) has been preparing recommendations for the authorisation of certain substances other than vitamins and minerals for use in the manufacture of food supplements with the aim of including these in the new Annex III of Royal Decree 1487/2009. In this respect, the Scientific Committee has issued up to four reports on the safety of different substances and maximum recommended quantities and various warnings to be included in the labelling.

In the different reports of the Scientific Committee, various drafts have been used in relation to the warnings on the use of medication and fibre-based supplements and the AECOSAN has recommended unifying and simplifying the drafting of the recommendations proposed by the Scientific Committee in their reports.

The Scientific Committee has concluded that the recommendation of the AECOSAN in relation to the warning "Avoid use together with medicines and other fibre-based food supplements" for Konjac glucomannan, guar gum, inulin and pectins, is adequate and covers the risks for which they have recommended warnings in their previous reports on each of these substances.

In addition, it is considered appropriate to include the warning "Must not be used by pregnant or nursing women, or by children and adolescents" on food supplements containing glucosamine sulfate or glucosamine hydrochloride.

Key words

Food supplements, fiber, Konjac glucomannan, guar gum, inulin, pectin, glucosamine.

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1. Introduction

The Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) has drawn up proposals for the authorisation of certain substances other than vitamins and minerals for use in the manufacture of food supplements and their corresponding maximum daily quantities for inclusion in a new Annex III of Royal Decree 1487/2009 (B.O.E, 2009). In this respect, the Scientific Committee has issued four reports to date with regard to the safety of various substances and maximum recommended quantities and on various warnings to be included in the labelling.

In the different reports of the Scientific Committee, various drafts have been used in relation to the warnings on the use of medication and fibre-based supplements. In the drafting of the text of the project of royal decree amending Royal Decree 1487/2009, of 26 September, on food supplements, which is intended to authorise a national list of substances which may be used in food supplements, the AECOSAN has recommended unifying and simplifying the drafting of the recommendations proposed by the Scientific Committee in their reports. It has also attempted to satisfy the concerns of the representatives of the sector consulted in the hearing Procedure and during the communication procedure established in Directive 2015/1535 (EU, 2015), in Regulation (EU) No 1169/2011 (EU, 2011) and in Regulation (EU) No 1925/2006 (EU, 2006).

Therefore, a single common warning is proposed for Konjac glucomannan, guar gum, inulin and pectins, although the method used to express the warnings recommended by the Scientific Committee in their respective reports varies from one substance to another.

In addition, in the text of the legal project, the AECOSAN recommends including warnings for glucosamine in line with the warning given in the data sheet of authorised medicines in Spain which contain this substance as the active ingredient, applying the precautionary principle.

Consequently, the AECOSAN has asked the Food Safety and Nutrition Section of the Scientific Committee the following questions:

1. If the drafting of the warning "Avoid use together with medicines and other fibre-based food supplements" proposed by the AECOSAN for Konjac glucomannan, guar gum, inulin and pectins, covers the risks for which the Scientific Committee of the AECOSAN recommended warnings in their reports on each of these substances.
2. It is considered appropriate to include the warning "Must not be used by pregnant or nursing women, or by children and adolescents" on food supplements containing glucosamine (sulfate or hydrochloride forms).

2. Warning on the use of Konjac glucomannan, guar gum, inulin and pectins together with medicines

In the "Report of the Scientific Committee of the Spanish Agency of Food Safety and Nutrition on conditions of use of certain substances other than vitamins, minerals and plants for use in food supplements-1" approved in 2012 (AECOSAN, 2012), the following warnings relating to the use of products containing Konjac glucomannan (*Amorphophallus konjac K. Koch*), guar gum, inulin or pectins together with medicines should be included on the labelling:

- For Konjac glucomannan, inulin or pectins, the following is indicated "Given that the fibre may

interact with some medicines, altering their efficiency, please seek medical advice if taken at the same time as other medicines".

- In the case of guar gum, "It must be mentioned that the product must not be taken together with medicines or fibre complements, to prevent the risk of loss of absorption of the pharmacological active ingredient".

3. Warning on the use of Konjac glucomannan, guar gum, inulin and pectins together with other fibre-based food supplements

The report of the Scientific Committee mentioned in the previous point recommends that the labelling of food supplements which contain Konjac glucomannan (*Amorphophallus konjac K. Koch*), guar gum, inulin or pectins should include the following warnings relating to their use together with other fibre-based food supplements:

- In the case of Konjac glucomannan, guar gum and the pectins specify "When taking this type of formula, other dietary fibre-based food supplements must be avoided".
- Whereas for Inulin, the following is recommended "When taking this type of supplement, other dietary fibre-based food supplements must be avoided".

4. Warning on the use of glucosamine by pregnant or nursing women or by children

The Scientific Committee does not include among the conclusions given in the first report on the conditions of use of certain substances other than vitamins, minerals and plants for use in food supplements, any warning on the labelling of these products if they contain glucosamine as an ingredient.

The technical data sheets for medicines authorised in Spain containing this substance as an active ingredient (AEMPS, 2017) specify a number of warnings with regard to the use of glucosamine by pregnant or nursing women or by children:

- It is not recommended for use by children or adolescents under the age of 18 years due to the absence of data on its safety and efficacy.
- Neither the safety nor the efficacy has been established in children and young people under the age of 18 years, and therefore it must not be administered to these patients.
- There is no adequate information on the use of glucosamine in pregnant women. The information available on studies in animals is inadequate. Glucosamine must not be used during pregnancy.
- There is no information available on the excretion of glucosamine through breast milk. Therefore, and due to the lack of information on safety for the newborn infant, the use of glucosamine while nursing is not recommended.

Conclusions of the Scientific Committee

The Scientific Committee has concluded that the recommendation of the AECOSAN in relation to the warning "Avoid use together with medicines and other fibre-based food supplements" for

Konjac glucomannan, guar gum, inulin and the pectins, is adequate and covers the risks for which they have recommended warnings in their previous reports on each of these substances.

In addition, it is considered appropriate to include the warning "Must not be used by pregnant or nursing women, or by children and adolescents" on food supplements containing glucosamine sulfate or glucosamine hydrochloride.

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