

Application for consultation to determine the status of a novel food, pursuant to Article 4(2) of the above Regulation

Extract from *Epimedium brevicornum* Maxim leaves

Recipient Member State: Italian Ministry of Health. Directorate-General for Hygiene, Food Safety and Nutrition.

Justification

Firstly, we have no knowledge of significant use of the extract from *Epimedium brevicornum* Maxim leaves in food, including food supplements.

It appears from our assessment of the dossier which you sent us that you have been unable to gather any proof of food use prior to 15 May 1997.

We would note that:

- as with any other substance, medicinal and other uses, whether in Europe or in non-member countries, are of no relevance to the food use of the extract in question;
- the presence on the European market of a food supplement which contains the extract in question, or notification of such a supplement - which is not the same as an authorisation - to an EU Member State does not indicate significant food use, unless a certificate has been issued by an authority competent in the area of novel foods explicitly stating that the extract should not be regarded as a novel food. (No such certificate has in fact been issued.)

Nevertheless, in order to obtain information on instances of significant use from the competent authorities of the other Member States, we undertook a brief consultation, which yielded the same findings.

We would therefore inform you that the extract from *Epimedium brevicornum* Maxim leaves should be regarded as a novel food within the meaning of Regulation (EU) No 2015/2283 and can, accordingly, only be placed on the EU market once prior authorisation within the meaning of that Regulation has been obtained.