

Letter dated:
26 July 2011

From:
Federal Service for Public Health, Safety of
the Food Chain and the Environment
(*Federale Overheidsdienst Volksgezondheid,
Veiligheid van de Voedselketen en Leefmilieu*)
Directorate-General for Animals, Plants and Food
Section for Food, Feed and Other Consumer Products
Victor Hortaplein 40, bus 10
B-1060 Brussels

To:
FUGEIA NV
Attn Olivier Lescroart
Gaston Geenslaan 1
B-3001 Heverlee

Subject: Wheat Bran Extract

Our ref.: 179.602/L460/ERS

CONTACT Eline Rademakers
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Dear Mr Lescroart,

With regard to your request for authorisation to introduce "Wheat Bran Extract" onto the market as a novel food ingredient, I would like to inform you of the following.

On 25 January 2010, you submitted to us, on behalf of Fugeia NV, an application to place "Wheat Bran Extract" on the market as a food ingredient pursuant to Article 4(1) of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients (hereinafter: "the Regulation").

The Belgian Health Council (*Hoge Gezondheidsraad*) examined the dossier and, in accordance with the procedure described in Article 6(2) of the Regulation, drew up an initial assessment report at its meeting on 3 November 2010. The Council has concluded that no additional assessment is required.

The European Commission passed on the initial assessment report to the Member States on 8 February 2011. According to Article 6(4) of the Regulation, the Member States then had 60 days within which to make comments or present a reasoned objection to the marketing of the product. No reasoned objections to the product's being placed on the market were submitted by the European Commission or the Member States.

On the basis of the initial assessment report and the fact that no reasoned objection to the marketing of the product was presented, I am able to inform you that the "Wheat Bran Extract" fulfils the criteria described in Article 3(1) of the Regulation, subject to the following conditions being met:

- the "Wheat Bran Extract" must meet the specifications and conditions of use set out in Annexes I and II to this letter;
- the "Wheat Bran Extract" may not be introduced onto the market as a food supplement or food supplement ingredient. Nor may it be added to infant formulae;
- given that the "Wheat Bran Extract" contains traces of gluten and ingredients derived from wheat protein which can cause allergic reactions or gluten intolerance, Directive 2003/89/EC (amending Directive 2000/13/EC), which was transposed by means of the Royal Decree of 13 February 2005, is applicable. Foods in which the "Wheat Bran Extract" is an ingredient should thus be labelled accordingly;
- the product must comply with all other applicable legislation.

The findings of the evaluation indicate that no studies were carried out on individuals with an impaired insulin metabolism, and that the "Wheat Bran Extract" is thus not intended for persons with an impaired insulin metabolism.

You have received individual comments from Member States concerning the placing of your product on the market. We would ask that you respond briefly to these comments, and that you send your response to all Member States and the European Commission.

In accordance with Article 4(2) of the Regulation, Fugeia NV may therefore introduce the "Wheat Bran Extract" onto the market under the conditions set out in this letter. A copy of this letter will be sent to the European Commission, which will forward it to all other Member States. The letter will also be posted on the official website of the European Commission on the page showing all novel foods which have been authorised.

Yours sincerely,

(signature)

Carl Berthot

Acting Head of Section