Food Standards Agency
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Andrew Cockburn
on behalf of
AJINOMOTO CO., INC., JAPAN
Wellness Business Development Department
15-1, Kyobashi
Chuo-ku
1-Choume
104-8315
Tokyo
Japan

e-mail: andrew_cockburn@btinternet.com

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Dear Andrew,

**REGARDING AUTHORISATION FOR EXTENSION OF USE OF DIHYDROCAPSIATE (DHC) FOR FOOD SUPPLEMENT USE**

I am writing to inform you of the outcome of your application made to the UK for the extension of use of Dihydrocapsiate (DHC) for food supplement use in accordance with Articles 4 and 6 of the Novel Food Regulation (EC) Regulation 258/97.

1. In May 2014, Ajinomoto Co. Inc. submitted an application to the UK Competent Authority to extend the uses of its synthetic Dihydrocapsiate (DHC) to include use in food supplements in accordance with Article 4 of Regulation (EC) 258/97.

2. In June 2014 the Food Standards Agency issued its initial assessment report, having obtained expert advice from the Advisory Committee on Novel Foods and Processes (ACNFP), the committee that advises the Agency on all novel food issues. This report concluded that the

Aviation House
125 Kingsway
London WC2B 6NH
T: 0207 276 8716
ruth.willis@foodstandards.gsi.gov.uk

application for extension of use of DHC meets the criteria for acceptance of a novel food, as defined in Article 3(1) of the Regulation.

3. The Commission forwarded the initial assessment report to all Member States on 20 November 2014. Within the 60 day period laid down in Article 6(4) of Regulation (EC) 258/97, no reasoned objections were presented by the Commission or the Member States.

4. Certain points of clarification were requested by Belgium, Hungary, Austria and Germany. These related to:

    a) Confirming that labelling would be included on the extended uses of the product indicating that the product is not intended for pre-school children aged 1.5 - 4.5 years.

    b) The suggestion of further restrictions for sensitive groups as a precaution and therefore labelling to indicate the product is ”not intended for pregnant or breastfeeding women or persons under the age of 18 years” be included.

    c) That the use level proposed by the applicant for Dihydrocapsiate (DHC) in 'drink mixes' should be 14.5 mg/kg rather than 15 mg/100 ml to be consistent with the original risk assessment. Moreover there was concern that the 'drink mixes' category in particular could include alcoholic beverages.

5. The Food Standards Agency has considered your responses which were submitted on 14 May 2015 which we have forwarded to the Belgian, Hungarian, Austrian and German authorities. These were:

    I. That you accept that, as a condition of authorisation, food supplements containing Dihydrocapsiate (DHC) will be labelled as “not intended for young children (1.5-4.5 years)”.

II. You consider it is unnecessary to apply a precautionary label that the product is not suitable for other vulnerable groups. This is because this is a substance naturally present in the human diet and has been shown to be of low toxicity across a range of endpoints and with large Margins of Safety. The EFSA opinion on Dihydrocapsiate (DHC) issued in June 2012 concluded that Dihydrocapsiate (DHC) is safe under the proposed uses and use levels in the original application. No warning labelling for these groups is provided under the current authorisation.

III. You advised that the category “Drink mixes” was assessed as part of the risk assessment for the original application by EFSA but was not included in the original EU authorisation. You wish this to be corrected in this extension of use. Following the views of Member States on the need for clarification, it was agreed that the original Drink Mixes category would now be referred to as “non-alcoholic powdered drink mixes”, and would be included in this authorisation with Dihydrocapsiate (DHC), to be added up to 14.5mg/kg which is equivalent to 1.45 mg/100ml

6. Therefore, on the basis of the initial assessment report, it is established that synthetic Dihydrocapsiate (DHC) complies with the criteria laid down in Article 3(1) of Regulation 258/97 when placed on the market in accordance with the following conditions:

   I. That the Dihydrocapsiate (DHC) meets the requirements laid down in Annex I of Commission Decision 2012/726/EU.

   II. That, as a condition of authorisation, food supplements containing synthetic Dihydrocapsiate (DHC) will be labelled as ‘not intended for young children (1.5-4.5 years).’

   III. Without prejudice to the provisions of Directive No 2002/46/EC relating to food supplements, in addition to what is presented in

Annex II of Commission Decision 2012/726/EU, the uses of Dihydrocapsiate can be extended to the following product groups:

| **Product category** | **Maximum use level of DHC** |
|---|---|
| Food Supplement | 3mg per single intake<br><br>Total maximum daily intake of 9 mg/person. |
| Non-alcoholic powdered drink mixes | 14.5mg/kg equivalent to 1.5 mg/100ml |

7. Ajinomoto Co. Inc. may therefore place Dihydrocapsiate (DHC) on the EU market in accordance with the conditions in this letter. This letter will be published on the Food Standards Agency website and a copy will be forwarded to the Commission for transmission to all other Member States and general publication.

Yours sincerely,

*[By E-mail]*

Ruth Willis
**Novel Foods Unit**