ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

OPINION ON AN APPLICATION UNDER THE NOVEL FOODS REGULATION FOR EXTENSION OF AUTHORISATION OF SYNTHETIC DIHYDROCAPSIATE FOR FOOD SUPPLEMENT USE

Applicant: **Ajinomoto Co. Inc.**

Responsible Person: **Andrew Cockburn**
EC Classification: **1.2**

Introduction

1. In August 2010, an application was submitted to the UK by the Japanese company Ajinomoto Co. Inc. for authorisation of synthetic dihydrocapsiate (DHC) as a novel ingredient to be added to a range of foods in the EU.

2. On 10 March 2011, based on the advice of this Committee, the UK issued a favourable initial opinion for this application.

3. In November 2011, the European Food Safety Authority (EFSA) was asked to provide an additional assessment of this novel ingredient as a result of objections raised by particular member states. In June 2012, EFSA issued an opinion concluding that DHC is safe under the proposed use conditions[1]. DHC was subsequently authorised in November 2012 (Commission Decision 2012/726/EU)[2].

4. Ajinomoto is now requesting to extend the uses of DHC to include use in food supplements. This application was submitted to the Food Standards Agency in May 2014.

5. The present application for authorisation of DHC was prepared pursuant to Commission Recommendation (97/618/EC) of 29 July 1997 concerning the scientific aspects and presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients. DHC has been classified as a pure chemical or simple mixture from non-GM sources where the source of the novel food has no history of food use in the EU (class 1.2). The requirements for a submission for this

[1] http://www.efsa.europa.eu/en/efsajournal/doc/2812.pdf

[2] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012D0726&from=EN

class are as below however, the applicant highlighted that there are no changes in the product specification or the production process and the only new data supplied for this application are those relating to anticipated intake and extent of use. The Committee therefore focussed its assessment of this application on anticipated intakes and extent of use, as this is the only new section of the dossier:

I	**Specification of the NF**	**X**
II	**Effect of the production process applied to the NF**	**X**
IV	*Effect of the genetic modification on the properties of the host organism*	**-**
V	*Genetic stability of the GMO*	**-**
VI	*Specificity of expression of novel genetic material*	**-**
VII	*Transfer of genetic material from GM microorganisms*	**-**

VIII	*Ability to survive in and colonise the human gut*	**-**
IX	**Anticipated intake/extent of use of the NF**	**X**
XI	**Nutritional information on the NF**	**X**
XII	**Microbiological information on the NF**	**-**
XIII	**Toxicological information on the NF**	**X**

IX. Anticipated intake/extent of use of the novel food

6. DHC has already been authorised for use in a number of foods such as baked goods, beverages, confectionery, cereals and desserts and other miscellaneous foods. The applicant produces the food ingredient for use by third party food manufacturers but does not itself manufacture foods containing DHC.

7. Estimates by EFSA showed that, when DHC is added to each of these foods at concentrations delivering 3 mg DHC/portion or serving, the mean daily intake of DHC would be 12 – 13 mg (8.1 mg/day for pre-school children) and the 97.5th percentile intake of adults and the elderly would be around 34 mg/day (18.5 mg/day for pre-school children). On a body weight basis, the highest intakes would be for pre-school children (mean: 0.6 mg/kg bw/day; 97.5th percentile: 1.3 mg/kg bw/day).

8. Extensive evaluation of DHC in genotoxicity and developmental studies in the previous application found no evidence of toxicity and the no-observed adverse effect level (NOAEL) from three subchronic oral toxicity studies in rats of up to 6 months duration was consistently at 300 mg DHC/kg bw/day. Placebo controlled bolus oral administration human studies with DHC of up to 12 mg DHC/volunteer for eight days or 9 mg DHC/volunteer for four weeks were well tolerated with no evidence of clinically significant findings.

9. The applicant draws attention to EFSA's recent opinion on DHC, which highlights that there is a sufficient margin of safety in relation to the NOAEL of

300 mg/kg bw/day, including for the highest estimated intake of 1.3 mg/kg bw/day for pre-school children.

10. In this application, the applicant intends to extend the currently approved uses, to include the marketing of DHC as a food supplement at doses up to 3mg, to be consumed up to three times a day, i.e. a total maximum daily intake of 9 mg/person. The applicant states that DHC-containing supplements are not intended for pre-school children[3].

11. The applicant has also recalculated intakes of DHC from its authorised use as a novel food ingredient, using more recent UK survey data. This has resulted in a small decrease in the potential intake of DHC from this source and the highest level has fallen from 1.3 mg/kg bw/day for pre-school children at the 97.5th percentile based on data from 1992-2001 to 1.1 mg/kg bw/day for the same age group in 2008-11.

12. The applicant states that adding 9 mg/day, from food supplements, to the potential intake from food ingredient use gives a highest maximum total intake in schoolchildren of 1.42 mg/kg bw/day at the 97.5th percentile (based on 1998 food consumption data) or 1.38 mg/kg bw/day (based on 2008-11 data). However, this scenario is unlikely to occur in reality as data from the UK NDNS indicate that schoolchildren are unlikely to consume non-nutrient food supplements, pre-school children are excluded from this application.

13. The applicant states that, even in the unlikely situation described above, the revised total daily intake estimate remains in the same range as that estimated in the original application for pre-school children (1.3 mg/kg bw/day), where the safety margin in relation to the NOAEL (more than 200-fold) was considered to be sufficient by EFSA. The applicant therefore concludes that an extension of use of DHC, to include food supplement use, should not raise any safety concerns for the target population.

***Discussion**: The Committee was content with the data provided by the applicant and did not have any concerns relating to extending the use of DHC to include food supplements. No additional data were requested.*

[3] The application dossier refers in several places to pre-school children being excluded "in accordance with Directive 2002/46/EC (2002) and Part E of Annex II of Regulation (EC) No 1333/2008". However, this appears to be a mis-reading of the relevant legislation:
(a) Directive 2002/46 deals with food supplements and requires products to carry a statement about storing them out of the reach of young children; it does not prohibit products being marketed for consumption by that age group;
(b) Regulation 1333/2008 controls the use of food additives and it lists the additives that may be used in supplements "excluding food supplements for infants and young children". This wording reflects the fact that all foods for infants and young children (including supplements) are treated separately in the legislation.

Labelling

14. The applicant highlighted that an appropriate and clear designation (name) representing dihydrocapsiate (DHC) or formulated products containing DHC will be displayed on the labelling of the product as such, or in the list of ingredients of foodstuffs containing it. Labelling of DHC-containing supplements will comply with Directive 2002/42/EC on food supplements.

Discussion: *The Committee noted that DHC-containing supplements are not intended by the applicant to be consumed by pre-school children and consequently, data relating to estimated intakes for pre-school children were not provided in the dossier. However, relevant existing legislation does not ensure adequate provisions to exclude pre-school children (see Footnote 3). The Committee therefore recommended that, as a condition of authorisation, food supplements containing DHC must be specifically labelled as not intended for young children (1.5-4.5years).*

CONCLUSION

The ACNFP has completed its assessment of this application to extend the use of DHC to food supplements and did not identify any significant safety concerns. The Committee was satisfied with the data provided by the applicant in the dossier and no further data were requested. The Committee recommended that, as a condition of authorisation, food supplements containing DHC must be specifically labelled as not intended for young children (1.5-4.5 years).

November 2014