

## SCIENTIFIC OPINION

### Enfamil<sup>®</sup> Premium and visual development

#### Scientific substantiation of a health claim related to Enfamil<sup>®</sup> Premium and visual development pursuant to Article 14 of Regulation (EC) No 1924/2006<sup>1</sup>

#### Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies

(Question No EFSA-Q-2008-689)

Adopted on 13 March 2009

#### PANEL MEMBERS

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#### SUMMARY

Following an application from Mead Johnson Nutritionals submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to Enfamil<sup>®</sup> Premium and visual development.

The scope of the application was proposed to fall under a health claim referring to children's development and health.

The food constituent which is the subjects of the health claim is Enfamil<sup>®</sup> Premium. DHA and ARA in Enfamil<sup>®</sup> Premium are derived from single cell oils. The absorption of DHA and ARA is well documented. The Panel considers that the food constituents DHA and ARA are sufficiently characterised.

The claimed effect is the contribution to the optimal visual development of infants and young children. The target population proposed by the applicant is infants and young children (from birth to three years of age). The Panel considers that a normal visual function is beneficial for infants' and children's development and health.

The applicant identified a total of 43 publications as being pertinent to the health claim. A total of 12 publications which report original data from randomised controlled trials (RCTs) on the effects of DHA supplementation (with or without ARA) on visual development in physiological conditions and in infants born at term and one pooled analysis including four of

<sup>1</sup> For citation purposes: Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from Mead Johnson Nutritionals on Enfamil<sup>®</sup> Premium and visual development. *The EFSA Journal* (2009) 1004, 1-8

the RCTs indicated above were considered as pertinent to substantiate the claimed effect. An additional RCT not included in the application also met these requirements.

All the studies presented by the applicant as pertinent to the health claim have been already evaluated by the Panel in a previous Opinion in relation to the effects of DHA and ARA supplementation on visual development in infants and young children (from birth to three years of age). No data has been presented showing an effect of any of the components of Enfamil® Premium on visual development in addition to that observed for DHA. The Opinion of the Panel on the effects of DHA and ARA supplementation on visual development in infants and young children applies to the present application.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the intake of infant and follow-on formula supplemented with DHA at levels around 0.3% of total fatty acids and visual function at 12 months in formula-fed infants born at term from birth up to 12 months and in breastfed infants after weaning up to 12 months. The Panel could have not reached this conclusion without considering the studies claimed by the applicant as proprietary.

The following wording reflects the scientific evidence: “DHA contributes to the visual development of infants”.

In order to bear the claim a formula should contain at least 0.3% of the total fatty acids as docosahexaenoic acid. Such amounts can be easily consumed as part of a balanced diet.

The target population is infants (formula-fed infants born at term from birth up to 12 months and breastfed infants after weaning up to 12 months).

**Key words:** Docosahexaenoic acid, arachidonic acid, visual development, visual function, visual acuity, visual evoked potential, infants

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## **BACKGROUND**

Regulation (EC) No 1924/2006<sup>2</sup> harmonises the provisions that relate to nutrition and health claims and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of that Regulation and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Articles 14 to 17 of that Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims.

According to Article 15 of that Regulation, an application for authorisation shall be submitted by the applicant to the national competent authority of a Member State, who will make the application and any supplementary information supplied by the applicant available to European Food Safety Authority (EFSA).

### **Steps taken by EFSA:**

- The application was received on 14/02/2008.
- The scope of the application was proposed to fall under a health claim referring to children's development and health.
- During the check for completeness<sup>3</sup> of the application, the applicant was requested to provide missing information on 21/03/2008 and on 23/09/2008.
- The applicant provided the missing information on 31/08/2008 and on 06/10/2008.
- The scientific evaluation procedure started on 15/10/2008.
- During the meeting on 13/03/2009, the NDA Panel, after having evaluated the overall data submitted, adopted an opinion on the scientific substantiation of a health claim related to Enfamil<sup>®</sup> Premium and visual development.

## **TERMS OF REFERENCE**

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16 of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: Enfamil<sup>®</sup> Premium and visual development.

## **EFSA DISCLAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of Enfamil<sup>®</sup> Premium, a positive assessment of its safety, nor a decision on whether Enfamil<sup>®</sup> Premium is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 17 of Regulation (EC) No 1924/2006.

<sup>2</sup> European Parliament and Council (2006). Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

<sup>3</sup> In accordance with EFSA "Scientific and Technical guidance for the Preparation and Presentation of the Application for Authorisation of a Health Claim"

## **ACKNOWLEDGEMENTS**

The European Food Safety Authority wishes to thank Carlo Agostoni and the members of the Working Group for the preparation of this opinion: Jean-Louis Bresson, Albert Flynn, Marina Heinonen, Hannu Korhonen, Ambroise Martin, Andreu Palou, Hildegard Przyrembel, Seppo Salminen, Sean (J.J.) Strain, Inge Tetens, Henk van den Berg, Hendrik van Loveren and Hans Verhagen.

## **1. Information provided by the applicant**

**Applicant's name and address:** Mead Johnson Nutritionals, 3 rue Joseph Monier-BP 325, 92506 Rueil-Malmaison Cedex, France.

The application includes a request for the protection of proprietary data.

### **1.1. Food/constituent as stated by the applicant**

Enfamil<sup>®</sup> Premium, follow-on formula containing docosahexaenoic acid (DHA) and arachidonic acid (ARA) at specific levels and ratio, and from specific sources.

### **1.2. Health relationship as claimed by the applicant**

Enfamil<sup>®</sup> Premium contains docosahexaenoic acid (DHA) and arachidonic acid (ARA) that are important constituents of brain and retinal tissues. Enfamil<sup>®</sup> Premium has been shown to have beneficial effect on visual development compared to a regular formula without DHA and ARA.

### **1.3. Wording of the health claim as proposed by the applicant**

Enfamil<sup>®</sup> Premium contributes to optimal visual development of infants.

### **1.4 Specific conditions of use as proposed by the applicant**

This claim is only applicable for Enfamil<sup>®</sup> Premium. The product should constitute the principal liquid element in a progressively diversified diet.

## **2. Assessment**

### **2.1. Characterisation of the food/constituent**

The food which is the subject of the health claim is Enfamil<sup>®</sup> Premium, a follow-on formula containing docosahexaenoic acid (DHA) and arachidonic acid (ARA) at a level of 17 mg DHA per 100 kcal of product (~0.3% of total fatty acids) and ARA/DHA ratio of ~ 2 for which complete specifications, manufacturing process, stability information and complete fatty acid spectra are provided. DHA and ARA are derived from single cell oils. DHA is derived from the alga *Cryptothecodinium cohnii* and ARA from the fungus *Mortierella alpina*.

DHA and ARA are well characterised fatty acids the absorption of which is well documented and can be quantified in foods by established methods. This evaluation will apply to DHA and ARA from all sources with appropriate bioavailability in the specified amounts.

The Panel considers that the food constituents DHA and ARA are sufficiently characterised.

### **2.2. Relevance of the claimed effect to human health**

The claimed effect is the contribution to the optimal visual development of infants and young children. The target population proposed by the applicant is infants and young children (from six months to three years of age).

The Panel considers that normal visual function is beneficial for infants' and children' development and health.

### 2.3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed and Scopus to identify randomised controlled trials (RCT) on the effects of formulae intended for infants and young children (from birth to 36 months) containing DHA and ARA on visual development (as primary or secondary outcome) using the search terms DHA, ARA, infant, visual development, visual acuity, visual, preterm, long-chain polyunsaturated fatty acids, weaning food, fatty acids, stereoacuity, visual evoked potential, Teller Card, omega 3, omega 6, and toddler milk. The snow ball method (search for additional references in the papers identified through the search) was used for hand searching.

The applicant identified a total 41 publications as being pertinent to the health claim (18 RCTs of which only 12 were presented as full-text, one observational study, one pooled analysis of RCT, three meta-analysis of RCTs, one systematic review, nine review publications, six guidelines/consensus opinions and one other publication). The applicant also included one unpublished human study and one animal study in the pertinent literature.

All the studies presented by the applicant as pertinent to the health claim have been already evaluated by the Panel in a previous Opinion in relation to the effects of DHA and ARA supplementation on visual development in infants and young children (from birth to three years of age). No data has been presented showing an effect of any of the components of Enfamil® Premium on visual development in addition to that observed for DHA. The Opinion of the Panel on the effects of DHA and ARA supplementation on visual development in infants and young children applies to the present application (EFSA, 2009).

The Panel concludes that a cause and effect relationship has been established between the intake of infant and follow-on formula supplemented with DHA at levels around 0.3% of total fatty acids and visual function at 12 months in formula-fed infants born at term from birth up to 12 months and in breastfed infants after weaning up to 12 months.

The Panel could have not reached this conclusion without considering the studies claimed by the applicant as proprietary.

### 2.4 Panel's comments on the proposed wording

Taking into account the scientific evidence presented, the Panel considers that the following wording reflects the scientific evidence:

“DHA contributes to the visual development of infants”

### 2.5 Conditions and restrictions of use

The Panel considers that, in order to bear the claim, a formula should contain at least 0.3% of the total fatty acids as docosahexaenoic acid. Such amounts can be easily consumed as part of a balanced diet. The target population is infants (formula-fed infants from birth up to 12 months and breastfed infants after weaning up to 12 months).

## CONCLUSIONS AND RECOMMENDATIONS

On the basis of the data presented, the Panel concludes that:

- The food constituents DHA and ARA are sufficiently characterised.
- The claimed effect is the contribution to the optimal visual development of infants and young children. The target population proposed by the applicant is infants and young

children (from birth to three years of age). Normal visual function is beneficial for infants' and children's development and health.

- A cause and effect relationship has been established between the intake of infant and follow-on formula supplemented with DHA and visual function at 12 months in formula-fed infants born at term from birth up to 12 months and in breastfed infants after weaning up to 12 months.
- The following wording reflects the scientific evidence: "DHA contributes to the visual development of infants".
- In order to bear the claim a formula should contain at least 0.3% of the total fatty acids as docosahexaenoic acid. Such amounts can be easily consumed as part of a balanced diet.
- The target population is infants (formula-fed infants born at term from birth up to 12 months and breastfed infants after weaning up to 12 months).

#### **DOCUMENTATION PROVIDED TO EFSA**

Health claim application on Enfamil® Premium and visual development pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No:0130c-FR). October 2008. Submitted by Mead Johnson Nutritionals.

#### **REFERENCES**

EFSA (European Food Safety Authority), 2009. Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from Mead Johnson Nutritionals on DHA and ARA and visual development. *The EFSA Journal* (2009) 941, 1-8.

#### **GLOSSARY / ABBREVIATIONS**

ARA	Arachidonic acid
DHA	Docosahexaenoic acid
RCTs	Randomised controlled trials