

## **DHA and ARA and visual development**

### **Scientific substantiation of a health claim related to docosahexaenoic acid (DHA) and arachidonic acid (ARA) 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-2008-211)

**Adopted on 22 January 2009**

#### **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 docosahexaenoic acid and arachidonic acid 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 constituents that are the subject of the health claim are docosahexaenoic acid (DHA) and arachidonic acid (ARA), which are well characterised fatty acids that can be quantified in foods by established methods. 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 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.

Of the 13 full publications of RCTs, three include long term observations on subjects supplemented in the first months of life, while one publication reports complementary observations on visual function, so that the results from nine original study designs are

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<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 DHA and ARA and visual development. *The EFSA Journal* (2009) 941, 1-3

available. Of these, six include term infant populations fed different formulas from birth through the first months of life up to 12 months at the maximum, while three included breastfed infants starting either a DHA plus ARA supplemented formula or DHA-enriched weaning foods at different time points (six weeks to six months) and continuing up to 12 months.

### ***RCTs in term infants with randomisation at birth***

Four of the RCTs presented found no effect of formula supplemented with either DHA or DHA and ARA on visual outcomes as compared to the unsupplemented formula. The doses of DHA and/or ARA used in three of these studies were significantly lower than those proposed by the applicant to obtain the claimed effect. The two other RCTs showed better results on visual outcomes through the first year of life in infants fed formulae supplemented with either DHA or DHA and ARA as compared to the unsupplemented formula group. In these two studies, the doses of DHA used were in the range of those proposed by the applicant to obtain the claimed effect and sample sizes were based on power calculations considering sweep visual evoked potential (VEP) acuity as primary outcome.

The Panel notes that none of the studies presented has shown a benefit of either DHA alone or DHA plus ARA on visual development as compared to the breast fed control group, that no studies have observed an additional benefit of DHA plus ARA supplementation over DHA alone on visual acuity in term infants, and that direct associations only between markers of DHA (but not ARA) status and visual outcomes have consistently been reported.

From the studies presented in term infants with randomisation at birth, the Panel considers that the consumption of infant formulae supplemented with DHA at around 0.36% of total fatty acids from birth up to 12 months is associated with better visual function in term infants as compared to the consumption of unsupplemented formulae, even if a dose-response relationship has not been directly tested and not all the studies performed at the recommended dose reach the same conclusion.

### ***RCTs in term infants with randomisation after weaning***

The three studies presented were conducted using doses of either DHA or DHA and ARA in the range proposed by the applicant to obtain the claimed effect, have power calculations performed considering sweep VEP acuity as primary outcome, find better visual acuity up to 12 months in infants fed supplemented formulae/weaning foods as compared to the unsupplemented group, and report direct associations between markers of DHA (but not ARA) status and visual outcomes.

One pooled analysis including data from four of the RCTs presented in the two sections above and including a total of 243 infants found a positive correlation between the duration of intake of either human milk or DHA and ARA via formulae (containing 0.36% DHA and 0.72% ARA) and better sweep VEP acuity at 52 weeks of age.

Taking into consideration both the studies with randomisation at birth and the studies with randomisation post-weaning, the Panel notes that supplementation with either DHA alone or with DHA plus ARA has shown no benefit on the visual development of term infants as compared to breast feeding. The Panel also notes that no studies investigating the effects of both DHA and DHA plus ARA supplementation have observed an additional benefit of DHA plus ARA supplementation over DHA alone on visual acuity in term infants, and that direct associations between markers of DHA (but not ARA) status and visual outcomes have been consistently reported. The Panel considers that a role of ARA on visual development of term infants cannot be established on the basis of the data presented.

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