EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the food chain

Information document

regarding issues raised in the Motion for a Resolution concerning the health claim

'DHA contributes to the normal visual development of infants up to 12 months of age'

Following the vote in the ENVI Committee on the 16 March 2011 the European Food Safety Authority (EFSA) has provided some additional information on scientific points of the Motion for a Resolution. This Information document aims to inform MEPs on issues raised therein.

- The Regulation on nutrition and health claims sets a clear procedure for the authorisation of health claims, involving the Commission, EFSA, stakeholders, the Member States and the European Parliament and the Council through their scrutiny. This procedure has been strictly followed.

- The European Food Safety Authority (EFSA), which is the EU independent scientific body, is responsible for assessing applications submitted by food business operators. EFSA evaluates claims on the basis of "*generally accepted scientific evidence*" and after a scientific assessment of the "*highest possible standard*" as required by the Regulation.

- EFSA has concluded that a cause and effect relationship has been established for the claim that is reflected by the wording *"Docosahexaenoic acid (DHA) contributes to the visual development of infants"*.

- The favourable EFSA assessment was based on studies made on DHA supplemented formulae. Therefore, it is shown scientifically that even DHA added in formulae has a health benefit for infants. Those studies are not confidential and their publication references are listed in the EFSA opinion.

- A number of points in the Motion for a Resolution cast doubts about the scientific justification for the claim and the degree of the scientific consensus. EFSA has provided additional information regarding those points by letter of 25 March 2011, which is attached to this Information document.

- The Standing Committee on the Food Chain and Animal Health delivered a favourable opinion to authorise the claim "*Docosahexaenoic acid (DHA) intake contributes to the normal visual development of infants up to 12 months of age*" under specified conditions of use as recommended by EFSA. When the claim is finally approved, Member States will have to enforce the relevant rules to avoid that it is misused through exaggerated messages to the consumer.

- The measure under scrutiny by the EP will not authorise the claim for use in infant formulae. The claim may be used in other food products (including follow-on formulae) for infants from 6 – 12 months.

- Indeed claims for infant formulae are very tightly controlled and are included in Annex IV of the relevant specific Directive (2006/141/EC). Any amendment of that Annex has to be done through current Comitology with scrutiny procedure. There has been no such request made for this specific claim for infant formulae.

For information:

- DHA (docosahexaenoic acid) is an omega-3 long chain polyunsaturated fatty acid.
- 'Infants' means children under the age of 12 months. Infant formulae are suitable for use from birth and follow-on formulae are suitable for use from 6 months of age onwards.
- It needs to be borne in mind that under current legislation concerning infant formulae, such products are required in any case to bear a compulsory statement about the superiority of breast-feeding.

European Food Safety Authority

DIRECTOR OF RISK ASSESSMENT

Parma, 25 MAR 2011
Ref. RM/JK/jj (2011) **out- 5647810**

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Subject: Your e-mail of 21 March 2011 in relation to a European Parliament motion for a resolution B7-0000/2011

Dear Mr. Poudelet,

We would like to provide you with some additional information on the scientific points of European Parliament motion to oppose a draft Commission Regulation related to the authorization of a claim on DHA intake contributes to the normal visual development of infants up to 12 months of age and in particular on points O, P, Q, S as referred to in your e-mail of 21 March 2011.

Point O: Cochrane Library in 2008 did not find that feeding term infants with milk formula enriched with DHA has a proven benefit regarding vision

We would like to point out that the Cochrane review (Simmer, et al 2008) was among the references submitted by the applicant. The Panel reviewed in its opinion all studies which assessed visual function and which were included in the Cochrane review individually. The Panel found consistent positive results on visual acuity when DHA was given at a concentration of about 0.3% of total fatty acids in formula fed to infants from birth up to 12 months and in formula fed to breastfed infants after weaning up to 12 months. However studies with lower DHA levels did not show any effect. This is why the Panel considered that in order to bear the claim, a formula should contain at least 0.3% of the total fatty acids as DHA. The Cochrane Review concluded that evidence for an effect of DHA on visual acuity was inconsistent when studies at various dose levels were considered but, that review did not consider separately a possible effect of DHA concentrations of 0.3% or higher.

Point P: Publication by Kennedy et al. (2010) on a ten-year follow-up of DHA supplementation in preterm infants found some adverse effects.
This publication was issued after the NDA Panel opinion of 2009. In addition the publication is not related to the claim on DHA and vision. We consider that the study by Kennedy et al 2010 had considerable weaknesses (e.g. very low number of subjects) and is not a reliable source to draw any scientific conclusion on the safety of DHA. A short analysis of the study is given in an annex to the letter. Please also note that there is another study by Forsyth et al. (2003)[1] on a follow up of a randomised controlled trial of DHA supplementation in term babies which reported that dietary supplementation with DHA during infancy is associated with lower blood pressure in later childhood.

Point Q and S: More research on the beneficial and harmful effects of DHA supplementation is needed and no clear scientific consensus on the effect DHA fortified formulae have on infants:
We would like to point out that DHA is a fatty acid found in breast milk. DHA in breast milk is either derived from the mother's diet, mother's conversion from ALA to DHA or maternal DHA stores. DHA is a major structural and functional fatty acid in the brain and retina and is readily incorporated into neural tissues during the brain growth spurt and throughout the first years of life. We are unaware of any factor in breast milk which is needed for DHA to exert its "optimal" effect. DHA levels in formula as proposed for the claim (≥ 0.3% of total fatty acids) are in the normal range of DHA content naturally present in mothers's milk (0.17 to 1% of total fatty acids).

As indicated under point P we consider that the study by Kennedy et al 2010 is not a reliable source to draw any scientific conclusion on the safety of DHA and therefore does not justify a need for additional research on the safety of DHA at the proposed intake levels.

Yours sincerely,

Riitta Maijala
Director of Risk Assessment

Cc: Ladislav Miko, Basil Mathioudakis, Robert Vanhoorde, Juliane Kleiner, Catherine Geslain-Lanéelle

Enclosure: Annex

[1] J S Forsyth, P Willatts, C Agostoni, J Bissenden, P Casaer, G Boehm (2003)Long chain polyunsaturated fatty acid supplementation in infant formula and blood pressure in later childhood: follow up of a randomised controlled trial. British Medical Journal, 326, 953

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ANNEX

Annex: Short analysis of the Kennedy et al. (2010) study on the 10-year follow up of a randomised trial of DHA supplementation in preterm infants

Only 107 subjects (out of 238 subjects in the intervention) completed the follow-up at 10 years (drop out rate >50%). There were no significant differences for any outcome measures between control and DHA supplemented groups for the whole cohort (boys and girls combined) but in the subgroup analysis including only girls (31 girls in the control and 25 girls in the DHA supplemented group) a marginally significant effect was seen for body weight ($p = 0.05$) (but not for body mass index) and systolic and diastolic blood pressure ($p= 0.04$ and 0.05 respectively). As the number of subjects which was followed up at 10 years was very low and probably too low for a subgroup analysis by sex, the findings maybe spurious. The authors of the study also noted themselves that a relatively high proportion of the girl subjects had already entered puberty and that they cannot exclude this as an explanation for the observed differences in stature and adiposity between supplemented and unsupplemented girls. It is also noted that when the blood pressure was adjusted for weight no significant difference was observed anymore.

Overall the considerable weaknesses of the follow-up study by Kennedy at al. (2010) greatly limit its value as a source of data to draw any scientific conclusion.

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