



**EHPM Comments on EFSA Opinions on DHA & Visual & Cognitive
Development of unborn child and breastfed infants
(EFSA Q – 2008 – 773 & EFSA Q – 2008 –675 published on April 15, 2009)
May 12, 2009**

On behalf of EHPM, we would like to submit comments on the opinions given by EFSA regarding the two opinions above, in accordance with article 16 of regulation 1924/2006.

Our comments are based on the information provided by EFSA in its opinions as we do not have knowledge of the specific details of these company-based applications.

These opinions concern DHA (docosahexaenoic acid; 22:6n-3) and the effect claimed is that “DHA supports cognitive development of the foetus (unborn child) and infant”. The proposed wording being “DHA is important for early development of the brain in the foetus (unborn child) and infant. Maternal DHA supply contributes to the child’s cognitive development.”

Our understanding of the above is that the claim relates to the role of DHA for the brain development of the foetus and not to the value of supplementation by DHA. We are therefore very surprised to see that EFSA opinion concludes that “the claimed effect is that maternal supplementation with DHA supports cognitive development of the unborn child and breastfed infant.” The EFSA opinion further states that “There is insufficient evidence to establish a cause and effect relationship between the consumption of supplementary DHA during pregnancy and lactation and cognitive/visual development in unborn children or breastfed infants”. We believe such conclusions seem to focus on the role of supplementation instead of the evaluating the role of DHA and therefore deviates from the scope of the claims submitted.

We are concerned that it would therefore not justify the prohibition of the use of such claim on the role of DHA in a general way as this would have an unacceptable impact on other similar claims based on generally accepted scientific evidence, including those similar claims submitted under article 13.1.

We would also strongly object to any undue emphasis given to nutritional need as a decisive factor in the validation of scientific substantiation of health claims as this is clearly not the basis foreseen by the Regulation or the terms of reference to EFSA notably for EFSA consultation on article 13.1 claims.

In addition, we note that there are elements in the EFSA opinion, as well as numerous generally available references and authoritative reviews¹ that support the role of DHA for the visual and cognitive development on unborn children. In our view,

¹ For example: Canadian Food Inspection Agency. Guide to Food Advertising and Labeling (2003) approved the claim “DHA, an omega-3 fatty acid, supports the normal development of the brain, eyes and nerves, eyes and nerves” [8.5.6]; See also chapter 7 of the WHO/FAO Expert Committee on Fats and Oils in Human Nutrition (1994); and chapter 1 & 2 (2. 12).



the previous opinion from EFSA regarding ALA and brain development (EFSA-Q-2008-666) which concluded that “alpha-linolenic acid contributes to brain development” was validated by scientific evidence, does support the present claim also as ALA is an established precursor of DHA.

Another factor of concern is that the approach taken by EFSA, contrary to what is required by the Regulation, does not seem to take into account all the existing available scientific evidence, which would support the recognition of a claim on the role of DHA for brain and visual development.

In particular, the EFSA panel discarded the consideration of all intervention studies where infants were fed enriched food, or that demonstrated the transfer of DHA from mother to fetus or infant via biological fluids, as they considered these as not relevant to the supplementation effect. As stated above, we believe this is a serious flaw in the approach taken by EFSA as the claim appears to be on the role of DHA and not on the value of supplementation.

We also have a serious question about the approach followed by the Panel, which, according to our analysis, appeared to be focused on getting proof of an improvement to cognitive or visual development between mother getting supplementation and those not getting any. However, we note again that the claim did not relate to the effect of supplementation but to the role of DHA. The purpose of supplementation is to complement the diet, therefore supplementation would contribute to the role played by DHA and not necessarily to an increase of such an effect.

We therefore call on the Commission not to adopt any prohibition on claims relating to DHA & brain and visual development of foetus before further clarification of these opinions is provided.

We thank you for taking our comments into consideration.

Best Regards

Peter van Doorn,
Chairman