



**Paper for information: Government Updates on Nutrition
Related Activities
EFSA**

Agenda Item: 9

Please see attached paper for information.

**Scientific activities of the EFSA Panel on
Dietetic Products, Nutrition and Allergies (NDA Panel)**

(submitted by Dr. Rodríguez Iglesias and Dr. Leng Heng, scientific secretariat of the NDA Panel)

- 1) On 5-6 July, EFSA held an inaugural plenary meeting of the new NDA Panel. Members, who were elected to serve a new three-year-mandate (2006-2009). At this plenary meeting, a statement was adopted concerning the addition of DHA-rich oil from micro algae to an extended range of foods. The European Commission requested EFSA to specify whether in the light of the information provided, the addition of DHA-rich oil to an extended range of foods would lead to intakes exceeding 1.5 g per day of DHA from micro algae. Detailed information is provided in the Annex.
- 2) In addition, the Panel adopted on 1st September by written procedure an Opinion related to the safety of noni juice (juice of the fruits of *Morinda citrifolia*). Details about this evaluation are also provided in the Annex.

Annex. Opinion and statement adopted by the NDA Panel at its last plenary meeting

Summary of Opinion related to the safety of noni juice (juice of the fruits of *Morinda citrifolia*)

(Full statement is available on EFSA Website:

http://www.efsa.europa.eu/en/science/nda/nda_opinions/nda_op_ej376_noni.html)

- 3) On the basis of the “Opinion on Tahitian Noni[®] juice” adopted by the Scientific Committee on Food (SCF) on 4 December 2002, the Commission authorised the use of “noni juice” (juice of the fruit of *Morinda citrifolia* L.) as a novel food ingredient to be used in pasteurised fruit drinks on 5 June 2003, under Regulation (EC) N° 258/97. On 20 June 2005, the Austrian Competent Authority informed the Commission of a case report that might be of concern with respect to the safety of noni juice. The Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH (AGES) upon request of the Austrian Competent Authority delivered an opinion on this case report and on two further recently published cases. As this new information might possibly have an impact on the opinion on the safety of noni juice and because of the Community interest in this matter, the European Commission has decided to seek the opinion of the European Food Safety Authority.
- 4) In response to a request by EFSA, the manufacturer provided additional information on noni juice regarding analysis for the presence of anthraquinones, updated data on consumption, information on reports of any adverse effects associated with the consumption, data on genotoxicity and cytotoxicity and a report on a study in humans.
- 5) The Panel agrees with the conclusions of the SCF regarding the studies on acute, subacute and subchronic toxicity as well as genotoxicity and allergenicity. From a toxicological point of view noni juice has been adequately tested and the studies evaluated by the SCF as well as the additional toxicological studies provided do not raise concern. The Panel considers the SCF opinion to be appropriate.
- 6) On the basis of the available toxicological information and against the background of the data provided on consumption of noni juice without the reporting of hepatotoxic effects, the Panel considers it unlikely that consumption of noni juice, at the observed levels of intake, induces adverse human liver effects. This would also apply to the anthraquinones potentially present in the commercially produced noni juice.
- 7) The Panel concluded that there is no convincing evidence for a causal relationship between the acute hepatitis observed in the case studies reported and the consumption of noni juice.

Extract from**the Statement of the NDA Panel on a request from the Commission related to the addition of DHA-rich oil from micro algae to an extended range of foods**

(Full statement is available on EFSA Website:

http://www.efsa.europa.eu/en/science/nda/nda_statements/nda_statement_dha_microalgae.html)

- 8) In response to an application under Article 4 of the Novel Foods Regulation (EC) N° 258/97 by the company Martek and following the initial assessment carried out by the Competent Authorities of the United Kingdom, the Commission decided to authorise DHA (docosahexaenoic acid)-rich oil¹ (from the micro alga *Schizochytrium sp.*) as an ingredient to foods, provided that the intake of DHA from micro algae would not exceed 200 mg per portion. This decision took into account comments and objections by the other Member States. The rationale was to ensure that through consumption of up to seven portions of food containing DHA from micro algae per day (1.4 g in total), a consumer would remain below 1.5 g per day. For that reason, only the following uses of DHA from micro algae were accepted: dairy products except milk-based drinks (maximum use level of DHA: 200 mg/100 g or for cheese products 600 mg/100 g); dairy analogues except drinks (200 mg/100 g or for analogues to cheese products 600 mg/100 g); spreadable fat and dressings (600 mg/100 g); breakfast cereals (500 mg/100 g); food supplements (200 mg per daily dose as recommended by the manufacturer); dietary foods for special medical purposes (maximum use level in accordance with the particular nutritional requirements of the persons for whom the products were intended); foods intended for use in energy-restricted diets for weight reduction (200 mg/meal replacement).
- 9) The company Nutrinova also placed on the market DHA (from the micro alga *Ulkenia sp.*) for the same uses following the simplified procedure (Article 5) of the Novel Foods Regulation (EC) N° 258/97.
- 10) On 4 November 2004, Nutrinova applied to the German Competent Authority (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) for the authorisation of additional uses for DHA-rich oil. Following the notification of the German initial assessment report of this application, the Member States presented their comments/objections and it emerged that views differed on this issue. Several Member States opposed the extension of use of this product. In particular, there were concerns that these additional uses may lead to consumption of more than 1.5 g per person per day of DHA from micro algae.
- 11) In view of the divergent opinions of the Member States and the Community interest in this matter, the European Commission has decided to seek the opinion of EFSA.

¹ Commission Decision 2003/427/EC. OJ L144, 12.6.2003, p.13.

- 12) During its 14th plenary meeting, the NDA Panel expressed the following conclusion:
- 13) The Panel considered data from Nutrinova, the German Competent Authority's initial assessment report of the application by Nutrinova, comments from Member States and data from Martek Biosciences Corporation (see below documentation provided to EFSA).
- 14) Estimated intake data, which were provided by only one of the two applicants (i.e. Nutrinova), were based on one European country only. These data do not allow a general conclusion to be drawn as regards the intake for the European population as a whole.
- 15) In the light of the information provided, the Panel was unable to draw a conclusion as to whether the intake of DHA from micro algae in the EU population would exceed or not 1.5 g-per person per day. Representative intake data for existing and proposed uses of DHA from micro algae would be required for such a conclusion.