

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

PAPER FOR INFORMATION

EU UPDATE

This paper provides Members with an update on novel food applications under regulation (EC) No 258/97 and other EU issues that are relevant to the work of the Committee.

Novel and GM Food applications:

1. The Standing Committee on the Food Chain and Animal Health, the regulatory committee made up of representatives of the member states' governments, met on 25 January and 14 February when two novel food applications were discussed:
 - (a) GA21 maize: The technical content of the Commission's proposal for authorisation of foods derived from this line of GM maize was discussed but no vote was taken. The proposal will be discussed again at a future meeting of the Standing Committee.
 - (b) Isomaltulose: The European Commission's proposal for authorisation of isomaltulose manufactured by Cerestar was adopted unanimously. The authorisation decision includes a requirement for products to be labelled to indicate that isomaltulose is a source of glucose and fructose. The ACNFP opinion on isomaltulose had also recommended the inclusion of a statement referring to the energy value of this ingredient and the rate of energy release. The Commission argued against special labelling requirements on the grounds that these issues are covered by existing legislation on nutrition labelling and general legislation on claims. The ACNFP had also proposed special post marketing surveillance to confirm that consumers understood the energy content of foods containing isomaltulose, which might be described as providing reduced sweetness and/or delayed energy release. The Commission opposed the inclusion of this as a condition of authorisation and there was limited support from other member states. However, it is open to individual member states to undertake this type of study if they wish.
2. The Commission Working Group on Novel Foods, a group that includes representatives of all EU novel food competent authorities (CAs), met on 4 March and reviewed the status of the current applications under the novel foods regulation, in particular the following:

(a) Chia seed, the meeting reviewed the applicant's response to objections raised by national CAs that had reviewed the ACNFP's initial assessment report. The application dossier was referred to the European Food Safety Authority (EFSA) as there were outstanding concerns about the absence of formal toxicity studies and about potential allergenicity.

(b) DAG-oil (diacylglycerol oil): the applicant gave a short presentation on the presence of trans fatty acids in this modified oil, in response to the following comments from the EFSA Panel on Dietetic products, Nutrition and Allergies:

"... in order for [the product] not to be nutritionally disadvantageous to consumers, the trans fatty acid (TFA) content should be reduced to the level in the conventional vegetable oils that the novel oil is intended to replace. Vegetable oils and liquid margarines have a low proportion of TFA, usually below 1%.

The applicant explained that the modified oil contains significantly lower levels of trans-fatty acids than the oils it is intended to replace, but it does not contain less than 1%. The Commission is seeking clarification from EFSA over the interpretation of this aspect of the Panel's opinion before a final decision on authorisation is taken.

(c) Isomaltulose: The Commission explained that national CAs who had commented on the German initial assessment report had raised objections to this application from Suedzucker. As these mirrored the concerns raised in relation to the earlier application from Cerestar for the same ingredient (see 1(b) above), it would be possible to address them through a similarly worded authorisation decision. A draft decision will therefore be presented to a future meeting of the Standing Committee.

3. The Commission Working Group on GM food and feed met on 28 February and discussed the application for authorisation of 1507 maize (see discussion paper ACNFP/71/8). EFSA's opinion on this application is currently undergoing a 30-day period of public comment and the Commission is obliged to make a proposal for an authorisation decision to the Standing Committee by early June 2005. This will be the first application to be decided under the GM food and feed regulation and the format of this decision was discussed.

European Food Safety Authority

4. EFSA has continued to hold further meetings of its scientific panels. In March, the Panel on Dietetic products, Nutrition and Allergy published its opinion on the application for use of betaine as a novel food ingredient. This application had attracted objections from CAs in a number of member states, including the UK, and the EFSA Panel concluded that the safety of betaine for use in food has not been established. The summary of the Panel's opinion is attached (Annex 1).
5. The published minutes of the GMO Panel's 15th meeting, held in December 2004, are attached at Annex 2. The EFSA Panel's draft guidance on risk assessment of GM micro-organisms and derived food and feed products is

expected to be published for comment in April-May 2005. As indicated in the minutes of the 15th meeting, the Panel is also beginning work on two further "self-tasking" topics:

- the use of animal feeding trials for the safety evaluation of whole GM food/feed. (This task will be extended to cover both GM and non-GM foods and will be conducted jointly with other EFSA Panels);
 - assessment of allergenicity of genetically modified foods.
6. On 16 March the Secretariat of the GMO Panel held a meeting with the national authorities involved in applications made under the GM food and feed regulation (regulation 1829/2003). The main topic for discussion was the management and operation of the IT systems through which information is passed between EFSA and the national authorities. EFSA also described its initial thinking on the way that national bodies, such as the ACNFP, may be able to assist in specific components of risk assessment. This will be developed further as EFSA establishes a general network of risk assessment bodies across the EU.

**Secretariat
March 2005**

Annexes attached:

Annex 1 – Summary of the EFSA Panel on Dietetic products, Nutrition and Allergy's opinion on betaine

Annex 2 – Minutes of the 15th plenary meeting of the Scientific Panel on Genetically Modified Organisms held on 8-9 December 2004

Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies
on a request from the Commission related to
an application concerning the use of betaine as a novel food in the EU
(Request No EFSA-Q-2004-090)

(adopted on 22 February 2005)

SUMMARY

This opinion refers to an application for the placing on the EU market of a novel food ingredient, betaine, intended for use in beverages, cereal products, confectionary and dairy products.

The Panel has addressed the main concerns raised by the Members States (MS) on the initial assessment report. In particular, the Panel has considered the available evidence on the safety of betaine from both animal and human studies. Based on these studies, a number of safety questions remain unresolved.

Animal studies showed treatment-related effects that were observed at all tested doses of betaine the biological or toxicological significance of which have not been satisfactorily clarified. Since the available studies do not allow the derivation of a no observed adverse effect level (NOAEL) for betaine and data on reproduction and developmental toxicity are lacking, an acceptable daily intake cannot be established.

The available data in human studies are insufficient to allow the Panel to rule out the safety concerns raised by the MS.

Therefore, it is concluded that the safety of betaine for the intended use as proposed by the applicant has not been established.

The full opinion is available at:
http://www.efsa.eu.int/science/nda/nda_opinions/850_en.html

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Minutes of the 15th plenary meeting of the Scientific Panel on Genetically Modified Organisms held on 8-9 December 2004.

Available at: http://www.efsa.eu.int/science/gmo/gmo_meetings/729_en.html

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