

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 following novel food applications were discussed at meetings of the Standing Committee on the Food Chain and Animal Health, the regulatory committee made up of representatives of the Member States' governments, in May and June:
 - Isomaltulose (Sudzucker): Member States unanimously agreed to authorise this product, which was almost identical to an earlier application for the same ingredient (produced by Cerestar), authorised in early 2005.
 - Betaine: Member States accepted the proposal from the Commission that this substance should not be authorised as a novel food ingredient. Members will recall that a number of safety issues were highlighted by the UK and other Member States, and EFSA agreed with these concerns. This rejection does not affect the continued use of betaine in dietary supplements, which have a history of consumption prior to 1997 and fall outside the scope of the novel foods regulation (EC)258/97.
 - Diacylglycerol oil: A vote on the Commission's draft authorisation for this product was postponed following concerns raised by Member States that the nutritional issues highlighted in the EFSA Opinion (See ACNFP/70/8) were not reflected in the authorisation. In particular, some MS consider that the presence of relatively high amounts of trans-fatty acids is nutritionally disadvantageous, and that the product therefore does not satisfy the criteria for acceptance of novel food. The Commission has suggested that the judgement should be based on the combined content of trans-fatty acids and saturated fatty acids but the EFSA Opinion is unclear on this point. The Commission advised that they would discuss this with EFSA and would redraft the authorisation in line with MS comments. An amended draft authorisation will be presented at a future meeting.
 - MON863 maize: A vote on authorisation of foods derived from this GM maize line was taken, but the necessary majority for reaching a decision was not reached. The Decision will now be referred to the Council of Ministers (see para 2).

2. The Commission is referring a number of applications to Council of Ministers, following the failure of the Standing Committee to reach a clear decision by the necessary majority. In this situation, standard EU decision-making procedures require the decision to be passed to the Council, which has three months to act starting from the date of the referral. These applications are:
 - GM maize GA21, for food use (novel food application)
 - GM maize MON 863, for food use (novel food application)
 - GM maize 1507 for food and animal feed use (GM food and feed application)
 - three phytosterol applications. These cover two outstanding food categories (rye bread and reduced fat sausages) following the authorisation of the addition of phytosterols to various dairy based products in 2004.
3. The Commission Working Group on Novel Foods, a forum that includes representatives of all EU novel food competent authorities, met on 10 June and reviewed the status of current applications under the novel food regulation. Members may wish to be aware of the following:
 - DHA Rich oil from microalgae. This is to be referred to EFSA by the Commission to review the safety issues related to over consumption.
 - Noni Juice A recent scientific paper by a group of Austrian researchers attributed the consumption of noni juice to a number of health concerns. The Commission accepted Austria's request that the publication together with additional unpublished data should be referred to EFSA for review

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4. EFSA has continued to hold further meetings of its scientific panels, and a number of relevant papers have been published.. Minutes of the meetings of the GMO Panel in January, March, April and June are attached (**Annex 1**). The Panel has also issued various scientific opinions (see ACNFP/73/6 and 7).
5. EFSA's NDA Panel¹ has published two novel food opinions: In its opinion on lycopene from *Blakeslea trispora* (**Annex 2**), the Panel has concluded that:
“[the lycopene product], for use as a novel food ingredient in foodstuffs leading to an additional intake of up to about 2 mg/day is not of concern from the safety point of view. However, this does not hold for the proposed levels of use of lycopene in foods that would give rise to an additional intake of 20 mg per day.”
6. In its opinion on ‘two scientific publications concerning aspects of serum levels of phytosterols’ (**Annex 3**), the NDA Panel has advised that the issues raised in these papers were taken fully into account when the safety of phytosterols was originally reviewed by the former Scientific Committee on Food.
7. The NDA Panel has also published an opinion on tolerable upper level of phosphorous (**Annex 4**).

¹ Panel on dietetic products, nutrition and allergies

8. The EFSA Scientific Committee, which oversees the work of the individual Panels and considers cross-cutting issues, has also recently published its opinion on “A generic approach to the safety assessment by EFSA of microorganisms used in food/feed and the production of food/feed additives” (see ACNFP/73/ 9).
9. EFSA has invited member states to nominate suitably qualified organisations to join a scientific network that will assist EFSA and allow optimum use of resources across the EU. Interested organisations must complete a questionnaire for the relevant national authorities (in the UK this is the Food Standards Agency), who will check that they meet the necessary criteria of competence and independence.
10. EFSA is continuing its relocation from Brussels to its permanent location in Parma, which should be completed in October 2005. Also, EFSA has invited applications for the post of Executive Director, following the announcement that the current postholder, Geoffrey Podger, will retire in November.

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September 2005

Annexes attached:

Annex 1: Minutes of EFSA GMO Panel meetings held in January – June 2005

Annex 2: NDA Panel Opinion on lycopene from *Blakeslea trispora*

Annex 3: NDA Panel Opinion on two scientific publications concerning aspects of serum levels of phytosterols

Annex 4: NDA Panel Opinion on the tolerable upper intake level of phosphorus

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Minutes of EFSA GMO Panel meetings held in January – June 2005.

These documents have been published on the EFSA website at:

http://www.efsa.eu.int/science/gmo/gmo_meetings/catindex_en.html

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NDA Panel Opinion on lycopene from *Blakeslea trispora*.

This document has been published on the EFSA website at:

http://www.efsa.eu.int/science/nda/nda_opinions/951/nda_op_ej212_lycopene_en2.pdf

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NDA Panel Opinion on two scientific publications concerning aspects of serum levels of phytosterols.

This document has been published on the EFSA website at:

http://www.efsa.eu.int/science/nda/nda_opinions/950/nda_op_ej211_phytosterol_en1.pdf

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NDA Panel Opinion on the tolerable upper intake level of phosphorus.

This document has been published on the EFSA website at:

http://www.efsa.eu.int/science/nda/nda_opinions/1098/nda_op_ej233_ulphosphorus_en1.pdf

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