

# **ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES**

## **DRAFT MINUTES OF THE EIGHTIETH MEETING HELD ON 17 JANUARY 2007**

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DRAFT/ACNFP/80Min

**DRAFT MINUTES OF THE EIGHTIETH MEETING OF THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES, HELD ON 17 JANUARY 2007 IN CONFERENCE ROOM 5, AVIATION HOUSE.**

**Present** Professor Mike Gasson – **Chairman**  
Ms Jill Brand  
Dr Paul Brantom  
Mr Neville Craddock  
Professor Harry Flint  
Professor Peter Lund  
Professor Alan Malcolm  
Professor Ian Rowland  
Dr Anthony Williams  
Professor John Warner

FSA Assessor Dr Clair Baynton

**Secretariat** Ms Alison Asquith – **Minutes**  
Mrs Alison Dyson  
Ms Azuka Aghadiuno  
Ms Shuhana Begum  
Dr David Jefferies  
Dr Chris Jones  
Dr Sandy Lawrie - **ACNFP Secretary**  
Mrs Kate May  
Ms Annie-Laure Robin  
Ms Nicola Walker

FSA Chief Scientist's Team Dr Julie Norman (Item 12)

*Members are required to declare any personal interest in matters under discussion. Where Members have a particularly close association with any item, the Chairman will limit their involvement in the discussion. In cases where an item is to be discussed in their absence, a Member may make a statement before leaving.*

## 1. Apologies and announcements

- 1.1 Apologies were received from Ruth Chadwick, Gary Foster, Stephen Holgate, Claire Mills and Peter Shewry and Apologies were also received from observers from FSA Scotland, Wales and Northern Ireland (Mrs Elspeth MacDonald, Mr Phil Morgan and Mr Gerry McCurdy)
- 1.2 The Chair welcomed Nicola Walker, who is working temporarily as a Scientific Officer in the Food Standards Agency's Novel Foods, Additives and Supplements Division.
- 1.3 The Chairman reminded Members of the need to announce any commercial interests in the business of the Committee, prior to the discussions on each item.
- 1.4 Clair Baynton apologised for the cancellation of the November meeting. Dr Baynton explained that due to an impending Judicial Review the Secretariat had been unable to prepare papers for the meeting .

## 2. Minutes of the seventy-eighth meeting DRAFT/ACNFP/79/Min

Members agreed that the minutes were a true record of the 79th meeting of the ACNFP held on Thursday 21 September.

## 3. Matters Arising ACNFP/80P/2 ACNFP/80/11

Prior to the discussion Neville Craddock notified the Committee that he had an indirect interest in this item as he was working with a company on a potential competitor product. The Committee agreed he should remain for the discussion of this item.

Members had considered this application by post in November 2006 and had highlighted concerns regarding the basis for the claim of equivalence. Members were asked to consider the additional information provided by the applicant on this point and to indicate whether it provided sufficient reassurance that the case for equivalence could be made.

Members were of the view that it was reasonable to compare the applicant's product with the dried mushroom product that is already on the market, although the application still did not contain sufficient compositional and biochemical information for them to conclude their evaluation. Members also sought further information regarding the presence of products on the market that were compositionally closer to the applicant's product. The Committee also asked whether the Secretariat had received a response from the Medicines and Healthcare products Regulatory Agency (MHRA) as to whether the proposed uses of the product fell within the scope of medicines legislation.

The Secretariat agreed to obtain further information on these points for discussion at the Committee's next meeting.

**4. Echium Oil** **ACNFP/80/1**

Members were asked to consider Croda Chemicals' response to the comments raised at the September meeting on this application for the approval of refined echium oil as a novel food ingredient.

The Committee accepted the applicant's responses concerning the estimated daily intake, labelling and HACCP but was concerned that protein profiling information was not provided. Members remained of the view that a better estimate could be made of the protein intake and that further analysis should be carried out. The committee also considered that criteria in the Novel Foods Regulations regarding nutritional disadvantage had not been addressed, as the applicant's comments about nutritional implications were couched in terms of health claims and did not address existing ingredients that might be displaced from the diet.

The Secretariat agreed to obtain further information from the applicant for discussion at the next meeting.

**5. Ice Structuring Protein from GM Yeast** **ACNFP/80/2**

Prior to the discussion of this item, Professor Ian Rowland notified the Committee that his research department is about to carry out some research for the applicant, but this is not related to the subject of this application. The Committee agreed this was an indirect interest and he was allowed to remain for the discussion of this item.

The Committee was asked to consider Unilever's response to the comments and questions raised at the September meeting. The Committee was content with the explanation provided by the applicant that the inactive glycosylated form of ISP protein has no function in the preparation and **that the novel ingredient undergoes minimal purification in order to keep its maximum functional activity. The Committee agreed that the applicant has demonstrated that** there were no secondary integration sites in the genome of the production strain and that the mechanism of integration does not lead to generation of any new open reading frames.

The Committee was still concerned about the potential for yeast proteins present in the preparation to induce allergic reactions in some sensitive individuals, in which case the novel ingredient should be labelled as derived from a yeast source. The Committee noted that this was a generic issue for all products derived from yeast.

The Committee also asked whether this novel food ingredient would need to be labelled as derived from a genetically modified (GM) source and the Secretariat agreed to check this with Agency's experts on GM labelling.

The Secretariat agreed to draft an opinion to be considered by the Committee prior to their next meeting.

**6. Glucosamine from *Aspergillus niger***

**ACNFP/80/3**

Prior to the discussion Professor Ian Rowland notified the Committee of a non personal indirect interest as his department has a research contract with a company which is now owned by the applicant. Neville Craddock notified the Committee of a personal interest as he has had contact, since September, with the applicant regarding a different version of glucosamine. The Committee agreed that both members should remain for the discussion of this item.

Members were invited to review information provided by the application in response to concerns raised at the September 2006 meeting regarding the possible presence of protein and the potential effect on individuals with diabetes.

The Committee was not content with the information regarding the presence of protein in the product, as it would be necessary to use alternative testing methods to confirm that the protein levels were insignificant.

Members remained unconvinced that the applicant had answered their concerns regarding the possible effect that the long-term consumption of the product may have in individuals with Type 2 diabetes. Members also noted that foods containing the ingredients would be attractive to older consumers who in demographic terms would be most likely to suffer from Type 2 Diabetes. The Committee considered that any risk to diabetics was difficult to manage through labelling as some diabetics are unaware they have the disease.

Concerning labelling, the Committee was of the view that the applicant should be encouraged to mention the fungal source of glucosamine when labelling the product. They considered the toxicological data were satisfactory.

The Secretariat agreed to draft an opinion reflecting the Committee's discussions on this application.

**7. Baobab fruit pulp**

**ACNFP/80/4**

Prior to the discussion of this item Neville Craddock notified the Committee that he had a non personal indirect interest as he previously drafted a report for the UN Commission on Trade and Development to look at the role of EU Novel Food Regulations in relation to traditional crops using Baobab as an

example. The Committee considered his interest and agreed he could remain in the meeting.

The Committee was asked to consider the application for Baobab Fruit Pulp. The applicant has submitted a full novel food application for the pulp of this fruit, which is a traditional food that is consumed widely throughout Africa.

The Committee accepted the view of the applicant that this was a traditional foodstuff in Africa with evidence of safe consumption and, on this basis, the application could proceed without the provision of data from conventional toxicology tests.

Members considered that the information provided on the presence of Ochratoxin A, a mycotoxin commonly associated with cereals, was of limited value. Given that the product may contain low levels of yeast and moulds, Members requested reassurance that mycotoxins which are commonly associated with dried fruit (eg Aflatoxins) are not present in the in the baobab fruit products.

The applicant had indicated that Baobab is not farmed but is a traditional crop, harvested in the wild. Members requested detailed information regarding the harvesting, storage and transport procedures that would be employed. In particular members sought more information in relation to the quality of the fruit as a result of early or late harvesting, and what would happen to damaged fruit.

The Secretariat agreed to contact the applicant and obtain the necessary information for the next meeting of the committee.

## **8. Synthetic Lycopene**

**ACNFP/80/5**

The Committee was asked to consider the positive initial assessment report prepared by the Dutch Competent Authority on a synthetic lycopene manufactured by BASF. This paper had only been circulated shortly before this meeting and the preliminary comments made by the Committee was as described below.

The Committee noted that the Dutch opinion referred to the Joint FAO/WHO Expert Committee on Food Additives (JECFA) setting an acceptable daily intake (ADI) of 0-0.5 mg/kg body weight for synthetic lycopene (as a food colour) in June 2006. This value was 3 to 4 times lower than the estimated intake of this proposed novel food ingredient.

The Committee noted that the applicant has specified that the pure synthetic lycopene contains 6-9% related compounds include *cis*-isomers, rhodopin, acetyl-rhodopin. However, the test material used in the toxicological studies only contains approximately 2% of these related compounds. The Committee therefore requested an explanation for this discrepancy.

The Secretariat invited the Committee to submit any further comments in writing for inclusion in the UK's response to the Dutch opinion.

**9. Phytosterols from Lipofoods**

**ACNFP/80P/1  
ACNFP80/6**

The Food Standards Agency received a request for an opinion on substantial equivalence of phytosterols produced by Lipofoods, compared with phytosterols currently marketed by ADM. The Committee had considered this request by postal consultation in November 2006. Members were content that these products could be considered substantially equivalent and did not request any further information. The Committee was invited to consider the text of a draft opinion before it is issued for public comment.

The Committee was content with the text of the draft opinion.

**10. Astaxanthin rich oleoresin from *Haematococcus pluvialis* algae**

**ACNFP80/7**

The Committee was invited to consider the text of the draft opinion on substantial equivalence of astaxanthin-rich extract before it is issued for public comment. The ingredient was considered by the Committee in September 2006. It indicated it was generally satisfied with the applicant's response but noted that there appeared to be no routine scheme in place for the screening of cyanobacterial toxins. The Committee indicated that the applicant should ensure that such testing is carried out periodically to confirm the effectiveness of production controls.

The Committee was content with the text of the draft opinion.

**11. Effects of GM Soya on newborn rats**

**ACNFP80/8**

The Committee was invited to reconsider their statement, made in November 2005, on research conducted by a Russian research team who had reported high levels of mortality in newborn rats fed with flour from GM (herbicide-resistant) soya beans. At the time the Committee was unable to draw any conclusions from this research as experimental conditions and results were not available in sufficient detail and there were several possible explanations for the findings. The Committee agreed to reconsider the study if further information became available or if a fuller report was published in the scientific literature.

The researcher, Dr Irina Ermakova, had now replied to the Committee by providing a list of additional publications. Dr Ermakova had also indicated that a paper containing information on pathological changes in the GM-soya fed rats was "in press".

The Committee noted the reply from Dr Ermakova and the associated publications. The Committee advised that their original statement should remain as it still reflected their views. Members asked to see the paper on pathological changes once the peer-reviewed paper was published.

**12 Feedback from the Annual meeting of advisory committee chairs**  
**ACNFP/80/9**

The Committee was asked to consider a proposal to set up a new overarching scientific committee which would be comprised of the existing chairs plus additional scientists. This proposal had initially been considered by the chairs of the Agency's various advisory committees when they met in November 2006. The proposal was due to be discussed by the Agency Board in February. Each of the existing chairs had been formally asked for their views. The Committee agreed with the general principal to establish the Committee and was content with its potential functions. On a separate point arising from the chairs' meeting, it was suggested that the work of advisory committee members' could be formally acknowledged by writing to the Heads of the relevant academic institutions.

**13. Items for Information**

**13.1 EU update**

The Secretariat will be consulting the Committee by post on an EFSA consultation on the use of feeding trials in the evaluation of GM food and feed products.

**13.2 Recruitment of new consumer representative.**

A letter to the successful applicant was due to be sent out shortly

**14 Other Business**

The Committee was advised, following recent press reports, that products derived from cloned animals should be treated as a Novel Food, and therefore need to be authorised before they can be marketed. The European Commission had agreed that this was the case and the issue of cloned animals and their offspring was due to be referred to a future meeting of the Standing Committee on the Food Chain and Animal Health.

**14. Date of next meeting**

The next meeting is scheduled for **22 March 2007**, in Aviation House.