ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

MINUTES OF THE ONE HUNDRED AND TWENTY SECOND MEETING HELD ON 18 NOVEMBER 2015

ACNFP Secretariat
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These Minutes are subject to confirmation by the Committee at its next meeting.
MINUTES OF THE HUNDRED AND TWENTY SECOND MEETING OF THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES, HELD ON 18 NOVEMBER 2015 IN CONFERENCE ROOM 4, AVIATION HOUSE.

Present
Professor Peter Gregory – Chairman
Professor Michael Bushell
Dr Susan Duthie
Professor Harry McArdle
Professor John Mathers
Dr Rohini Manuel
Professor Peter Meyer
Professor Clare Mills
Professor Chris Ritson

Apologies
Mr Simon Flanagan
Ms Claire Nicholson
Dr Camilla Pease

Secretariat
Alison Asquith – Minutes
Dr David Jefferies (Item 4)
Dr Stephen Johnson – ACNFP Secretary
Dr Cath Mulholland
Firth Piracha
Ruth Willis

Observer

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**

Three members had sent apologies for non-attendance and had provided comments for the meeting.

The Chair congratulated Susan Duthie on her recent promotion to Professor.

Apologies were received from observers from FSA offices in Scotland, Wales and Northern Ireland.

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. Professor Harry McArdle announced he had become a member of European Food Safety Authority’s Panel on Dietetic Products, Nutrition and Allergies (NDA).

2. **Minutes of the 121st meeting**

The Committee adopted the minutes of the 121th meeting subject to amendments.

3. **Matters Arising**

- Hoodia parviflora – (Item 10: 16 September meeting) UK sent an objection to the European Commission (EC) following concerns from ACNFP members. The applicant is considering its response.

- Anatabine – (Item 8: 16 September meeting) In the UK Anatabine is regarded as a medicine by MHRA. We forwarded the Committee’s comments to the EC, agreeing with the negative opinion of the Netherlands. The application has been withdrawn.

- 1-MNA (Item 4: 16 September meeting) – The Secretariat is working with the Committee to finalise the opinion.

- Oligonol (Item 5: 16 September meeting) - The applicant is generating the additional allergy information required and this is expected to come back to the next meeting.

- UV treated mushrooms (postal consultation in November 2015) – Following the postal consultation the Committee agreed with the favourable Irish assessment subject to appropriate labelling. Our comments have been forwarded to the EC

- Chia seeds 2nd extension of use (Chia Love)(Item 8: April 2015) – UK sent comments about compositional changes to fatty acids and sought 3 samples of fatty acid data. The application has been authorised.
• Hydroxytyrosol – (Item 9: April 2015). The UK sent objections to the EC as there was insufficient information provided on the chemical reactions in the product during cooking, with concerns about storage and that it may be nutritionally disadvantageous if added to supplement inferior oil instead of a more expensive oil. We have been sent the applicant’s response and have maintained our objections. The application is going to EFSA for a risk assessment.

• Phosphotydylserine (postal consultation in Nov 2015) - The Committee made comments on labelling and sustainability of the fish. The Committee’s advice that its comments have been satisfactorily addressed by the applicant has been forwarded to the EC.

• Lactitol (Item 3 from July teleconference) – The Committee’s advice that its comments on the NOAEL values, labelling and the benefits of consuming Lactitol have been satisfactorily addressed by the applicant have been forwarded to the EC.

4. Cycloastragenol  

ACNFP/122/1

The Committee considered the response from the applicant following its review of cycloastragenol as a novel food at its April and June 2014, and September 2015 meetings.

The proposed mode of action of the novel ingredient is to stimulate telomerase which increases the length of telomeres. This has the theoretical potential to increase lifespan and is therefore of interest to the pharmaceutical industry. The Committee again expressed its concerns that lengthening telomeres may create a greater cancer risk and was also concerned that the mechanism of lengthening telomeres may have unintended consequences. The Committee was informed of a study by Julin et al\(^1\) which associated longer telomeres with an increased risk of prostate cancer. The Committee was also informed of a study which resulted in tumours developing in the liver in treated animals, though the study was too small to draw conclusions.\(^2\)

The Committee considered it was difficult to assess the safety of the novel food as the methods of assessment did not measure the length of telomeres.

The Committee considered there was an evidence gap as mouse studies could not be used to demonstrate the effects of telomere lengthening in humans. Mouse telomeres were much longer than those in humans and maintained their length over time, whereas human telomeres reduce in length over time due to cell division.

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The Committee acknowledged that the author of the expert opinion on cycloastragenol provided by the applicant was an expert in this field. The Committee also noted that the expert has been involved with companies producing products to lengthen telomeres over a number of years.

The Committee reiterated its previous view that it was not aware of any hazard characterisation test for telomere modification and the applicant has not been able to provide any additional data to confirm the safety of cycloastragenol in relation to telomerase activation.

In response to the applicant’s information that cycloastragenol had GRAS (Generally Recognised as Safe) status in the US, the Committee was informed that this was for use as a medicinal food under the supervision of a physician for a particular medical condition. This use differs from the use of cycloastragenol in the current application for authorisation under the Novel Foods Regulation (EC) 258/97.

The Committee agreed that the additional information provided by the applicant did not change the Committee’s opinion that cycloastragenol should not be authorised as a novel food, and that, a negative opinion should be drafted.

The applicant had requested changes to the minutes of the September meeting as the applicant considered some of the information on cycloastragenol was incorrect. The Committee was firmly of the view that the minutes must reflect the actual discussion in the meeting and it would only consider amending the minutes if there were factual inaccuracies, or the reports of the discussions were incorrect. It did not consider either of these criteria was met so it could not agree to the changes to the minutes suggested by the applicant.

*The Secretariat to communicate the views of the Committee to the applicant and draft a negative opinion for cycloastragenol unless the application is withdrawn*

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5. **DHA-rich algal oil**

The Committee was asked whether it agreed that substantial equivalence had been established between DHA-rich algal oil produced by Daesang Corp and DHA oil currently marketed by Martek.

The Committee considered that whilst the micro-organisms were similar to those used to produce the authorized DHA oil currently marketed, the metabolic profile differed was reflected in the different fatty acid composition profile. The oil could, therefore, have been produced by a different process to Martek’s DHA oil. The Committee was not making a judgement about the safety of the product, they simply concluded that the DHA-rich algal oil produced by Daesang Corp was not substantially equivalent to that currently on the market.

*Action: the Secretariat to notify the applicant that substantial equivalence had not been met.*
6. **Chia Seeds (Crescendo Organics)**  

The Committee was asked whether it agreed that substantial equivalence had been established between chia seeds produced by Crescendo Organics and Natural Products and chia seeds currently marketed by The Chia Company.

The Committee was informed that a public consultation on this application had taken place and no comments had been received by the Secretariat.

The Committee noted the data for chia seeds were within the range of The Chia Company’s data. It requested further information on the table separator used in the seeds production, in particular it sought further information on which colour the separator selects for and whether this results in significant waste from rejected chia seeds.

The Committee noted the carbohydrate values differed from The Chia Company’s chia seeds and the sodium and iron values were high, although all data was within the range of values for The Chia Company’s seeds.

The Committee agreed that Crescendo Organic’s chia seeds were substantially equivalent to chia seeds currently marketed by The Chia Company.

*Action: The Secretariat to draft an opinion and clear by Chair’s action*

7. **Chia Seeds (Terrafertil)**  

The Committee was asked whether it agreed that substantial equivalence had been established between chia seeds produced by Terrafertil and chia seeds currently marketed by The Chia Company.

The Committee was informed that the public was currently being consulted on the chia seed application and it would be notified of the public’s response.

The Committee agreed that Terrafertil’s chia seeds were substantially equivalent to chia seeds currently marketed by The Chia Company.

The Committee noted the data showed that mycotoxins are present. It supported the applicant’s proposals for vigilance over storage conditions on all consignments.

*Action: The Secretariat to consult on the draft opinion and clear by Chair’s action.*

8. **Di Calcium Malate (DCM)**  

The Committee reviewed the favourable initial opinion of the Irish Competent Authority (CA) on an application for the authorisation of a new source of calcium, Di Calcium Malate (DCM) as a novel food.

The Committee noted the application was to be referred to EFSA for review as this is required under Directive 2002/46/EC and Regulation (EC) No 1995/2006 before a new
source of minerals and/or vitamins can be added to the list of permitted minerals and vitamins.

The Committee queried the data for the microbiological specifications for DCM in the application as the text in the body of the application differed from the certificate of analysis by a factor of 10.

The Committee considered the assertion that calcium in the final product had better absorption rates was not supported by the data. The Committee was also concerned that the characterisation of the novel ingredient was insufficient. The structure of the new ingredient was not fully verified and the Committee considered an Infra-Red Spectrum of the structure should be provided. The Committee noted the production method could result in a mixture and the steps taken to ensure the composition of the product meets the specification were unclear. The Committee questioned the stability of the product in acidic foods.

The committee considered that to avoid sodium hydroxide absorbing water from the air and spoiling the shelf life of the novel ingredient the applicant should provide good instructions on storage.

*Action: The Committee’s advice will form the basis for the UK’s formal response to the European Commission.*

9. **Betaine**

The Committee reviewed a favourable initial opinion of the Finnish Competent Authority on an application for the authorisation of Betaine as a novel ingredient.

Betaine is manufactured as a by-product from the sugar refining of sugar beets. The applicant is seeking to place Betaine on the market in foods intended particularly for sports people and other people engaged in muscular activities to meet the expenditure of energy during intense muscular effort.

The Committee commented that the application was well produced. The animal data showed slight bleeding in some subjects at 4 times the intended dose. The Committee commented that there was a small margin between the proposed dose and the dose at which adverse effects were noted in the toxicological studies. In a human study the lipids showed slight changes at 6g, this was considered acceptable.

The Committee agreed with the favourable initial opinion of the Finnish CA.

*Action: The Committee’s advice will form the basis for the UK’s formal response to the European Commission.*

10. **Open Meeting**

The Committee considered an amended agenda and more detailed arrangements for the Open Meeting scheduled to take place on 4 February 2016.
The Committee agreed the draft agenda, more detailed arrangements for the meeting and a timeline for the preparation of the meeting.

*The Secretariat will finalise the open meeting arrangements for the February meeting*

11. **Health Claims**

The Committee reviewed a workshop it had held on health claims, classification of medicines and the associated borderline issues which was held in July 2015.

The Committee was concerned the overlap between novel foods and health claims was increasing. It considered it may be useful to give a paper to the FSA’s General Advisory Committee on Science and to the Department of Health, EFSA and the European Commission. It was particularly concerned about the possibility of substituting foods with known nutritional benefits with foods containing no or less nutritional benefits because of health claims. To avoid this scenario the Committee considered the nutritional benefits of consuming foods should be highlighted when commenting on applications and opinions should flag up foods which had no nutritional benefits.

12. **Items for Information**

12.1 **EU Update**

The Committee was given an oral update on the progress of the revised EU Novel Food Regulations and an oral update on the authorisation of particular novel foods.

12.2 **Commission Proposal to amend legislation on the authorization of GM food and feed**

The Committee was given an oral update on the Commission Proposal on GMOs and an associated European Scrutiny Debate which took place in the House of Commons.

12.3 **Scientific Advisory Committees Update**

This is a routine update paper which summarises the work of other scientific advisory committees sponsored by the Food Standards Agency or whose remit is linked to the ACNFP’s.

12.4 **EFSA Guidance Document on the Agronomic and Phenotypic Characterisation of Genetically Modified Plants:**

12.5 **EFSA Guidance Document for the Renewal of Authorisations of Genetically Modified Plants.**

The Committee was invited to note two guidance documents from the EFSA GMO Panel.
13. **Any other business**

The Secretariat informed the Committee that it would arrange a date for a teleconference in mid January.

14. **Date of next meeting**

The next meeting was scheduled for the afternoon of Wednesday 3 February 2016 in Aviation House.