ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

MINUTES OF THE ONE HUNDRED AND TWENTY SEVENTH MEETING HELD ON 9 FEBRUARY 2017

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MINUTES OF THE HUNDRED AND TWENTY SEVENTH MEETING OF THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES, HELD ON 9 FEBRUARY 2017 IN CONFERENCE ROOM 4, AVIATION HOUSE.

Present	Professor Peter Gregory – **Chairman** Dr Camilla Alexander-White Dr Anton Alldrick Professor Michael Bushell Professor Susan Duthie Dr Rohini Manuel Professor John Mathers Professor Harry McArdle Mrs Rebecca McKenzie Ms Claire Nicholson Professor Christopher Ritson Dr Lesley Stanley
Apologies	Dr Hamid Ghoddusi Mrs Nichola Lund Professor Clare Mills
Secretariat	Alison Asquith – **Minutes** Ruth Willis - **ACNFP Secretary** Dr David Jefferies Firth Piracha Sabrina Roberts Dr Jane Ince - (Item 11)

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 sent apologies for non-attendance, comments were received from two members.

The Chair congratulated Dr Rohini Manuel on her recent appointment to the Advisory Committee for the Advisory Committee on the Microbiological Safety of Food (ACMSF), a scientific advisory committee sponsored by the Food Standards Agency.

Apologies were received from observers from the FSA offices in Wales and Northern Ireland and Food Standards Scotland.

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.

2. Minutes of the 126th Meeting DRAFT/ACNFP/126/Min

The Committee agreed that subject to amendments the minutes were a true record of the 126th meeting of the ACNFP held on Wednesday 14 September 2016 and the November telecom.

3. Matters Arising

Calanus Oil (Item 3 September meeting). The opinion has been forwarded to the Commission.

2'-Fucosyllactose (Item 3, September meeting). The response has been sent to the European Commission informing them that our earlier comments have been addressed. These concerns were about the distinction between lactose intolerance and milk protein allergy in the applicants risk management strategy.

Xylo-Oligosaccharide (XOS) (Item 5, September meeting). This was a 60 day consultation on the Hungarian CA opinion. The Committee had raised a number of comments which have been forwarded to the European Commission in the UK's response.

Pyrroloquinoline Quinone Disodium Salt (PQQ) (Item 6, September meeting). This was a 60 day consultation on the Irish CA opinion. The Committee agreed with the Irish opinion that the novel ingredient should be assessed by EFSA and this view was communicated to the Commission.

MemreePlus – Extension of Use (Item 7 September meeting). This was a 60 day consultation on the Finnish CA opinion. Comments from the Committee about the intake levels of the target market and the toxicological testing were forwarded to the Commission.

Chia Seeds (Selva Organic Foods Ltd) (Item 8, September meeting). The Committee's comments about the high level of sodium and calcium and low level of iron had been passed to the applicant, who had been asked to confirm the agronomic growth conditions of their chia seeds. To date the applicant has not responded.

Public Consultation on the draft Guidance Document on the Allergenicity Assessment of GM Plants **(**Item 9, September meeting): Comments from the ACNFP were submitted to the EFSA consultation on the draft guidance document.

4. Tongkat Ali ACNFP/127/7

The Committee had considered the application from Biotropics Malaysia Berhad for authorisation of Tongkat Ali root extract as a novel ingredient for the first time at its September meeting. At that meeting it raised a number of points for clarification and requested further information from the applicant including specifications of the novel food and the source material, as well as its toxicology and allergenicity and whether the novel food has any physiological effects. It had also been concerned that there was a potential for consumers to be misled, and had requested these issues be addressed by the applicant.

The Committee considered that the proximate analysis presented was inadequate and requested a robust quantitative analysis and considered the data which had been presented to date was of a poor standard with no detailed characterisation of the novel food. It further noted that 40% of the novel food consisted of glycosaponins which had not been identified. The Committee requested that a detailed characterisation of the glycosaponin component of the NI be carried out.

Similarly no attempt has been made to characterise the 40% protein component of the NI and therefore it was not possible to identify whether there were any potential allergenicity issues associated with the NI. The Committee requested that a detailed characterisation of the proteins in the novel ingredient be carried out.

The Committee was concerned that the toxicological studies showed liver enlargement, whicht could be significant if linked to liver hyperplasia as it may indicate that consumers were at an increased risk of carcinogenicity. It considered the applicant should be asked for an explanation of these observations and noted that further studies may be required to explore these finding further. For example, either a 28 or 90 day study could be used to determine whether these effects were reversible. The Committee also considered that the criteria used to establish the NOAEL were not robust and should be assessed further.

The Committee noted the changes in proposed food categories to which the novel food would be added. However, they considered the applicant had not addressed its concerns about the target population. The Committee noted the novel food was traditionally sold in root form to mature men in Malaysia. In this application the applicant is extending the range of the product to the whole population. It was emphasised that on this basis the applicant would need to demonstrate that it was safe for all population subgroups. As the target population differs from the traditional users the physiological effects would vary and the product may mislead some consumers. It was particularly concerned as the novel food potentially has a physiological effect in the body and

sought further information on this aspect. Whilst there were no reported adverse effects there was no obvious mechanism for monitoring such effects.

The Committee was also concerned that to produce a sustainable crop the source material for the product would need to be cultivated. The source of the cultivated plant may be different from the plants grown in the wild which have been used to produce the data used in the application. The Committee considered that identification and characterisation of the source plant material was essential to standardisation of the novel ingredient.

Action: The Secretariat to request further information from the applicant.

5. DHA – Rich algal oil, Extension of Use ACNFP/127/1

The Committee considered an application for the extension of use of DHA-rich oil from *Schizochytrium sp* at its telecom meeting in November. The applicant is seeking to extend the use of this form of oil to additional food categories in particular fruit and vegetable purees, infant formula, other foods for special groups and baby foods.

At its previous meeting the Committee raised a number of concerns which the applicant has responded to. These were on the composition of the novel food, the production process, toxicological issues including the margin of safety calculation, long term exposure to the novel food and any risk associated with silicon levels in the novel ingredient.

The Committee noted the public comments following the 21 day consultation on the dossier and encouraged the secretariat to respond to the points raised.

The Committee commented that the data comparing the composition of different DHA containing oils did not reflect the complete composition and information was requested on the other components. The Committee also noted mean values of the compositional data were presented and requested that these be reformatted to present the range and that the basis of the percentage (weight or volume) should be clear.

The information provided on the algal toxins produced during the production process was considered and it was suggested that this was not a risk. The Committee sought further information on the applicant's quality control processes, such as a HACCP plan, to monitor adventitious contamination with other microorganisms once in production..

The Committee sought further clarification for the margin of safety calculation. Members noted the NOAEL was high but requested clarification of the range and groups exposed to high intakes of the novel food. It noted the high intake could be children who have lower body weights than adults but sought confirmation of this. The Committee accepted the information from the applicant that the level of silicon in the product as consumed was unlikely to be a safety concern.

Action: The Secretariat to request further information from the applicant.

6. Bonolive® ACNFP 127/2

The Committee was asked to consider an application from BioActor BV for the authorisation of Bonolive® as a novel food ingredient. The applicant's intention is to market Bonolive® as an extract from the leaves of the olive tree (*Olea europaea* L.). It is proposed to be used as an ingredient in a range of food categories, including yoghurts, fine bakery wares and beverages. The applicant proposes it for use in functional foods, food supplements and foods for special medical purposes targeted at people over the age of 50.

The Committee noted the applicant had incorrectly included flavonoids (polyphenols) in its calculation of carbohydrates and suggested the product component breakdown be revisited. The Committee considered a compositional nutritional analysis is required with tolerances of compounds in the Bonolive other than oleuropein. The Committee considered the data on the novel food should include a specification. It noted olive leaf extracts were not novel if put into food supplements.

The Committee considered that it was misleading to presume that all parts of the olive tree would be beneficial and safe to eat. The Committee was not clear where the olive trees would be grown, different countries may have different growing conditions which may affect the composition of the leaves. The Committee also noted the applicant had also not addressed the possible differences in the composition of the leaves at different times of the year and sought further information on these points to full characterise the novel food The data on pesticides residues was considered and it was suggested that there may be a difference between the February and August harvests as pesticide is used in May. It recommended continued monitoring for pesticides as part of the applicant's quality control systems.

The Committee discussed how olive pollen could give rise to allergenicity concerns as highlighted by the applicant. However they considered that if harvesting in February there were no concerns about olive pollen on the leaves but that this may need to be considered when leaves were harvested in August. The Committee was satisfied there were no microbiological concerns.

The Committee commented that the overall exposure to the product could be high due to the extent of categories to which it will be added. The analysis provided was felt to be sufficient to consider the impact on the general population The Committee was satisfied with the applicant's approach which was more conservative, for instances when people in the non-target market consumed the product.

The Committee requested an explanation as to why the longer term study in humans had a modest dose compared with the expected consumption of the novel ingredient. The Committee requested confirmation that the toxicological studies had used a representative batch of the product which would be marketed as this may differ depending on when the leaves were harvested.

Action: The Secretariat to request further information from the applicant.

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7. Algae dried biomass from *Haematococcus pluvialis* ACNFP/127/3

The Committee was asked whether it agreed that substantial equivalence had been established between Algalo Industries Ltd's algae dried biomass from *Haematococcus pluvialis* and an existing algae dried biomass from *Haematococcus pluvialis* which is already marketed in the EU by AstaReal AB. AstaReal's product had been marketed prior to May 1997.

The Committee considered the production process would not cause any microbiological concerns. It noted the difference in composition of the novel ingredient and that batch to batch variation was very large. The applicant's explanation for this was discussed but it was considered there was insufficient evidence provided to support this explanation. In order to assess whether the product was substantially equivalent the Committee requested the Secretariat supply them with tabulated composition data for the products which had already been authorised so that data for a complete range of products could be compared with Algalo Industries Ltd's novel ingredient.

The Committee requested information about the composition of the novel ingredient at a range of temperatures. The Committee noted the whole product would be consumed as a food rather than the astaxanthin extracted from the product.

Action: The Secretariat to request further information from the applicant and to tabulate data from applications already authorised

8. Phytosterol Ester – Substantial equivalence ACNFP/127/8

The Committee considered, at its January 2017 telecom whether phytosterol esters produced by Xi'an Healthful Biotechnology's phytosterol esters were substantially equivalent to phytosterol esters of Archer Daniels Midland who gained authorisation as a novel food in 2004. The Committee raised a number of concerns about the composition of the novel ingredient and the production process.

In order to provide full consideration of the further information provided by the applicant, the Committee agreed to provide comments following the meeting.

Action: The Committee to provide comments following the meeting.

9. Chia Seeds in Yogurt ACNFP/127/4

The Committee was asked to consider an initial opinion from the Croatian Competent Authority on an application for the authorisation of an extension of use of Chia Seeds in yogurt.

Dr Anton Alldrick declared an interest. In his employment at Campden BRI he has been involved in a number of projects on the use of chia seeds in new products and in giving advice to clients. Dr Alldrick had provided written comments to the Committee. The Committee agreed they would consider his written comments but that he should not take part in the discussion item.

The Committee was broadly supportive of the application but was unable to consider the extension of use fully using the documentation provided. It sought further information on the products composition including its fatty acid content, its microbiological contamination and the pH of the yogurt post production. There was insufficient data on the additional exposure to the Chia seeds, from eating yogurt containing it

The Committee considered there was a potential for allergenicity issues as chia is being added to a large range of products and is therefore being consumed more widely. However, it was suggested that this would not preclude the extension of use from being authorised.

Action: The Secretariat to request further information from the applicant.

10. Annual Report 2016 **ACNFP/127/5**

The Committee reviewed the Annual Report, which was agreed subject to amendments, and the Good Practice Guidance which the Committee agreed continued to be met by the ACNFP. Committee Members agreed to forward amendments to their interests and other personal details to the Secretariat.

Action: The Secretariat will amend the report as necessary and arrange publication.

11. Review of Scientific Advisory Committees **Oral**

The Committee considered information on digital platforms and their possible uses by Scientific Advisory Committees sponsored by the Food Standards Agency.

For Information

10.2 EU Update **ACNFP/127/6**

The Committee noted the information in the paper and oral briefing.

12. Any Other Business

13. Date of next meeting:

The next meeting is scheduled for Thursday 27 April 2017 in Aviation House.