ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

MINUTES OF THE ONE HUNDRED AND THIRTY FIRST MEETING HELD ON 21 SEPTEMBER 2017

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MINUTES OF THE HUNDRED AND THIRTY FIRST MEETING OF THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES, HELD ON 21 SEPTEMBER 2017 IN CONFERENCE ROOM 5, AVIATION HOUSE.

Present	Professor Peter Gregory – **Chairman**
	Dr Anton Alldrick Dr Camilla Alexander-White Professor Michael Bushell Professor Susan Duthie Dr Hamid Ghoddusi Dr Rohini Manuel Professor John Mathers Mrs Rebecca McKenzie Ms Claire Nicholson Professor Christopher Ritson Dr Lesley Stanley
Apologies	Ms Nichola Lund Professor Harry McArdle Professor Claire Mills
Secretariat	Ruth Willis - **ACNFP Secretary** Alison Asquith – **Minutes**

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

Two members sent apologies for non-attendance; no comments were received from members.

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

The Chairman welcomed Shreya Nanda as an observer.

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 129th and 130th Meeting — DRAFT/ACNFP/129/Min and DRAFT/ACNFP/130/Min

The Committee agreed that the minutes were a true record of the 129th meeting of the ACNFP held on 13 July subject to minor amendments and agreed that the minutes of the 130th meeting were a true record of the ACNFP meeting held on 16 August.

3. Matters Arising

Annual Report (Item 3, 13 July meeting), the 2016 Annual Report has been published on the ACNFP website.

Chia Seeds (Betterbody) (Item 9, 13 July meeting)
The consultation period on the draft Opinion has ended. Comments had been received, but none which related to the safety of the chia seeds. The comments will be circulated to Committee Members by email and the draft Opinion will be finalised by Chair's action.

Hens Egg Lysozyme (Item 12, 13 July meeting)
This was a 60 day consultation on the Irish Competent Authority's Opinion. The Committee's comments have been forwarded to the Commission as part of the UK's formal response.

Robuvit® (Item 13, 13 July Meeting)
This was a 60 day consultation on the German Competent Authority's Opinion. The Committee agreed with the German CA that the novel ingredient should undergo a further assessment by EFSA. The Committee's comments have been forwarded to the Commission as part of the UK's formal response.

Egg Membrane (Item 2, 16 August Meeting)
This was a 60 day consultation on the Danish Competent Authority's Opinion. The Committee raised concerns with the novel ingredient. In light of the Committee's advice the UK objected to the opinion when responding to the Commission.

Chondroitin Sulphate, UV Baker's Yeast, Basic Whey Protein Isolate, Chia Seeds Extension of Use in Cereal Based Ready Meals. (Items 3,4,6 and 7, 16 August meeting).
These were 60 day consultations. The Committee's comments have been forwarded to the Commission as part of the UK's formal response.

Tetraselmis Chuii (Item 5, 16 August meeting)
This was a 60 day consultation. The Committee's comments were forwarded to the Commission as part of the UK's formal response. The applicant has responded and we will be consulting Members shortly on this response.

4. Oligonol ACNFP/131/2

The Committee last considered an application for the authorisation of Oligonol® at the July 2017 meeting. The Committee had requested additional information in relation to the additional protein analysis that had been undertaken to validate the effectiveness of controls to exclude lychee nut from the Oligonol® starting material. The issue of the catechin content of the novel ingredient was also revisited as the Committee had noted that there was emerging evidence that catechins at high doses, when eaten after fasting, could be a cause for concern.

The Committee was reassured by the applicant's additional information on catechins, which explained that the exposure to catechins from the novel ingredient would be similar to exposure to one cup of green tea. It was also clarified that the novel ingredient would be added to other foods, suggesting the concerns on taking bolus doses of catechins after fasting were unlikely to cause problems with this product. The Committee remarked that the applicant had shown due diligence in its response about catechins.

In relation to the additional information requested on the protein analysis provided by the applicant, the Committee considered the applicant had not fully addressed the issue of potential cross reactivity with other nut allergens. It had been previously requested that a comparative protein analysis be undertaken to determine whether the lychee nut is in the product. Further questions were asked on the analysis that was undertaken and the similarity of the proteins identified in the product to known nut allergens. This was to determine whether the potential risk that individuals allergic to cashew nuts might react to the novel food was being effectively managed.

Subject to the further clarification requested this opinion was agreed subject to minor amendments.

The Secretariat to amend the draft opinion to be cleared by the Committee's allergy expert and the Chairman by Chairman's action.

5. DHA-rich algal oil from *Schizochytrium Sp*. Extension of use ACNFP/131/3

The Committee had considered an application for the extension of use of DHA-rich algal oil from *Schizochytrium sp.* at its telecom meeting in November and at its meetings throughout 2017. The applicant is seeking to extend the use of this form of oil to additional food categories in particular fruit and vegetable purees, and infant formula.

At the previous meeting a clarification had been sought on the exposure of infants being breastfed to the novel ingredient from their mothers consuming the novel ingredient. The Committee was content that the applicant had addressed all its points satisfactorily. It remarked that the modelling of the intake and composition of the milk was good.

The draft opinion was agreed subject to minor amendments.

The Secretariat to amend the draft opinion and for it to be cleared by Chairman's action.

6. Bonolive® ACNFP/131/1

The Committee considered an application for the authorisation of Bonolive® as a novel food at its meetings in February, April, and July 2017. The applicant is seeking to market Bonolive® an extract from the leaves of the olive tree (*Olea europaea L.)* as a food ingredient to be used in a range of food categories, including yogurts, fine bakery wares and beverages. At the last meeting the Committee raised a number of questions in relation to the novel ingredient, including composition, allergenicity and intended uses.

The Committee noted the applicant had clarified that Foods for Special Groups should be included as a category for authorisation under the application.

At the previous meeting the Committee had sought clarification on whether the novel food could cause allergic reactions in consumers allergic to lipid transfer proteins or other proteins in the leaves. While the applicant had provided details on potential pollen allergies and how these risk would be managed the question posed had not been fully addressed. It was noted that while there was a suggestion that the proteins would be denatured by the production process, as occurs for olives, no evidence had been provided to support this. If the production process effectively controls the allergy risk it was suggested that this should be reflected in the HACCP plan.

The Committee reiterated their request for further information on the composition of the product in order to ensure the novel food was fully characterised. Of particular interest was the carbohydrate composition. The further data provided by the applicant was noted but further clarification was sought on their relevance to the novel ingredient.

There was a discussion on the proposed food categories in which the novel ingredient was seeking authorisation to be used. The Committee commented that the proposed health claim related to menopausal women whereas the categories the novel ingredient would be used in included cereals and yogurts which were more widely consumed by a

range of age groups. A concern was raised with the applicant on the potential for consumption by children and teenagers which risked sensitising them to allergens present in the olive leaves.

The Committee commented that the website for the novel ingredient suggests the product is produced from the fruit of the olive tree not the leaves and this could be misleading and should be highlighted to the applicant.

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

7. Tongkat Ali ACNFP 131/4

The Committee considered an application for the authorisation of Tongkat Ali as a novel food ingredient at its September 2016 meeting and at its meetings in 2017. It was last considered at the July 2017 meeting. The applicant is proposing to place the novel ingredient in a range of products including non-alcoholic drinks. The proposed uses had been revised in light of the Committee's comments and a revised intake calculation provided for their consideration.

The Committee had previously raised concerns that the biological effects from the animal study had not been fully explained by the applicant. The Committee was particularly concerned as Testosterone is a biologically active substance, that there was potential for the effects seen such as changes in blood parameters and kidney and liver enlargement to be adverse. The Committee welcomed the additional data from the applicant but remained of the view that some of the effects seen had not been fully explained to understand if they were due to the study environment or the novel ingredient. On this basis the original NOAEL selection of 1000mg/kg/day was considered too high and should be reduced to 300mg/kg/day as a precaution allowing a larger margin of safety. The applicant agreed to this change.

It was suggested that if the higher daily dose was to be maintained further targeted studies should be undertaken to confirm the significance of the kidney and liver data in the one year animal study.

The Committee noted the applicant's willingness to restrict the number of products in the categories. It considered further thought should be given to whether there would be impacts on non-target groups if the novel ingredient included in some food categories proposed (such as sports drinks) were consumed by a wide range of consumers.

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

8. Vivinal®GOS PT from Frieslandcampina ACNFP/131/5

The Committee was asked whether it agreed that substantial equivalence had been established between FrieslandCampina's new GOS product, Vivinal®GOS PT and Vivinal GOS, which has been marketed in the EU prior to May 1997.

The Committee noted there was little literature about the organism. While it would have preferred further information about the characteristics of the organism, in this case the

main active ingredient is the isolated enzyme which was subject to safety assessment under other regulatory frameworks. The Committee therefore focused their consideration on whether the product generated by the enzyme was substantially equivalent to the existing product using the data provided.

The Committee was concerned that the production process was vague particularly as to where the separation takes place. On this basis, clarification was sought that the process to be used, if authorised, was the same as that used in the production of the samples that were tested. Information was also sought to ensure the enzyme was not present in the final product.

The Committee considered the application focussed on β galactosidase which is removed from the final product and not the oligosaccharide composition. However, it was suggested that the profile of oligosaccharides was unlikely to differ significantly between the new and existing final products.

The Committee requested that the tables in the dosier giving values for undesirable substances and minerals should be updated to provide absolute values or an indication of limits of detection for the methods used.

The Secretariat was asked to compile available data on the composition of GOS products on the market to ensure the authorisation was consistent with others made under the regulation. They were also asked to check the legislative requirements for enzyme authorisation to put the substantial equivalence application in its wider legislative context.

The Secretariat to advise the applicant of the Committee's decision and to seek further information to develop an opinion for discussion at the next meeting.

9. EPA rich Oil from *Phaeodactylum triconutum* ACNFP/131/7

The Committee was asked to consider an initial opinion from the Irish Competent Authority on an application for the authorisation of EPA-rich oil derived from the microalgae *Phaeodactylum triconutum* as a novel food ingredient.

The Committee considered that the composition of the five batches of the novel ingredient analysed was very variable particularly for the minor components. It noted a five-fold difference in the amount of tocopherols in the product between batches. Variation was also seen in the levels of undesirable substances. This level of variation would not be expected if the production system was well controlled. Further information was requested to understand the source of the variation. The Committee also requested that the absolute values should be given for the data on undesirable substances specified in tables 6, 7 and 8. Currently some of the information is expressed as "less than" values.

The Committee was concerned about the stability of the product. There were differences in the accelerator studies which suggested possible problems with the stability of the novel food over time. The Committee requested further explanation about the results of the study. The Committee noted the applicant had referred to

results from a long term study being available in late 2016 and requested these results be provided if available.

The Committee was concerned that no toxicological studies had been carried out on the novel food. They noted that an assumption made that the product would be similar to other authorised algal oils but this had not been verified. This was questioned by the Committee in part because CO_2 extraction methods are used in the production of the novel ingredient which differs to some of the other authorised algal oils and may result in a different composition of the product.

The Committee recommended that the UK objected to the Irish CA's initial opinion as there was insufficient information on the novel ingredient's composition and stability to determine its safety and there were no toxicological studies.

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

10. Report on New Breeding Techniques — ACNFP/131/8

The Committee was informed that the Report on New Breeding Techniques would be discussed by Member States and other interested parties at a meeting in Brussels on 28 September. If Members wanted to submit comments, to be included in an FSA response, they were invited to do so by email.

11. Open Meeting — ACNFP/131/9

The Committee agreed the format of the meeting and the agenda.

Action: The Secretariat to continue with planning for the open meeting.

12. For Information

15.1 EU Update — Oral

The Committee noted the oral briefing.

15.2 SACS Update — Oral

The Committee was informed of the next meeting of the Chairs of the FSA's SACs

13. Date of next meeting:

The next meeting is scheduled for Wednesday 22 November in Aviation House.