ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

MINUTES OF THE ONE HUNDRED AND TWENTY EIGHTH MEETING HELD ON 27 APRIL 2017

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MINUTES OF THE HUNDRED AND TWENTY EIGHTH MEETING OF THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES, HELD ON 27 April 2017 IN CONFERENCE ROOM 5, AVIATION HOUSE.

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

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

Six members sent apologies for non-attendance; comments were received from three members.

The Chair welcomed the observer from Food Standards Scotland. Apologies were received from observers from the FSA offices in 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.

2. Minutes of the 127th Meeting DRAFT/ACNFP/127/Min

The Committee agreed that subject to minor amendments the minutes were a true record of the 127th meeting of the ACNFP held on Thursday 9 February and the Workshop on Insects held in June 2016.

3. Matters Arising

Tongkat Ali (Item 4 February 2017 meeting). The secretariat has requested further information from the applicant which we are awaiting.

Chia Seeds in Yogurt (Item 9 February 2017 meeting). This was a 60 day consultation on the Croatian Competent Authorities opinion. The Committee had raised a number of comments which have been forwarded to the European Commission in the UK's response.

Annual Report 2016 (Item 10 February 2017 meeting). The Secretariat explained the Annual Report for 2016 is not expected to be published until after the General Election.

Review of Scientific Advisory Committees (Item 11 February 2017 meeting). The Committee was given an oral briefing on Yammer, a social media platform used by the FSA which also has an area for the FSA's advisory committees to use.

4. Bonolive® ACNFP 128/1

The Committee had considered the application from BioActor B.V for authorisation of Bonolive® as a novel ingredient for the first time at its February meeting. The applicant is proposing to use the novel ingredient in a range of food categories, including yogurts, fine bakery wares and beverages. At that meeting it raised a number of points in relation to the specification of the novel food and undesirable substances and requested further information from the applicant on the full characterisation of other key components in the product in addition to oleuropein.

The Committee was informed that a 21 day public consultation on the dossier had taken place and that one comment had been received and this was noted by the Committee.

The Committee considered the response from the applicant and commented that the components of Bonolive® had not been identified in the chromatogram provided and requested that it was labelled so that the specific peaks are identifiable.

It also noted the table of the proximate analysis of Bonolive® showed the mean values and not the range of values which would have been observed in multiple samples. The Committee requested confirmation that the samples are representative of the batches sampled.

The Committee was content with confirmation from the applicant that harvesting would be of the new growth in February before the leaves are exposed to pesticides. However, further clarification was requested to enable the Committee to understand how the dose given in the human studies supported the recommended intakes of the final novel food product.

The Committee noted the suggestion from the applicant in the intake assessment that consumers primarily consume food supplements instead of purchasing targeted food/beverage products containing the novel ingredient. The Committee was interested in understanding the evidence base to support this comment and whether this could be shared with the Committee.

The Committee noted the applicant has provided more detail on the target group than previously given. This being post-menopausal women. The Committee sought further information about the intended target group and how the novel food will be marketed.

The Secretariat to request further information from the applicant.

5. DHA – Rich algal oil, Extension of Use ACNFP/128/2

The Committee considered an application for the extension of use of DHA-rich oil from *Schizochytrium sp* at its telecom meeting in November and at its meeting in February 2017. 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 had responded to. These were on the composition of the novel food, the production process and the margin of exposure and how it differs for different population group.

The Committee was content with the information supplied by the applicant on the production process and HACCP plans to manage the risks of microbial contamination.

In further considering the information on the intake assessment and margin of exposure the Committee sought information on the NOAEL selection. This would allow evaluation of the identified margin of exposure and whether this was sufficient for the target population. To inform this assessment the Committee questioned whether there was any lactational transfer of the novel ingredient which would cause infants to be exposed

to it through breast feeding. They also noted that the potential impact of long term exposure could not be assessed with the data available.

The Committee was also concerned that the novel ingredient would replace existing sources of DHA in infant formula, and therefore further information was requested to understand if this would be nutritionally disadvantageous to consumers.

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

6. OLIGONOL® ACNFP 128/3

The Committee considered an application for the authorisation of Oligonol® as a novel food ingredient at a number of meetings. It was last considered at the April 2016 meeting where the Committee raised a concern about the production process and the potential for lychee nut to be present in the novel food raising potential issues of cross reactivity to known allergens.

To address this, the applicant had undertaken further analysis of the protein composition of Oligonol. The Committee considered that to further assess the submitted data a further evaluation by the allergy specialist on the Committee would inform the next steps for the assessment of this novel ingredient.

Action: The Secretariat to consult an allergy specialist on the ACNFP and draft an opinion for the next meeting.

7. Oleoresin from dried biomass from *Haematococcus pluvialis* ACNFP/128/4

The Committee considered, at its meeting in February, 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.

At the February meeting the Committee requested data, in tabulated form, to enable Members to compare the composition of Algalo Industries Ltd's product with products which the ACNFP had already agreed were substantially equivalent to other products already on the market. The Committee was consulted on the tabulated data but did not reach a conclusion on whether Algalo's product was substantially equivalent and the meeting provided a further opportunity to consider this dossier.

The Committee considered the proximate analysis of the authorised products on the market gave a wide range of values which covered Algalo Industries product. The Committee noted the oleoresin product's carotenoids were within the range of other products on the EU market, as were the carbohydrate and ash values. The levels of characteristic fatty acids for the product, were also similar to other products on the market. The Committee therefore concluded the novel ingredient should be considered substantially equivalent to products already on the market.

The Committee agreed to progress to an opinion and requested the production process reflected the production conditions accurately as this influenced the potential microbiological risks for the process.

The Committee requested data in a similar tabulated form for new substantial equivalent applications to enable it to compare products already on the market more easily.

A public consultation had been undertaken on the dossier and the Secretariat reported that no comments had been received.

Action: The Secretariat to draft an opinion for the next meeting.

8. Phytosterol Ester – Substantial equivalence ACNFP/128/5

The Committee considered, at its January 2017 telecom and at its February meeting, 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 questions about the composition of the novel ingredient and the production process including the source material.

The Committee reviewed the additional information provided by the applicant. Questions were raised on the changes that had been made to the production process and the Committee sought clarification on these and the impact the changes had on the levels of undesirable substances.

The Committee noted the variation in the feedstock and sought further information on how the specification identified for the product would be maintained once in production if a number of feedstocks were used. Clarification was sought on how different source material may affect the pesticide residues and the safety protocols in place to manage these.

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

9. Chia Seeds (Muscllediet) ACNFP/128/6

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

The Committee noted that Muscllediet's chia seeds had significantly higher sodium content than The Chia Company's seeds. It was reassured that the applicant had identified that the cultivation area had a soil with a higher sodium content that was likely to a result of the soil having a long history of agricultural use and that this would not affect the chia seeds nutritional value.

The Committee was concerned that the retinol content was close to the threshold for toxicity. It requested data which showed how much retinol was in the novel ingredient separately from beta carotene to make comparisons to the authorised product.

Action: The Secretariat to request further information from the applicant and draft an opinion for the next meeting.

10. UV Treated Mushrooms with increased vitamin D (Walsh) ACNFP/128/8

The Committee was asked to consider an initial opinion from the Irish Competent Authority on an application for the authorisation of UV treated mushrooms enriched with Vitamin D, a new novel food process to enrich commercial mushrooms. While an application was authorised for this process recently, as a new process further companies seeking to market this novel food need to seek authorisation through the full application route.

The Committee noted whilst the Vitamin D_2 content increased the UV light didn't affect any other nutrients. The Committee sought to understand whether the layer production system would result in the same amount of UV light would be absorbed by each layer of mushrooms. It also questioned whether there would be migration of substances from the packaging to the mushrooms. The Committee requested further information about the UV light range as it was very large. It was felt to be important to set a specification for the product.

It questioned whether the Vitamin D level could be further increased by consumers if they placed the mushrooms which had already been treated with UV light outside in the sun and the view was that while possible, it was not considered a safety concern. It also sought information as to what the Vitamin D levels in the mushrooms were prior to UV treatment to enable consumers to be informed about the increase in Vitamin D levels as a result of the enhancement.

The Committee agreed with the Irish Competent Authority's positive opinion but noted that the Vitamin D intake level for infants was close to the Tolerable Daily Intake (TDI) level. It considered that this was acceptable provided the intake level for infants didn't go above the TDI

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

11. UV Treated Mushrooms with increased vitamin D (Ekoidé) ACNFP/128/9

The Committee was asked to consider an initial opinion from the Swedish Competent Authority on an application for the authorisation of UV treated mushrooms enriched with Vitamin D, a new novel food process to enrich commercial sale mushrooms. As noted in the previous agenda item, while an application was authorised for this process recently as the novel food is a result of a new treatment, further companies seeking to market this novel food need to seek authorisation through the full application route.

The Committee considered the discussion on the application for UV Treated Mushrooms produced by Walsh Mushrooms also applied to this application particularly about the migration of particles from the packaging to the mushrooms and the Vitamin D level in the mushrooms prior to their treatment with UV light.

The Committee agreed with the Swedish opinion but sought clarification on the references in the sections on microbial control to previous advice in the UK and Ireland on cooking mushrooms, following an incident in 2001. The Committee queried how references to the previous incident relate to the microbial controls used in the production of this novel food.

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

12. Shrimp Peptide Concentrate **ACNFP/128/10**

The Committee was asked to consider an initial opinion from the Finnish Competent Authority on an application for the authorisation of refined shrimp peptide concentrate as a novel food ingredient.

The novel ingredient is to be placed on the market in food supplements targeted at individuals wishing to lower their blood pressure and it is not intended to be marketed at persons under the age of 18.

The Committee considered the *Staphylococcus aureus* count was high but noted it was considered within satisfactory limits for safety. It noted data was provided for inorganic mercury but that the analysis for organic mercury was missing and requested this data.

The Committee considered the NOAEL was acceptable but that further explanation of the toxicological data was needed to support the conclusions reached by the applicant. The committee noted that the studies presented had been undertaken on individuals who were hypertensive. The Committee questioned the effect of the novel ingredient on an individual who were hypotensive.

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

13. Open Meeting **ACNFP/128/11**

The Committee will be consulted further on the overall structure of the Open Meeting and its draft Agenda. The Meeting is scheduled to take place on 22 November 2017. Volunteers for the small discussion groups were identified.

14. For Information

14.2 EU Update **Oral**

The Committee noted the oral briefing.

14.3 Scientific Advisory Committees Update **Oral**

The Committee noted the oral briefing.

15. Any Other Business

16. Date of next meeting:

The next meeting is scheduled for Thursday 13 July 2017 in Aviation House.