ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

MINUTES OF THE ONE HUNDRED AND TWENTY NINTH MEETING HELD ON 13 JULY 2017

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MINUTES OF THE HUNDRED AND TWENTY NINTH MEETING OF THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES, HELD ON 13 JULY 2017 IN CONFERENCE ROOM 5, AVIATION HOUSE.

Present	Professor Peter Gregory – **Chairman**
	Dr Camilla Alexander-White Professor Michael Bushell Mrs Nichola Lund Dr Rohini Manuel Professor John Mathers Professor Harry McArdle Mrs Rebecca McKenzie Professor Clare Mills Ms Claire Nicholson Professor Christopher Ritson Dr Lesley Stanley
Apologies	Dr Anton Alldrick Professor Susan Duthie Dr Hamid Ghoddusi
FSA Advisor	Colin Clifford
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

Three members sent apologies for non-attendance; comments were received from one member.

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

The Chairman welcomed Colin Clifford, who is one of the FSA Advisors to the Committee and the Team Leader of the Novel Foods Unit.

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 128th Meeting DRAFT/ACNFP/128/Min

The Committee agreed that the minutes were a true record of the 128th meeting of the ACNFP held on Thursday 27 April.

3. Matters Arising

UV Treated Mushrooms with increased vitamin D (Walsh) (Item 10, 27 April 2017 meeting). This was a 60 day consultation on the Irish Competent Authority's opinion. The Committee had raised a number of comments which have been forwarded to the European Commission in the UK's response.

UV Treated Mushrooms with increased vitamin D (Ekoidé) (Item 11, 27 April 2017 meeting). This was a 60 day consultation on the Swedish Competent Authority's opinion. The Committee had raised a number of comments which have been forwarded to the European Commission in the UK's response.

Shrimp Peptide (Item 12 27 April Meeting).This was a 60 day consultation on the Finnish Competent Authority's 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 3, 27 April meeting). The Secretariat stated it would publish the Annual Report for 2016 before the next ACNFP meeting in September.

4. Tongkat Ali ACNFP/129/1

The Committee had considered an application for authorisation of Tongkat Ali Root Extract as a novel ingredient for the first time at its September 2016 meeting and had raised a number of concerns. Tongkat Ali is a product that is widely consumed in

South-East Asian countries including Malaysia mainly as a beverage (coffee, energy drink or tonic). The application is seeking novel foods approval to place an extract of Tongkat Ali in a range of products including non-alcoholic drinks and Parnuts foods, as well as grain based products such as cereal bars. The products are targeted at middle aged men.

The Committee reviewed the information provided on the potential allergenicity of the novel ingredient. It considered that ten percent of the novel food was protein, which was a significant amount and therefore could cause allergic reactions if allergenic. It noted that no information had been provided concerning the potential of the plant to contain proteins sufficiently similar in structure to those that cause adverse reactions in the most prevalent food-allergenic populations. A review of botanical relatedness of the novel food would provide clarity.

The proposed management strategy of the applicant for potential allergenicity was noted but it was felt to be important to better understand the potential risk before this was considered further. The Committee noted the allergic response is likely to be different in the UK than in South-East Asian countries, where it is widely consumed, as the UK has a more allergic population.

The Committee questioned whether the production process was standardised as the range of the protein concentration determined by the Kjeldahl method was between 7 and 15 percent. The Committee continued to seek information to characterise the novel food. It was requested that the glycosaponins should be labelled on the HPLC fingerprint provided to better allow this to be reviewed. It noted no information was provided about the standard quality parameters for this type of assay and further information on these aspects were requested.

The Committee revisited the potential for the product to be misleading to consumers. The amended range of food products for use of the novel ingredient was noted and would be considered further in the context of a revised exposure assessment.

The Committee noted that the applicant intended to submit the one year toxicology study on the novel ingredient in time to be reviewed by the Committee at its meeting in September 2017.

The Secretariat to request further information from the applicant.

5. Bonolive®

The Committee had considered an application for the authorisation of Bonolive® as a novel ingredient at its February and April meetings.

The applicant is proposing to use the novel ingredient in a range of food categories, including yogurts, fine bakery wares and beverages. At its meeting in April 2017 the Committee 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 key components in the product.

The Committee noted the further information provided by the applicant and that all the major components had been labelled on the HPLC fingerprint. The sampling protocols had been provided and the Committee was content that the samples tested were representative of the product. Further analysis of the carbohydrate component was requested as this made up 5% of the product which was a significant amount.

The Committee reviewed the response from the applicant on the target population for the product. They advised that the product would be targeted at the over 50 year olds and menopausal women. The applicant states that the product helps those people with osteoporosis. The Committee questioned whether this could mislead consumers as it may not emulate a Mediterranean diet but were reassured in part that the applicant has indicated that a health claim for the product is being sought.

The Committee considered the 1% protein in the leaves which equated to an intake of 6mg protein could cause allergic reactions in at-risk consumers if allergenic. Allergy to lipid transfer proteins in the outer layers of the fruit and in olive leaves have been found in Mediterranean countries and can cause severe effects including anaphylaxis. The Committee sought further information about lipid transfer proteins or proteins in the leaves which could cause allergic reactions in some parts of the population. The Committee requested a summary from the applicant about how it proposed to manage the potential allergy issue in leaves.

The Committee noted there were some inconsistencies between the intake information presented in different documents and sought clarification on this point.

The Secretariat to request further information from the applicant

6. DHA – Rich algal oil, Extension of Use ACNFP/129/3

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 meetings in February and April 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 questions on the nutritional content of the novel ingredient and on the toxicology to which the applicant responded. The Committee commented that the novel ingredient could be less nutritious than other forms of DHA rich oils used in infant formula which were already on the market. However, it was accepted that this would be managed in the case of infant formula containing the novel ingredient as these are blended to meet regulatory nutritional requirements.

The Committee considered the toxicological information provided by the applicant had addressed many of the outstanding questions on the NOAEL selection. The Committee noted that the NOAEL was based on the top dose in the study. This was a conservative value as no effects were seen at this dosage. The Committee was satisfied that while the margin of safety presented was less than would normally be sought, the conservative nature of the NOAEL would support this the lower value.

The Committee noted the response from the applicant on the likelihood of infants being exposed to the novel ingredient through breast milk and other sources. It was requested that the statements made were evidenced if possible. For example, through mathematical models or calculations to determine the intake level of the novel food from breast milk and other sources.

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

7. OLIGONOL® ACNFP 129/4

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 2017 meeting. The outstanding question with the dossier relates to whether lychee nut is effectively removed from the starting material managing potential allergenicity concerns.

The Committee considered the information from the applicant about the protein composition and suggested that further information on the analysis that was undertaken was needed to complete the assessment.

The Committee also commented that in the light of emerging evidence on the toxicity of catechins (a component of green tea) this needed further consideration with this product. It was noted that the toxicological safety of the product itself had been considered but how the level of catechins in the product related to safe levels in the diet needed to be evaluated.

The Committee noted the toxicological effects of concern referred to in a Norwegian Study[1] occurred when in the fasting state and questioned whether the assessment of the toxicity of the novel ingredient had included this situation in the testing protocol.

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

8. *Ilex Guayusa* ACNFP/129/5

The Committee was asked whether it agreed that substantial equivalence had been established between Ikiam University Consortium's *Ilex Guayusa* leaves and Yerba Mate leaf *(Ilex Paraguariensis)* which has been marketed in the EU prior to May 1997

The Committee requested additional information on the composition of *Ilex Guayusa* ; in particular any bioactive components as *Ilex Guayusa* and Yerba Mate were thought to have mild narcotic effects and only caffeine was referred to in the application. The Committee considered that the composition of both foods based on the information presented were similar but noted that some of the main compositional elements were

[1] Safety assessment on levels of (-) – Epigallocatechin-3-gallate (EGCG) in green tea extracts used in food supplements, Norwegian Institute of Public Health (2015).

missing from the data and would be needed to complete the assessment. The Committee questioned whether all the substances which in the novel food are all equally bioavailable.

The Committee considered the data on undesirable substances and was concerned about the cadmium content of the novel food as this appeared to be 10 times higher in *Ilex Guayusa* than in Yerba Mate. The Committee noted that no measurements had been included for mercury content. The Committee advised that the differences in composition between the two plants were likely to be caused by the differences in the soil types of the areas where the trees are grown but could be sufficient enough to affect substantial equivalence. The Committee noted the applicant had not investigated the aflatoxins in the novel food.

The Committee considered the leaves of *Ilex Guayusa* were not equivalent to the leaves of Yerba Mate, however if the applicant was able to show that the bioavailability and the composition were similar it would review this decision.

The Secretariat to advise the applicant of the Committee's decision

9. Chia (Betterbody) ACNFP/129/6

The Committee was asked at its April meeting whether it agreed that substantial equivalence had been established between Betterbody's chia seeds and those which are already on the market from the Chia Company. It considered that Betterbody's chia seeds were likely to be substantially equivalent, but requested further information on vitamin A levels.

The Committee was content with the additional information provided on the vitamin A levels and advised that it considered Betterbody's chia seeds were substantially equivalent to the Chia Company's chia seeds.

The Committee agreed the opinion for the Chia seeds from Betterbody subject to minor amendments.

The Secretariat to consult on the draft opinion and clear by Chair's action.

10. Oleoresin from dried biomass from Haematococcus pluvialis ACNFP/129/7

The Committee considered this application from Algalo Industries at its February and April meetings and also via correspondence in March. The Committee did not identify any reason for the applicant's oleoresin not to be considered substantially equivalent to other oleoresin products already on the market.

The Committee agreed the opinion for Algalo Industries product subject to minor amendments.

A public consultation is currently being undertaken on the opinion and the Secretariat reported that no comments had been received to date. The consultation would end on 17 July.

Action: The Secretariat to finalise the opinion and clear by Chair's action.

11. Phytosterol Ester – Substantial equivalence **ACNFP/129/8**

The Committee considered, at its meetings during 2017 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 questioned a change to the production process and was reassured by information from the applicant that indicated that the change was made to improve the product and reduce levels of undesirable substances. The Committee requested confirmation that the laboratory used for testing was appropriately accredited for the methods used.

The Committee agreed the opinion for Xi'an healthful Biotechnology's phytosterol esters subject to minor amendments.

A public consultation is currently being undertaken on the opinion and the Secretariat reported that no comments had been received to date. The consultation would end on 17 July.

Action: The Secretariat to finalise the opinion and clear by Chair's action

12. Hens Egg Lysozyme **ACNFP/129/9**

The Committee was asked to consider an initial opinion from the Irish Competent Authority on an application for the authorisation of LumiVida® (Hen Egg White Lysozyme Hydrolysate) as a novel food ingredient.

The product is intended as a nutritional ingredient to be included in food supplements in the form of tablets, capsules, soft gels, gel caps, liquids or powders with a recommended daily intake up to 1000mg/day as a fortification ingredient in non-alcoholic drinks and a range of low protein foods including chocolate and confectionary. The purpose of the ingredient is to create a favourable trytophan to large neutral amino acid ratio with the aim of inducing the purported health benefits. The target population are adolescents and adults.

The Committee considered that the range of foods containing the novel ingredient may cause consumers in the highest percentile to over consume. However, the intake levels of tryptophan would not be a safety concern.

The Committee noted that the efficacy of the novel food was outside the scope of the novel food regulation but raised questions on the assumptions made in relation to bioavailability. It was commented that as tryptophan is associated with drowsiness;

consideration should be given to whether the effect on those taking the novel ingredient would be significant enough to require this information on this to be provided to consumers.

As the product contains phenylalanine the Committee questioned whether the product interacted with products containing aspartame as this also contains phenylalanine.

The Committee noted that the enzyme used in the hydrolysis is derived from bacteria and therefore this should be reflected in the evaluation of microbiological risks. It advised that the hydrolysis procedure could be variable if not appropriately controlled producing different peptide distributions. It was commented that a marker of the process could be included as part of the specification of the product to ensure the product was being produced consistently.

The Committee noted that tryptophan was absorbed into the blood quicker if it was consumed in food supplements than in food. It considered as the assessment has only been provided for food supplements then they would advise risk managers to consider if evidence to support the novel ingredients use in other food categories had been demonstrated.

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

13. Robuvit® **ACNFP/129/10**

The Committee was asked to consider an initial opinion from the German Competent Authority on an application for the authorisation of Robuvit® (dried aqueous extract from *Quercus robur* oak wood) novel food ingredient.

The novel food ingredient is intended to be placed on the market in food supplements with a recommended intake of a maximum of 300mg per day.

The Committee agreed with the German Competent Authority that the genotoxicological study needed further investigation and the application should receive a further assessment by EFSA.

It questioned who the target consumer was, when it would be consumed and how it would be consumed. It questioned some of the assumptions made in the intake assessment around how energy drinks were consumed.

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

14. Open Meeting **Oral**

The Committee was informed the Open Meeting was being postponed until early 2018 for administrative reasons. Planning would continue at the September 2017 meeting.

15. For Information

15.1 EU Update — Oral

The Committee noted the oral briefing.

16. Any Other Business

The Committee discussed the proposal for an additional meeting of the ACNFP to be held in August because of the large volume of initial opinions from other member states being progressed ahead of the introduction of the revised novel food regulation.

17. Date of next meeting:

The next meeting is scheduled for Wednesday 16 August 2017 in Aviation House.