# ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

# MINUTES OF THE ONE HUNDRED AND THIRTY SECOND MEETING HELD ON 22 NOVEMBER 2017

ACNFP Secretariat
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**MINUTES OF THE HUNDRED AND THIRTY SECOND MEETING OF THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES, HELD ON 22 NOVEMBER 2017 IN CONFERENCE ROOM 5, AVIATION HOUSE.**

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| **Present** | Professor Peter Gregory – **Chairman** |
| | Dr Anton Alldrick<br>Dr Camilla Alexander-White<br>Professor Michael Bushell<br>Professor Susan Duthie<br>Dr Hamid Ghoddusi<br>Dr Rohini Manuel<br>Professor John Mathers<br>Professor Harry McArdle<br>Professor Clare Mills<br>Ms Claire Nicholson<br>Professor Christopher Ritson<br>Dr Lesley Stanley |
| **Apologies** | Ms Nichola Lund<br>Mrs Rebecca McKenzie |
| **FSA Assessor** | Colin Clifford |
| **Observer** | Siobhan Watt (Food Standards Scotland) |
| **Secretariat** | Ruth Willis - **ACNFP Secretary**<br>Alison Asquith – **Minutes**<br>Dr 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

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

The Chairman welcomed Siobhan Watt, the observer from Scotland. Apologies were received from observers in the FSA offices in Wales and Northern Ireland.

On behalf of the Committee, the Chairman congratulated Sabrina Roberts on successfully completing her PhD.

The Chairman thanked the Committee for all their good work reviewing applications under the Novel Food Regulations (EC) 258/97. The Committee will review traditional food applications under the Novel Food Regulations (EU) 2015/2283 after 1 January 2018.

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 131st Meeting DRAFT/ACNFP/131/Min

The Committee agreed that the minutes were a true record of the 131st meeting of the ACNFP held on 21 September subject to minor amendments.

## 3. Matters Arising

**Chia Seeds (Betterbody) (Item 9 July meeting)**
The Opinion has been finalised and sent to the applicant.

***Tetraselmis Chuii* (Item 5 August meeting)**
This was a dossier assessed by the Spanish Competent authority on which the UK was consulted. The Committee's comments have been forwarded to the Commission as part of the UK's formal response.

**Oligonol (Item 4, September meeting)**
The Committee's initial opinion has been forwarded to the Commission.

**DHA-rich algal oil from *Schizochytrium Sp.* Extension of Use (Item 5, September meeting)**
The Committee's initial opinion has been forwarded to the Commission

**Bonolive® (Item 6, September meeting)**
The Committee's initial opinion advising that a further assessment is necessary has been forwarded to the Commission.

**EPA rich oil from *Phaeodactylum triconutum* (Item 9, September meeting)**
This was a dossier assessed by the Irish Competent Authority's on which the UK was consulted. The Committee's comments on the opinion have been forwarded to the Commission as part of the UK's formal response.

**4. Summary of the Committee's consideration to date of dossiers under assessment in the UK to be transferred into the centralized risk assessment process. ACNFP/132/1**

The Committee considered the summary for the ongoing dossiers which were being reviewed by the FSA as the UK Competent Authority for novel foods. The summary had been drafted to assist the European Commission and EFSA in their consideration of the dossier when the new Novel Foods Regulation (EU) 2015/2283 comes into force on 1 January 2018. Under the transition measures, Member States will share the information with the Commission on these dossiers and applicants will be required to submit a revised application that meets the requirements under the new regulation. The summary will also be shared with the applicant to assist them when submitting a revised application under the new application process.

The Committee was informed that the application for Isomalto-oligosaccharides (IMO) Extension of use had been withdrawn by the applicant.

The Committee reviewed the summary table for Tongkat Ali. It reiterated the previous comment that the information on allergenicity and characterisation of the novel ingredient was very poor. It also highlighted the comments it had made that the toxicological studies showed changes in blood cell profiles, potential renal effects and potential liver enlargement. These affects should be investigated further to establish whether there were any safety concerns when consuming the novel ingredient. The Committee was also concerned about how the product would be marketed and how it would be ensured that consumers were not misled.

The Committee agreed the summary subject to some amendments.

The summary for the other outstanding dossier for heat killed *Mycobacterium Aurum Aogashima* was considered under the agenda item for that dossier.

*The Secretariat to provide a summary of the application to the European Commission and to provide feedback to the applicant.*

**5. Heat Killed Mycobacterium *Aurum Aogashima* ACNFP/132/2**

The Committee had last considered an application for heat killed *Mycobacterium Aurum Aogashima* at its meeting in June 2016. At that meeting the Committee had raised questions on the concept of the novel food, genetic information, including a full genome characterisation, specification of the novel food and allergenicity. The applicant had responded with a revised dossier and sought the view of the Committee on the revised application.

The Committee considered the applicant had not provided all the information requested by the Committee. The Committee considered that the additional information was difficult to navigate and this raised additional questions on the dossier.

The application stated that HSE had not classified the mycobacterium as a human pathogen,and advised that this was due to existing human exposure from the

environment. The Committee suggested that exposure from the environment was different to consumption of a bacterium and therefore the safety of the ingredient would need to be demonstrated.

There was no information on allergenicity and questions previously asked by the Committee had not been addressed by the applicant. The Committee maintained their concern that bacteria had the potential to activate the immune system and it was not clear from the information provided if this was a positive or negative effect in this case. This was a concern as bacteria are often used in cases to help illicit immune responses when producing antibodies for example.

The Committee noted that some information which had been in the original application was missing - for example the diagram showing the relationship between the species of interest and other bacteria in its genus which can cause disease in humans. There were also inconsistencies in the proposed uses for the novel ingredient. This missing information raised more questions about the safety of the novel ingredient by the Committee.

The Committee noted the specification of the novel food had changed and no longer referred to a red colour. This colour had been considered a good reference for the product by the Committee and suggested production of secondary metabolites. The Committee reiterated its request for a more detailed compositional analysis to understand whether secondary metabolites suggested in the earlier dossier were relevant to the assessment.

The Committee questioned the information provided on the concept of the novel ingredient and continued to have concerns that the novel ingredient had the potential to mislead consumers.

It was agreed to update the summary for this dossier in light of the further points raised by the Committee.

*Action: The Secretariat to provide a summary of the application to the European Commission and to provide feedback to the applicant.*

## 6. Vivinal®GOS PT From Frieslandcampina ACNFP/132/3

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. It had reviewed this application at its last meeting in September and had requested additional information about the composition and any undesirable substances in the novel ingredient. A public consultation has been held and the comments from the consultation were considered by the Committee.

The Committee considered the response by the applicant was good. The reference used to test β-galactosidase should be stated as there were many levels of sensitivity.

The Committee was content with the microbiological contamination information and with the new information provided about the composition. Several specific comments were

made on the draft opinion presented to the Committee for consideration to be taken on board by the Secretariat.

In response to comments made by the public during the consultation, the Committee requested that the draft responses be amended to make clear that its role was only to make judgements in relation to safety. The Secretariat reassured the Committee it would make sure the wording on the web fully reflected the Committee's role.

The Committee agreed that substantial equivalence had been demonstrated.

*Action: the amended opinion to be cleared by Chair's action and the substantial equivalence authorisation will be sent to the applicant.*

## 7. Cascara ACNFP 132/4

The Committee was asked to consider an initial opinion from the Austrian Competent Authority on an application for the authorisation of Cascara as a novel food ingredient. Cascara is made from *Coffea arabica L.* and is the dried skin of coffee cherries. It is also known as coffee cherry.

The Committee remarked that the novel ingredient is intended for use as an ingredient in tea, carbonated and non-carbonated drinks and cereal bars. It raised concerns that consumers would not expect these products, to contain caffeine, and further consideration of appropriate risk management measures such as labelling may be required.

The Committee noted cascara is a traditional food which is used in tea in many parts of the world. It also noted it was a laxative.

The Committee highlighted that when coffee is fermented to separate the beans from the berry husks organisms were also in the fermented product. It queried what organisms were in the fermented product and whether consideration had been given to the potential production of mycotoxins. It also noted that the toxicological studies were on the whole berries and not the dried skin of the coffee cherries which is the novel food/ingredient which would be consumed if authorised.

*Action: The Secretariat to consult the Committee further and this advice will form the basis for the UK's formal response to the European Commission*

## 8. UV Treated Mushrooms ACNFP/132/5

The Committee was asked to consider an initial opinion from the Netherlands Competent Authority on an application for the authorisation of UV treated mushrooms. The purpose of the novel treatment is to convert a precursor of the vitamin present in commercial mushrooms to increase the level of Vitamin D in the mushrooms.

The Committee considered the production process was well controlled to produce vitamin D in a consistent way. The Committee commented that depending on the

wavelength used there was the potential for a significant microbiological effect but this hadn't been measured. The Committee requested further clarification of whether the UV treatment was UVB or UVC and whether the Vitamin D concentration was 10µg/100g or higher.

The Committee commented that there was no information about when the vitamin D levels in the application were measured i.e. was it directly after the treatment. This was felt to be important as levels of vitamin D gradually reduce over time following exposure to UV light and it would have been useful to have information on when measurements of vitamin D levels were carried out.

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

## 9. Chia in Chocolate – Extension of use ACNFP/132/6

The Committee was asked to consider an initial opinion from the Spanish Competent Authority on an application to extend the use of chia as a novel food by authorising it for use in chocolate.

The Committee noted that one case of anaphylaxis because of a chia seed allergy had been reported. It raised concerns that a higher consumption of chia seeds might lead to a higher number of people being sensitised to chia which may lead to higher numbers of people having an allergy. It also commented that information on the presence of chia in products should be clearly labelled to inform consumers.

The Committee questioned the rationale for the approach to the shelf life testing. It requested information on how the data in the one month accelerated study had been used, in addition to the other stability data, to calculate that it was safe to store the novel food for a year. The Committee was satisfied with the stability of the novel food.

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

## 10. *Hovenia dulcis* ACNFP/132/7

The Committee was asked to consider an initial opinion from the German Competent Authority on *Hovenia dulcis* fruit extract in food supplements as a novel food.

The Committee agreed with the concerns of the German Competent Authority, that the material used in the toxicology testing was not the same as the novel ingredient for which authorisation was sought.

It made a number of other comments about the novel food and noted particularly that there was no explanation for the proposed intake level of the novel food in food supplements. It noted that the fruits are windfalls collected from the ground and questioned what quality control measures would be used to ensure the consistency and quality of the product.

The Committee requested a characterisation of the novel food particularly in relation to biological activity. This was felt to be important as potential effects on the liver were suggested from the information provided and it was not clear if these were positive or negative. It also requested more information about the fruit and whether the plant was botanically related to other fruits known to cause food allergy. Of interest was the similarity between the proteins present in the fruit and those of known allergens as this could suggest potential for allergenicity.

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

**11. Open Meeting** **ACNFP/132/8**

The Committee agreed the next steps in the organisation of the open meeting which will focus on the questions to be discussed in the breakout groups.

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

**12. Advice Paper** **ACNFP/132/9**

The Committee was provided with an update about all the applications it has reviewed since 2006.

The Committee thanked the Secretariat for the information.

**13. 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 on 30 November.

**14. Date of next meeting:**

The next meeting is an open meeting and is scheduled for Thursday 22 February in an external venue.