Draft 8 November 2013

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

DRAFT MINUTES OF THE ONE HUNDRED AND TWELFTH MEETING HELD ON 12 SEPTEMBER 2013

ACNFP Secretariat
Room 2A
Aviation House
125 Kingsway
London WC2B 6NH
Tel: (0)20 7276 8596

These Minutes are subject to confirmation by the Committee at its next meeting.

DRAFT/ACNFP/112/Min

DRAFT MINUTES OF THE HUNDRED AND TWELFTH MEETING OF THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES, HELD ON 12 SEPTEMBER 2013 IN CONFERENCE ROOM 5 AVIATION HOUSE.

Present	Professor Peter Gregory – **Chairman**
	Professor Michael Bushell
	Mr Simon Flanagan
	Mrs Nichola Lund
	Professor Harry McArdle
	Professor George Macfarlane
	Professor John Mathers
	Dr Rohini Manuel
	Professor Clare Mills
	Ms Claire Nicholson
	Dr Camilla Pease
	Professor Christopher Ritson
	Dr Carina Venter
Apologies	Professor Andrew Chesson
	Dr Susan Duthie
	Professor Peter Meyer
FSA Assessor	Mr Terry Donohoe
Secretariat	Ms Alison Asquith – **Minutes**
	Dr Chris Jones
	Dr Sandy Lawrie – **ACNFP Secretary**
	Dr Manisha Upadhyay

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 had sent apologies for non-attendance. No written comments from these members were received before the meeting. Apologies were received from the observers from the FSA offices in Scotland, Wales and N.Ireland.

The Chair gave feedback on his annual appraisal meeting with the FSA's Chief Scientist, Andrew Wadge. He also updated Members on a restructuring that will take place in the FSA after the Chief Scientist retires at the end of September.

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 111th meeting DRAFT/ACNFP/111/Min

The Committee agreed that subject to minor amendments the minutes were a true record of the 111th meeting of the ACNFP held on Wednesday 26 June 2013.

3. Matters Arising and Postal Consultations

The Committee received positive feedback from members of the Advisory Committee on Animal Feed, following circulation of the ACNFP's conclusions on the effects of GM feed and non-GM feed in pigs.

4. Buglossoides Oil ACNFP/112/1

The Committee reviewed the applicant's response to concerns raised at its previous meeting when it reviewed this application for the authorisation of refined Buglossoides Oil as a novel ingredient.

The Committee was satisfied with the applicant's response relating to production process details, in particular details about the seed harvesting procedure and the applicant's response to provide reassurance about seed homogeneity. The applicant's rationale for employing additional optional processing steps if required was also reviewed. No further information was requested on these aspects.

The Committee had requested reference papers for certain toxicology studies and, having reviewed these references, indicated that no further information was required.

The Committee reviewed the applicant's response regarding the absence of human study data. The Committee noted that there are no apparent safety concerns relating to this novel ingredient or its known constituents and was satisfied that it is not necessary for the applicant to conduct a human study.

Because neither the novel ingredient nor its source has a history of consumption anywhere in the world, the Committee considered that some type of post-market monitoring scheme (such as adverse effects monitoring) might be appropriate, should the oil be authorized and marketed in the EU. The Secretariat agreed to draft an opinion for discussion at the November meeting.

Action: The Secretariat will incorporate the Committee's comments into the draft opinion for discussion at the next meeting.

5. 1-Methylnicotinamide Chloride (1-MNA

The Committee was given an oral update on an application for the authorisation of 1- as a novel ingredient.

The Committee was informed that the FSA had recently received confirmation from the Medicines and Healthcare products Regulatory Agency that it did not consider 1-MNA to be a medicinal product. In line with the discussion at the June meeting, toxicologists on the Committee would now be asked to complete their scrutiny of the 28 day rat feeding study and the independent review of its results. Once this was completed the Committee would review their conclusions along with with the response from the applicant to the other concerns that were raised in June.

Action: The Secretariat will consult the Committee Toxicologists.

6. D-β-hydroxybutyrate ester **ACNFP/112/3**

The Committee was asked to consider a new application from TDeltaS seeking authorisation for D-β-hydroxybutyrate ester as a novel food ingredient, for use in food supplements targeted at high performance athletes.

The Committee queried why the applicant had not carried out mutagenicity and genotoxicity tests, noting that this would normally be a prerequisite for obtaining ethical approval for human studies with a new substance. The Committee also noted that some of the clinical chemistry parameters monitored during the 28 day rat feeding study showed significant differences and suggested that these findings should have resulted in a follow up 90 day study to assess their significance.

The ACNFP acknowledged that the proposed intake of D-β-hydroxybutyrate ester may be similar to the level of circulating ketone bodies seen under certain conditions where blood glucose levels are reduced, but was of the view that the production of ketone bodies is usually in response to an undesirable physiological condition and is more akin to a pathological response. The Committee also did not agree that the circulating levels of ketone bodies (including hydroxybutyrate) were a relevant comparison when

considering the safety of bolus doses of D-β-hydroxybutyrate ester as a food supplement.

The Committee noted that the bodies of high performance athletes undergo severe physical stress and requested information on the typical circulating levels of ketone bodies seen during extreme exertion and whether supplementation with D-β-hydroxybutyrate ester could increase these to a level which may be a cause for concern. The Committee also noted that the long term effects of consuming D-β-hydroxybutyrate ester as a supplement had not been examined and questioned whether such exposure could have a deleterious effect on an athlete's digestive system.

Action: Secretariat to ask for further information from the applicant

7. DHA rich algal oil from the microalgae *Schizochytrium* **ACNFP/112/4**

The Committee considered an application from DSM for to market oils rich in polyunsaturated fatty acids obtained from a specific strain of the microalgae Schizochytrium sp as a novel ingredient. The oil is proposed for use, primarily, in infant and follow on formula.
The Committee was unsure how the extraction process worked and queried whether, compared with traditional solvent extraction, there was a greater potential for other unidentified (non-lipid) components to be present in the oil. The Committee also requested additional taxonomic information regarding the production strain and whether it had been given a specific culture collection number.

The Committee also requested additional information regarded the extent of microbial control, specifically whether any tests had been carried out investigating potential contamination by Cyanobacteria. The Committee was content with the 90 day study.

Action: The Secretariat to ask for further information from the applicant.

8. Phytosterol Esters – Extension of Use **ACNFP/112/5**

The Committee reviewed the applicant's response to concerns raised at its meeting in June when it reviewed this application to extend the scope of the original authorisation for phytosterol esters.

Dr Camilla Pease informed the Committee that she had worked on similar products at Unilever between 2000 and 2010, however she has not been involved with these or similar products since leaving Unilever's employment in 2010.

The Committee reviewed the data the applicant provided in relation to phytosterol oxidation products,k which provided an indication of the levels present in a range of

different foods and food ingredients, including those with added phytosterol esters. However the Committee noted that these data did not quantify the increase in exposure to phytosterol oxidation products if consumers used exclusively these fortified products for cooking and baking.

The Committee also requested any relevant information on the level of consumption of similar liquid margarine products in EU Member States where they are marketed with added phytostanols.

Action:The Secretariat agreed to seek a view from the applicant and to draft an Opinion for the next meeting.

9. Uncertainty in Exposure Estimation **ACNFP/112/6**

The Committee considered a paper on the assessment of uncertainties following a request by the Committee at the previous meeting that the Secretariat provide an overview of the uncertainties that are associated with each of 4 intake assessments included in the application to extend the scope of the original authorisation for phytosterol esters (see previous item).

The Committee considered the table attached to the paper was useful. The table provided information on the potential sources of uncertainty and whether they would lead to under- or over-estimation of exposure. The Secretariat advise dthat the greatest influence was the assumption that all spreads are fortified, which leads to a significant over-estimation. The Committee considered it would be useful for a paper to be produced for each new application in future, and suggested that a semi-quantitative estimate of magnitude should be included.

Action: Secretariat to produce a paper assessing uncertainties for each application

10. Chia Seeds (Inversoria) **ACNFP/112/7**

The Committee reviewed the applicant's revised dossier and the new certificates of analyses, but indicated that it was still not satisfied with the quality of the information, for example Table 6 where figures for calcium levels for the applicant's seeds are incorrect. It also questioned whether the data had been obtained from accredited laboratories and what validated testing methods were used.

Action:The Secretariat to ask for further information from the applicant

11. Pasteurised milk products treated with *Bacteroides xylanisolvens* **ACNFP/112/8**

The Committee reviewed the favourable initial opinion of the Irish Competent Authority on an application for the authorisation of pasteurised milk products treated with

Bacteroides xylanisolven as a novel food. The Commtitee had commented on the application dossier at its previous meeting.

The Committee was content with the Initial opinion of the Irish Competent Authority and no concerns were raised. The Secretariat agreed to send favourable UK comments to the Commission.

Action: The Secretariat will inform the Commission that the UK does not have any objections to this application.

12. Open Event **ACNFP/112/9**

The Committee agreed the format and the Agenda for the Open Event which is scheduled to take place on the afternoon of 20 November.

13. Items for Information

13.1 EU Update **Oral Update**

13.2 Update on Scientific Advisory Committees (SACs) **ACNFP/112/10**

103.3 GM Wheat **ACNFP/112/12**

The Committee was given an oral update on item 13.1. The Committee noted item 13.2 without comment.

In item 13.3 the Committee was informed of recent advice from the European Food Safety Authority (EFSA) on the design and conduct of long-term feeding studies with whole foods, which is relevant to GM foods and also to novel foods.

14. Any Other Business

(none)

15. Date of next meeting

The next meeting was scheduled for Wednesday 20 November in Aviation House.