ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

MINUTES OF THE ONE HUNDRED AND FOURTEENTH MEETING HELD ON 12 FEBRUARY 2014

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

MINUTES OF THE HUNDRED AND FOURTEENTH MEETING OF THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES, HELD ON 12 FEBRUARY 2014 IN CONFERENCE ROOM 5 AVIATION HOUSE.

Present	Professor Peter Gregory – **Chairman** Professor Michael Bushell Dr Susan Duthie Professor Harry McArdle Professor John Mathers Dr Rohini Manuel Professor Peter Meyer Professor Clare Mills Ms Claire Nicholson Dr Camilla Pease`1 Professor Christopher Ritson Dr Carina Venter
Apologies	Mr Simon Flanagan Mrs Nichola Lund Professor George Macfarlane
FSA Advisor	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. Written comments were received from two of these members before the meeting. Apologies were received from the observers from the FSA offices in Scotland, Wales and N.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 113th meeting DRAFT/ACNFP/113/Min

The Committee agreed that subject to minor amendments the minutes were a true record of the 113th meeting of the ACNFP held on Wednesday 20 November 2013.

3. Matters Arising and Postal Consultations ACNFP /114/P1 & ACNFP/114/P2

The Secretariat reported back on actions taken following the previous meeting:

Item 4, Buglossoides oil: Three public responses were received on the draft opinion but these did not raise any issues that required detailed scrutiny or modifications to the text of the opinion (see attached Table). The opinion was therefore finalised and submitted to the European Commission on 6 January 2014, for circulation to the other Member States.

Item 5, 1-Methylnicotinamide chloride: The applicant has indicated that they intend to respond to the concerns of the Committee and the Secretariat understands that they have already commenced carry out a 13 week feeding study

Item 7, DHA-rich algal oil: The applicant is carrying out additional mycotoxins analyses and, provided that these demonstrate compliance with the stated limits the opinion can be finalised and submitted to the European Commission. A public consultation will commence before the end of February.

Item 9, Phytosterol esters: The Secretariat has provided the additional information about oxidation products and, in the absence of any comments, will carry out a public consultation before the end of February

Item 10, Chia seeds (Supernutrients): As there were no public comments on the application or the draft opinion, the opinion was finalised and sent to the applicant on 9 January 2014.

During December 2013 and January 2014, the Commission had been consulted by post on the following papers:

(i) Tetraselmus chuii (paper ACNFP/114/P1)

In December 2013, Members reviewed a favourable Spanish initial opinion for the novel algae*, Tetraselmis chuii.* Members did not raise any safety concerns and the UK issued a favourable response to the Commission on 7 January 2014. Members raised the following minor comments and these were relayed to the Commission:

- the applicant's proposed portions for "sauce" appear to be rather small. What steps will be taken to ensure that this quantity is not exceeded?
- salt preparations containing the novel ingredient should not be promoted as significant sources of iodine, as implied in one section of the dossier. This would be misleading and nutritionally disadvantageous, as the iodine content is much lower than that of existing iodised salt products.

(ii) EFSA opinions on 3 novel food applications (paper ACNFP/114/P2)

The Committee was invited to consider three opinions from the European Food Safety Authority on novel food applications, for which the Committee had previously raised concerns and questions:

(a) Coriander seed oil

Members accepted the view of EFSA that, if detectable levels of protein were present in the oil, these would present no greater allergenic risk than the protein in coriander seeds, which are widespread in the food chain. One Member suggested that there may still be an outstanding question about the metabolism of petroselinic acid but the consensus view, in line with EFSA; was that the 13 week feeding study offered a margin of safety of 50 and, while this is lower than would normally be expected, human studies offered sufficient additional reassurance that the safety of the oil has been demonstrated at the proposed level of use.

(b) <u>Rapeseed protein</u>

Members were content with EFSA's conclusions in regard to the presence of phytate and accepted that this did not present a cause for concern in terms of trace element bioavailability. Members also agreed with EFSA that the potential for the novel ingredient to trigger allergic reactions in mustard allergic individuals was likely and the suggested that, from an allergy perspective, the safety of rapeseed protein was wholly reliant on an appropriate risk management strategy

(c) <u>Citicoline</u>

Members accepted the view of EFSA in respect of their outstanding safety concern (the presence of unnamed compounds in the final product) but suggested that, as interactions with certain pharmaceuticals (e.g. L-Dopa) cannot be ruled out, it would be prudent for Citicoline to carry a precautionary statement.

The Committee's advice was taken into account when decisions on the authorisation of these novel ingredients were discussed at the Standing Committee on the Food Chain and Animal Health (see paper ACNFP/114/10).

4. Sporopollenin Shells ACNFP/114/1

The Committee considered the applicant's response to concerns raised following its review of this application, for the authorisation of sporopollenin shells as a novel ingredient, at its meetings in February and November 2013.

The Committee considered that its previous concerns had been addressed by the applicant.

The Committee noted that although the ingredient shared some of the structural characteristics of a starch it was a more complex type of biopolymer. It agreed the novel ingredient was highly stable and unlikely to be broken down in the gut. The Committee had no concerns on the physical effects of the novel ingredient.

The Committee noted that no data had been provided on commercial scale production but was satisfied that this was not a concern and that the information relating to the production process was satisfactory.

The Committee noted the novel ingredient had no detectable protein and would therefore be unlikely to be allergenic. While there were no outstanding safety concerns relating to sporopollenin shells themselves, Members remained concerned about some of the possible ingredients that may be incorporated within the shells, such as allergens (protein products, including probiotics) and substances where a small change in bioavailability could have significant consequences (such as iron).

The Secretariat agreed to draft an opinion reflecting the Committee's views, for discussion at the next ACNFP meeting in April.

Action: Secretariat to draft an initial opinion for the next meeting

5. Beta-Hydroxyubutyrate ester (Ketone ester) ACNFP 114/2

The Committee reviewed the applicant's response to concerns raised at its meeting in November 2013, where it requested further studies on mutagenicity, genotoxicity and a longer term animal feeding study.

The Committee was reassured by the mutagenicity study that the applicant had provided but remained concerned about other aspects of this application. While ketosis does occur in humans as a physiological response under certain conditions, the long-term effects are unknown and there is no information on the maximum circulating levels of ketones that can be safely tolerated,

The Committee confirmed its view that a longer term feeding study in animals would be a valuable addition to the existing dataset, given that the existing 28-day animal study had provided indications of possible adverse effects.

The Committee noted the novel ingredient is intended to be consumed when energy demands of elite athletes could not be met solely from glucose metabolism. The resulting ketosis would have a different effect in the body from ketosis caused by carbohydrate starvation.

The Committee also questioned how the novel ingredient was to be marketed. Whilst it noted it would be targeted at “elite athletes” it was not clear how this group would be defined. They therefore sought further information on who the ingredient would be marketed to and whether this would include adolescents who may train to a high level in sports such as swimming. The Committee questioned how the applicant would control marketing and sales.

The Committee asked the Secretariat to draw up a detailed response setting out the Committee’s position, to be cleared by a group of Members and the Chair.

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

6. D-Ribose ACNFP/114/3

The Committee considered the applicant’s response to questions raised at its November meeting concerning the assay method and the protein content of this novel ingredient.

The Committee was satisfied with the applicant’s responses and the Secretariat agreed to draft an initial opinion on this application, for discussion at the next meeting. The Secretariat would also check that the expert advice it previously received developmental toxicity is still valid.

Action Secretariat to draft an initial opinion for the next meeting:

7. Synthetic Resveratrol ACNFP/114/4

The Committee considered the applicant’s response to the concerns and questions that were raised at the previous meeting, concerning the use of synthetic resveratrol as a novel food in food supplements.

The Committee was satisfied with the applicant's responses concerning the production process and possible interaction with medicines. The applicant had reduced the recommended dosage of the ingredient to 150 mg/day, which addressed its remaining concerns about the adverse effects that had been reported in some clinical studies.

Action: The FSA will withdraw the objections that were previously entered against this application by the UK

8. Cycloastragenol ACNFP/114/5

The Committee was asked to consider a new application from K & L Gates on behalf of Telomerase Activation Science Inc., seeking authorisation for cycloastragenol as a novel food ingredient.

The Committee was content with the specification data, data on the production process, its history (as a constituent of complex mixtures extracted from other plant species), and microbiological data. It noted that cycloastragenol is rapidly broken down and has a low bioavailability and therefore suggested that information on nutritional effects should include the breakdown products. The Committee was content with allergenicity data as a crystallised substance would be unlikely to contain protein.

The Committee noted that the low solubility of the novel ingredient may limit the usefulness of in vitro tests.

In view of the rapid metabolism and low bioavailability of the novel ingredient, the Committee considered there was a need for further information on its metabolism and whether it was the same in rats and humans.

The Committee noted that cycloastragenol may alter telomerase activity and special attention should be paid to effects on carcinogenesis. Data from a study in nude mice carrying human tumour grafts were reassuring, but there were indications of an increase in liver tumours in another study where mice were given cycloastragenol for 4 months. This study had used a small number of animals and the increase in tumour incidence (~30%) was not statistically significant Nevertheless, as there was a plausible mechanism for such an effect, the Committee advised that it should be further investigated, for example through a lifetime feeding study.

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

9. Open Meeting ACNFP/114/6

The Committee noted the feedback from delegates who attended the open meeting. Several people had commented on the timing and the Chair observed that the start had been delayed due, in part, to a heavy agenda for the Committee's normal business

meeting that preceded the open event. Attendees had been doubtful whether the points they made would influence the Committee's future discussions. Members agreed that open events do not influence the Committee's opinions on individual dossiers, which are based on the evidence supplied, but the wider discussion certainly helps the Committee refine its approach, for example to traditional foods.

The Committee agreed to hold a workshop to consider points raised in the open meeting's discussion groups.

Action: Secretariat to organize a workshop and note feedback for next Open Event.

10. Annual Report **ACNFP/114/7**

The Committee considered a draft of the Annual Report for 2013. The Committee will feedback comments and amendments by postal consultation

Action: Secretariat to finalise the Annual Report, taking Members' comments into account

11. Items for Information.

11.1 FSA Board Discussion on Innovation **ACFNP/114/9**

11.2 EU Update **ACNFP/114/10**

11.3 Update on Scientific Advisory Committees (SACs) **ACNFP/114/11**

11.4 Proposals for a new EU Regulation on Novel Foods **ACNFP/114/12**

The Committee noted items 11.2 and 11.3 without comment.

Under item 11.1 the Chair updated the Committee on the FSA Board discussion which he had participated in on 16 January.

Under item 11.4 the Committee was provided with an update from the FSA.

12. Any Other Business

The Committee was informed of a workshop to be held by the Food Standards Agency, on 11 March, on research into the application of new technologies to the safety assessment of GMOs.

The Committee was informed there was currently a vacancy on the Committee following the resignation of Professor Andrew Chesson on 31 December 2013.

The Chair noted this was the last meeting for Dr Chris Jones, who would shortly be leaving the Food Standards Agency. The Members joined the Chair and Secretariat in

thanking him for all his work for the Committee over many years and wishing him luck in his new post.

13. Date of next meeting

The next meeting was scheduled for Wednesday 16 April in Aviation House.