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**ADVISORY COMMITTEE ON NOVEL FOODS AND
PROCESSES**

**DRAFT MINUTES OF THE SEVENTY-SEVENTH
MEETING HELD ON 20 JULY 2006**

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

1 **DRAFT/ACNFP/78/MIN**

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4 **DRAFT MINUTES OF THE SEVENTY-EIGHTH MEETING OF THE ADVISORY**
5 **COMMITTEE ON NOVEL FOODS AND PROCESSES, HELD ON 20 JULY 2006 IN**
6 **CONFERENCE ROOM 5, AVIATION HOUSE.**
7

8
9 **Present** Professor Mike Gasson – **Chairman**
10 Professor Ruth Chadwick
11 Mr Neville Craddock
12 Professor Jim Dunwell
13 Professor Gary Foster
14 Dr John Fowler
15 Professor Stephen Holgate
16 Dr Peter Lund
17 Professor Clive Meredith
18 Professor Ian Rowland
19 Professor Peter Shewry
20 Dr Anthony Williams
21

22
23
24 **Secretariat** Ms Alison Asquith
25 Ms Suhana Begum
26 Mrs Alison Dyson - **Minutes**
27 Dr David Jefferies
28 Dr Sandy Lawrie - **ACNFP Secretary**
29 Dr Sonia Molnar
30 Ms Annie-Laure Robin
31 Mrs Michelle Young
32

33
34 **FSA Assessor** Dr Clair Baynton

35
36 **Observers** Mr Clifton Gay – FSA
37

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41
42 *Members are required to declare any personal interest in matters under discussion.*
43 *Where Members have a particularly close association with any item, the Chairman*
44 *will limit their involvement in the discussion. In cases where an item is to be*
45 *discussed in their absence, a Member may make a statement before leaving.*

1 **1. Apologies and announcements**

2
3 1.1 Apologies were received from Jill Brand and Alan Malcolm. Apologies
4 were also received from observers from FSA Scotland, Wales and
5 Northern Ireland (Mrs Elspeth MacDonald, Mr Phil Morgan, and Mr Gerry
6 McCurdy).

7
8 1.2 The Chairman welcomed Alison Asquith who will join the secretariat in
9 August.

10
11 1.3 Members noted this was the final meeting for Professor Dunwell, Dr
12 Fowler and Professor Meredith whose term of appointment end at the end
13 of August. The Chairman thanked them for their contributions.

14
15 1.4 The Chairman reminded Members of the need to announce any
16 commercial interests in the business of the Committee, prior to the
17 discussions on each item.

18
19
20 **2. Minutes of the seventy-seventh meeting**

DRAFT/ACNFP/77/MIN

21
22 Members agreed that the minutes were a true record of the 77th meeting of
23 the ACNFP held on Wednesday 17 May.

24
25
26 **3. Matters Arising**

27
28 There were no matters arising.

29
30
31 **4. Noni juice produced by Leap of Faith Farms**

ACNFP/78/1

32
33 At the May meeting the Committee had confirmed it was satisfied with the
34 additional information provided by the applicant but wished to ratify the
35 wording of the sections on botanical identity of the noni fruit used and the
36 shelf life and stability of the dried product. Members were invited to consider
37 the revised text of the draft opinion on equivalence.

38
39 The Committee confirmed that subject to two textual changes they were
40 content with the text of the opinion.

41
42 The Secretariat would arrange the draft opinion to be published on the
43 ACNFP website for a 10 day publication before finalising any changes with
44 the Chairman.

1
2 **5. Ice Structuring Protein from GM yeast**

ACNFP/78/2
ACNFP/78/2 - Addendum

3
4
5 Prior to the discussion of this item Mr Neville Craddock notified the Committee
6 that in the past he had collaborated with one of the individuals named on the
7 application, but not with respect to the subject of this application. The
8 Committee agreed this was indirect interest and he was permitted to remain
9 for the discussion of this item.

10
11 The Committee were asked to consider an application for the approval of an
12 ice structuring protein preparation as a novel food ingredient. The applicant
13 intends to use the novel ingredient in ice cream and other edible ice products
14 to increase their nutrition profiles, organoleptic properties and stability.

15
16 The Committee asked for further explanation of the variability between
17 batches of the ISP preparation, including the extent and pattern of
18 glycosylation.

19
20 Members considered the potential allergenicity of the protein preparation and
21 requested expert advice on the significance of homologies in the amino acid
22 sequences of the ISP and proteins from *Aspergillus niger*. The Committee
23 also requested further details of the sequence analyses conducted by the
24 applicant in 2005. Members also requested that a study be carried out using
25 an animal sensitisation model, noting that the arguments against such a study
26 appeared to be outdated.

27
28 It was suggested that that using cod allergic individuals in Phase I of the
29 assessment of the allergic potential of the ISP preparation may not be
30 representative of the entire fish allergic population, in which case a wider
31 panel of fish-allergic subjects should be studied.

32
33 The Committee confirmed that they were broadly content with the
34 toxicological data provided but requested clarification on two points.
35 Members noted that a concentrated version of the ISP preparation was used
36 in the 90 day subchronic rat study and requested additional information on the
37 preparation of the test material for compositional comparison with the novel
38 ingredient. The Secretariat had received comments from the Independent
39 Science Panel suggesting a need to conduct studies to test long-term
40 inflammation in both young and older animals. The Committee requested
41 expert advice on this point.

42
43 During the discussion on GM yeast the Committee requested sight of the
44 available data on the molecular characterisation of the insert, including the
45 analysis of the insert flanking sequences. Members also requested protein
46 analysis data of the yeast with its non-GM counterpart.

47
48 The Secretariat agreed to contact the applicant to request additional
49 information on the points raised by the Committee.
50

1 **6. Astaxanthin**

ACNFP/78/3
ACNFP/78/3 - addendum

2
3
4 Members were asked to consider an application made by Cyanotech
5 Corporation for an opinion on substantial equivalence of their astaxanthin-rich
6 extract compared with the existing whole-algal product marketed by
7 Astacarotene.

8
9 The applicant intends to market its extract as an ingredient to be used in hard
10 and soft gelatine capsules and tablets to manufacturers of human dietary
11 supplements.

12
13 Members noted that the applicant had failed to address possible differences
14 between the proportions of esterified and non-esterified astaxanthin in the two
15 products. The Committee requested the applicant demonstrate substantial
16 equivalence by providing compositional data to show the levels of free and
17 esterified astaxanthin in both products.

18
19 One comment received following the public consultation had raised concerns
20 that the production method could be prone to contamination resulting in the
21 presence of toxin producing micro organisms. Members requested details of
22 any quality assurance procedures that are in place to prevent contamination
23 of the algal culture. The Committee requested additional information to
24 demonstrate the absence of toxins during the production process including
25 the potential impact of seasonal variations on levels of toxins.

26
27 The Secretariat agreed to contact the applicant to seek additional information
28 on the points raised by the Committee.

29
30
31 **7. Phytosterol food ingredient Cardiabeat**

ACNFP/78/4

32
33 Prior to the discussion of this item Mr Craddock declared a non-personal, non-
34 specific interest and informed the Committee that he had acted as a
35 consultant for another company who had submitted an application for a
36 phytosterol ingredient. The Chairman concluded that he should remain.

37
38 The Committee was asked to consider an initial opinion from the Dutch
39 Competent Authority (CA) on an application submitted by Enzymotec Ltd, for
40 the authorisation of a phytosterol food ingredient for use as a novel food
41 ingredient.

42
43 The Committee confirmed it agreed with the Dutch assessment and was
44 content for authorisation to be granted.

45
46 The Agency, as the UK Competent Authority, will send a formal reply to the
47 Commission reflecting the Committee's conclusion.

1
2 **8. Allanblackia seed oil**
3

4 The Committee was asked to consider an initial opinion from the German
5 Competent Authority (CA) on an application for the authorisation of
6 allanblackia seed oil for use as a novel food ingredient. The applicant intends
7 to use the ingredient in the manufacture of spreads at a level of up to 20%, as
8 a substitute for palm oil or palm kernel oil.
9

10 The Committee noted the inclusion of a sustainable agriculture programme in
11 the application but expressed concern that *Allanblackia stuhlmanii*, one of the
12 sources of the novel food ingredient, is included in the Conservation of Nature
13 and Natural Resources (IUCN) red list of threatened species¹. The Committee
14 noted that the applicant did not identify the species used to obtain the oil
15 samples used in the toxicological tests. It was also unclear whether the
16 samples subjected to chemical analysis were representative of the full
17 diversity of *Allanblackia* species found in the different areas of Africa from
18 which the oil might be harvested.
19

20 Members noted that the applicant had not offered an explanation for the
21 decrease in the white blood cells in the rats fed allanblackia seed oil
22 compared with the control group during the toxicity study. The Committee
23 recommended that this product be labelled as *Allanblackia* seed oil.
24

25 The Secretariat agreed to draft a response to the Commission reflecting the
26 concerns of the Committee.
27

28
29 **9. Alpha-cyclodextrin**

ACNFP/78/6

30
31 At the November 2005 meeting, Members considered an opinion from the
32 Belgian Competent Authority on the application for authorisation of alpha-
33 cyclodextrin as a novel food ingredient. The Committee had raised a number
34 of concerns and the applicant had provided reasoned arguments in response.
35

36 The Committee stated it was content that the information provided by the
37 applicant satisfactorily addressed the effect of the NI consumption in the
38 diabetic population. Members were content that the product would be labelled
39 in line with the labelling Directives 2001/13/EC and 90/496/EC.
40

41 The Committee agreed with the applicant that at the present time there was
42 no pan-European food consumption database to provide intake data but
43 requested that consumption estimates be obtained from the UK National
44 Dietary and Nutrition Survey database. Members confirmed they would await
45 sight of these data before finalising their decision on this issue.
46

47 Members were satisfied with the applicant's explanation that the metabolic
48 fate of the product was expected to be similar to that of similar ingredients.

¹ <http://www.icnredlist.org/search/details.php/34745/summ>)

1 The Committee noted that the rate of metabolism of the NI would have an
2 impact on gas production and GI intolerance, and recommended that the
3 applicant conduct an *in vitro* study to compare the fermentation rate of the
4 product with products of similar composition such as inulin.

5
6 Members were not satisfied that the applicant had addressed their concerns
7 regarding the use of the term 'dietary fibre' in the labelling of such a product.
8 The Committee remained concerned that the novel ingredient could be
9 nutritionally disadvantageous if it was marketed as an alternative to natural
10 dietary fibres.

11
12 The Secretariat indicated it would draft a response reflecting Members'
13 comments for clearance by Chairman's action.

14
15 **10. Italian research on sub-cellular effects of GM Soya ACNFP/78/7**

16
17 The Committee was invited to consider a series of papers published by Italian
18 researchers which examined the differences between the cells from mice
19 given genetically modified (GM) and non-GM soya. Members were asked to
20 identify any conclusions that could be drawn regarding the safety of GM
21 herbicide-resistant soya.

22
23 Members noted that the papers did not state the origin of the GM and non-GM
24 soya used in the feeding studies. There were no details of whether the soya
25 had been grown in a field or under controlled conditions and whether or not
26 the GM and non-GM soya were grown, handled and processed under similar
27 conditions. It was also not clear whether the soya used in the control and GM
28 experiments had a similar genetic background.

29
30 The Committee was unable to determine whether or not the GM and non-GM
31 soya crops had been treated with the herbicide glyphosate, although the
32 authors had suggested that differences in residual levels of glyphosate might
33 be responsible for the observed differences.

34
35 The Committee also requested data on the nutritional equivalence of the two
36 diets and as well as confirmation on whether or not the same experimental
37 animals were used in each study.

38
39 The Secretariat agreed to contact the author of the studies for clarification on
40 these points and to report back to the Committee.

41
42
43 **11. Date of next meeting**

44
45 The next meeting is scheduled for **Thursday 21 September 2006**, in Aviation
46 House.