

1 **Draft 8 December 2008**

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10 **ADVISORY COMMITTEE ON NOVEL FOODS AND**
11 **PROCESSES**

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14 **DRAFT MINUTES OF THE NINETY-FIRST MEETING**
15 **HELD ON 20 November 2008**

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22 ACNFP Secretariat
23 Room 707C
24 Aviation House
25 125 Kingsway
26 London WC2B 6NH
27 Tel: (0)20 7276 8595
28 Fax: (0)20 7276 8564

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

1 **DRAFT/ACNFP/91/Min**

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4 **DRAFT MINUTES OF THE NINETY-FIRST MEETING OF THE ADVISORY**
5 **COMMITTEE ON NOVEL FOODS AND PROCESSES, HELD ON 20 NOVEMBER**
6 **2008 IN CONFERENCE ROOM 3 & 4, AVIATION HOUSE.**
7

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9 **Present** Professor Andrew Chesson – **Chairman**
10 Dr Paul Brantom
11 Professor Harry Flint
12 Professor Gary Foster
13 Dr Paul Haggarty
14 Professor Stephen Holgate
15 Professor John Mathers
16 Dr Clare Mills
17 Mrs Gillian Pope
18 Professor John Warner
19

20
21 **Apologies** Professor Michael Bushell
22 Ms Jayam Dalal
23 Professor Mike Gasson
24 Professor Christopher Ritson
25 Professor Peter Shewry
26 Mr Kevin Swoffer
27

28
29 **FSA Observer** David Gott (item 7)
30 Elaine Stone
31 Paul Willetts (item 8)
32

33 **FSA Assessor** Clair Baynton
34

35 **Secretariat** Ms Azuka Aghadiuno
36 Ms Alison Asquith
37 Ms Shuhana Begum
38 Dr Chris Jones
39 Dr Darren Key
40 Dr Sandy Lawrie - **ACNFP Secretary**
41 Dr Manisha Upadhyay
42 Ms Sandeep Virdee - **Minutes**
43

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

1 **1. Apologies and announcements**

2 Six members had sent apologies for non-attendance. In the absence of Mike
3 Gasson, Andrew Chesson agreed to chair the meeting. Apologies were also
4 received from observers from FSA Scotland, FSA Wales and Northern Ireland (Mrs
5 Elspeth MacDonald, Mr Phil Morgan and Mr Gerry McCurdy).

6
7 The Chairman reminded Members of the need to announce any commercial
8 interests in the business of the Committee, prior to the discussions on each item.
9

10
11
12 **2. Minutes of the 90th meeting**

DRAFT/ACNFP/90/Min

13 Subject to two minor amendments, Members agreed that the minutes were a true
14 record of the 90th meeting of the ACNFP held on Tuesday 16 September 2008.
15

16 **3. Matters Arising**

17 The Secretariat provided the following update on items arising from the
18 previous meeting.
19

20 Item 4 (beta-glucan-rich extract from *Lentinus edodes*): the Committee's draft
21 opinion had been issued for public consultation and no comments were
22 received. The opinion had been made final and was sent to the European
23 Commission as the basis of the UK's initial assessment.
24

25 Item 6 (D-ribose). The Secretariat tabled the letter that had been sent to the
26 applicant setting out the Committee's outstanding concerns about this
27 product. The applicant had asked the Secretariat whether the Committee
28 required additional mechanistic studies on the interaction between ribose and
29 glucose metabolism, in addition to a new study on reproductive toxicity.
30 Members confirmed that they did not.
31

32 Items 7, 8 and 9 (Conjugated linolenic acid, synthetic lycopene and
33 policosanol): the Secretariat confirmed that the Committee's comments had
34 been forwarded to the Commission.
35

36 Item 12 (use of Extranet): there had been no further progress on the
37 development of an Extranet system. The Secretariat would examine the
38 possibility of providing an archive of committee papers for each meeting on
39 CD-ROM.
40

Action: Secretariat

1 **4. Phosphate Distarch Phosphate**

ACNFP/91/1

2 The Committee considered the two outstanding issues that had been raised during
3 the final consultation on their draft opinion, regarding phosphorus levels and the
4 need for an advisory statement highlighting potential GI intolerance in children .
5

6 The Committee accepted that the guidance for dietary management of renal patients
7 had previously been misreported as 'phosphate' rather than 'phosphorus', and that
8 the corrected values meant that any increase in phosphorus intake from the
9 consumption of this novel ingredient (NI) would be negligible. The Committee
10 therefore agreed that there was no need for renal patients to be informed of the
11 presence of phosphorus in the NI.
12

13 The Committee rejected the applicant's view that it was unduly precautionary for all
14 products containing the NI to carry a warning about possible laxative effects in young
15 children. The Committee stated they could not ignore the lack of relevant studies in
16 children particularly as many of proposed food categories such as tinned pasta and
17 biscuits would be attractive to the young.
18

19 The Committee was also of the view that, as these food categories are very likely to
20 be consumed by young children, it would not be unreasonable for the applicant to
21 seek ethical approval to carry out a non-invasive in vivo study in this age group to
22 investigate potential intolerance. Members rejected the applicant's suggestion that a
23 programme of post launch monitoring could be carried out to determine the extent of
24 any GI intolerance on the basis that it would be extremely difficult to obtain
25 meaningful data.
26

27 The Secretariat agreed to alter the opinion to reflect the discussion, and advised that
28 as the draft had undergone two separate public consultations, the final text would be
29 circulated to the Committee for final clearance prior to publication.
30

Action: Secretariat

31
32
33 **5. Touchi (Black Bean) Extract**

ACNFP/91/2

34 The Committee considered this application for the authorisation of Touchi (Black
35 Bean) extract as a novel food ingredient in July and September 2008. It was asked
36 to consider further information provided by the applicant in response to its request for
37 a better analysis to demonstrate the similarity of the proteins in Touchi extract and
38 black bean sauce from the September meeting. It was also invited to consider the
39 text of the draft opinion.
40

41 Members were satisfied that the HPLC traces provided indicated proteins in Touchi
42 extract and black bean sauce were similar however this was subject to confirmation
43 of various experimental details.
44

45 The Secretariat agreed to request further information from the applicant on the
46 method used for HPLC analysis (including sample preparation and UV wavelengths)
47 and on the labelling of the chromatograms.
48

1 The Secretariat agreed to revise the draft opinion to reflect members' comments and,
2 once the experimental details had been confirmed, to issue the document for public
3 consultation.

4 **Action: Secretariat**

5
6
7 **6. Draft EFSA Opinion on Nanotechnology**

ACNFP/91/3

8 Andrew Chesson informed the Committee that, as Chair of EFSA's FEEDAP Panel,
9 he was a member of the EFSA Scientific Committee that had issued this draft
10 opinion and that he would therefore not take part in this discussion.

11
12 Members drew attention to the recently-published report on new materials, from the
13 Royal Commission on Environmental Pollution. This report had highlighted the
14 limited availability of data on ingested nanomaterials and stressed the need to
15 evaluate materials based not only on size but also on their functionality. Public
16 understanding of nanomaterials was a prerequisite for effective risk communication.

17
18 Members also noted that most work to date has been on inorganic nanomaterials
19 and carbon nanotubes, whereas many of the potential food applications were "bio-
20 nanomaterials" such as micelles. It would be valuable to consider the potential risks
21 from "new" nanomaterials in the context of those occur naturally in food and the
22 environment. Also, the interaction of nanoparticles with macromolecules in foods
23 was potentially important, as the resulting complexes could enhance their
24 absorption.

25
26 Members agreed that the EFSA document was valuable but there were apparent
27 contradictions about the adequacy of current approaches to risk assessment, as set
28 out in different sections of the opinion. It would also be useful to prioritise the long
29 list of recommendations and to explain what is driving the development of
30 nanotechnologies in relation to food and food ingredients, since this would give an
31 appreciation of type of applications that come to market.

32
33 The Secretariat agreed to relay the Committee's comments to EFSA, together with
34 those of other FSA Committees.

35
36
37 **7. Conjugated Linoleic Acid (CLA) – Rich Oil**

ACNFP/91/4

38 Paul Haggarty informed the Committee that a group in his Institute was carrying out
39 industry-research on CLA and that he had not previously reported this as he had
40 only recently become aware of this work. The Committee agreed that this did not
41 represent a conflict of interests and did not prevent him from taking part in this item.

42
43 The Committee considered the Irish Competent Authority's (CA) initial opinion on this
44 application for CLA-rich oil derived from safflower oil as a novel food ingredient in
45 July 2008. The Committee raised a number of comments and concerns and these
46 had formed the basis of the UK's response to the CA's opinion. Several other
47 Member States had also raised objections. The Committee was asked to consider
48 the applicant's response to the points raised by the UK and by other Member States.

1
2 The Committee was not satisfied with the applicant's response to its concerns about
3 intake of the novel ingredient, stability/oxidative stress and animal studies.

4
5 The Committee reiterated its concerns about intakes, noting that the estimated
6 intake for children is similar to adults but the proportion consumed in relation to body
7 weight is substantially higher. Children are therefore likely to be overexposed to the
8 novel ingredient considering the wide range of food products it is intended to be used
9 in. The Committee noted that the EFSA report referenced in the applicant's response
10 appeared to confirm the recommendations from COMA (Committee on the Medical
11 Aspects of Food and Nutrition Policy).

12
13 In relation to this issue, Members raised a general question on whether the balance
14 of isomers in CLA products is of concern. However the Committee noted the
15 Scientific Advisory Committee on Nutrition (SACN) report 'Update on Trans Fatty
16 Acids and Health 2007'¹ which considered recent evidence regarding the health
17 effects of *trans* fatty acids (TFA). The review endorses the current recommendation
18 set by COMA (1994), that the average TFA intake should not exceed 2% of food
19 energy.

20
21 The Committee was also not satisfied with the applicant's response regarding
22 oxidative stress and noted that markers of oxidative stress do increase with ingestion
23 of the novel ingredient. In terms of product stability the Committee was of the view
24 that the comparison with vegetable oils, such as safflower oil from which the
25 ingredient is sourced, was incorrect as these oils contain natural antioxidants e.g.
26 tocopherols. The Committee reiterated its concerns that appropriate anti-oxidants
27 need to be used to ensure the stability of the product.

28
29 The Committee noted that the applicant continued to put a low weighting on animal
30 studies and therefore its original comments should stand.

31
32 The Secretariat noted that the Committee's comments will be used to inform the
33 Food Standards Agency's position in future EU discussions on the authorisation of
34 this novel ingredient.

35 **Action:Secretariat**

36
37
38 **8. Emerging Technologies**

ACNFP/91/5

39 The Committee was invited to consider a recent review of emerging technologies for
40 food processing, which had been carried out by the Food Processing Faraday
41 Partnership on behalf of the Food Standards Agency, and to identify any topics
42 requiring detailed consideration.

43
44 The Committee noted the increasing interest in modifying the composition of food
45 and suggested that nutritional knowledge was lagging behind the ability to derive
46 new ingredients with postulated beneficial effects. Any proposed benefits and the
47 associated health or nutrition claims were not evaluated in the EU as part of the
48 novel food procedures. This was in contrast to the approach taken in New Zealand,

¹ Available at http://www.sacn.gov.uk/pdfs/sacn_trans_fatty_acids_report.pdf

1 where safety and claims are examined together. This raised the question whether
2 new foods and processes might be examined on the balance of risks and benefits,
3 rather than solely on the basis of risk.

4
5 The Committee noted the increased emphasis on ingredients derived from fungi and
6 algae, which was already seen in recent novel food applications and underlined the
7 need to have appropriate expertise among the Committee membership for the
8 assessment of such products and of their production methods.

9
10 Finally the Committee noted that the development of new plant varieties by
11 conventional (non-GM) plant breeding was being accelerated by the application of
12 new technologies, and that the introduction of new varieties could lead to step
13 changes in the composition of crops.

14
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16 **Action: Secretariat**

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18 **9. Reproduction studies in mice with GM Maize NK603×MON810ACNFP/91/6**

19 The Committee considered a report on three long term reproduction studies in mice
20 whose diets contained 33% of maize flour from a GM source (NK603 x MON810), a
21 non-GM source related to the NK603 line (ISO), or an unrelated non-GM source
22 (REF).

23
24 The Committee observed that the report described what had been done and what
25 results were obtained but it did not go into the level of detail that was needed to
26 make a full evaluation, as would be required when carrying out a risk assessment on
27 a new GM food.

28
29 Although the three test materials used in these studies were reported to be
30 "substantially equivalent" this was not tested statistically and the results of the
31 nutrient analyses were reported only as single values. Among these figures there
32 appeared to be differences in some micronutrients that could be important for
33 reproductive performance (iron and zinc).

34
35 Although it is a general principle that safety tests should be conducted on materials
36 that are representative of what is consumed (as food and/or feed), it was notable that
37 the maize meal used in these studies was not heat-treated, which would be the case
38 for commercial maize products used as food or feed. The multi-generation study
39 was of a conventional design but used an outbred mouse strain, which meant that
40 the analysis was complicated by possible genetic differences in the successive
41 generations due to inbreeding.

42
43 The Committee noted that the report highlighted differences in reproductive
44 performance between the GM and ISO groups in the continuous breeding study.
45 This is not a type of study that is used in Europe and most experience with this
46 methodology is in the USA, where it has been used in the National Toxicology
47 Program. The current study differs from the standard protocol in that the pups
48 remained with their parents until weaning. This means that each subsequent litter
49 was conceived during the lactation phase of the previous reproductive cycle.

1 Although the authors reported a reduction in the number of litters in the GM group
2 compared to the ISO group, they did not carry out any further investigations into the
3 possible causes. They also did not report any results from examination of the
4 offspring.

5
6 The Committee noted that the statistical treatment of the results was simplistic and
7 should be reviewed. The Committee also noted that it was not valid (in the multi-
8 generation study) to compare the GM group with a pooled control consisting of the
9 ISO and REF groups, since the latter two groups were shown to be significantly
10 different.

11
12 The treatment groups in the long term feeding study were relatively small (10
13 animals of each sex) which would have limited the ability to detect possible
14 differences. An assessment of the power of this study would have been helpful.

15
16 In conclusion, the Committee was satisfied that the observations were correctly
17 reported and that there were differences in some parameters. However, it was not
18 possible to draw any conclusions about cause and effect or to assess the
19 significance of these differences for human or animal health, for the reasons set out
20 above.

21 22 23 **10 ACNFP Open Event**

ACNFP/91/7

24 Members considered the proposed programme for the annual ACNFP open event to
25 be held on the afternoon of 18 February 2009.

26
27 The Committee agreed the topics for discussion and the opening presentations. Post
28 marketing surveillance was proposed as a possible additional topic. The Committee
29 agreed that it could be included either in the discussion on estimating and controlling
30 intake levels of novel food or in the presentation on novel foods and how they are
31 handled across the European Union.

32
33 Three members of the Committee agreed to volunteer as chairs for the small
34 discussion groups and to give short presentations on the specific topics.

35 36 37 **11. Items for Information**

38 **Update on other Scientific Advisory Committees**

ACNFP/91/10

39 **FDA Guidelines for the assessment of GM Animals**

ACNFP/91/11

40 The Committee noted these information papers without comment. The Secretariat
41 informed the Committee that the information paper ACNFP/91/8 (on EU
42 developments) would be distributed by post after the meeting and the information
43 item on novel food notifications was deferred to the next meeting.

1 **12 Any other business**

2 None

3 **13 Date of next meeting**

4 The next meeting was scheduled to be on 19 February 2009

draft