Minutes

Advisory Committee on Novel Foods and Process. Minutes of the 168th Meeting held on the 17th and 18th of September 2024

These minutes are subject to confirmation by the Committee.

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.

Minutes of the 168th meeting of the Advisory Committee on Novel Foods and Processes, held on the 17th and 18th of September as a hybrid meeting**.**

Attendance

Committee Chair

Dr Camilla Alexander-White

Committee Members

Dr Anton Alldrick

Ms Alison Austin

Dr Meera Cush

Dr Sophie Foley

Dr Andy Greenfield

Professor Wendy Harwood

Professor Huw D. Jones

Dr Elizabeth Lund

Professor Dimitris Charalampopoulos

Professor Clare Mills

Dr Lesley Stanley

Dr Ray Kemp

Prof Hans Verhagen

Professor George Bassel

Dr Lynn McIntyre

Dr Isabel Skypala

Dr Maureen Wakefield

Professor Harry McArdle

Professor Susan Fairweather-Tait

Dr Mark Berry

Apologies

Professor Paul Fraser

Professor Bruce Whitelaw

Dr Cathrina Edwards

Assessor

Mr Paul Tossell - Head of Radiological, GM, Novel Foods & Radiological Protection

Observers FSA

Mr Joshua Ravenhill - Head of Policies Priorities

Mr Shaun Jacobs - Senior Policy Advisor

Mr Wecktone Munyai - Senior Policy Advisor

Ms Jessica Dewhurst - Policy Advisor

Ms Sophie Burder - Policy Advisor

Ms Claire Rue - Policy Advisor

Observers Devolved administration

Mr Jeremy Mills - Policy, FSA Wales

Ms Kaila Lee Policy - FSA Wales

Ms Katy Williams Policy - FSA Wales

Mr Peter Madden Policy - FSA Wales

Ms Siobhan Watt - Food Standards Scotland

Dr Karen Pearson - Food Standards Scotland

Ms Aileen Livingstone - Food Standards Scotland

Ms Krystle Boss - Food Standards Scotland

Mr Evangelos Katsoulis - Food Standards Scotland

Mr Daniel Lynch Policy - FSA NI

Secretariat

Mrs Ruth Willis - Technical Secretary

Dr Rachael Oakenfull - Technical Secretary PGT subcommittee

Mrs Priscilla Wanjiru - Lead Secretariat

Dr Karin Heurlier - Lead Secretariat PGT subcommittee

Mr Ben Haynes - CBD Lead Secretariat

Dr Daniel Lloyd - Science Secretariat

Dr Rhys William - Science Secretariat

Mr Matt Hall - Science Secretariat

Mrs Afielia Choudhry - Science Secretariat

Ms Lucy Thursfield - Science Secretariat

Mr Will Smith - Science Secretariat

Miss Victoria Balch - Administrative Secretariat

1. Apologies and Announcements

Apologies were received from Professor Paul Fraser, Professor Bruce Whitelaw and Dr Cathrina Edwards for non-attendance on both days, while Professor Harry McArdle and Professor Peter Gregory could not attend on day 2.

This was Professor Harry McArdle's last meeting as he has asked to resign from the ACNFP due to his other commitments. He was thanked for his long service both as the SACN representative on the ACNFP and as one of the ACNFP's nutrition specialists. His contribution and expertise were recognised by the Committee.

The Chair reminded Members of the need to announce any potential conflicts of interests prior to the discussions on each item.

Dr Anton Alldrick and Professor Harry McArdle previously declared interests in relation to CBD. Professor Hans Verhagen also declared a conflict of interest in relation to Dried Miracle Berry. The Chair and Secretariat advised that these members would not be present for the discussion of these items.

The members were also informed of Dr Tahmina Khan's promotion to lead the Additives, Flavourings and Enzymes Team in regulated products risk assessment unit. They wished her well in her new role.

2. Welcome

The Chair welcomed the Members, representatives from the FSA, the observers from the devolved administrations and the Secretariat team.

3. Meeting Minutes for the 167th Meeting

ACNFP/167/MINS

The Committee agreed the 167th meeting draft minutes for publication on the ACNFP website.

4. Matters Arising from the last meeting

ACNFP/167/MA

The Secretariat reported on actions from the 167th meeting:

- GMO RP1962 – The Committee Advice Document for this application was reviewed by the members with a few amendments suggested to be finalised by Chair's action. This application has now moved to the publication process.
- Baru nut – This traditional food from a third country was reviewed by the members where they highlighted data gaps that could be relevant to safety on various aspects of the application. A summary was provided by the Secretariat to inform Risk Managers for their decision on whether to raise reasoned safety objections. The application is with risk managers.
- Corn Protein – Following the review by members of the Committee on various concerns for this application, the Secretariat explored a way forward with the applicant. The applicant has since withdrawn this application.
- Akkermansia muciniphila – Members raised some queries with this application at the last meeting. Further information was sought from the applicant and the response was used to update the CAD that was sent for clearance by correspondence. Members were thanked for their input, and this will now move to publication.
- Cannabidiol RP11 – Members were requested to review the draft Committee Advice Document where they identified areas for the Secretariat to amend. This has now entered the publication process.
- Cannabidiol RP340 – Members were requested to review the draft Committee Advice Document where they identified areas for the Secretariat to amend. They also advised that a review of the genotoxicity data was needed. Further information is being sought from the applicant to allow the assessment to be finalised.
- Cannabidiol RP349 – This application was postponed allowing further review of the analytical and compositional data. This will be presented on day 2 of the 168th meeting as agenda item 11.
- Annual Report – The annual report was reviewed by the members with a few amendments suggested. These were cleared by Chair's action. The annual report can now be found on the ACNFP website.

- Items 5 and 6 Akkermansia muciniphila RP1468 (ACNFP/168/01) and Vitamin D2 mushroom powder RP1550 (ACNFP/168/02) were intersessional papers. The Committee Advice Documents (CADs) for these applications were circulated to members via correspondence. Following their agreement, these have moved on to the publication process.

7. Genetically Modified Organism application RP307 (reserved business)

ACNFP/168/03

The Committee reviewed the Committee Advice Document which had been prepared by the Secretariat following review of the application by the ACNFP-PGT Subcommittee.

The Committee reviewed the approach taken by the applicant regarding the use of the comparative analysis of the MS11 × RF3 stacked event in B. napus as a surrogate for assessment of the sterile MS11 B. napus event due to technical limitations. The technical reasons for the difficulties in gathering data on MS11 B. napus were reviewed in detail. The Committee agreed with the opinion of the ACNFP-PGT Subcommittee that this was an appropriate method to review safety of the stacked event in these specific circumstances.

The Committee also reviewed the molecular characterisation of MS11 B. napus and MS11 × RF3 B. napus as a stacked event, and the food/feed safety assessment encompassing assessments of toxicity allergenicity and nutrition and agreed with the ACNFP-PGT Subcommittee that there are no safety concerns.

The Committee Advice Document was agreed subject to amendments to be finalised by Chair’s action.

Action: The Secretariat to update the Committee Advice Document to conclude the assessment.

8. Krill Protein RP1290

ACNFP/168/04

An application for Krill Protein Hydrolysate was discussed for the second time by the ACNFP at the 168th meeting. Two requests for information and corresponding responses from the applicant were reviewed. Members also made comments on

the draft CAD. A number of points were raised to be addressed in the next draft.

The Committee advised that further clarification was needed to ensure the information on the production process and its food safety management plan were consistently reported. Of particular interest was the use of heat treatment steps and any influence this had on the microbial composition of the novel food.

To appropriately characterise the novel food, it was agreed that information on the degree of hydrolysis of the novel food should be included in the CAD along with the data provided on biotoxins. As part of the review of the wider composition, it was suggested that the values provided for arsenic and selenium be checked to ensure any implications for safety be placed in the context of the proposed use of the novel food. The compositional analysis suggests that the fishing grounds used may be important in influencing any contaminants present.

There was exploration of the evidence provided to support the toxicological safety and tolerability of the novel food, no concerns were identified in terms of general acute or chronic systemic toxicity. The basis for safe upper intake would be linked to compositional factors including contribution to protein consumption.

Krill are crustaceans and as such are considered to be allergenic foods. They are required to be labelled under assimilated regulation 1169/2011 EU. To inform the allergenicity assessment, further consideration was needed of whether the presence of fish allergens from by-catch during fishing of krill were a risk for sensitive allergic consumers. Further information was sought on whether by-catch is consistently monitored by the applicant and the level of unintended presence of allergenic food (fish) in the raw material for the novel food.

Action: Secretariat to seek clarification on production process, specification and allergenicity.

Action: Secretariat to update the Committee Advice Document in light of the points raised and the applicant’s responses for clearance by the Committee via correspondence.

9. Dried Miracle Berry (DMB®) RP1351

ACNFP/168/05

Professor Hans Verhagen declared an interest. It was agreed with the Chair that he would not be present for the discussion.

The Committee reviewed this application previously at the September 2023 meeting. This resulted in further information being sought from the applicant on the production process, composition and specification. Members reviewed the applicant’s responses and agreed that the information was sufficient.

The Committee was also asked to review a first draft Committee Advice Document for this application and suggested amendments and points to review further. It was highlighted that the quantification of the miraculin, considered as characterising the novel food by the applicant, was assessed by a method that has not been appropriately validated, limiting its value in the assessment.

Members had previously commented on the potential for miraculin to be a kunst inhibitor protein which are known to be stable. As stability of proteins can be an indicator for allergenicity this warranted further review in the allergenicity assessment. It was noted that the applicant had used testing approaches which were not consistent with the guidance used in the UK for novel foods and as such this should be reflected in the CAD. Members also suggested the Secretariat check the production information and the microbial results presented to ensure these were consistent and representative.

The Secretariat was advised to circulate the CAD to the members, to be cleared by correspondence.

Action: The Secretariat to amend the Committee Advice Document for clearance by correspondence.

10. Esterified Propoxylated Glycerol RP1363

ACNFP/168/06

An application for Esterified Propoxylated Glycerol (EPG) was reviewed for the first time. The discussion of the application identified areas where further information is required to complete the assessment.

Members noted that the novel food is manufactured from propoxylated glycerol and fatty acids. Given the range of fatty acids and the different forms of propoxylated glycerol available, a very large number of different EPG molecules could be produced. How the range of products could be managed to help limit the scope of the substances in the ingredient was raised as a point for discussion with the applicant. The Committee advised clarification to be requested from the applicant on the different types of EPG, for which authorisation is being sought

under this application and their chemical structures. This will inform appropriate characterisation of the novel food seeking authorisation.

EPG can be manufactured as a softer, spreadable form or a harder, confectionary form. The Committee suggested that test data including compositional and toxicological data should be provided for each form of the novel food seeking authorisation to inform the assessment of safety.

The Committee reviewed the stability data for the novel food. Members felt the environmental conditions used in these studies were not representative of 'real-life' use. Members recommended further stability data be generated for both the harder and softer forms of EPG, in conditions the product is likely to be stored by end users. Any study should include the impact of heating or cooking. Stability data on the novel food in finished products was also recommended.

The Committee reviewed the sub-chronic studies provided in support of the application. Members noted that these were conducted over twenty years ago and therefore suggested further safety data was needed conducted using the current OECD guidelines under Good Laboratory Practice (GLP) conditions. This is because the design of the study has changed significantly since that time.

The Committee noted that the applicant also conducted a human study to assess the impact of the novel food on different biomarkers. No calculation on the sample size of the study was provided, therefore the significance of the results remained unclear. A further human study is suggested with reference to fat soluble vitamins, plasma levels of which may change upon consumption of the NF.

Action: The Secretariat to seek further information from the applicant to further the assessment of the novel food.

11. Alternative and Cell Cultivated Proteins Sub-committee

ACNFP/168/08

The Committee reviewed the proposal to establish a Sub-committee of the ACNFP to consider cell cultivated proteins and alternative proteins. The Sub-committee would allow consideration across applications on cross cutting issues for these new novel foods. Following questions on the operation of the Sub-committee, its formation was agreed by the Committee, as this provided an efficient model for

considering these topics, building on experience from other ACNFP subgroups. The terms of reference will be developed for consideration at the next meeting. Volunteers from the Committee to be involved with the work were sought including the Chair of the Scientific Advisory Committee on Nutrition (SACN). Members were asked to contact the Secretariat after the meeting if interested.

The potential topics to be considered by the Sub-committee were explored. The discussion also considered how the range of stakeholder's views could be taken into account. It was proposed by the Secretariat that an open session of the ACNFP could be held early in 2025 to prioritise the key topics for the Subcommittee's consideration. This was agreed in principle, subject to budget and further details on the running of the session being developed for review at next meeting.

Action: The Secretariat to develop the terms of reference for the group for finalisation with the Committee at the November meeting.

Action: The Secretariat to develop a proposal for an open session of the Committee to prioritise topics for the subcommittee's review.

12. Cannabidiol (CBD) RP793 (Reserved Business)

ACNFP/168/09

The Committee's advice was sought on the handling of applications which sought a higher use level for CBD than the provisional ADI of 10 mg/day. One such application was RP793. The dataset for RP793 includes several good quality toxicology studies where >98% pure CBD has been tested. Taken in isolation, the data indicated a higher point of departure than had been selected to assess the safety of >98% pure CBD, using the totality of the FSA's knowledge and wider body of evidence that underpins the provisional ADI. The data submitted by the applicant indicated that it was applicable to consider the provisional ADI, and the product would be considered safe up to an intake of 10 mg/day.

It was agreed that for applications seeking higher use levels than 10 mg/day intake of CBD, that a section needed to be developed for use in the CAD relating to such products. From the FSA's wider evidence on CBD, the safety of intakes higher than 10mg/day had not been demonstrated for RP793. The CAD would be revised based on the review of the evidence for RP793.

The question of what data if any would support upwards revision of the ADI was explored. It was noted that a single study is only likely to influence the ADI if it identified a new more sensitive adverse effect such as an impact on another system in the body than liver or thyroid at doses lower than the effects seen in the data so far. In such cases the ADI may be lowered. The potential to raise the ADI was considered unlikely as new data does not negate the evidence already considered that suggests effects could be seen at lower levels. As such, there is a clear message from the Committee that scientifically no further sub-chronic 90-day studies for >98% pure CBD would in principle be needed to evaluate the safety of >98% pure CBD in products.

The Committee discussed the apparent conflict between a scientific approach to derive a provisional ADI from the body of evidence, as is commonly done in foods safety evaluation, vs the legal need for applicants to provide relevant and specific data under Novel Foods regulation. Also, the FSA has a duty to use all available data and evidence to assure consumer safety i.e. evidence of more sensitive effects or studies with lower points of departure cannot be ignored in the interests of consumer protection. It was agreed to highlight this issue within the FSA to ensure an appropriate balance between meeting the requirements of the legislation, ensuring decisions are based on all relevant scientific evidence and efficiency in the assessments, could be identified.

Following the discussion, it was commented that other approaches to producing an ADI for CBD had been published in the academic literature. The ACNFP asked the joint ACNFP/ COT Subgroup to take another look at the specific evidence used to support ADIs developed by Henderson et al 2023 and compare with the FSA's wider evidence base that underpins the FSA provisional ADI.

Action: The Secretariat to update the CAD for RP793 in light of advice from the ACNFP for clearance by Chair's action.

Action; The Chair to work with the Secretariat to raise the topic of legal data requirements within novel foods regulation for CBD. A meeting would be scheduled with the Chief Scientific Adviser in October 2024.

Action: The Secretariat will request the ACNFP/COT sub-committee to review the available ADI's in the published literature, including Henderson et al., 2023.

13. Cannabidiol (CBD) applications from British Cannabis (Reserved Business)

ACNFP/168/10

The Committee reviewed a new application for Cannabidiol (CBD) Isolate as outlined in applications RP220, 245- 256, 324-325 from British Cannabis for the first time. The >98% pure CBD novel ingredient is proposed by the applicant for use in food supplements.

The Committee were also asked to review a draft Committee Advice Document for this application.

The toxicology studies provided in support of the application were reviewed and were considered scientifically sufficient to support the safety of the novel food if they had been produced to the principles of GLP. However, the Committee advised that there are administrative gaps on the completeness and provenance of the study reports provided.

Redacted and incomplete study reports for the OECD TG408 sub-chronic study and the OECD TG471 bacterial reverse mutation study raised concerns regarding the administrative provenance of these studies. Furthermore, a study report was not provided for the OECD TG487 in vitro micronucleus assay, resulting in an incomplete genotoxicity safety assessment of the novel food.

The Committee concluded their assessment and considered that insufficient data of appropriate quality had been provided. This would be needed for the application to progress to a positive outcome. It was noted that the study used for this application is from a consortium and as such the views on this application would apply to others in the consortium using the study.

Action: Secretariat to explore the way forward for the novel food.

Action: Secretariat to refine CAD in light of Committee advice and discussions with the applicant for clearance by Chair’s action.

14. Cannabidiol (CBD) RP349 (reserved business)

ACNFP/168/11

The Committee reviewed application RP349 for isolated cannabidiol for the first time. The toxicology studies provided in support of the application were reviewed and were considered sufficient to support the safety of this novel food. The NOAEL identified in the sub-chronic toxicology data to support this application was consistent with the evidence used to develop the provisional ADI and the wider evidence seen on CBD. As such it would be scientifically appropriate to apply the provisional ADI as per Government advice. The Committee advised that the safe upper intake for the novel food was considered to be the provisional ADI for ≥98% pure CBD of 98% or above purity of 0.15 mg/kg bw/day, equivalent to 10mg CBD per day in a healthy 70 kg adult.

Members also identified areas for the Secretariat to amend in the draft Committee Advice Document to accurately reflect the assessment that had been done. The CAD was agreed subject to amendments for clearance by Chair's action.

Action: Secretariat to revise the CAD for clearance by Chair's action.

15. Cannabidiol (CBD) RP176 (reserved business)

ACNFP/168/12

The Committee reviewed a new application for Cannabidiol (CBD) Isolate as outlined in applications RP176 from 'Curesupport holding b.v' for the first time. The novel ingredient is proposed by the applicant for use in food supplements.

The Committee were also asked to review a draft Committee Advice Document for this application.

Following discussion clarification was sought on the advice from the ACNFP/COT Subgroup for this application to complete the toxicological aspect of the review. The Secretariat was asked to check the details of the review of the data by the Subgroup for this application, in order to support a fuller review by the Committee.

Action: Secretariat is to confirm the view of the ACNFP/COT CBD Subgroup for this study to inform further review by the ACNFP by correspondence.

16. Draft statement on Tetrahydrocannabinol (THC) as a contaminant in food (reserved business)

ACNFP/168/13

The Committee was provided with an introduction to the draft statement on THC as a contaminant being developed by the joint ACNFP/ COT Subgroup. Members were introduced to the scope and the key thinking and data used to underpin the current draft. This will be refined and brought to the Committee for review by the end of 2024.

17. Dry Cacaofruit Cascara RP1484

ACNFP/168/07

The Committee reviewed a novel food application for the first time for Dry Cacaofruit Cascara. In March 2022, the FSA received the submission for Dry Cacaofruit Cascara from Cabosse Naturals N.V. The novel food is the outer husk of the cacao fruit that has been emptied off the cacao beans, cleaned, dried and ground into a powder. It is proposed to be used as an ingredient in various foods and beverages for the general population.

Members identified data gaps in the production process and composition. Queries were raised on the controls in place in the product process which address hazards. Further information on the sources of variation in the production process was also sought. Further information was needed on the level of chlorate residues in the husk from washing with chlorine.

Members noted the comparator used to inform the investigation of potential contaminants (pesticides, heavy metals) and antinutritional factors and the interpretation of whether the levels found were safe. The relevance of the comparator needed further explanation given the level of exposure for this product would be higher than in cocoa beans. The level of theobromine in the novel food was explored but members were reassured that the levels present in the final novel food were lower than for chocolate.

The allergy data presented were explored. It was noted the applicant had followed the guidance in use in GB with the allergy analysis demonstrating a good outcome. Members recommended that the Secretariat ensured this was captured

fully in the CAD.

Action: The Secretariat to request further information from the applicant.

18. Items for Information

18.1 Novel Foods Policy Update - Written

The Committee were provided with a written update on the issues under consideration regarding novel foods.

18.2 GM Policy Update - Written

The Committee were provided with an oral update on the issues under consideration regarding GM.

18.3 SACS Update - Written

The Committee were provided with a written update on the activities of the different SACs.

18.4 Decisions Panel Outcome - Written

The Committee were updated on the outcome of the FSA’s Regulated Products Decision Panel.

Date of next meeting

The next ACNFP meeting will be held online on 20th November 2024.