Meeting

Advisory Committee on Novel Foods and Process. Minutes of the 153rd Meeting held on the 8th June 2022

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 153rd meeting of the Advisory Committee on Novel Foods and Processes, held on 8th June at Asia House, London and as a hybrid meeting on Teams.

Attendance

Committee Chair

Dr Camilla Alexander-White

Committee Members

Dr Anton Alldrick

Ms Alison Austin

Dr Mark Berry

Professor Susan Duthie

Professor Susan Fairweather-Tait

Professor Paul Fraser

Dr Hamid Ghoddusi

Professor Wendy Harwood

Professor Huw Jones

Dr Elizabeth Lund

Ms Nichola Lund

Dr Rohini Manuel

Professor Harry McArdle

Mrs Rebecca McKenzie

Professor Clare Mills

Dr Lesley Stanley

Prof Hans Verhagen

Dr Maureen Wakefield

New Members

Professor Dimitris Charalampopoulos

Dr Andy Greenfield

Dr Ray Kemp

Assessor

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

Observers FSA

Mr Hoa Chang - FSA GM Policy Advisor

Mr Shaun Jacobs - FSA Senior Policy Advisor

Ms Elizabeth Davies - FSA Novel Food Policy Advisor

Ms Gemma Jones - FSA Novel Food Policy Advisor

Mr Donal Griffin - Head of Regulated Products Risk Assessment (Feed and GM)

Ms Shila Sultana - Regulated Products Risk Assessor

Dr Elli Amanatidou - Trade Risk Assessor

Mr Ka Man Au - Trade Risk Assessor

Ms Helen Kardos-Stowe - Regulated Products Policy Advisor

Ms Chun-Han Chan - Science Assurance & Coordination

Ms Lisa Nelson - Communication Manager

Ms Louise Byass - Strategic Coordinator

Ms Melissa Bookbinder - Strategic Communications

Observers Devolved administration

Ms Alexia Sully Karlis - Policy, FSA Wales

Mr Andrew Dodd - Policy, FSA Wales

Ms Hannah Reid - Policy, FSA Wales

Ms Siobhan Watt - Food Standards Scotland

Mr Joshua Evans - Food Standards Scotland

Ms Lucy Smythe - Food Standards Scotland

Ms Krystle Boss - Food Standards Scotland

Ms Ciaran Weir - Policy, FSA NI

Ms Colleen Mulrine - Policy, FSA NI

Observers (External)

Ms Claire Nicholson - Science Council

Secretariat

Mrs Ruth Willis - Technical Secretary

Mrs Priscilla Wanjiru - Science Secretariat

Dr Karin Heurlier - Science Secretariat

Mr Will Smith - Science Secretariat

Mrs Afielia Choudhry - Science Secretariat

Dr Andrew Hudson - Science Secretariat

Mr Matt Hall - Science Secretariat

Dr Johann Trotter - Science Secretariat

Dr Annalisa Leone - Science Secretariat

Mr Rhys Williams - Science Secretariat

Ms Katie Schultz - Science Secretariat

Mr Ben Haynes - Science Secretariat

Mr Nathan Allen - Science Secretariat

Miss Victoria Balch - Administrative Secretariat

Ms Aisling Jao - Administrative Secretariat

1. Announcements

This was the first hybrid meeting since the beginning of the pandemic with the face-to-face meeting held in London.

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

The Chair also welcomed four new members (Ray Kemp and Dimitris Charalampopoulos were in attendance online and Andy Greenfield was present in person). Bruce Whitelaw sent his apologies as he could not attend the meeting on this occasion. Outgoing Members were thanked for all their hard work at their various capacities within the ACNFP.

2. Meeting Minutes for the 152nd Meeting

ACNFP/152/MINS

The Committee were content with the minutes of the 152nd meeting. Now that these have been agreed they will be circulated to members for information and placed on the website. Reserved business sections and information on CBD will be held until such a time as they can be considered by our internal FSA publication committee.

3. Matters Arising from the last meeting

ACNFP/153/MA

- The Committee reviewed an application for Mung Bean Protein RP19. Further information was sought on the production process, nutritional information and allergenicity. The response from the applicant was discussed under item 7.
- The Committee reviewed a traditional food notification, Bambara groundnut. A summary of the points raised, and the Committee's views were subject to a 10-day consultation which resulted in no responses or additional data from the public. The summary will be finalised and sent to risk managers in the four nations of the UK to develop their risk management advice for Ministers.
- The Committee examined a suggested timeline for the development of criteria to support FSA Policy in establishing a new regulatory framework for Genome Edited (GE) food and feed. There was no further action at this stage, and it was noted that this would be discussed further with the new ACNFP subgroup on Products from Genetic Technologies (PGT) once established.
- In light of the urgency to proceed with supporting technical work on assessing the Products from Genetic Technologies (Precision Breeding) Bill going through Parliament, an agreement was sought to formally appoint the Chair for the new PGT sub-group so work could formally begin in July 2022. The qualities identified for a candidate by the Committee in its 150th meeting (ACNFP/150/06) were; to have a neutral position on the issue, strong chairing expertise, be scientifically respected and with some knowledge of the technical aspects of the group's work. On this basis, Dr Andy Greenfield was nominated by the Secretariat and the Chair of ACNFP and members were invited for comments or objections; none were raised and the committee were supportive of this nomination. Dr Andy Greenfield was formally accepted and welcomed as the Chair of the PGT subgroup and congratulated on his new position. The Secretariat will organise dates for the subgroup meetings for 2022. This sub-group will report back to the ACNFP in

September 2022.

- The Committee also agreed a proposal for the formation of a joint COT and ACNFP subgroup which will address issues surrounding the toxicological safety of cannabidiol (CBD) and hemp-derived food products. Work was ongoing to arrange the first meeting in July 2022.
- The members reviewed for the first time an application on Hemp derived CBD that is intended to be used as an ingredient in the manufacture of food supplements. There was no further action at this stage and the response from the applicant would be considered when available. Progress for this application will be linked to the timing of a wider review of the cross-cutting issues for CBD.
- Lastly, the Committee reviewed for the third time an application for a synthetic form of CBD for use in food supplements. It was noted that there was no further action at this stage and progress for this application will be linked to the timing of a wider review of the cross-cutting issues for CBD.

4. Tetradenia Riparia (Dossier Number RP 1500)

ACNFP/153/01

The Committee reviewed a notification for a traditional food from a third country for Iboza (*Tetradenia riparia*). The product is a plant of the mint family which is traditionally used in teas and as an ingredient in foods in Southern Africa. The applicant is seeking market authorisation for use as a food supplement in the form of a free-flowing powder and capsules, as well as ingredient use in flavoured drink blends. A number of queries were raised on identity, production, composition, toxicology and allergenicity sections of the information provided. It was commented by the Committee that significant information was missing, making it difficult to identify specific risks and determine to what extent the applicant has mitigated those. However, there was some evidence that suggested that this traditional food is associated with hazards and risks that require further explanation.

Areas where information was insufficient particularly focused on the characterisation of the *Tetradenia riparia* both as a source material and a final product seeking authorisation. Queries were raised in relation to the production and the measures taken to manage hazards such as pesticide residues and mycotoxin formation.

The Committee were particularly interested in the information around the traditional use and whether some of the uses were medicinal in nature. A query was raised for risk managers on whether the traditional use was consistent with the requirements of the traditional food process. Some of the information provided was on historical cases of adverse effects from consuming the product. Some of the effects were severe; indeed, there was evidence for fatalities following consumption of the traditional food. Further follow up is needed to determine whether there are conditions under which the product could be used safely.

The committee highlighted that there is no consideration of allergenicity provided, although the proposed product contains high levels of protein – meaning the potential risk for the product is unclear.

Action: The Secretariat to draft a summary for agreement by the Committee which will be subject to a public consultation for 10 days. The advice to the FSA will inform risk managers' decisions on whether to raise reasoned safety objections triggering a further review.

5. I (LNFP-I) and 2'-fucosyllactose (2' FL) mixture (LNFP-I/2'-FL) (Dossier Number RP 549)

ACNFP/153/02

This novel food application for a mixture of two human milk identical oligosaccharides, lacto-N-fucopentaose I **(**LNFP-1) and 2'-fucosyllactose **(**2'-FL) was considered for the first time. The two oligosaccharides have been characterised, and the total saccharides in the novel food ingredient have been quantified, with the remainder identified as water. The applicant intends to use the ingredient in conventional foods and beverages, infant formulas, follow-on formula, foods for infants and young children (including processed cereal-based food, baby foods, and milk-based drinks), foods for specific groups (including FSMPs and total diet replacement for weight control), and food supplements.

The Committee discussed the production process and commented that the micro-organism used to produce the product can produce Gram negative endotoxins and that these had been detected in low quantities in some batches of the novel food ingredient. The Committee advised the FSA to seek further clarification on this issue and the level of variability in the production system for these compounds in order to understand the relevance for safety considerations in the

target groups.

The Committee remarked that whilst oligosaccharides are generally accepted as not being absorbed in the gastro-intestinal tract, the applicant had provided no information to support this statement for the novel food ingredient. Members also noted that oligosaccharides are usually considered to be prebiotic but can also cause bloating in high doses which may benefit from some risk communication with consumers.

The Committee had no major concerns relating to the allergenicity of the novel food, but noted that lactose is present in the final product. This ingredient must be avoided as far as possible by sensitive individuals, with daily lactose intake limited to 25 mg/100 kcal (EFSA, 2010). Precautionary labelling required for the novel food to inform lactose intolerant consumers.

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on lactose thresholds in lactose intolerance and galactosaemia. EFSA Journal 2010;8(9):1777. [29 pp.]. doi:10.2903/j.efsa.2010.1777

Action: The Secretariat to request clarification from the applicant on the potential for endotoxin contamination.

6. 3-Fucosyllactose (Dossier Number RP 1202)

ACNFP/153/03

The novel food application for oligosaccharide, 3'-fucosyllactose (3’-FL), was reviewed for the first time as a novel food. The ingredient which is produced in a crystallised form (using acetic acid as a recrystallisation solvent) or a non-crystallised form is intended to be used in conventional foods and beverages, infant formulas, follow-on formula, foods for infants and young children (including processed cereal-based food, baby foods, and milk-based drinks), foods for specific groups (including FSMPs and total diet replacement for weight control), and food supplements. The novel ingredient had been characterised, and the total saccharides in the novel food ingredient have been quantified, with the remainder as water.

The Committee discussed the production process and commented that the micro-organism used to produce the product can produce gram negative endotoxins and that these had been detected in low quantities in some batches of the novel food ingredient. The Committee requested further clarification on this issue and

the level of variability in the production system for these compounds in order to understand the relevance for safety considerations in the target groups.

The Committee remarked that whilst oligosaccharides are generally accepted as not being absorbed in the gastro-intestinal tract, the applicant had provided no information to support this statement for the novel food ingredient. Members also noted that oligosaccharides are usually considered to be prebiotic but can also cause bloating in high doses which may benefit from some risk communication with consumers. The Committee had no major concerns relating to the allergenicity of the novel food, but noted that lactose is present in the final product. This ingredient must be avoided as far as possible by sensitive individuals, with daily lactose intake limited to 25 mg/100 kcal (EFSA, 2010). Precautionary labelling required for the novel food to inform lactose intolerant consumers.

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on lactose thresholds in lactose intolerance and galactosaemia. EFSA Journal 2010;8(9):1777. [29 pp.]. doi:10.2903/j.efsa.2010.1777

Action: The Secretariat to request clarification from the applicant on the potential for endotoxin contamination.

7. Mung Bean Protein (Dossier Number RP 32)

ACNFP/153/04

The dossier was first considered by the Committee in April 2021. Subsequent responses to requests for additional information were reviewed by the Committee in September 2021, November 2021, and March 2022. Committee members considered further the outstanding questions on production process, proposed use, intake and allergenicity.

The Committee discussed the applicant’s response concerning the management of pesticide residues on the mung beans. Members felt that the response provided by the applicant concerning the pesticide residue surveillance programme was sufficient to address this issue and no further queries were raised.

The Committee reviewed the response from the applicant concerning the proposed uses of mung bean protein as a novel food ingredient. Members agreed that this additional information provided a better understanding on the

recommended uses of the finished products by consumers and therefore put the exposure in context.

The Committee discussed the applicant’s request for further guidance relating to the allergenicity assessment of the novel food ingredient. Previous information from the applicant had suggested the potential for cross reactivity to the product in those with legume allergies.

The Committee restated the need to better characterise the risk from the cross-reactivity to the product in individuals with other legume allergies. Given the identified potential for allergenicity of mung bean protein, this triggers the need for the next tier of allergenicity assessment. Members suggested that ideally clinical work would utilise individuals who have a clinical allergic response to legumes identified with the highest sequence homology to mung bean protein. A further discussion was held amongst the Committee on the proportionality of what could be requested from an applicant given the wider evidence need for legume allergies in general. A consensus was reached that the information would be requested from the applicant as according to the existing approach in technical guidance for allergenicity assessment, the next tier when a protein is identified as a likely allergen would be to generate further data in a clinical study. The Secretariat would explore with risk managers their need from addressing allergenicity risk.

The Committee discussed wider issues surrounding allergenicity assessment and the move towards alternative proteins as novel foods. Allergenicity risk assessment is considered an area of high importance by ACNFP: the work of the Science Council on the topic of Net Zero (covered in item 13) indicates the potential for innovation of novel protein sources and also recent examples of dossiers at the ACNFP have highlighted that further research is needed and the potential for revised guidance based on evolving science. Members recommended to the FSA that research into characterisation of legume allergies other than peanut and soya would be beneficial.

The further guidance that could be provided to the applicant was considered in depth and members considered there was a high need for the FSA to provide improved and consistent guidance on the assessment of the allergenicity of new proteins to provide a clearer framework for review.

Actions: The Secretariat to request further information from the applicant on the allergenicity to conclude the assessment.

The Secretariat to pass on the suggestion of the need for further review of the impact of legume allergies other than peanut and soya as a research area to colleagues working on food allergy.

The Secretariat to consider what further work should be taken forward by the ACNFP on the allergenicity assessment of new foods.

8. Barley Rice Protein (Dossier Number RP 19)

ACNFP/153/05

This dossier was considered by the Committee in April and September 2021, and in January 2022. The latter resulted in the continued request for additional information regarding the identity and composition of barley rice protein.

The Committee discussed the response provided by the applicant and discussed the variability in the starting material and whether this was now appropriately defined. The Committee recognised the applicant had previously provided compositional analysis for batches that demonstrated variability in the ratios of starting material and how this related to their specification which will form the basis of any authorisation. Therefore, it was agreed no further information was required, and the Committee can conclude on the safety evaluation of barley rice protein.

The Committee considered a draft opinion on the product that will be further refined in light of the comments raised for agreement with the Committee.

Action: The Secretariat to refine the draft opinion for ACNFP input and agreement.

9. Cetylated Fatty Acids (Dossier Number RP 200)

ACNFP/153/06

The dossier was first considered by the Committee in November 2021 where further information was requested from the applicant. Committee members considered further the outstanding questions on the production process and ADME.

The Committee discussed the applicant’s response concerning the manufacturing process for the cetylated fatty acids and possible side-reactions. The applicant’s explanation for why the formation of trans fatty acids was unlikely and not expected to be a cause for concern in consumers was accepted by the Committee. Members noted that the applicant had not considered other dietary sources of trans fatty acids in their discussion, but no further queries were raised.

The Committee reviewed a study report from the applicant concerning the distribution of cetylated fatty acids in male Wistar rats. Members noted that this study was conducted 20 years ago and did not follow the expected protocol for ADME assessment and there were limitations in the protocol used. However, on the basis of the evidence in the dossier no new queries were raised as a safety concern.

The Committee considered a draft opinion on the product that will be further refined in light of the comments raised for agreement with the Committee.

Action: The Secretariat to refine the draft opinion for ACNFP input and agreement.

10. Approach to opinions for Novel Foods under Assessment in the UK

ACNFP/153/06

The Opinions for Barley Rice Protein and Cetylated Fatty Acids are the first opinions to be developed by the Committee since the UK’s departure from the EU and were reviewed in technical detail as items ACNFP/153/05 and ACNFP/153/06, respectively. Templates for FSA opinions prior to EU exit and for EFSA opinions were also provided to support Members in exploring the generic principles to developing opinions under the new UK assessment regime, and to determine which approach and level of detail would ensure consistent, accurate and robust outcomes of the Committee’s assessment of dossiers while ensuring efficiency through good management of the workload.

Detailed comments were provided that the Secretariat will take into account in further developing the current draft opinions and development of future outputs of the ACNFP’s review.

Action: The Secretariat to implement advice on the format and approach of ACNFP opinions.

11. Calcidiol (Dossier Number RP 35)

ACNFP/153/08

This is the third time the Committee reviewed this dossier. The first time in June 2021 and the second time in November 2021. The Committee reviewed the response to the request for further information on identity, production process, proposed use and intake and toxicology.

The Committee advised the information provided on identity of the Novel Food needed further clarification. The information provided partially addressed the question of how Calcidiol was quantified but context was needed on the testing that had been done. Further information was needed on the structure to ensure that the Calcidiol produced from the process detailed was the same as that produced in the body when metabolising vitamin D.

Members assessed the second HACCP plan provided by the applicant. It was advised that the HACCP plan still did not cover the full requirements needed to understand the risks managed in the production process. Further information was requested to address this gap.

The Committee appreciated that the applicant is willing to state Calcidiol is five times more bioavailable than ingested vitamin D. However, they noted that there is only a 2-fold margin of safety for the proposed use. The Committee regarded this MOS too low to ensure safe use as a food in the general public who may consume vitamin D from supplements. A query was raised on how the Applicant would ensure individuals who want to take the daily dose of 10µg/day of Vitamin D would have the relevant information to do so. They were also concerned about children taking Calcidiol because the stated dosage applies to adults, not children.

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

12. Annual Report

ACNFP/153/09

The Committee issues a report annually, outlining the work it has conducted in the preceding year. A draft of the 2021 report was presented to the members for their comment and agreement. It was however highlighted that 2021 was the first year the UK was conducting risk assessments for full applications following the UK's departure from the EU. It was therefore concluded that the Annual report needed a new approach to put into context the work done by the Committee and the principles around their work such as openness, transparency and proportionality. A revised draft will be produced and circulated to members for input.

Action: The Secretariat to redraft the Annual Report in light of the feedback received.

13. Introduction to the work on net zero by the Science Council

ACNFP/153/10

The ACNFP Chair, Chair of the Science Council and Claire Nicholson had agreed in a prior meeting that it would be useful for the ACNFP to hear about the FSA work on net zero and resulting priority themes. The Science Council member observer to the ACNFP, Claire Nicholson, presented to the Committee on Science Council's work on Food Safety and Net Zero Carbon. A number of areas that would be relevant to the ACNFP and their future assessment work were highlighted including use of insects in the diet and the future uses of alternative protein sources as novel foods. One significant area of consumer safety that was highlighted in this work as relevant to the ACNFP was allergenicity risk assessment for future innovative alternative proteins in the diet. The Committee thanked the Science Council for the relevant update and will be looking forward to reading the full report upon publication.

Action: The Secretariat to circulate the Science Council Net Zero report once it is published.

14. Items for Information

14.1 Novel Food Policy Update - Written

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

14.2 GM Policy Update - Written

The Committee was provided with a written update on the issues under consideration regarding GM.

14.3 SACS Update - Written

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

15. Any other business

The Chair and technical Secretary thanked Dr Rohini Manuel, Ms Nichola Lund, and Prof Susan Duthie for their work on the Committee. They had reached their maximum term and therefore the June meeting was their last meeting. All Members and Secretariat wished them well and thanked them for their constructive and informed input into the Committee’s work.

Date of next meeting

The next meeting is scheduled for 7th September 2022. It will be a hybrid meeting in London. Venue to be confirmed.