Advisory Committee on Novel Foods and Process. Minutes of the 152nd Meeting held on the 30th March 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.

This meeting was held online using Microsoft 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

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

Assessor

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

Observers FSA

Dr Sabrina Roberts - FSA Senior GM Policy Advisor

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

Monique Von Tonder - FSA Novel Food Policy Advisor

Ms Sophie Burder - FSA Novel Food Policy Advisor

Ms Chloe Thomas - Exposure Assessment & Trade

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

Ms Shila Sultana - Regulated Products Risk Assessor

Mr Shadad Saleh - Risk Assessment Support

Observers Devolved administration

Ms Alexia Sully Karlis - Policy, FSA Wales

Mr Andrew Dodd - Policy, FSA Wales

Ms Siobhan Watt - Food Standards Scotland

Ms Tamara Satmarean - Food Standards Scotland

Mr Joshua Evans - Food Standards Scotland

Ms Lucy Smythe - Food Standards Scotland

Ms Krystle Boss - Food Standards Scotland

Secretariat

Mrs Ruth Willis - Technical Secretary

Ms Stephanie Boateng - Lead Secretariat

Dr Tahmina Khan - Senior Secretariat

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 Andrew Hartley - Science Secretariat

Mr Ben Haynes - Science Secretariat

Miss Victoria Balch - Administrative Secretariat

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1. Apologies and Announcements

Apologies were received from Dr Hamid Ghoddusi and Ms Claire Nicholson from the Science Council.

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

Dr Anton Alldrick and Professor Harry McArdle declared potential conflict of interest in relation to CBD and were not present for the discussions on those items. To facilitate this, the agenda had been arranged to separate out the CBD items 5, 6 and 7 from the other items for discussion. To note, ACNFP items 1 and 2 are missing from the agenda (Barley Rice and Cetylated fatty acids) as the items had been delayed until the next meeting.

2. Meeting Minutes for the 151st Meeting

ACNFP/151/MINS

The Committee were content with the minutes of the 151st meeting. Now that these have been agreed and circulated to members for information they will be placed on the website. Reserved business sections and information on CBD will be removed until such time as they can be considered by our internal publication committee.

3. Matters Arising from the last meeting

ACNFP/152/MA

• The Committee discussed at the previous meeting an application for Barley Rice Protein RP19 where further information was sought on the composition

- and the balance of the starting ingredients. The response was received from the applicant and is being used to develop an opinion for the Committee's consideration at the June meeting.
- The Committee also considered two dossiers for Cannabidiol (CBD) RP70 and RP85. A number of gaps in the data provided were identified. A request for further information for the data gaps relating to these specific dossiers were sent to the applicant. The cross-cutting issues highlighted in the discussion were noted and used to inform the approach detailed in the papers presented in this meeting.

4. Mung Bean Protein (Dossier Number RP 32)

ACNFP/152/03

This dossier was first considered by the Committee in April 2021, and reviewed again in September 2021 and November 2021. The dossier is for a mung bean derived ingredient to be used as an egg replacement. A request for additional information was submitted to the applicant after the last meeting and the subsequent response was reviewed. Committee members considered further the outstanding questions on production process, nutritional information and allergenicity.

The Committee discussed the applicant's response and suggested further explanation of the management steps taken to control the potential for undesirable substances to be present as contaminants, would be useful to understand the effectiveness of the management strategies used.

The Committee reviewed the response from the applicant concerning the proposed uses of mung bean protein. Members agreed that the information provided a better understanding of the intended use of the novel food ingredient and the format of the finished products.

Given the nature of the product, it could play a significant role in the diet for some people, and so it was recommended that information be sought to understand the likely exposure at the meal occasion level. While outside the scope of the assessment, the applicant was recommended to consider how the marketing standards for egg products would impact the marketing that was permitted for this egg replacement product.

Committee members considered in detail the outstanding question on the level of evidence required to support an allergenicity assessment for the product. The

Committee agreed that the data reported in Jensen et al (2008) indicated the potential for sensitisation, but the implications in a clinical context could not be extrapolated from the data. It was also noted that little is known about the prevalence of legume allergy, making interpretation of the available data less clear.

The Committee considered that with the current evidence a potential hazard could be identified but that further information was needed to understand the nature of any risk to legume allergic consumers from cross reactivity when consuming the novel ingredient.

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

5. Bambara Groundnut (Dossier Number RP 1086)

ACNFP/152/04

This application (a traditional food from a third country) was considered for the first time. The applicant is requesting authorisation within the UK market for the product (a type of legume) in 4 forms i.e., dried, roasted, canned and as a flour with an adult population as the target population. The FSA and FSS has four months to provide any reasoned safety objections to the Traditional Foods sale in the UK. Discussion was held on the identity, production process, composition, stability, specification and proposed conditions of use within the UK market.

The Committee raised concerns in several areas where the data was not available to complete the assessment, including the development of mycotoxins, levels of saponins and alkaloids present in the final food, stability of the product and questions regarding allergenicity.

The Committee evaluated the production process and commented that there was a potential for mycotoxin development and further explanation of the controls in place would be needed to understand the risk posed. Also, where there might be insect damage, fungal infection can occur leading to further risks. Queries were also raised on the production certification standard used and the details of the management of the risk identified.

Members noted that the levels of lectin were much higher in Bambara groundnut than other legumes hence an evaluation of this would be essential especially on the cooking process for their removal. It was suggested that it would be helpful to have a further understanding of the characterisation of antinutritional factors in the food and the hazards this could potentially bring and how these were risk managed. Phytochemical safety was also not well explained.

The Committee commented that, since this was a traditional food that has been consumed in African regions, there should be an indication of how long this product was stored for traditionally or some exploration through literature review. This was identified as a data gap.

The Committee considered, in the context of the evolving knowledge of the allergenicity of legumes, that further consideration of allergenicity issues would be appropriate. The Committee noted that the UK population has a higher rate of food hypersensitivity than countries where the crop is consumed traditionally. Members commented that where there is potential allergenicity risk, this becomes more acute when an ingredient is hidden in a product such as the ground Bambara flour which increases the risk further. They also noted that the name 'groundnut' might be misleading as this is a legume and would also put off people with peanut allergies.

It was acknowledged that for traditional food from third countries application, the requirements for allergenicity assessment are different to other novel foods. Due to data gaps on cross-reactivity, it makes it difficult to assess the allergenicity of this product. The members noted that the applicant had made a comparison to other legumes such as soybeans. However, the novelty of this specific new legume in the UK market population may present an unknown risk of new allergies and this would need to be adequately managed.

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 whether risk managers need to consider reasoned safety objections.

6. GE work timeline for ACNFP Sub-Committee (Reserved Business)

ACNFP/152/08

A suggested timeline for the development of criteria to support FSA Policy into establishing a new regulatory framework for Genome Edited (GE) food and feed

has been examined. The Committee considered the challenges posed by the need to have time to establish a specialised GM (Genetically Modified) / GE Committee subgroup, an understanding of the amount of new work to be covered, and member availability during the summer recess, to estimate when meetings could be convened and first drafts of outputs could be delivered.

Action: The Secretariat to feed back to Policy.

Action: The Secretariat to feed back to the Chair of the GM / GE Committee subgroup when in place.

7. Items for Information

7.1 Novel Food Policy Update - Written

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

7.2 GM Policy Update - Written

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

7.3 SACS Update - Written

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

8. Any other business

- The Chair said goodbye to both Erin Oliver and Stephanie Boateng and wished them well in their future endeavours. The Members were subsequently informed that the Lead Secretariat post was now vacant and would be undergoing recruitment.
- The Members were thanked for responding to the survey on hybrid meeting arrangements. Plans are underway to hold the June meeting as a hybrid meeting in London. Further details will be circulated shortly.
- Finally, Members were forewarned that the annual appraisal forms that inform the annual report will be circulated shortly. Feedback helps to improve the working of the Secretariat and to ensure that the right support

9. Subgroup proposal for the ACNFP and COT to consider cross cutting issues related to CBD products (Reserved Business)

ACNFP/152/05

Dr Alldrick declared a potential conflict of interest relating to his previous employment and was not present during this item.

Prof Harry McArdle declared his work with EFSA's novel food committee in considering data requirements for CBD. While not seen as a conflict, to avoid Prof McArdle being subject to information that would influence his EFSA work, it was agreed that he would also not be present in the discussions on CBD but could supply comments for consideration by the Committee upon review of the minutes.

The Committee reviewed a proposal for the formation of a joint sub group of the Committee on Toxicity (COT) and Advisory Committee on Novel Foods and Processes (ACNFP) which will address issues surrounding the toxicological safety of CBD and hemp-derived food products. The formation of the proposed subgroup was agreed by members and comments on the proposal were provided.

Action: Secretariat to organise recruitment of a Chair and of other necessary experts for a first meeting.

Action: Secretariat to alter the draft terms of conditions, if required, based on the Committee's feedback.

10. Cannabidiol (Dossier Number RP 793) (Reserved Business)

ACNFP/152/06

Dr Alldrick declared a potential conflict of interest relating to his previous employment and was not present during this item.

Prof Harry McArdle declared his work with EFSA's novel food committee in considering data requirements for CBD. While not seen as a conflict, to avoid Prof

McArdle being subject to information that would influence his EFSA work, it was agreed that he would also not be present in the discussions on CBD but could supply comments for consideration by the Committee upon review of the minutes.

An application has been received under the novel food authorisation process for a cannabidiol isolate (CBD). The Committee reviewed the application for the first time. The applicant intends to use the isolated CBD ingredient in the manufacture of food supplements. Discussions were held on composition, production process, toxicology and proposed use.

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

Action: The ACNFP/COT subgroup on CBD to review the toxicology data, extraction solvent issue and safeguarding against misuse.

11. Cannabidiol (Dossier Number RP 07) (Reserved Business)

ACNFP/152/07

Dr Alldrick declared a potential conflict of interest relating to his previous employment and was not present during this item.

Prof Harry McArdle declared his work with EFSA's novel food committee in considering data requirements for CBD. While not seen as a conflict, to avoid Prof McArdle being subject to information that would influence his EFSA work, it was agreed that he would also not be present in the discussions on CBD but could supply comments for consideration by the Committee upon review of the minutes.

An application has been received under the novel food authorisation process for a synthetic cannabidiol (CBD) for use in food supplements. The applicant intends to use the synthetic CBD as an ingredient in the manufacture of food supplements. The Committee reviewed the responses from the applicant on ADME, toxicology and proposed uses and intake on CBD.

Action: The Secretariat to draft an opinion paper

Date of next meeting

The next meeting is scheduled for 8th June 2022. It meeting in London.	will tentatively be a hybrid