Thursday, 09 September 2021

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

DRAFT MINUTES OF THE ONE HUNDRED AND FORTY EIGHTH MEETING HELD ON 09th June 2021

ACNFP Secretariat
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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.

ACNFP/148/Min

MINUTES OF THE ONE HUNDRED AND FORTY EIGHTH MEETING OF THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES, HELD ON 9th June 2021, ONLINE USING MICROSOFT TEAMS.

ATTENDANCE

Committee	Dr Camilla Alexander-White	**Chair**
	Dr Anton Alldrick	**Member**
	Ms Alison Austin	**Member**
	Dr Mark Berry	**Member**
	Professor Susan Duthie	**Member**
	Professor Susan Fairweather-Tait	**Member**
	Professor Paul Fraser	**Member**
	Dr Hamid Ghoddusi	**Member**
	Professor Wendy Harwood	**Member**
	Professor Huw Jones	**Member**
	Ms Nichola Lund	**Member**
	Dr Rohini Manuel	**Member**
	Professor Harry McArdle	**Member**
	Mrs Rebecca McKenzie	**Member**
	Dr David Mela	**Member**
	Professor Clare Mills	**Member**
	Dr Lesley Stanley	**Member**
	Prof Hans Verhagen	**Member**
	Dr Maureen Wakefield	**Member**
Apologies	Dr Elizabeth Lund	**Member**
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**
	Mr Andrew Dodd	**FSA Novel Foods Policy Advisor**
	Ms Gemma Jones	**FSA Novel Food Policy Advisor**
	Prof Rick Mumford	**FSA Head of SERD**
	Dr Amie Adkin	**FSA Head of Risk**
	Ms Natasha Gladstone	**FSA Evidence Coordination**

		Donal Griffin	**Head of regulated products risk assessment (Feed and GM)**
		Mr Adam McDowell	**FSA Wales Policy Advisor**
		Ms Alexia Sully Karlis	**FSA Wales Policy Officer**
		Ms Georgina Finch	**Food Standards Scotland**
		Ms Krystle Boss	**Food Standards Scotland**
		Ms Siobhan Watt	**Food Standards Scotland**
	Observers External	Ms Claire Nicholson	**Science Council**
		Prof George Gaskell	**Advisory Committee on Social Science (ACSS)**
	Secretariat	Mrs Ruth Willis	**Technical Secretary**
		Mrs Erin Oliver	**Lead Secretariat**
		Dr Francisco Matilla-Garcia	**Senior Secretariat**
		Dr Rachael J Oakenfull	**Senior Secretariat**
		Dr Tahmina Khan	**Senior Secretariat**
		Mr Richard Uchotski	**Secretariat**
		Ms Sophy Wells	**Administrative Secretariat**

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1. Apologies and announcements

Apologies were received from Dr Elizabeth Lund.

The ACNFP welcomed two new members: Prof Hans Verhagen (Toxicologist and Nutritionist) and Mrs Alison Austin (Consumer Representative). Dr Lund the third new member will be joining the Committee at the next meeting.

The ACNFP welcomed Donal Griffin, who has joined the FSA as Head of regulated products risk assessment (Feed & GM).

Welcome was also made to Dr Tahmina Khan, who has joined the Secretariat and Regulated Products Risk Assessment Team as a senior risk assessor. As well as Hetty Gbormittah who will be the Committees administrative Secretary from next the meeting.

2. Meeting Minutes for 146th Meeting ACNFP/146/MINS

The Committee had previously agreed the minutes for the 146th meeting. Members were asked to review an amendment to the minutes of the 146th meeting that reflected that the response to the Defra consultation on genetic engineering had not yet been published. The Committee's response to the Defra consultation would be publicly available in due course.

3. Meeting Minutes for 147th Meeting ACNFP/147/MINS

The Committee had agreed the minutes via correspondence of the 147th meeting of the ACNFP held on 21st April 2021. Further minor amendments were identified before the minutes were adopted by the Committee.

4. Matters Arising from the last meeting. ACNFP/148/MA

The Committee received two applications under the novel food authorisation process for Mung Bean Protein and Barley Rice Protein respectively. A request for information detailing the areas identified by the Committee was drafted by the Secretariat and sent to both applicants.

The CBD feedback statement discussed at the last meeting has been updated considering comments received and was discussed again at this meeting.

The 2020 final report has been finalised and was uploaded to the website the following week.

5. Calcidiol-RP35 ACNFP/148/01

An application had been received under the novel food authorisation process for "Calcidiol" as a nutrient source in food supplements. The Committee reviewed the application for the first time.

Prof Paul Fraser declared a conflict of interest and did not participate in the discussion of this item but was present as an observer. His interests were brought to the Secretariats and Chair's attention ahead of the meeting. Comments he had regarding this item were circulated to the Committee after the meeting for information.

Prof Harry McCardle declared a potential conflict of interest, stating that he was a member of the EFSA panel that had previous reviewed RP35. This was regarded as none conflicting by the Committee and Prof McCardle contributed to the discussion.

The Committee suggested that the applicant creates a properly structured dossier that incorporates any new integrated information, and consistently uses one compound name for Calcidiol throughout.

Identity of the Novel Food

The Committee stated the particle size of the product should be addressed/commented on in this section.

Production Process

The applicant did not describe the formulation of the product. The Committee advised that the formulation of the product is described with the solvents used, the purity of the final product and excipients described.

The applicant had not adequately described the HACCP in the production process or listed what the critical control points are within their production process. The Committee advised that a comprehensive HACCP plan from the start of the process to end is provided.

Composition

The applicant had not completed a full chemical characterisation of the product and had relied heavily on using HPLC data. Although, this data is useful as a quality control, it does not provide a full chemical evaluation of the composition of the product. The Committee recommend that other methods are used (e.g. Mass Spectrometry, NMR) to fully characterise the product.

The applicant had not elucidated on the formulation of their product, and it was unclear what the compounds and constituents were in the final formulation, what the formulation would be (i.e. capsule, tablet etc), the particle size, and whether they were diluting their product or using the modal formulation. The Committee advised that a full description of the final formulation be provided.

Specifications

The Committee stated that a specification is required for the final chemical synthesis of the product as well as on for the final commercial preparation, with both considering the impact of nano materials due to small particle size formulations.

History of Use

The Committee noted that the applicant could have provided more information for the history of use of the product, such as how vitamin D products had been packaged/added to foods, and relevant pharmaceutical information on the use of the product.

Proposed use and intake

The applicant needs to provide a better justification for the expressed upper limit. The Committee suggest that the evidence around the selection of the upper limit and the mechanisms of the conversion into 25(OH)D as well as the mechanisms of any negative effects are considered. The applicant states the bioavailability of the Calcidiol is three times more than regular vitamin D, which has a recommended dose of 400IU/day (10µg/d). The applicant is suggesting a dose of Calcidiol at 10µg/day (meaning its effective dose could be ~1200IU/d) which would be over the UK recommended dose of vitamin D. There is no reference made to this by the applicant. The Committee expressed concerns with how this would be communicated to the consumer to ensure that consumers did not reach the upper limit (which is 100µg/day in the UK), by over supplementation.

The Committee note that there is no advice or mechanism provided to stop manufacturers and/or consumers to overuse this supplement if it used as a replacement for vitamin D, and that there is no health warning or communication of advice of when this would be favourable or worse than a vitamin D supplement. The applicant was also asked to consider foreseeable misuse and how this could be managed.

Absorption, Distribution, Metabolism and Excretion (ADME)

The applicant does not consider the downstream metabolism and the homeostatic regulation of the product, and they assume it will have the same effects as vitamin D without supporting this with evidence.

The applicant has not considered the impact of the product to the population of people that are susceptible to vitamin D toxicity.

The applicant provided studies that use clinical monitoring of endogenously formed 25-Hydroxy form in the blood for patients with severe vitamin D deficiencies but note

that there is no mechanism for controlling/monitoring the level of the product and its metabolites in the body when it is used as a food.

Toxicology

The Committee were unclear on whether the formulation used in the toxicological testing was the same as the formulation that is intended to be marketed by the applicant. Effects during pregnancy and lactation were considered a data gap from the evidence provided that have not been considered by the applicant.

Significant discussion was held in considering the risk of over supplementation and the interplay between recommended levels and safe levels of consumption. It was noted that the proposed dosing was close to or could exceed recommended values but did not exceed safe levels identified.

The Committee noted that the initial vitamin D status of those using the product could be important and asked for this to be considered by the applicant.

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

6. Go Wolffia (RP128) ACNFP/148/02

An application for the traditional food "Go Wolffia" (*Wolffia arrhiza and Wolffia globose)*, was received by the FSA under the traditional food authorisation process. The Committee reviewed the application for the first time. The advice of the Committee will inform whether risk managers at the FSA and FSS wish to raise reasoned safety objections which would trigger a further assessment. The applicant is seeking to use the traditional food as a fresh vegetable produce.

The Committee suggested that the risk managers may wish to consider whether the product is viable for assessment under the traditional food process. This was because the proposed food differs from the traditional product in a number of ways:

- Traditional duckweed is served cooked into dishes and the applicant is proposing to sell it as a fresh vegetable, like spinach. Therefore, the use of the final product is not the same as the traditional use.

- The applicant is not growing wild type duck weed in open ponds systems but is using vertical farming processing. Although, this makes the process more controlled, it is not the traditional approach.

- The plants used are domesticated lines/clones of *Wolffia globosa* and *Wolffia arrhiza* obtained from a seedbank and are not necessarily representative of the wild type varieties/strains grown traditionally.

On this basis it is a question to what extent the experience of the traditional use of Wolffia can be used to support the assessment of the proposed product. A question was therefore raised to risk managers on whether the points highlighted would mean the product is or is not a traditional food.

In considering the risks for the food and to what extent they had been characterised in the application. The Committee commented that the applicant stated that there are only two adult varieties out of eleven duckweed species that are edible/can be used as foods. The Committee wanted to understand why the other nine species of duckweed are not edible, whether there are any anti-nutritional and toxic factors in these species. This could inform consideration of whether any of these may be present in the two edible duckweed varieties.

Identity

The strain of duckweed to be used during production is unclear and whether strains change over time. The applicant had originally sourced their strain from a collection and had maintained it over multiple years. Due to the high growth rate and variable nature of the different strains it is likely that the strains change overtime. Therefore, the Committee required further clarity on the identity of the product.

The applicant had not described how the seed is selected, how it is stored in a gene bank, how the seed/strains are cloned and how they maintain the seed/germ line, therefore it is unclear whether the strain develops over time, or whether the line is replenished from a seed every time, and whether this is stored correctly. This was felt to be important to understand the variability of the product. Evidence was needed to allow consideration of the genetic variability of the product.

Production Process

The Committee noted that the assessment could only consider the proposed production system highlighted in the application. Further production methods would need a separate review to understand the nature of the risks posed for those products.

The Committee advised that a full HACCP plan and explanation of the food management system be provided for the application. (i.e. what are the cleaning mechanisms, critical control points, management systems etc). This would allow verification of the potential food safety risks from the process proposed.

The Committee explained that temperature range during cultivation (15-30 degrees) provides conditions that support the rapid growth of microbes. The Committee suggested that further evidence be sought to show the sterilisation process used is effective.

The Committee were unclear on the dewatering step of the product, as it was not well explained and elucidated. The Committee believe this step is to remove excess water and not to fully dry the product. The applicant should be asked to confirm this.

Composition

The analytical data supplied by the applicant suggested a high level of variability in the production process that was not explained. There was up to 5 to 10 times variation in components across samples e.g. oxalate levels. Considering that the applicant is starting from a defined genotype, and the production process is grown on culture medium in controlled conditions, the product should be reasonably constant. However, this is not the case, and it was questioned whether the controls were performing effectively.

The Committee expressed considerable concern about the long shelf life on the product. The applicants stated that wet fresh duckweed, is packaged under sterile conditions, and sold like spinach and has a shelf life of 28 days. The Committee sought justification for the provided shelf life of 28 days taking into consideration action of degradation enzymes.

The Committee commented that analysis in this section of the application was not complete. This is because the carbohydrates were not actually analysed from the plants but worked out as a subtraction from the other components.

The Committee note the applicant's assertion that dried duckweed could be used as an alternative protein source as it contains 41.1-51% protein by dry weight. However, in light of there being only 2g of protein in 100g of wet duckweed, fresh duckweed would not meet the current requirements to be claimed as a high protein source. In light of this the Committee recommended that protein levels should be clearly indicated on the product.

Allergenicity

The Committee noted that any component containing protein could invoke an allergic reaction in a sensitive individual. From the evidence presented a specific allergenicity issue was not identified.

Action: The Secretariat to draft a summary of the Committee comments and put this out for a 10-day consultation to gather public comments.

7. CBD Feedback Summary ACNFP/148/03

In January 2021, the Committee reviewed an application under the novel food authorisation process (Regulation 2015/2283) for a Cannabidiol (CBD) product made through chemical synthesis to produce a 99% pure CBD crystal that is intended to be

used in a food supplement. The Committee were asked in the last ACNFP meeting (21st April 2021) whether the request for further information prepared to be sent back to the applicant is a correct representation of their views and concerns. Further comments were raised and the draft refined.

In this meeting, a revised version was presented for review by the Committee with minor edits and amendments suggested. Considerations on the toxicological aspects of CBD were still ongoing between the ACNFP and the Committee on Toxicity (COT) to identify the further information needed for assessment in light of the COTs consideration of CBD.

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

8. Terms of Reference and Code of Practice ACNFP/148/04

Since the 1st January 2021 the ACNFP has had a greater role in considering applications for novel foods and genetically modified food and feed. The terms of reference and code of practice had been refreshed by the Secretariat to reflect the evolving role of the Committee.

The members reflected on their new ways of working to ensure that the Terms of Reference on the website as well as the Code of Practice were aligned to current working practices.

The Committee reviewed and commented on the suggested revised text for the Terms of Reference and the Code of Practice and provided minor amendments. Members were given a further opportunity to comment by correspondence before the document is finalised with the Chair

Action: The Secretariat will publish the agreed text on the ACNFP website.

9. Items for Information

9.1 Novel Food Policy Update Oral

The Committee was provided with an oral update on the issues under consideration regarding novel foods.

9.2 GM Policy Update Oral

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

9.3 SACS Update Written

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

10. Date of next meeting

The next meeting is scheduled for 15th of September. The meeting will be online due to concerns surrounding Covid-19.