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ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

MINUTES OF THE ONE HUNDRED AND THIRTY THIRD MEETING HELD ON 25 APRIL 2018

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These Minutes were confirmed by the Committee on the 22nd of November 2018.

MINUTES OF THE HUNDRED AND THIRTY THIRD MEETING OF THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES, HELD ON 25 APRIL 2018 IN THE GROSVENOR HOTEL, 101 BUCKINGHAM PALACE ROAD, LONDON, SW1W 0SJ

Present	Professor Peter Gregory – **Chairman**
	Dr Anton Alldrick Dr Camilla Alexander-White Professor Michael Bushell Dr Hamid Ghoddusi Dr Rohini Manuel Professor John Mathers Professor Harry McArdle Mrs Rebecca McKenzie Professor Clare Mills Ms Claire Nicholson Professor Christopher Ritson Dr Lesley Stanley
Apologies	Professor Susan Duthie Ms Nichola Lund
Observer	Solomon Okoruwe Freddie Lachhman
Secretariat	Ruth Willis - **ACNFP Secretary** Alison Asquith – **Minutes** Ceyhun Güngör Louisa Williams

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.

1. Apologies and announcements

Two members sent apologies for non-attendance; no comments were received from these members.

The Chairman welcomed Louisa Williams and Ceyhun Gügör who have recently joined the Secretariat. He also welcomed Solomon Okoruwe and Freddie Lachhman who were observers from the FSA in London. Apologies were received from the observer in Scotland and observers in the FSA offices in Wales and Northern Ireland.

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

Professor Harry McArdle declared an interest in item 4, handling traditional foods dossiers as he sits on the EFSA panel on NDA (Dietetic Products, Nutrition and Allergies) which advised on guidance for traditional food applications. The Committee decided Professor McArdle could take part in the discussion.

Dr Anton Alldrick declared an interest in item 5 as he was involved in the berries of *Lonicera caerulea* (Haskaps) application. The Committee decided Dr Alldrick should not take part in the discussion of this item.

2. Minutes of the 132nd Meeting ACNFP/132/Min

The Committee agreed that the minutes were a true record of the 132nd meeting of the ACNFP held on 22 November subject to amendments.

3. Matters Arising

Vivinal® GOS PT from Frieslandcampina (Item 6 November meeting)
The Opinion has been finalised and sent to the applicant. The authorisation was included in the initial Union list of novel foods.

Cascara (Item 7 November meeting)
This was a dossier assessed by the Austrian Competent Authority on which the UK was consulted. The Committee's objections have been forwarded to the Commission as part of the UK's formal response.

UV Treated Mushrooms (Item 8 November meeting)
This was a dossier assessed by the Netherlands Competent Authority on which the UK was consulted. The Committee's comments have been forwarded to the Commission as part of the UK's formal response. The mushrooms have been authorised.

Chia in Chocolate Extension of Use (Item 9 November meeting)
This was a dossier assessed by the Spanish Competent Authority on which the UK was consulted. The Committee's comments have been forwarded to the Commission as part of the UK's formal response.

***Hovenia dulcis* (Item 10 November meeting)**
This was a negative opinion from the German Competent Authority on which the UK was consulted. The Committee's comments have been forwarded to the Commission as part of the UK's formal response.

4. Handling Traditional Foods Dossiers ACNFP/133/1

The Committee considered the approach to assessing traditional food notifications in the UK under Novel Food Regulations (EU) 2018/2283. This included key aspects of the assessment and how the ACNFP could help the FSA fulfil its openness and transparency remit whilst making sure the FSA and ACNFP met its obligations under data management law.

The Committee considered that the EFSA guidance document was excellent and would be a useful template for notification dossiers. The Committee noted that traditional foods may have to undergo a two-stage authorisation. If safety objections were raised to the food, the applicant would have to put in a full application if they intended to market the food. It questioned whether an extract would be considered traditional if the food it was extracted from was a traditional food. It was confirmed that for extracts to benefit from the traditional foods authorisation route the traditional food would need to be the extract itself and appropriate evidence provided.

The Committee considered the dossiers must demonstrate three areas: they must show the traditional food is safe, does not mislead consumers and is not nutritionally disadvantageous. It must also have a full specification which includes a comprehensive description of the safety management system, trading details, description of product including if a grain, grain size, and permitted plant parts used. The Committee concluded that if there were any reasoned safety concerns, a full application should be submitted.

The Committee explored some of the challenges in this type of assessment noting there may be compliance issues when food is produced in a third country where standards are different. The example raised was HACCP, but they were reassured that to be compliant with EU law key standards would need to be met. Full information would need to be provided if standards were used which were not EU standards.

The Committee considered the dossier should demonstrate that the traditional production process could be scaled up for the European market and maintain safety. It noted that the manufacturing process could affect the amount and concentration of micro-organisms in a product, particularly if it was a fermented product. Different assessments would be required for different foods. For example, fruits would need to be assessed differently to roots or leaves.

Previous generations processed foods in particular ways so that the food would be safe to consume. This knowledge was sometimes lost by subsequent generations. While ideally the information presented to support safe use would be quantifiable and peer reviewed, for many novel foods undergoing the traditional foods notification process grey literature could be important. This will have a role in establishing the measures used to ensure the food remained safe when introduced to a new market.

The Committee considered that the traditional use of the food was an important part of the assessment. The dossier and assessment must show this use is safe provided it is used in the same way as the traditional use. The intake of a food is also important. For example, a food may be safe if consumed in a tea but at higher intakes it may be unsafe. The Committee noted that the EFSA guidance suggested equal value should be given to grey literature, which included recipe books and non-scientific or peer reviewed material to establish a safe use.

The Committee explored the question of how to ensure that the food safety risks had been addressed and that the assessment is not hampered by risks not being well characterised. For example, it was noted that some third countries may not have reporting systems in place or may have less data on long term health risks in which case safe use may be difficult to determine. This is particularly the case if the population using the food is small and would be a consideration in weighting the evidence in the assessment.

Composition of a food grown in a different environment to its traditional location may be an issue, as the soil type in the new area may be different to the area where it is traditionally grown, or drought may affect its composition. To overcome this issue, it may be necessary to make the geographical area or production method a requirement of the traditional food. These different conditions may raise reasoned safety concerns and need for further risk management.

The Committee would like to continue to have information, where available, on known compounds with toxicological or anti-nutritional issues such as polyphenols as this would reassure it about the potential for known risks to occur. It pointed out there was never a zero risk, but post market monitoring may have a role in proportionate consideration of these issues.

The Committee advised that dossiers must meet a minimum standard of being compliant with EFSA guidance. The dossier must include a stated composition and consider the likely variation in the food and seek to measure this so that the specification in the Union list is robust.

To meet the Food Standards Agency's remit on openness and transparency the Committee considered openness issues relevant to traditional foods notification dossiers.

The Committee considered the UK was exceptional in the way that Scientific Advisory Committees work, both in the way they were used and how they provide advice. The Committee considered the UK had taken the lead in the approach to transparency on risk assessment and this should continue. Lay members views were very important as they represented the consumers. It considered that openness was useful to both consumers and industry. Industry can use minutes and summaries to determine if there are any problems they may have if they market a product and can then produce a better dossier if there are concerns about a food.

The Committee advised that they would like to continue to put the minutes on the website and a summary of the Committee's advice to the FSA should also be published for the public to make input. The time-period for consultation may be short, to meet the wider deadlines outlined in the regulation.

It was noted that the dossier could provide important context but that sections of the dossier were confidential under EU law. Therefore, reference by the Committee should be to publicly available evidence and the summaries of the dossiers available on the Commissions website.

The Committee's advice would be used to inform the UKs approach to assessing traditional foods going forward

5. *Lonicera caerulea* (Haskaps or Honey berries) ACNFP/133/3

The Committee considered a notification dossier for traditional food, *Lonicera caerulea* also known as Haskaps or honey berries. The small blue fruits are proposed for authorisation to be eaten either as fresh or frozen fruit. The application is based on the traditional use in the Hokkaido region of Japan. Information was also presented in the dossier on their use in North America.

The Committee noted composition and nutritional information was missing which made the evaluation difficult. For example, no proteins had been identified. There was no data on variation in heavy metals and therefore no information on different areas where the berries were grown. There was also no information on precautions or restrictions on use. Pesticide residue data was from Poland which may not be relevant to other areas where it is grown. There was also no evidence provided to support the shelf life identified of 18 months.

The dossier states there is no evidence of allergies in Japan and therefore the applicant argues Haskaps are unlikely to cause allergies in the EU. The Committee stated it would be helpful if the applicant had stated what evidence it had for this view, for example from a literature search. Allergenicity was not considered a significant issue on the basis that there were few known allergies to plants in the botanical family to which the novel food belongs which includes elderberry. However, the potential for new allergies to develop could not be ruled out.

No particular safety risk was identified by the Committee. However, concerns were raised that there was insufficient data in the dossier to support the depth of assessment felt to be appropriate. Key aspects of the EFSA's guidance on composition, and any variation in composition had not been provided. Of particular concern was that literature searches to explore available information on known risks such as allergenicity, toxicity, and microbiology were not provided. Also absent was the methodology that the applicant had used to conduct the searches they had made to inform risk assessors that evidence had been sought and not found. This was felt to be important information to allow the Committee to validate that the safety had been demonstrated

The Committee recommended that the FSA should object on the grounds that the applicant had not provided sufficient evidence that the product was safe.

The Committee's advice would be used to inform the UK's view in responding to the Commission on this application.

6. *Digitaria exilis* (Fonio) ACNFP/133/2

The Committee considered a notification dossier for a traditional food, *Digitaria exilis* also known as Fonio. It consists of tiny seeds slightly larger than grass seeds. The notification is based on the traditional uses of the novel ingredient in porridge, couscous and in beverages in countries in Africa. Fonio is related to sorghum, maize and millet.

While recognising the information provided supported a long history of use, the Committee noted there was little information on hazards in the food processes described in the dossier. The Committee was particularly concerned with the water quality used to remove the husks of the grain in the production process and the potential to introduce heavy metal contamination in some geographic areas. The control processes should be assessed for this type of product and the hygiene status of the drying surface used in the production was considered critical.

It noted that the production processes were not properly described so it was not possible to establish how polyphenols and known antinutritional factors present in Fonio that could affect thyroid activity would be removed. The phytate levels in the food may affect the uptake of iron creating problems for some vulnerable groups. It was commented that the processing specified reduced the protein content in sorghum which may lead to nutritional issues if used as a stable food by those with a gluten free diet.

The Committee noted that a big issue with this type of crop was seeds from weeds mixed with the Fonio seed. The Committee had no data on the standards producers were using and what species of weed seeds were in the crop to assess the potential risk.

The Committee considered the known risk of mycotoxin growth in the novel food was not well documented. It noted the seeds were washed and advised that in such conditions there was likely to be microbial growth including pathogens and mycotoxins. This effect would be exacerbated by the specified packaging of the processed Fonio seed in polythene bags. Condensation from seed respiration was considered a risk when shipping the grain to Europe as would condensation resulting from changes in temperature resulting in the dew point being exceeded. This is often a problem when grain is exported from a tropical country to temperate ones. The applicant hadn't provided certificates of analysis for five batches of the novel food suggested in EFSA's guidance. It was difficult to assess how well the microbial and mycotoxin risks would be managed for products reaching the EU market. No shelf life data were provided.

The Committee recommended the FSA should object on the grounds that the applicant had not provided sufficient evidence that the product was safe.

The Committee's advice would be used to inform the UK's view in responding to the Commission on this application.

7. Annual Report ACNFP/133/4

The Committee reviewed both the Annual Report, which was agreed subject to amendments, and the Good Practice Guidance which the Committee agreed continued to be met by the ACNFP. Committee Members agreed to forward amendments to their interests and other personal details to the Secretariat.

8. Open Meeting ACNFP/133/5

The Committee reviewed feedback from the recent open meeting held on 22 February. It noted comments had been positive and the smaller group discussions had generated some useful comments.

9. For Information

9.1 EU Update Oral

The Committee noted the oral briefing.

9.2 SACS Update Oral

The Committee was informed of a meeting to be held on 24 May, to be attended by the Chair, hosted by the Chief Scientific Officer of the FSA.

10. Any other Business

The Committee was updated on appointments.

11. Date of next meeting:

The next meeting is scheduled for Wednesday 27 June, the venue is to be confirmed.