ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

MINUTES OF THE ONE HUNDRED AND THIRTY SIXTH MEETING HELD ON 7^{TH} MAY 2019

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MINUTES OF THE HUNDRED AND THIRTY SIXTH MEETING OF THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES, HELD ON 7TH MAY 2019 IN CONFERENCE ROOM ONE, TWO AND THREE AT 70 PETTY FRANCE, WESTMINSTER, LONDON SW1H 9EX.

Present Professor Peter Gregory – Chairman

Dr Anton Alldrick

Dr Camilla Alexander-White

Dr Hamid Ghoddusi
Dr Lesley Stanley
Dr Rohini Manuel
Mrs Rebecca McKenzie
Ms Claire Nicholson
Ms Nichola Lund

Professor Christopher Ritson Professor Harry McArdle Professor John Mathers Professor Susan Duthie

Apologies Professor Clare Mills

Professor Michael Bushell

Assessor Mr Paul Tossell (by teleconference)

Observer Ms Alison Asquith

Ms Georgina Finch Mr Hoa Chang Dr Linden Jack Dr Sabrina Roberts

Mr Steve Wearne (by teleconference)

Secretariat Mrs Ruth Willis – Technical Secretary

Ms Erin Oliver – **Lead Secretariat**Mr Richard Uchotski –**Secretariat**Dr Elspeth Ransom – **Secretariat**

Mr Francisco Matilla-Garcia - Secretariat

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

Apologies for non-attendance were received from Prof Michael Bushell and Prof Clare Mills and the Observers from N. Ireland and FSA Wales

The ACNFP welcomed Georgina Finch from Food Standards Scotland; Paul Tossell, Head of Novel food and GM Policy; and Steve Wearne, Director of Science; to observe the meeting.

Also, in attendance were Dr Linden Jack, Head of Regulatory Modernisation, Food Policy to discuss item 7; Alison Asquith, Dr Sabrina Roberts, and Mr Hoa Chang, Novel Foods and GM Policy, Food Policy, to discuss item 10.1.

2. Secretariat Welcome

The ACNFP welcomed Ms Erin Oliver, Mr Richard Smith-Uchotski, Dr Elspeth Ransom, and Mr Francisco Matilla Garcia, the new members of Regulated Products Team to the Secretariat for the Committee. They gave an overview of their scientific background and future roles in the Secretariat.

3. Minutes of the 135th Meeting

ACNFP/135/Min

The Committee agreed that the minutes, subject to minor amendments were a true record of the 135th meeting of the ACNFP held on 14th of November 2018.

4. Matters Arising

Work has been undertaken at EU level to improve the consistency of applications under the traditional food notifications in the European Union discussed at the previous meeting. The Commission has noted comments from the UK and other Member States about the level of information required to support an appropriate assessment of the food. They have continued to ask Member States to contribute to application validations to improve quality of the dossiers.

At the previous meeting an updated advice paper and table summarising advice given to the FSA by the Committee between 2005 and 2018 was presented and noted by the Committee. It was agreed to continue the practice of providing feedback to the Committee on the use of their advice in future.

Other matters arising were covered in the substantive items for discussion.

5. Traditional Food Summaries

ACNFP/136/01

Previously, the ACNFP considered how it communicates its advice on novel food applications, agreeing that the Secretariat would produce summaries on the novel food applications based off the Committee's discussions. These summaries would then be cleared by the Committee, signed off by the Chair before a 10-day public consultation period.

At this meeting, the Committee considered three new summaries produced by the Secretariat, on Fonio, Sorghum Syrup and Haskaps. The Committee assessed these documents and provided feedback.

The Committee commended the Secretariat's work confirming that the style of writing, content and length of summaries in the examples was appropriate and informative. They agreed that this approach should be used for future summaries.

The Committee also provided further suggestions on improving the summaries including formatting and use of headings relating the information to guidance for applicants and a clearer conclusion.

This topic also led into discussions on how the Committee deals with a lack of evidence provided by an applicant, suggesting that, going forwards, the Committee takes a structured approach to dealing with lack of relevant information and accessibility issues with the information provided. Members requested use of a checklist guide on the requirements as outlined in the guidance to support their review of the application.

A detailed discussion was held on how to represent the outcomes of the assessment in a way that supported the UK submitting reasoned safety objections where relevant. The Committee felt that more attention should be drawn to where applicants did not follow the guidance and the implications this has for the assessment. They also recommended that the Committee should state in their conclusion more strongly when the evidence does not demonstrate the food is safe.

Action: The Secretariat will review the comments made by the committee to incorporate these as practices when writing summaries.

ACNFP/136/2

6. Moringa stenopetala

The Committee considered a notification dossier for traditional food, the dried leaf powder of *Moringa stenopetala*. The product seeking authorisation is a powder obtained by washing and drying the leaves, then mechanically milling the dry leaves. The applicant claimed that products from *Moringa stenopetala* tree have been consumed in Ethiopia for over 25 years, and that the powder resembles that of *Moringa oleifera* species, with previous history of consumption in the EU and currently commercialized in powder form.

The Committee made several general comments, including that the dossier lacked structure, and failed to follow the EFSA Guidance Document for traditional food authorisations. This made accessing the information provided for assessment difficult. It was noted that many of the resources that were presented were either not peer reviewed literature and/or did not address the areas for consideration in a safety assessment.

Additionally, members commented that the product seeking authorisation was not the food consumed traditionally but a "processed product derived from a traditional food", and that the potential risks from exposure to concentrated components of the leaf were not explored. The dossier contains no evidence that Moringa stenopetala flour has been produced and consumed safely in Ethiopia; indeed, their own consultant's report states that this is a "new product".

Members highlighted that the production process was not clearly described, which raised concerns as to how any authorised product would be produced to ensure EU standards. This, coupled with no analysis of the applicant's product, did not allow assessment of whether potential risks are managed effectively in the process. Members also suggested that clarification was needed on the acceptability under EU regulations of using *Bacillus thuringiensis* for insecticidal and fungicidal purposes during cultivation.

The Committee pointed out that a product with a low water content, added to the UV treatment received, would reduce the potential microbiological risk. However, potential for fungal growth, highlighted in the supporting material, raised concerns about potential microbial risks. In particular, the development of mycotoxins and whether this would be managed in the proposed production process.

The Committee expressed significant concerns that the glycosides, flavonoids and antinutritional factors mentioned in the dossier could have adverse effects which were not explored. Some flavonoids are known to interact with medications commonly used in the EU, but this potential risk had not been investigated in the dossier.

Another substantial concern raised by the Committee was the information from the applicant describing the use of Moringa stenopetala dried leaf powder as a flocculant in water treatment. It apparently adsorbs heavy metals, including cadmium and lead,

when in contact with contaminated water. Depending on the mechanism of action, members were concerned that the nature and quality of the water sources in which the leaves are washed during production might affect the concentrations of heavy metals in the final product.

The Committee noted that the applicant did not perform a literature review, thereby missing the opportunity to add to the understanding of the risks the food might pose. Members also commented that the applicant had not considered possible allergenicity risks which made assessment of this high protein food incomplete. In considering the intended use and intake, members considered that these were not clear and that, when suggesting potential uses, these had not been matched to European Union intake recommendations for their type of food.

Action: The Secretariat will draft a summary of the Committee comments and put the document out for a 10-day public consultation as previously agreed.

7. Future arrangements for Risk Assessment Guidance ACNFP/136/3

The Committee received an update on risk analysis guidelines that are being produced to support the Agency's work and the next steps for embedding these into the working practices of the FSA.

Action: For workstream leads to consider points raised by the Committee in the continued development of risk analysis processes and documentation being developed.

8. Annual Report

The Secretariat presented the draft annual report to the Committee, highlighting the reflection of the year and the changes to the format of the Report. The Committee agreed that the Annual Report was a true reflection of the year for 2018 and agreed that they were happy with the document, subject to minor amendments.

Action: The Secretariat will review comments, made by the Committee, update the report before publication.

9. For Informatio

9.1 Policy Update

Oral

The Committee noted the oral briefing.

9.2 GM Policy Update

Oral

The Committee received an oral update on the recent GM meeting.

10. Any other Business

The Secretary raised the issue of how individual Committee members would like to receive dossiers and supporting annexes in future. Committee members were content to receive files electronically, especially for sizeable dossiers with the Secretariat applying judgement on which annexes to be provided for traditional food notifications in the first instance with the opportunity further annexes to be sent on request.

The proposition was put forward that the FSA create an online workspace for the access of documents electronically, which the Secretariat continues to explore.

The Committee also reflected on the working practices between the Committee and Secretariat. It was stated that consideration should be given to ensuring members had the maximum amount of time to read large and complicated dossiers.

Action: The Secretariat will review the working practices to expedite and increase accession to information for the Committee.

11. Date of next meeting:

The next meeting is scheduled for 10th July 2019. The venue will be confirmed.