

Minutes

Minutes of the 31st January 2023 meeting - SFWG

**Joint Expert Group on Additives, Enzymes and other
Regulated Products Smoke Flavouring Working Group (AEJEG
SFWG)**

**Meeting of the Committee at 10:00 on Monday 23rd January
2023 via Microsoft Teams**

Chair

Dr Allain Bueno

Prof Qasim Chaudhry

Dr Claude Lambré

AEJEG Members

Dr Olwenn Martin

Dr Martin Rose

Dr Gill Clare

FCMJEG Member

Dr David Lovell

Co-opted Experts

Dr Adam Thomas

Dr Claire Stevenson

Prof Michael Walker

FCMJEG Member

Ms C Tsoulli

Dr G Spedalieri

Mr M Dickinson

Ms N Adams

Dr A Cooper

Food Standards

FSA Scientific Secretary

Agency (FSA)

Dr G Drummond

Secretariat

FSA Scientific Secretary

Ms J Frimpong-Manso

Ms C Hoppie

Mr T Hornsby

Dr E Hudson

Ms F M Uy

Mrs C Potter FSA

FSA and other Officials: Ms V Balch FSA

Dr L Smythe Food Standards Scotland (FSS)

Contents

Declaration of interest(s)

1 Welcome and apologies

2 Introduction

3 RP1523 Application for the renewal of smoke flavouring primary product
'Fumokomp concentrate (SF-009)' (Reserved)

4 RP1614 Application for the renewal of smoke flavouring primary product
'proFagus R709 SF-008" (Reserved)

5 Any other business

Closing remarks

Declaration of interest(s)

1. Dr Gill Clare previously declared a personal non-specific interest for Covance, a contract research organisation, which was commissioned for genotoxicity testing by the majority of Applicants. As previously agreed by Members, Dr Clare can participate in the general discussions but will not be able to contribute to forming conclusions on applications where new testing was performed by Covance.

2. No other interests were declared.

Item 1: Welcome and apologies

3. The Chair welcomed AEJEG SFWG Members and other attendees.

4. Apologies were received from Dr Ruth Morse. Dr Olwenn Martin and Dr Adam Thomas were present for the first half of the meeting.

Item 2: Introduction

5. Members were requested to scrutinize the dossier provided by the Applicants, raise questions for clarification or request the generation of additional data, and were reminded that the complete assessment of the product was not expected to be finalised during the initial meetings, where the intention was to provide a 'first reading' of the submitted data. The AEJEG was asked to highlight any key issues or missing information for an 'Request for Further Information' (RFI) at this stage, beyond those identified by the Secretariat at the suitability check stage. 'Deep dives' into the dossiers would occur at later meetings to allow for further discussion and for conclusions to be made.

6. Members were of the view that significant biological changes in the animal models used for toxicity and genotoxicity testing (e.g., rats and mice) were not expected between the date of the re-evaluation and 20 years prior when the historic studies were conducted. However, the product specifications 20 years ago might have been different from those of the product at the time of the re-evaluation. Members agreed that a comparison should be made between the specifications of the test item used for the historic studies with recent specifications provided in the dossier. The Secretariat reminded Members that as part of the renewals process, the Applicants had to provide proof that the chemical specifications had not changed since the original authorisation.

7. In addition, Members noted that the Organisation for Economic Co-operation and Development (OECD) test guidelines have been updated since the historic tests were performed. Therefore, changes made as a result of updates would need to be taken in to account when weighing the available evidence.

Item 3: RP1523 Application for the renewal of smoke flavouring primary product 'Fumokomp concentrate (SF-009)' (Reserved)

8. The AEJEG were introduced to the dossier for RP1523 for the renewal of Fumokomp Concentrate, a smoke flavouring primary product. Members were presented with the previously assessed information as well as updated information relating to genotoxicity and a signed study plan for intended genotoxicity work.

9. Based on the above information, it was agreed that the Secretariat would prepare questions to be circulated to the AEJEG, prior to being included in an RFI letter which would be sent to the Applicant. The questions were to address the need for more information regarding the manufacturing process, the provision of correct laboratory certification and analytical methodology as well as additional information on product stability and the toxicological information. This item would be revisited upon receipt of the requested additional information.

Item 4: RP1614 Application for the renewal of smoke flavouring primary product ‘proFagus R709 SF-008” (Reserved)

10. The AEJEG were introduced to the dossier for RP1614 for the renewal of proFagus R709, a smoke flavouring primary product. Members were presented with the previously assessed information as well as updated information relating to genotoxicity and a signed study plan for intended genotoxicity work.

11. Other areas, where further information was required, were identified by the AEJEG, specifically for the information provided regarding the manufacturing, identification, exposure and batch-to-batch variability of the product. Due to time constraints, the discussion of the dossier was stopped and would resume in the following meeting.

Item 6: Any other business

12. A Member presented to the group an internal document for the proposed quality and expectations of the analytical methodology and generated results.

13. It was proposed that the only accreditation required would be for PAH’s and metals. For all other analytical methods, Validation and performance characteristics and competently documented methods, such as a quality system would be required. Members would revisit the discussion at a future meeting with a view to either supply the document to Applicants, or for use to formulate standard questions in RFIs.

Closing Remarks

14. The Secretariat informed Members the agenda for the next meeting (27th of January 2023) would be updated to carry over the review of RP1614. Members were also reminded that the next AEJEG meeting on Smoke Flavourings would take place online via Microsoft Teams on Friday 27th of January 2023 at 10:00AM.