Meeting

Minutes of the 25th April 2023 meeting

Meeting of the Committee at 10:00 on Tuesday 25th April 2023 via Microsoft Teams.

Chair	Dr Allain Bueno
	Prof Qasim Chaudhry
	Dr Martin Rose
AEJEG Members:	
	Dr Olwenn Martin
	Dr Claude Lambré

	Ms Chara Tsoulli	
	Dr Gaetana Spedalieri	
	Ms Jocelyn Frimpong-Manso	
Food Standards Agency (FSA)	Mr Thomas Hornsby	FSA Scientific Secretary
Secretariat:	Ms Natasha Adams	
	Ms Abigail Smith	
	Dr Katie Schulz	
FSA and other Officials:	Ms Claire Potter	FSA
	Ms Michelle Hutchison	FSA

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Announcements

1. The chair welcomes Members and other attendees.

2. The Members welcomed Dr Katie Schulz, who had recently joined the FSA Secretariat Team for the AEJEG as an HSO.

Interests

3. No conflicts of interest were declared.

Item 1: Apologies for absence

4. Apologies were received from Dr Claude Lambré, and Ms Claire Potter of the Secretariat.

Item 2: Minutes from the last meeting

5. Members were presented with the minutes of the AEJEG meeting held on 13th February 2023.

6. The minutes of the last meeting were agreed as accurate record, subject to minor editorial changes and amendments discussed during the meeting.

Item 3: Update on the authorisation of 2-methyl-1-(2-(5-(p-tolyl)-1H-imidazol-2-yl)piperidin-1-yl)butan-1-one for use as a new flavouring substance (RP1330)

7. The AEJEG was presented with and asked to evaluate the Applicant's response to a request for further information (RFI) for RP1330 received on Monday 20th March 2023. This is an application for the authorisation of 2-methyl-1-(2-(5-(p-tolyl)-1H-imidazol-2-yl)piperidin-1-yl)butan-1-one for use as a new flavouring substance. The RFI was sent following a discussion which took place during the meeting on Thursday 13th October, in which Members agreed that clarification on ranges of the isomers in the specifications were needed, in addition to a recalculation of exposure for children, and an explanation of the methodology used to calculate the overall margin of safety. The AEJEG were not satisfied with the arguments and statistics provided across the application, especially in the toxicity section and therefore requested a re-evaluation of the data by a statistician and to present them with standard deviations, thresholds of statistical significance and a clear indication of whether the data was normally distributed or not.

8. Overall Members deemed the responses to the specification and manufacturing sections as acceptable. The AEJEG raised concerns with the TTC level calculated for children and did not deem the NOAEL level derived as acceptable, therefore the AEJEG requested further information and data be provided using in silico and in vitro assays to eliminate concerns for at risk groups such as children and pregnant women.

9. Based on the above information, it was agreed that the Secretariat would prepare questions which would be circulated to the AEJEG, prior to being included in an RFI letter to be sent to the Applicant. This item would be revisited upon receipt of the requested additional information.

Item 4: Update on authorisation of blue microalgae extract or blue Galdieria extract for use as a new food additive (RP507)

10.The AEJEG was presented with and asked to evaluate the Applicant's response to a request for further information (RFI) for RP507. This is an application for the authorisation of blue microalgae or blue Galdieria extract for use as a new food additive. The RFI was sent following a discussion which took place during the meeting on Thursday 13th October, in which Members agreed that further additional details of the Applicant's historical control data were required in order to carry out a comprehensive risk assessment. Members were invited to consider the Applicant's response to the RFI, received on Friday 25th November 2022.

11. Overall, the AEJEG was satisfied with the Applicant's response on historical control data. However, it was agreed that additional clarification on the comparability of historical control rats and the toxicological rats diet, and a scientific rationale for the units used for TSH levels were needed.

12. It was agreed that the Secretariat would prepare additional questions to circulate to the AEJEG, prior to being included in an RFI letter to be sent to the Applicant. This item would be revisited upon receipt of the requested additional information.

Item 5: Draft Opinion on the Application for the Approval of Steviol Glycosides (E 960) From Stevia Leaf Extract Produced by Enzymatic Conversion (RP1084)

13. Members were presented with the draft Opinion paper for the modification of the existing specifications for E 960 Steviol Glycosides to allow for the inclusion of the enzymatic conversion manufacturing process as an alternative method to produce high purity steviol glycoside preparations obtained by water extraction

from the leaves of the Stevia rebaudiana Bertoni plant. The new manufacturing process uses two UDP-glucosyltransferases and one sucrose synthase, derived from genetically modified strains of E. coli K-12.

14. A Member stated it would be beneficial to have a template for what opinion papers should contain. They stated this would be beneficial to ensure no parts of the assessment were missed. This would include an introduction which would include sections on the chemical's background, properties, previous risk assessments, how the additive is produced and industrial information. This would be followed by an exposure assessment and the toxicological information. The Secretariat responded that this Opinion had been based on previous Opinions that have been cleared by the Committee on Toxicity and that once further Opinions have been cleared a general template would be constructed.

15. A Member queried at what point the literature provided by the Applicant would be considered out of date. The Secretariat responded it would be the Applicant's responsibility to notify the AEJEG of new information. Information when it is received should be current. A Member stated that the information could be assumed to be up to date from when the latest request for information response was received. A Member raised a concern that an Applicant may not provide updated information.

16. The Secretariat stated that the equivalent Opinion produced by EFSA was published shortly after the end of the transition period. They stated that following current rules the application may have been assessed by the Secretariat however this was not the case and the assessment by the AEJEG was being conducted.

17. A Member suggested an amendment within paragraph 2 to reflect the reason that a dietary exposure assessment had not been performed as exposure in consumers would not change as a result of approval of this Application.

18. A Member queried if there was a systematic process for risk assessment checking and evaluations from other bodies. The Secretariat pointed out the information provided to members relate to what was provided by the applicant. Members agreed that a system for checking for existing authorisations would be helpful. A Member stated some evaluations form global authorities may not be accessible due to language barriers.

19. A Member queried whether only 95% of the mixture was identified. The Group confirmed that over the 95% represented the 11 steviol glycosides with other identified components increasing the identified content above 95%.

20. A Member noted an editorial issue. They stated that the line ‘below identified 11 steviol glycosides’ be amended as the steviol glycosides were no longer listed below. The Secretariat responded this would be addressed.

21. The secretariat noted that the sections marked as confidential had not yet been finalised and that these sections would be subject to amendment following agreement with the Applicant.

22. The Secretariat noted it could be beneficial to include ‘similarly to traditionally produced steviol glycosides’ when discussing the plant-based origin of steviol glycosides manufactured by enzymatic conversion. The AEJEG agreed to this alteration.

23. Overall, Members were satisfied with the structure and content of the Opinion and accepted it as an accurate reflection of AEJEGs discussions.

24. Members agreed to the finalisation of the opinion by Chair’s action, subject to some minor editorial changes.

Item 6: Draft Opinion on the Application for the Approval of Steviol Glycosides (E 960) Produced by Yarrowia lipolytica (RP1140)

25. Members were presented with the draft Opinion paper for the modification of the existing specifications for E 960 Steviol Glycosides to allow for the inclusion of the fermentation of sugars (dextrose) by Yarrowia lipolytica as an alternative method to manufacture high purity steviol glycosides.

26.A member queried if there was any available guidance or standardisation with regard to batch-to-batch variation. The Secretariat confirmed that the present time, this was not available, and this would possibly be a discussion for the COT and JEGs.

27. The AEJEG noted paragraph 43 was missing some context regarding the identity of substances lost by loss on drying.

28. A Member noted that with regard to previous assessments, that some of the evaluations carried out by now superseded bodies were described by the applicant in a way that sounded as if they had been recently conducted and queried if there was a time limit within which past evaluations could be cited. The AEJEG agreed that the year of evaluation by each Authority would be added to the

opinion.

29. Overall, Members were satisfied with the structure and content of the Opinion and accepted it as an accurate reflection of AEJEGs discussions.

30. Members agreed to the finalisation of the opinion by Chair’s action, subject to some minor editorial changes.

Item 7: Draft Opinion on the Application for the approval of Steviol Glycosides from fermentation (Reb M) (RP1112)

31. The AEJEG were to be presented with a draft opinion paper for the modification of the existing specifications for E 960 Steviol Glycosides to allow for the inclusion of the production of Rebaudioside M (Reb M) by fermentation with a genetically modified production strain of S. cerevisiae.

32. Members considered that due to time constraints within the meeting RP1112 could be reviewed at a later date. The Secretariat suggested that the response to the request for information could be reviewed by correspondence, to which members agreed.

Item 8: Update on the Extension of use of phosphates (E 338–341, E 343, E 450–452) to a new food category “egg analogues” (RP40)

33. Members were presented with an update paper for Regulated Products Application RP40, a request to extend the use of phosphates to a new food category “egg analogues” which would be further subdivided into solid and liquid egg analogues. The AEJEG reviewed the response to a request for information they had received following their November 2021 meeting. This response had previously been reviewed in their February 2023 meeting.

34. Based on the above information, it was agreed that the Secretariat would prepare questions which would be circulated to the AEJEG, prior to being included in an RFI letter to be sent to the Applicant. This item would be revisited upon receipt of the requested additional information.

Item 9: Any Other Business

35. Members were reminded the next Smoke flavourings AEJEG meeting was 12th June and would be an in-person meeting. Members were requested to ensure travel and accommodation was booked, and informed the AEJEG's admin hub could assist with this process. The Secretariate stated this would still be going ahead even if the RFI's had not been returned by this point.

Date of next meeting

36. The next meeting of the AEJEG will be at 10:00 on 1st June 2023 on Microsoft Teams.