Ninety-second Advisory Committee on Animal Feedingstuffs meeting
17th July 2024 – Online meeting

ACAF	**FSA**
Nick Jonsson (Chair)	Nathan Allen
Martin Briggs	Mark Bond
Emily Burton	Alexander Cooper
Katrina Campbell	Emily Davies
Matthew Fisher	Edward Fuller
Chris McAlinden	Beth Hall
Donald Morrison	Emily Hudson
Derek Renshaw	Michelle Hutchinson
Mike Salter	Leigh-Anne Kemp
Adam Smith	David Kovacic
Christel Wake	Kaila Lee
Helen Warren	Francisco Matilla
Nick Wheelhouse	Barry Maycock
	James Metcalfe
	Johann Trotter
	Alba Ureña Rusillo

1. Apologies

Hannah Kane and Susan MacDonald sent their apologies.

2. Welcome

The Chair welcomed members of the Committee, Secretariat and observers from the Devolved Administrations.

3. Risk Assessment update

The Regulated Products Team Leader Francisco Matilla-Garcia updated the Committee, informing them of a new team that has been formed within Regulated Products that will focus on providing process support, mostly around publications. The updated organisation chart including this new team was highlighted. Members were also informed of the new publication system, noting that the next set of publications are on track. An update on application RP859 was provided, indicating its withdrawal by the applicant. Members were told that the recruitment campaign for the scientific advisory committees would be starting soon and that an advert will be disseminated for members to share with contacts.

4. Policy update

Feed Additives Senior Policy Advisor, Mark Bond, briefed the Committee on the number of new applications received since the last meeting, of which there have been seven. Four of these new applications are renewals, which will need to be checked for any modifications, pending the upcoming potential removal of renewals. A new Senior Policy Advisor within the Policy team was introduced, Rebecca Greenaway, and Mark updated members on his upcoming secondment for six months.

5. Minutes from 91st Meeting

The Committee reviewed the minutes from the 91st ACAF meeting and provided feedback to be reviewed by the Secretariat.

6. Response to RFI: RP1280 Formaldehyde

Martin Briggs declared a direct conflict of interest and so participation was limited to discussions regarding experience working with formaldehyde.

Further information relating to the identity of the additive had been provided by the applicant, however Members were still not able to conclude on the identity of the product, and determined that it is unclear what the additive being assessed in this application is. Concerns were specifically raised regarding the inclusion of different components within the specification. Members discussed the conditions of use proposed by the applicant and were confused as to the steps taken to determine when, or if, the application of the additive is needed. Further clarification regarding application of the additive is also required, such as if it is intended to be applied pre- or post-pelleting. If the additive is to be applied pre-pelleting, relevant stability studies would be required. The Committee also determined that homogeneity would need to be assessed using a study that meets the requirements for homogeneity testing.

The Committee could not conclude on safety for the target species as a margin of safety could not be determined. There were also concerns regarding safety for the consumer, namely, the potential for the accumulation of formate residues in edible tissues of target species. Regarding the safety for user/worker, members expressed uncertainty regarding occupational exposure limits and therefore could not reach a conclusion. The Committee also determined that more information would be needed to conclude on safety for the farmers who would be working with the formaldehyde-treated feed.

7. Response to RFI: RP1341 Avizyme 1505

Emily Burton declared a direct conflict of interest and left the meeting for this discussion. Adam Smith declared an indirect conflict of interest and remained in the meeting.

The Committee reviewed the information provided to demonstrate absence of viable cells from the final additive and concluded the data was suitable for assessment. The

Applicant's justification for not providing MSDS documentation for all the ingredients used in the manufacturing process was not accepted by the Committee who concluded that all MSDS documentation would be required to allow a comprehensive assessment of the manufacturing process. **The applicant would be asked to provide MSDS documentation for all ingredients used, ensuring all documentation is no more than five years old.**

Members noted that the skin sensitisation study provided was performed to a high standard, however, the composition of the additive being used in the study was unclear, **the applicant would be asked to provide further detail of the additive used in the skin sensitisation study and to demonstrate its comparability to the additive described in the dossier.** Members raised concerns over the use of sieving during the study and the potential for larger particles to be removed changing the composition of the additive tested. **The applicant would be asked to provide further detail of the sieving step in the process, including why this is performed and if all the additive passes through or if some material is removed.**

8. Response to RFI: RP1243 L-methionine (*C. glutamicum* & *E. coli*)

No conflicts of interest were declared for this item.

Members reviewed the updated MSDS documentation provided, noting that the updated MSDS for corn cob powder was unsuitable for assessment as it did not meet international standards and was not dated, **the applicant would be asked to provide an updated MSDS document ensuring it meets international standards and is dated.** The Committee reviewed the Applicant's justification for not providing stability studies in a further form of feed, however, the Committee concluded that in the absence of further data they are only able to conclude on the stability of the additive in mash and pelleted feeds for poultry and swine. The Committee noted that data had not been provided to demonstrate the absence of microbial contamination for the stability testing performed in water. **The applicant would be asked to provide data to demonstrate the absence of potential contaminating microorganisms in the stability testing and reminded that in the absence of these data ACAF would be unable to conclude on the additive's stability in water.**

9. Response to RFI: RP1421 HiPhorius

Adam Smith declared a direct interest and left the meeting for this discussion.

The Committee were satisfied with the applicant's response regarding the composition of the carbohydrate binder. The applicant also provided translated MSDS documentation, which was deemed satisfactory by the Committee. As requested, the applicant provided HACCP details, however members noted that no accreditation certification was provided for the manufacturing plant. As such, **the applicant would be asked to provide recognised assurance certificates.**

The Committee were satisfied with the eye irritancy study information provided but noted that the formulations used in the skin irritancy studies were still unknown. As such, **the applicant would be asked to provide the details of the mixture entitled X-phos, batch ELN-20-THF-0044.**

The Committee were satisfied with the applicant's response relating to the differences between the safety data sheets.

Addendum: Members reviewed the efficacy studies offline and concluded that the studies with diets containing high amounts of copper compared to EFSA legislation were suitable for assessment. It was concluded by the ACAF that the additive has the potential to be efficacious.

10. Response to RFI: RP1154 BioPlus 2B

Martin Briggs declared an indirect conflict of interest and left the meeting for this discussion.

The Committee discussed the responses provided for various queries sent to the applicant, concluding that the questions relating to batch-to-batch variation, impurities, microbial contamination, stability and homogeneity of the final product had been correctly addressed. Furthermore, Members noted that the applicant had provided a clear and detailed analysis of the Whole Genome Sequence (WGS) data of the organisms for the presence of acquired antimicrobial resistance. In addition, the applicant had provided recent Pulsed-Field Gel Electrophoresis (PFGE) DNA fingerprint data which the Committee agreed demonstrated the genetic stability of the organisms.

The Committee reviewed the FAMI-QS certificate and HACCP plan submitted by the applicant. Members noted that FAMI-QS certificates had not been provided for all the manufacturing sites listed in the HACCP plan. **The applicant would be asked to provide FAMI-QS certificates for all manufacturing sites.** Members reviewed the Safety Data Sheets (SDSs) provided for the raw materials used during the manufacturing process. Members noted that the SDS for one raw material was outdated. **The applicant would be asked to provide a recent SDS for this raw material.** Members reviewed the updated conditions of use and product label provided by the applicant. Members noted that the label did not include a retention time for the pelleting process, and that the respiratory protection required was not described correctly. **The applicant would be asked to update the conditions of use and label with the retention time for pelleting and a clear description of the type of respiratory protection required.**

The Committee agreed that the applicant had addressed members' previous concerns regarding extrapolation for efficacy. Members concluded that efficacy could be extrapolated from weaned piglets to suckling piglets for the period in which solid feed is given, and from calves for rearing to calves for fattening.

11. Response to RFI: RP1393 Ronozyme WX (CT) and Ronozyme WX (L)

Adam Smith declared a direct conflict of interest and left the meeting for this discussion.

Members were satisfied with the analytical testing for total yeasts, filamentous fungi, and testing provided for *Bacillus cereus* from batches of enzyme concentrate was reasonable. The applicant was asked to provide quantification of how much medium is incorporated into the final product. **It was agreed that the original submission would be checked to see if the 48h stability test in water for microbial growth was done and if not, the applicant would be asked to provide this testing.** The clarification on what was meant by slight increase and what is considered in the case-by-case evaluation was considered satisfactory by members. The applicant was asked to clarify what they meant by tests for infection and provide more details of these tests. **It was agreed that the original submission would be checked to see if the applicant specified which impurities are monitored and how frequently. If the information is deemed unsatisfactory, the applicant will be asked to provide more details on the impurity testing.** Members were satisfied with the provided HACCP plan for the production process of the additive and provided information on critical points. The provided MSDS were deemed satisfactory, and members were satisfied with the additional information provided on the pelleting.

The applicant was asked to provide justification of the use of 4-nitroquinoline-1-oxide (NQO) for the positive control of TA100 in the Bacterial reverse mutation test and members were satisfied with the provided justification. The provided reproduction/developmental toxicity screening study (OECD 422) did not raise any concerns.

Members could not conclude on the efficacy for gestating sows without additional data and therefore extrapolation to all stages of a pig's life is not possible.

12. Draft safety assessments: RP1026/RP1027, RP1579 and RP2059.

Members were presented with draft Committee's Advice documents for applications RP1026/RP1027 and RP2059.

The Committee was also presented with the final draft of the Committee's Advice document for application RP1579. The Committee provided feedback on final corrections and approved the opinion to be finalised and sent to Risk Managers.

13. Annual Report

Members had a final chance to comment on the annual progress report before it is published on the ACAF website.

14. Recommendations to applicants

Members were invited to review the latest iteration of this recommendation document to be shared with applicants.

15. Discussion: Efficacious vs potentially efficacious

The Secretariat requested that members provide guidance on how to determine if an additive is efficacious or if the additive merely has the potential to be efficacious. Members had a discussion relating to efficacy and what factors enable them to reach their conclusions.

16. Discussion: Guidance improvement

Due to time constraints, members were not able to discuss areas where the current Guidance may require updating based on their experience. This item will be rearranged for a future meeting.

17. Any other business

An update on upcoming applications was provided.

Next ACAF meeting: 17th September on Microsoft Teams.