**Eighty Ninth Advisory Committee on Animal Feedingstuffs meeting**
31st January 2024 – Online meeting

| **ACAF** | **FSA** |
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| Martin Briggs (Chair) | Nathan Allen |
| Emily Burton | Amanda Blackler |
| Katrina Campbell | Mark Bond |
| Matthew Fisher | Aaron Bradshaw |
| Oonagh Markey | Edward Fuller |
| Susan MacDonald | Beth Hall |
| Donald Morrison | Emily Hudson |
| Derek Renshaw | Michelle Hutchison |
| Mike Salter | David Kovacic |
| Adam Smith | Francisco Matilla |
| Helen Warren | Chris Rundle |
| Nick Wheelhouse | Shila Sultana |
| | Johann Trotter |

## 1. Apologies

Nick Jonsson, Chris McAlinden and Hannah Kane 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, highlighting that 26 ACAF-led Safety Assessments have been published so far and there are 6 Safety Assessments currently drafted after going through the ACAF process. Twenty-eight applications are currently being assessed via one of the potential assessment processes. An additional 10 Safety Assessments are to be published between March and April, 4 of which are ACAF-led assessments. Three new members are set to join the Secretariat and another member will be welcomed to ACAF soon.

## 4. Policy Update

Feed Additives Senior Policy Advisor, Mark Bond, briefed the Committee on the number of feed additives currently in the system and the number of new applications received since the last meeting. An update was provided relating to a recent meeting

paper on Regulated Products, of note is the intention to create a more harmonised application process, as well as the proposal put forward relating to the renewal of authorisations. A new member was welcomed to the Policy team, with further recruitment expected.

## 5. AOB – Regulated Products Service and continuous improvements

Head of Regulated Products Risk Assessment, Chris Rundle, presented a paper on continuous improvement in the Regulated Products service that had previously been presented at the SAC chairs meeting. The paper highlights the three routes of assessment to be implemented moving forward.

## 6. Minutes from 88th Meeting

The Committee reviewed the minutes from the 88th ACAF meeting and provided feedback to be reviewed by the Secretariat.

## 7. Dossier for assessment: RP1072 Avatec 150G (Chickens, turkeys & minor avian species)

No conflicts of interest were declared for this item.

Members noted that safety for the target species and efficacy were previously evaluated at the June 2023 ACAF meeting. Following the initial evaluation, a request for information was communicated to the applicant, who in response, clarified a proposed withdrawal period of three days and confirmed the removal of chickens reared for laying from the remit of the authorisation.

Identity and characterisation of the additive was assessed by the Committee. Members noted that testing for *Bacillus cereus* had not been included within the impurities section of the dossier. **The applicant would be asked to provide testing for *Bacillus cereus*.** Discrepancies were noted between the units detailed in the dossier and associated annex documentation, with some studies reporting in imperial units. **The applicant would be asked to clarify the use of these units for this data.** Members noted that HACCP documentation was not provided for assessment. **The applicant would be asked to provide HACCP documentation ensuring the critical control points of the manufacturing process are fully described.** Pelleting stability data had been provided by the applicant; however, the conditioning time of the process has not been included. **The applicant would be asked to provide further detail of the pelleting process, including clarification of the conditioning time and temperature.** Members noted discrepancies in the proposed withdrawal period for turkeys for fattening and minor avian species between the proposed conditions of use and the proposed label, **the applicant would be asked to clarify the proposed withdrawal period for these species and to provide corrected documentation ensuring consistency throughout.**

Members reviewed the data provided for safety for the target species, safety for the consumer and safety for the environment, concluding that no further information would be required for assessment. The residue studies provided by the applicant would be reviewed offline and any further information required would be communicated to the Secretariat before a request for information was communicated to the applicant. Members noted that the exposure limits detailed had not been included in the proposed label. **The applicant would be asked to provide an updated label including the exposure limits.** The Committee concluded that the additive is an eye irritant, but is not a skin irritant or skin sensitiser, the additive should be regarded as harmful by inhalation and appropriate PPE should be used when handling.

Members reviewed short-term efficacy studies provided in the updated version of the dossier. **The Committee concluded that the studies did not change their previous conclusions and that the additive can be considered efficacious at the proposed dose of 90 ppm**. No further information would be required from the applicant.

**Addendum:** *Members reviewed the residue studies provided offline and concluded that the studies were suitable for assessment and no further information would be required from the applicant. The data provided on antimicrobial resistance and susceptibility was also reviewed and Members concluded that further information would be required from the applicant to allow a comprehensive assessment.* ***The applicant would be asked to provide detail of the bioinformatic pipeline and antimicrobial databases used for the analysis provided. The applicant would also be asked to provide a literature review to support the results for antimicrobial susceptibility.***

## 8. Dossier for assessment: RP1070 Avatec 150G (Game birds)

No conflicts of interest were declared for this item.

An application for Avatec® 150 G was evaluated. The applicant requested the renewal of authorisation of the additive under Regulation (EC) No 1831/2003 for use in game birds. The additive falls under the category and functional group “coccidiostats”.

A set of questions were sent by the FSA prior to this meeting. Members discussed the response from the applicant and were satisfied with the response regarding the missing annex, translation of annexes and the HACCP, FCA and FAMI-QS certification.

The genetic stability of the bacterial strain was discussed, and it was noted that the applicant provided whole genome sequencing for the production strain but had not demonstrated the stability of the production strain. **The applicant would be asked to demonstrate the stability of the production strain using an appropriate technique**. The additive displayed good stability after 3 months and also demonstrated good homogeneity. It was noted that the proposed mode of use table stated that “simultaneous use with certain medicinal substances can be

contraindicated", **the applicant was asked to update the table with the name of the medicinal substance being referred to, i.e., tiamulin**.

Members discussed the safety section of the application and noted that the guidance for renewals states that the literature search should cover at least the period since the last assessment until not more than 1 year before the date of submission of the application. The applicant submitted a literature search that covers up to 2019, therefore **the applicant would be asked to provide an updated literature search that covers from 2019 to 2023 that specifically relates to the target species of this application**. The Committee discussed the MRLs and withdrawal period of the additive, it was pointed out that some of the studies submitted from the previous authorisation were quite old and no residue studies were submitted for a 3-day withdrawal period. However, members concluded that as low levels were found after 24 hours and at 5 days, **it was safe to assume that a 3-day withdrawal was sufficient**. It was concluded that **a NOAEL of 135 mg/kg was appropriate in chickens for fattening, and this could be extrapolated to game birds**.

Members noted that the efficacy studies were submitted within the 2-year window as stated by the guidance. From the three studies provided, it was noted that efficacy was stronger for pheasants and slightly weaker for guinea fowl and quail. **It was concluded that the studies provided demonstrate that the additive has the potential to be efficacious.**

## 9. Dossier for assessment: RP1512 PB6 (*Bacillus velezensis* ATCC PTA-6737)

No conflicts of interest were declared for this item.

An application was evaluated for the additive PB6 (*Bacillus velezensis* ATCC PTA-6737). The additive has previously been authorised for use in weaned piglets and weaned minor porcine species and as a feed additive for sows. The applicant seeks to renew this authorisation and extend its use to all pig species. The additive falls under the category "zootechnical additives" and the functional group "gut flora stabiliser".

The Committee evaluated the available data relating to the identity and characterisation of the additive, noting that the Secretariat had recently asked the applicant to provide more recent data demonstrating batch-to-batch variation and impurity testing. The Secretariat had also requested supporting documentation and certification relating to quality assurance, missing MSDS and further information on HACCP. The outstanding data will be assessed at the next possible ACAF meeting. **Members agreed that the strain has been fully characterised using whole genome sequencing**.

Members noted that the additive is authorised for use in weaned piglets at a minimum application rate of 1 x $10^7$ CFU/kg complete feed and is intended for use in growing pigs at a minimum content of 1 x $10^7$ CFU/kg complete feed and in sows and minor reproductive species at 1 x $10^8$ CFU/kg complete feed. A query was raised regarding determination of the dose for growing pigs, as efficacy trials were used to determine the doses for weaned piglets and sows. **The applicant would therefore**

**be asked to clarify how they concluded on a dose of 1 x $10^7$ CFU/kg complete feed for growing pigs.**

The Committee assessed the efficacy section of the application, concluding that the evidence for efficacy was stronger in piglets than in sows. Several inconsistencies were highlighted within the sow trials with only two of the trials considered to show efficacy, however three trials are needed to provide a conclusion. Using the data provided, the Committee decided they would only be able to conclude that the additive has the potential to be efficacious unless an additional study was provided for sows. Therefore, **the applicant would be asked if they wished to accept this conclusion regarding potential efficacy or if they would provide an additional efficacy study for sows.**

## 10. Response to RFI: RP1275 Quantum Blue

Mike Salter, Emily Burton and Adam Smith declared an interest, which was deemed to not pose a conflict, and they remained in the meeting for the discussion.

Members noted that testing for *Bacillus cereus* had been provided, as well as more recent impurity testing. However, no reference for the acceptance limit of < 1000 CFU/g for yeasts and moulds was included, therefore **the applicant would be asked to provide a reference for this acceptance limit.** Members were satisfied with the more recent analytical data provided relating to the absence of antibiotic activity, absence of production strain, absence of mycotoxins and absence of DNA from the production strain. Although, it was noted that in the study demonstrating the absence of DNA from the production strain the exact formulation tested was not clear, therefore **the applicant is asked to clarify which formulation was used in this study and from which phase of the manufacturing process the test substance was taken**. The applicant had provided more recent MSDS, but not for all components, therefore **the applicant would be asked to provide the MSDS for Celite and Solulys E095**. The Committee was satisfied with the requested additional data provided to support the shelf-life of the product. Queries had been raised regarding the low recovery of the additive in animal feed and the applicant provided a potential explanation for these lower levels. However, the Committee indicated that there are improved extraction techniques available and that more precise data could be obtained. **The applicant would therefore be asked to provide additional data to support the stability of the additive in animal feed.** The applicant had provided assays to demonstrate the phytase activity of feed after soaking in water. Members decided that data showing the activity at earlier time intervals would be needed to allow for a more useful conclusion. **The applicant would be asked to provide this additional data demonstrating phytase activity of the additive after 1 and 2 minutes of soaking in water.** Members were satisfied with the dusting potential data for three batches of each solid formulation, concluding that neither formulation is expected to form dust during handling.

Members were also satisfied with the information provided relating to formulation of diet used in the tolerance study, as well as the *in vitro* micronucleus assay provided. The results of this micronucleus assay when viewed alongside results from other

genotoxicity studies seen by the Committee confirmed that the additive is not mutagenic. Members agreed with the applicant that the additive is to be considered a respiratory sensitiser due to its proteinaceous nature.

## 11. Draft safety assessments: RP552, RP634, RP746, RP1015, RP1047 and RP1087

Members were presented with draft Committee's Advice documents for applications RP552, RP634 and RP1015.

The Committee was also presented with the final drafts of the Committee's Advice documents for applications RP746, RP1047 and RP1087. The Committee provided feedback on final corrections and approved the opinions to be finalised and sent to Risk Managers.

## 12. List of requests to applicants

Members had a final chance to comment on the proposed recommendations to applicants to improve the status of dossiers at the time of submission.

## 13. Ways of working

Members reviewed the document intended to be published on ACAF website outlining the updated proposed ways of working and provided feedback to be reviewed by the Secretariat.

## 14. Reclassification of RP1087

Upon request from Policy risk managers, the ACAF evaluated whether the reclassification of application RP1087 from nutritional to zootechnical would pose any additional safety risks. The Committee concluded that the reclassification would not present additional safety risks.

## 15. Microbiology workshop

The Secretariat proposed an outline for an upcoming microbiology teaching session, and encouraged discussion to ensure that the session will cover specific areas relating to microbiology and whole genome sequencing that are often sticking points when performing risk assessments.

**Next ACAF meeting: 3rd April 2024 on Microsoft Teams**