

**One Hundred and Second Advisory Committee on Animal Feedingstuffs
meeting**

10th December 2025 – Microsoft Teams

ACAF

Nick Wheelhouse (Chair)
Barry Bradford
Martin Briggs
Emily Burton
Katrina Campbell
Nick Jonsson
Hannah Kane
Chris McAlinden
Donald Morrison
Derek Renshaw
Mike Salter
Adam Smith
Carla Viegas
Christel Wake
Helen Warren

FSA

Nathan Allen
Lorcan Browne
Emily Davies
David Evans
Emily Hudson
Kaila Lee
Francisco Matilla
Barry Maycock
James Metcalfe
Shila Sultana
Abigail Timothy
Johann Trotter
Alba Ureña Rusillo
Josephine Walker
Elisabeth Watson

1. Apologies

Apologies were received from Susan MacDonald.

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 provided an update on the publication of risk assessments as well as an update on the number of applications progressing through alternative routes.

4. Policy update

Animal Feed Policy Adviser, David Evans, provided an update on the number of applications received since the previous ACAF meeting.

5. Minutes from 101st Meeting

The Committee reviewed the minutes from the 101st ACAF meeting and provided feedback to be reviewed by the Secretariat.

6. Discussion on coccidiostats and antimicrobial resistance

The Committee reviewed the use of coccidiostats in UK livestock, focusing on ionophores and synthetic compounds, particularly narasin. Members noted that coccidiostats currently remain viewed as essential for controlling coccidiosis in poultry, as hygiene and husbandry alone are insufficient. EU policy currently permits their use despite concerns about antimicrobial resistance (AMR).

Coccidiostats are widely used in poultry and occasionally in cattle and swine. Ionophores are generally preferred for reducing clinical symptoms, while alternatives such as vaccines and synthetic compounds present challenges related to cost, efficacy, and administration. Complete eradication of *Eimeria* is impractical due to environmental ubiquity and stress factors.

AMR risks were highlighted as a concern. Evidence shows narasin, salinomycin and maduramicin select for resistance genes in *Enterococcus*, with bans in some countries reducing AMR prevalence. Environmental contamination and potential harm to ecosystems were also highlighted.

Members acknowledged benefits, such as improved production efficiency but stressed the need to balance these against AMR risks and food security. The Committee agreed to consult with VMD, DEFRA and other advisory groups before forming a position and will draft a consolidated paper for further review.

7. Response to RFI: RP1592 Interban

The Committee reviewed the response document provided for assessment noting that the nomenclature of the production strain was incorrect. **The applicant would be asked to confirm the name “*Streptomyces* sp.” accurately reflects the identity of the production strain.** Members noted that the updated HACCP documentation did not include considerations for the GMO. **The applicant would be asked to provide an updated HACCP ensuring that GMO considerations are included.** The updated pelleting stability data provided did not align with the data originally submitted for assessment and did not allow on a conclusion on pelleting stability to be reached. **The applicant would be asked to provide clarification on the pelleting stability of the additive, ensuring that pelleting temperature and conditioning length are included, this information should also be reflected in the conditions of use and on the proposed label for the additive.** Members reviewed the freezer storage stability data and noted that data has not been provided to cover the period of storage for the material utilized in the residue studies provided. **The applicant would be asked to provide storage stability data covering the period of storage.**

The Committee reviewed the updated post-market monitoring plan provided, noting that further detail would be required for assessment. **The applicant would be asked to provide further details for the post-market monitoring plan due to the lack of details in the PMM regarding the process for addressing the possible effect of narasin use on the prevalence (due to co-selection) of resistance in enterococci on farms to antibiotics, especially to vancomycin, tetracycline and erythromycin. Due to the urgency of this issue it was noted that part of the detailed plan should include short and regular reporting times. The applicant would also be asked to provide a statement confirming their continued involvement in the EASSA program.** Based on the evidence concerning the potential risk of AMR co-selection by Interban, the Committee noted their reservations in decision making regarding the post-market monitoring plan.

8. Response to RFI: RP2187 *Pediococcus pentosaceus* NCIMB 12674

Members were satisfied with the applicant's results of the proficiency testing which demonstrated competency of the laboratory in performing the analyses using internationally recognised methods. They also agreed that the applicant provided evidence of genetic stability using a suitable method.

The applicant stated that the product label will include appropriate safety indications and recommendations to minimise skin exposure to reflect that the additive is a potential skin irritant and skin sensitiser. **The applicant would be asked to provide the updated product label.**

9. Response to RFI: RP2247 *Enterococcus lactis* NCIMB 10415

Helen Warren declared an indirect conflict of interest and remained in the meeting for the discussion.

Members were satisfied with the justification provided by the applicant explaining why Total Aerobic Microbial Contamination (TAMC) testing is not necessary for this additive. Evidence of relevant laboratory accreditation was provided; however, **the applicant would be asked to provide evidence of proficiency testing or verification of the method used for the quantitative composition testing.**

The applicant provided an updated SDS and conditions of use, however, the updated conditions of use do not mention the additive's potential to cause skin irritation, nor does it state that the additive is a sensitiser by skin or inhalation exposure. Therefore, **the applicant would be asked to update the conditions of use to include these safety aspects.**

10. Response to RFI: RP2252 Vitamin B12

No conflicts of interest were declared for this item.

The Committee confirmed that the WGS data supplied by the applicant was sufficient to speciate the organism. A concern was raised that this strain has been passaged multiple times and has undergone multiple changes. The applicant stated that they are unable to determine whether the strain has a history of GM as they purchased it from a company that no longer operates, however, they confirmed that they have not carried out any genetic modifications. The Committee concluded that neither the whole genome alignment, nor the gene-by-gene alignments, as presented, were sufficient evidence to show genetic modification. **The applicant would be asked to provide all available information regarding the history of genetic modification of the production strain, as outlined in the Guidance. The Panel acknowledges that the strain was purchased from a supplier that is no longer in operation. However, the application cannot progress without evidence confirming the genetic modification history of the production strain.**

The applicant's updated stability study shows that the organism's production of Vitamin B12 appears to be significantly reduced over serial passage. Further information regarding the observation of a significant decrease of Vitamin B12 production at subculture nine was requested and the applicant responded that they only use the fifth subculture for the fermentation process and for this reason, they do not believe that the decrease in F10 is relevant for the production process of the feed additive. The Committee considered that no evidence for genetic stability has been presented. **The applicant would be asked to provide evidence demonstrating that the original strain and any subsequent strains used are genetically identical. Additional genetic testing, such as Whole Genome Sequencing (WGS) or Pulsed-Field Gel Electrophoresis (PFGE), is required. The applicant would also be asked to supply evidence of genetic stability across the passages intended for use in production.**

The Committee was satisfied with the information provided by the applicant in relation to AMR and virulence genes. It was also satisfied that production DNA fragments are not present in the final product. The annexes provided by the applicant relating to toxigenicity and virulence for humans and target species were also deemed sufficient. The applicant claimed that the AMR of the strain is of no concern as resistance is intrinsic to the species. Therefore, evidence from the literature to support this claim was requested. The Committee stated that, as the applicant does not have detailed information about the origin (the source from which the strain was isolated) or any history of modifications, it is not possible for them to prove that the resistance is intrinsic. The applicant has provided WGS analysis using two AMR databases as required and did not find any AMR. The Committee was satisfied with the WGS analysis.

The Committee were satisfied that the applicant confirmed that the strain used is *Ensifer adhaerens* CICC 11008s, which is also deposited under the strain identification number *E. adhaerens* CCTCC M 20241585.

The applicant was asked to provide evidence that endotoxins are routinely tested for in both the additive preparation and the active substance. The Committee reviewed the information provided but **the applicant would be asked to provide clarity around the frequency of testing for endotoxins** as this production strain is a Gram-negative bacteria that contains lipopolysaccharides (LPS) in their outer

membrane, which act as endotoxins. The applicant confirmed that cyanide was used in excess in production. A minimum of three batches is tested each month, **the applicant would be asked to confirm if cyanide is tested in every batch.**

The certifications provided to demonstrate laboratory accreditations were not deemed sufficient to meet requirements. **The applicant would be asked to provide laboratory accreditation (ISO 17025) certificates for all testing laboratories.** The Committee were satisfied that the applicant provided sufficient evidence for the testing of contaminants in the water used in the manufacturing process. However, Members were dissatisfied with the evidence provided regarding testing for pathogens, **the applicant would be asked to provide clarity on the number of batches produced/frequency of testing. The applicant would be asked to provide a more comprehensive risk assessment, HACCP plan, and analysis schedule. Members further suggest that the applicant explain the rationale behind the current testing frequency and how this approach is adapted when manufacturing levels increase or decrease.**

The applicant confirmed that all stability tests in premixture and feed have been done with the Vitamin B12 1% feed additive. The Committee was dissatisfied with the applicant's response regarding stability in pig mash and pig pellets. The applicant tested batches manufactured with a 50% overage to allow for expected losses during storage to ensure that the product meets its label claim following storage for up to 3 months. It is the view of Members that the actual amount in feed should be as close as possible to the declared amount. Members agreed to further discuss acceptable degrees of overage before requesting more stability data. The Committee further discussed the percentage loss and the impact this will have on the product. **The applicant would be asked to clarify the anticipated variability in overage when using their manufacturing methods.**

The Committee noted that the applicant did not carry out pelleting or heat treatment tests at higher temperatures but has referenced literature to support the application. Members were dissatisfied with this response as the literature provided were in association with other strains. It was also noted that no retention time was given. **The applicant would be asked to provide a stability study in accordance with the relevant guidance, as well as a revised label that includes pelletisation temperature and retention time.**

The applicant had been asked to provide an up-to-date extensive literature search for *Ensifer adhaerens* CICC 11008s with regards to the safety of the additive. It was noted that the applicant performed a literature search on the incorrect product, as the provided literature search was for Vitamin B12. **The applicant would be asked to provide an up-to-date extensive literature search on the production organism *Ensifer adhaerens* CICC 11008s.** Members also noted that the applicant provided safety assessments that lacked the necessary information for assessment. In the absence of data provided by the applicant and based on public literature, the Committee will consider the additive a skin and respiratory sensitiser. **The applicant would be asked to state that the product is a skin and respiratory sensitiser on the SDS and product label, as well as stating the PPE requirements on the product label.**

The applicant would be asked to provide all information submitted to EFSA that hasn't currently been submitted to the FSA.

11. Response to RFI: RP2258 Availa CR

Helen Warren declared an indirect conflict of interest for this item.

The Committee reviewed the additional data provided for the detection of undesirable substances, noting that the documentation provided was for the microtracer only. **The applicant would be asked to provide evidence of their proficiency at testing for the specified undesirable substances.** The applicant provided an additional tolerance study for assessment; Members noted that many of the samples were haemolysed leading to many parameters not being reported. **The applicant would be asked to provide clarification on the extent of the haemolysis observed and the impact this has on the results of the study and use of the additive. The applicant would also be asked to propose a default value of feed intake for fin fish and to derive a safe daily dose in line with EFSA guidance.**

12. Horizon scanning review

The Chair introduced the Paper and discussion topics and noted the comments left by Members and the Secretariat.

It was highlighted that an update regarding the latest developments on the deletion of the footnote in Regulation (EC) No 396/2005 had been recently circulated, which had been one of the discussion points during Horizon Scanning. Members had previously raised the idea of issuing a statement to clarify ACAF's position on this matter. There is now more information available, providing better insight into the direction the Commission is taking with the SPS (Sanitary and Phytosanitary) agreement. It was acknowledged that these developments will have implications for the UK, and Members agreed it would be beneficial to reflect on this update and consider ACAF's position moving forward.

The Committee agreed to convene in an additional meeting to review minutes from the SCoPAFF meeting, which are not publicly available, in order to provide advice on the deletion of the footnote. The Chair also recommended updating the document to incorporate the most recent developments.

13. SPS

Members were given the opportunity to discuss SPS and the potential implications.

14. Any other business

An update was provided in relation to the Science Council.

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Next ACAF meeting: 10th February on Microsoft Teams.

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