Ninety-ninth Advisory Committee on Animal Feedingstuffs meeting
24th July 2025 – Online meeting

ACAF	**FSA**
Martin Briggs (Chair)	Nathan Allen
Barry Bradford	Victoria Balch
Emily Burton	Lorcan Browne
Katrina Campbell	Brian Cassidy
Hannah Kane	Emily Davies
Susan MacDonald	David Evans
Chris McAlinden	Beth Hall
Donald Morrison	Emily Hudson
Derek Renshaw	David Kovacic
Mike Salter	Kaila Lee
Adam Smith	Francisco Matilla
Carla Viegas	Barry Maycock
Christel Wake	James Metcalfe
Helen Warren	Claire Moni
Nick Wheelhouse	Lauren Murdie
	Shila Sultana
	Abigail Timothy
	Johann Trotter
	Alba Ureña Rusillo
	Elisabeth Watson

1. Apologies

Apologies were received from Nick Jonsson.

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 informed the Committee that following their previous consideration of the latest EFSA guidance for efficacy, safety for the user and whole genome sequence analysis, this guidance will be incorporated from August 1st. This has been communicated to stakeholders, indicating that there will be a period of adaptation wherein applications abiding by the previous guidance or the future guidance will be accepted depending on when it is submitted. Members were also reminded that the time to make claims post-meeting is reducing from 90 days to 30 days.

4. Policy update

Animal Feed Policy Adviser, Beth Hall, provided members with an update on the number of applications received since the last meeting. Members were also informed that urea, niacin, choline chloride and folic acid have all been reinstated on the GB feed additive register.

5. Update regarding the GB register

ACAF'S Interim Chair, Nick Wheelhouse, provided the following statement on actions taken by the Committee related to the issue with the GB Feed Additive Register:

"On the 18th of June, several members of ACAF raised with Fran and myself urgent concern regarding the removal of urea and other relevant products from the UK Register of Feed Additives. In response to that, the Chair consulted with the Secretariat, Committee Members in ruminant and animal farming to draft a letter from ACAF to the FSA. The letter outlined the risks that the removal of these additives posed to animal health and welfare and to national food security, highlighting the potential consequences of being unable to use these additives in maintaining adequate nitrogen levels in ruminant diets and ensuring the safe and efficient manufacture of animal feed. The letter also noted the likely increase in uncertainty for both industry and farmers, which could affect the market stability and affordability of the UK meat and dairy products. The letter was addressed to the Chief Scientific Advisor of the FSA, requesting urgent action to reinstate these additives on the Register. ACAF also offered support in conducting a risk assessment should one be required. The CSA acknowledged receipt of the letter and confirmed that the FSA is working at pace to address the issue."

6. Minutes from 98th Meeting

The Committee reviewed the minutes from the 98th ACAF meeting and provided feedback to be reviewed by the Secretariat.

7. Dossier for assessment: RP2258 Availa® CR

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

The Committee reviewed the identity and characterisation of Availa® Cr noting discrepancies in the composition of the additive when compared with previous Availa® Cr applications. **The applicant would be asked to provide clarification on the correct composition of the additive and to amend the dossiers accordingly**. The certificates of analysis provided were performed in-house by Zinpro and did not include the appropriate accreditation documentation. **The applicant would be asked to provide evidence of relevant laboratory accreditation demonstrating technical competence (e.g., ISO/IEC 17025 or an internationally equivalent**

standard). The manufacturing process provided was deemed adequate for assessment, however, **clarification that 'micro tracer F-lake' is approved for use in the EU would be required from the applicant**. Members confirmed that the conditions of use were consistent with the previous application for the use of Availa® Cr in Salmonids and concluded that the same labelling and conditions of use would apply.

The Committee reviewed the tolerance study provided, noting that the additive is well tolerated up to 4000 mg/kg. Members reviewed the genotoxicity studies provided, noting a positive result for the *in vitro* micronucleus test. The subsequent *in vivo* micronucleus test returned a negative result, however, there was no evidence of bone marrow exposure and so a conclusion on the genotoxicity of the additive could not be reached. **The applicant would be asked to provide further data to demonstrate the absence of genotoxicity.** The Committee noted that in the absence of further data, the additive should be considered mutagenic at the site of exposure as no evidence of target tissue exposure has been provided. Members discussed the safety of the micro tracer for the consumer, concluding that consumer exposure is unlikely as the micro tracer is not expected to be absorbed in the gut of the target species.

Members noted discrepancies in the name of the additive used in the skin and eye irritation trial trials and the dossier. **The applicant would be asked to clarify that 'Availa Cr 1000' is the same as the additive described in the dossier.** The Committee concluded that the additive used in the trials is not an irritant to the skin or eyes. The additive should be regarded as a skin and respiratory sensitiser owing to the presence of nickel in the additive. The additive does not pose a risk to the environment when used under the proposed conditions of use.

Members reviewed the efficacy trials submitted, noting that efficacy was only demonstrated at 0.4 mg/kg and not at the proposed minimum and maximum doses of 0.2 mg/kg and 0.6 mg/kg respectively. Members also noted species differences in their responses at the doses tested. The trial provided in African catfish was not suitable for assessment owing to the measured doses tested varying substantially from the planned dose rates, as well as the high level of chromium in the control (CTRL) diet. **The applicant would be given the opportunity to provide a further efficacy trial to demonstrate the efficacy of the additive.** In the absence of a further efficacy trial, a conclusion can only be reached on the efficacy of the additive for salmonids at 0.4 mg/kg.

Members discussed the post-market monitoring plan provided for assessment, highlighting chromium's potential to select for anti-microbial resistance. **The applicant would be asked to provide a risk assessment for the use of chromium in feed, and to provide a specific post-market monitoring plan for the use of the additive considering its AMR potential.**

8. <u>Dossier for assessment: RP1087 Guanidinoacetic acid (Creamino®)</u>

The Committee was asked to consider the zootechnical efficacy potential of

guanidinoacetic acid (GAA). The application had been assessed before as a nutritional additive, concluding it could be considered efficacious in growing pigs and all growing poultry.

The Secretariat provided an overview of the regulatory distinctions between nutritional and zootechnical additives. The Committee discussed the biochemical role of GAA as a precursor to creatine. Although GAA is derived from two amino acids, it does not revert to them, and instead contributes to increased creatine levels, which support muscle energy metabolism and may influence fat deposition. This was considered to align more closely with the definition of a zootechnical additive than a nutritional one. Members agreed that zootechnical classification requires demonstrable improvements in animal performance, not just physiological changes.

No new efficacy data was submitted for the Committee's evaluation. Members noted that, for poultry and particularly broilers, multiple trials demonstrated performance improvements. **It was agreed that the evidence was sufficient to demonstrate efficacy as a zootechnical additive for growing poultry**. For pigs, however, the data was less robust. Only one trial in piglets was submitted, with additional support drawn from published literature. Concerns were raised about relying on literature alone when assessing efficacy in any application, as such studies often lack the rigour and documentation required for regulatory assessments. While some evidence of efficacy exists, it does not fully meet the requirements outlined in EFSA guidance. Some trials were noted to be short in duration and lacking sufficient detail. **Based on the available evidence, the Committee concluded the additive could be considered to have the potential to be efficacious in growing pigs. No conclusion could be drawn for other species or developmental stages.**

The Secretariat proposed amending the original safety assessment to reflect the Committee's conclusions.

9. Response to RFI: RP1592 Interban®

No conflicts of interest were declared.

Members reviewed the updated species identification data provided for assessment noting that the methods used were appropriate for assessment, however, the species name '*aurofaciens'* is still used throughout the dossier. **The applicant would be asked to provide updated documentation, ensuring the correct species name (*Streptomycin spp*) is used.** The applicant demonstrated that the Ole(C) gene appears to be present in many *Streptomyces* strains, however, data demonstrating that it is not near a mobile element has not been provided for assessment. **The applicant would be asked to provide evidence that the Ole(C) is not near a mobile element.** The applicant's response on testing for amyl alcohols was reviewed, however, the response did not adequately address the Committees query. **The applicant would be asked to provide further clarification on why only five of the amyl alcohols are tested, and to provide an updated manufacturing process to reflect the response provided.**

The annual testing documentation provided is not for the additive under assessment. **The applicant would be asked to provide an updated SOP ensuring annual testing documentation for Interban® is included.** The HACCP documentation provided for assessment is only a feed safety summary and not the HACCP itself. **The applicant would be asked to provide a full HACCP plan for the production of Interban®.** The applicant provided a GMO statement indicating that monthly GMO testing is performed for the rice hulls used in the manufacturing process, however, supporting documentation has not been provided for assessment. **The applicant would be asked to provide the monthly GMO analysis to support this statement.**

The applicant did not provide further data on the pelleting stability of the additive, **the applicant would be asked to provide updated pelleting stability data indicative of standard UK conditions, and reminded in the absence of this data, the stability of the additive during pelleting cannot be concluded upon.** The applicant has not provided updated conditions of use for the additive to reflect the contraindications of the additive; **the applicant would be asked to provide updated conditions of use for the additive ensuring contraindications are included.** The updated freezer storage stability study provided for assessment did not cover the period of storage for the material used in the residue studies. Members questioned whether the study provided is an interim report and the study ongoing to cover the storage period. **The applicant would be asked to clarify if the documentation provided is an interim report, and reminded that in the absence of this data, the Committee are unable to conclude on the storage stability of the additive.**

Members reviewed the liver histopathology data provided to demonstrate the safety of the additive for the target species, concluding that there were no treatment-related adverse effects observed in chickens and that no further data would be required from the applicant.

The Committee reviewed the updated post-market monitoring plan provided, noting that the method of reporting suggested (VeDDRA PT) would only identify clinical incidence retrospectively, and is unlikely to identify vancomycin resistant enterococci. A specific strategy to monitor literature has not been provided and further details of the search strategy would be required to ensure their reliability in AMR surveillance. The Committee debated the potential request of biological monitoring to identify AMR from use of the additive; however, the Committee reached a consensus that in this instance a tighter post-market monitoring plan would be adequate for assessment. Whilst a consensus was reached on the need for a more specific plan and monitoring, this was not a universal agreement, and some Members consider biological monitoring should be stipulated in the post-market monitoring plan. **The applicant would be asked to provide further detail of how monitoring for resistance in farm animals would be performed, and to provide specific detail of the timing of the testing. The applicant would also be asked to provide further information to demonstrate that considering the current knowledge, the additive remains safe under the proposed conditions of use. Furthermore, the**

applicant would be asked to provide detail of the specific search strategy that would be used in systematic monitoring of literature.

10. Response to RFI: RP2105 *Saccharomyces cerevisiae* CNCM I-1079

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

The Committee evaluated the response to the request for clarification on how the additive was intended to be administered to dogs and other Canidae. The applicant had provided examples of ways in which the additive may be added to feed and suggested that it may not be suitable for pre-pelleting or pre-extrusion applications due to poor viability of yeast cells when exposed to high temperatures. However, the applicant had not included this on the proposed label text, and the ACAF reiterated that processing stability claims should be included on the proposed label text. **The applicant would be asked to state in the proposed label text that the additive is not suitable for addition prior to pelleting or extrusion. In addition, the applicant would be asked to include the processing stability time and temperature for both the coated and non-coated formulations.**

The Committee raised concerns over one of the proposed methods of administration, specifically the mixing of the additive in powder form into the feed in a domestic setting. Members observed that this presented a potential inhalation risk, as well as the possibility of inaccurate dosing. However, since the additive would require clear labelling and adherence to all safety and usage conditions if authorised, Members felt it was unnecessary to examine every possible downstream use. However, the Committee agreed that with the current proposed label, the additive was not suitable for selling directly to consumers. **The applicant would be asked to clarify whether the additive is intended to be sold directly to consumers in its current form, or whether it is intended to be used only in an industrial setting.**

11. Response to RFI: RP2245 GalliPro® Fit

GalliPro® Fit 10 is a microorganism product that contains spores of active substances *Bacillus subtilis* DSM32324, *Bacillus subtilis* DSM32325 and *Bacillus amyloliquefaciens* DSM25840. This additive falls under the category ‘zootechnical,’ functional group ‘gut flora stabiliser.’ The applicant is seeking authorisation for use in feed and water for laying hens and other birds kept for egg production or breeding, plus modification of a 10-fold increase in the content of the active substance.

The Committee discussed the applicant’s response to the RFI and noted a significant increase in the volume and detail of information provided compared to the initial submission. Members noted that the limited time available before the meeting did not allow for a thorough review of all newly submitted materials.

The applicant provided data on the total *Bacillus* spp. count and the ratio in which the strains are mixed; the Panel acknowledged that it’s technically difficult to quantify *Bacillus* spp. in a mixture. The applicant cultured the final product and performed

qPCR on all colonies. Members considered the qPCR experiments to be adequate; however, they noted that the results were presented as cumulative data across five batches. The Panel expressed a preference for data showing intra-batch variation in relative levels, rather than a cumulative total. Members agree that the results submitted are sufficient; the colony qPCR result was compared and correlated with the CFU/g obtained on the respective plates and this showed good correlation. Members also highlighted the value of qPCR testing and indicated that it would be useful for applicants to consider providing this in the future.

In response to the request for evidence of accreditation and details of the test methods used, the applicant confirmed the methods applied. However, they also stated that the laboratory conducting the tests is not specifically accredited; the production site is certified in accordance with FAMI-QS (Feed Additives and Premixtures Quality System). The Committee stated that the production site being FAMI-QS does not cover the lab, so further verification is required. **As the applicant has conducted testing in-house, the Panel requests that the applicant provides verification of accuracy and reliability of the results. The applicant is asked to provide the results of the verification testing, conducted by an independent, accredited lab in accordance with the requirements of section 2.6.1.3 of Reg (EC) No 429/2008.**

The Committee had previously requested homogeneity studies for the additive, as the initial evidence provided was considered insufficient. In response, the applicant reiterated that the results presented in Annex II, Section 4.2 are sufficiently representative of the entire batch of premixture and align with the relevant EFSA guidance. The Committee commented that, according to the guidance '...*the content of the additive should be analysed in a minimum of 10 subsamples from a single batch (of the premixture or feedingstuff) and the coefficient of variation calculated.'* The Committee states that the evidence submitted is not sufficient to demonstrate homogeneity. **The applicant is asked to repeat homogeneity testing in accordance with the Guidance, therefore ten subsamples are required from the whole batch.**

Members noted that stability in water had been demonstrated at 24 hours but not at 48 hours. It was also noted that the applicant did not use the minimum dosage for the stability trials. **The applicant is asked to demonstrate stability in water at the recommended minimum dosage for the required stability periods.** Without this information the Committee will be unable to conclude on the stability of the additive in water.

The Committee agree that the applicant has adequately demonstrated the stability of the additive during pelleting up to 95°C for 30 seconds of holding time. It was noted that the applicant has used a dilute form of the additive however, this should have the same effect as the more concentrated form. **The applicant is asked to include the pelletization conditions under the 'conditions of use' on the product label.**

The Committee confirmed that the applicant had provided sufficient evidence of production strain stability however it was noted that the latest test was from 2016.

The applicant is asked to provide evidence of the stability of a current production isolate.

The Committee were satisfied that the applicant provided MSDS for Struktol SB 509 in English and the MSDS for the final additive however the final additive MSDS dates from 2020. **The applicant is asked to provide a more recent English translated MSDS for the final additive.**

The Committee noted that the applicant provided a complete HACCP plan for the production process of the additive and critical control points for both the CZ and USA production sites; however, no certifications were submitted for the USA plant. **The applicant is asked to provide all certification for the US manufacturing plant.**

The Committee were satisfied that the applicant has provided all previous unredacted EFSA opinions in relation to the additive seeking authorisation. Due to the substantial volume of recently submitted annexes, the ACAF requested additional time to review and discuss the materials offline. The application will be discussed in a future meeting after members have thoroughly reviewed and assessed the additional documentation.

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

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

Members discussed the updated whole-genome sequence analysis provided by the applicant and were satisfied that the taxonomic identification as *E. lactis* has been confirmed, and that the strain does not contain any acquired antimicrobial resistance genes or virulence factors of concern.

The applicant had provided short-term stability in water for an additional three batches of the additive. The ACAF noted that two of the batches showed losses, but that viable cell counts were within 0.5 log of the initial value, which was the specification set by the applicant. The applicant had updated the conditions of use to include stability information and instructions for proper use in water, which the ACAF were satisfied with.

The applicant provided additional information to demonstrate that the organism was suitable for classification as a Group 1 biological agent, which the Committee agreed with.

The applicant confirmed the manufacturing site, and ACAF were satisfied with the HACCP plan and FAMI-QS certification provided. The Committee evaluated the evidence of laboratory accreditation supplied by the applicant but agreed that it was insufficient. **The applicant would be asked to provide evidence of relevant laboratory accreditation demonstrating technical competence (e.g., ISO/IEC 17025 or an internationally equivalent standard), or evidence of method validation and verification conducted by an independent, accredited laboratory.**

In response to the request to provide additional data to demonstrate safety for the user, the applicant had not provided any studies. In the absence of additional data, the Committee concluded that the additive is a potential skin and eye irritant and a potential skin sensitiser. It was noted that the user safety conclusions were not reflected in the SDS and conditions of use. **The applicant would be asked to update the SDS and conditions of use to include the conclusions and recommendations to minimise exposure via the respiratory system, skin and eyes.**

Members discussed the additional information provided regarding the design of the efficacy studies. Members raised concerns that the design was not optimal. However, ACAF accepted that this is industry standard and that the study could be considered acceptable in line with guidance requirements.

Addendum: The Committee discussed stability in water further offline and concluded that the <0.5 log threshold proposed by the applicant was acceptable. The ACAF therefore concluded that the additive was stable for 48 hours in water.

13. Committee's Advice: RP2264 XTRACT EVOLUTION-B, CODE X60-6930

Questions were posed to the Committee regarding RP2264 XTRACT EVOLUTION-B, CODE X60-6930 and the potential effects of changing the particle size of the additive. Members were able to advise the Secretariat, concluding that this change on particle size would not have an adverse effect on the safety and efficacy of the additive.

14. Draft safety assessments: RP2071

Members were presented with a draft Safety Assessment document for application RP2071.

Members reviewed the draft safety assessment provided but raised concerns that the homogeneity testing and some of the stability studies were performed with the commercial premixture (Enterosure™), and not the additive (Enterosure™ Conc), for which the applicant is seeking authorisation. Members agreed to revisit the data and discuss further offline.

Addendum: The Committee discussed the stability and homogeneity data further offline and agreed that stability had been demonstrated for the additive. However, the ACAF agreed that evidence of homogeneity in feed was required for the additive, Enterosure™ Conc. The applicant would be asked to provide additional data to demonstrate homogeneity in feed and advised that in the absence of data Members would only be able to conclude on homogeneity when added in the form of a premixture.

15. Any other business

An update on upcoming applications was provided.

Members were asked for their advice on two applications in the validation phase. Members were also reminded to inform the Secretariat when they receive a new work phone or laptop to facilitate access.

Next ACAF meeting: 10th September 2025 on Microsoft Teams.