Eightieth Advisory Committee on Animal Feedingstuffs meeting

6th October 2022 – Online meeting

ACAF	FSA
Nicholas Jonsson (Chair)	Nathan Allen
Martin Briggs	Mark Bond
Katrina Campbell	Aaron Bradshaw
Matthew Fisher	Michael Dickinson
Donald Morrison	Donal Griffin
Derek Renshaw	Emily Hudson
Mike Salter	Aisling Jao
Adam Smith	Kaitlyn Jukes
Helen Warren	Francisco Matilla
Nick Wheelhouse	Barry Maycock
	Shila Sultana
	Katie Schulz
	Johann Trotter

1. Apologies

Christine McAlinden extended her apologies for the meeting.

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 Donal Griffin gave an update on the status of feed additive applications currently being processed by the Regulated Products Risk Assessment Team. Currently thirty-five applications are undergoing suitability checks and twenty-one are ready to commence the assessment process. Members were informed about the plans to increase the Committee in size and to develop new ways of working to reduce workloads and speed up the assessment process.

4. Policy Update

Feed Additives Senior Policy Advisor, Mark Bond, briefed the group on the status of applications. Since the last meeting of AFFAJEG, fifteen new applications had been received, for a total of 150. The first set of authorisations for applications that went through the Tranche-1 process are currently awaiting sign-off by ministers.

5. Terms of Reference of ACAF

The Committee was presented with the proposed Terms of Reference for ACAF after its reinstitution as a risk assessment only committee. Members provided feedback to be reviewed by the Secretariat prior to publication on the ACAF website.

6. Ways of working

The Committee received a presentation detailing the proposed ways of working for ACAF moving forward. Members discussed the proposed measures and gave feedback to the Secretariat on how to improve these for the future.

7. Labelling

Members were presented with the legal framework surrounding requirements of labelling specification to be provided by applicants in the dossiers. It was discussed that, as part of Section II of the assessment, the label could be evaluated by the Committee as part of the package to mitigate risks proposed by the applicant. However, it was recognised that labelling was primarily a risk management responsibility, and that the Committee could not determine what should or should not appear in the label. Recommendations could be provided to risk managers upon request.

8. Minutes from 15th Meeting

The Committee evaluated the minutes from the 15th AFFAJEG meeting and provided feedback to be reviewed by the Secretariat.

9. Dossier for assessment: RP665 – Dimethylglycine sodium salt

No conflicts of interests were declared for this item.

An application was evaluated for an additive of dimethylglycine sodium salt (Taminizer® D). This application is for a renewal of authorisation to use in chickens for fattening, under the category “zootechnical additive”, functional group “other zootechnical additives”.

The Group evaluated the identity and characterisation information contained within the dossier, and expressed concern over the description of the additive’s production process. It was concluded that ACAF would focus the assessment on the levels of contaminants remaining in the final product. Members discussed that, while it is expected that no contaminants will remain in feed after the pelleting process, **the applicant would have to provide data on levels of contaminants in the final product**.

In relation to user/worker exposure, **the Committee noted that the dusting potential of the additive would have to be provided by the applicant, expressed in mg/m^3 of air**. Members clarified that when using this product, workers would be expected to operate under adequate PPE conditions to minimise exposure. The

Committee agreed with previous scientific conclusions that the product is not a skin irritant, but has the potential to be an eye irritant and a skin sensitiser. The dusting potential, expressed in mg/m^3 of air, would be required before establishing a conclusion on the safety of the additive.

No further safety or characterisation concerns were raised by the Committee. Efficacy was not evaluated for the additive, as it is a renewal of authorisation.

10. Dossier for assessment: RP593 – Hostazym® C

Adam Smith declared an indirect conflict of interest. The Chair allowed for him to stay in the discussion.

An application was evaluated for the additive Hostazym® C (endo-1,4-beta-glucanase) of sodium benzoate, which is available in two solid forms and one liquid form. The application is for a renewal of authorisation for its use in chickens for fattening, minor poultry species for fattening and weaned piglets, and new use in turkeys for fattening and reared for breeding, chickens reared for laying, minor poultry species reared for laying or breeding, ornamental birds and suckling piglets. The applicant seeks authorisation under the category "zootechnical additives", functional group "digestibility enhancers".

The Committee recognised that, although the characterisation was not extensive, it was sufficiently complete after the provision of particle size distribution information according to the Secretariat's prior request. It was noted by members that the application mentioned the commission of a study confirming absence of the production strain from the final product, but the study was not provided. **The applicant would be asked to provide this study for the Committee's consideration**.

Members noted that the conditions of use of the additive described the instruction to be used in compound feed rich in non-starch polysaccharides, without providing any further detail. **The applicant would be asked to clarify what type of feed the applicant recommends using the product in and whether there are any considerations for other feed types.** The Committee noticed that the variability in homogeneity values presented in the application were abnormally high (normally expected to be at around 10**%). The applicant would be asked to explain and justify these values**. The Committee could not conclude on the potential loss of activity at high temperatures, as the applicant only tested this for a few seconds. **The applicant would be asked to provide further evidence of stability at 85ºC for several minutes**.

No new concerns were raised by the Committee about the safety and efficacy sections of the dossier. On consideration of the literature review provided by the applicant, it was concluded that previous conclusions drawn by EFSA could be accepted, and the additive could therefore be considered safe for the target species, the consumer and the environment. It was also concluded that the product should be considered a potential skin and eye irritant, and a potential skin and respiratory

sensitiser. It was concluded the additive remains efficacious and that these conclusions can be extrapolated to the new uses proposed.

12. Dossier for assessment: RP686 – *Lactococcus lactis* DSM 11037

No conflicts of interest were declared for this item.

An application was evaluated for *Lactococcus lactis* DSM 11037. The application is for a renewal of authorisation in all animal species, under the category "technological feed additives", functional group "silage additives".

The Committee evaluated the identity and characterisation of the additive, noting that the application shows testing performed on products that are very similar to the additive requesting reauthorisation. It was concluded that the products used were representative of the characteristics that the product under assessment would show. Members noted an anomaly in the way that the stability of the product decreased by a factor of ten at 20ºC, yet no drop was reported at 40ºC. The Committee noted that no testing was carried out for *Salmonella spp*. in the final product since 2011. **It would be requested that the applicant provide testing data for Salmonella on 25g of the final product.**

The application presented a literature review as evidence of safety. Members noted that one of the papers identified strains of *Lactococcus lactis* as encoding genes enabling the production of the biogenic amine putrescine. Upon evaluation of the whole genome sequence analysis, it was concluded that the *Lactococcus lactis* strain of this application does not produce biogenic amines. As a renewal of authorisation for a qualified presumption of safety (QPS) organism, no data on safety for animals or consumers was required. The Committee noted that, being a microorganism, the principle of precaution should be applied, and it should be considered a potential respiratory sensitiser. As no testing was provided for evaluating the effects of the additive on skin and eyes, the Committee concluded the additive has the potential to be irritant to skin and eyes, and to be a skin sensitiser.

Efficacy was not evaluated for the additive, as it is a renewal of authorisation.

13. Dossier for assessment: RP694 – Saccharomyces cerevisiae

An application was evaluated for *Saccharomyces cerevisiae* CNCM I-1079 'Levucell', which is available as both a microencapsulated/coated preparation and a non-encapsulated preparation. The application is currently authorised as a feed additive for use in chickens for fattening and minor poultry species for fattening, sows and weaned piglets, all pigs other than weaned piglets and sows and all minor porcine species, and turkeys for fattening. The applicant wishes to extend the authorisation of the additive to new species/categories: calves, all other ruminant species (for rearing and for fattening) and camelids (for rearing and for fattening). The additive falls under the category "zootechnical additives" and functional groups "gut flora stabilisers" and "physiological condition stabilisers".

The identity and characterisation of the additive was evaluated, with the Committee highlighting that *Saccharomyces cerevisiae* CNCM I-1079 is a QPS and FDA GRAS

(generally recognised as safe) organism, isolated from grape. The genomic characterisation was thought to be quite comprehensive, without any existing ambiguity regarding the identity of this additive. Members questioned the ingredients used as part of the production process. **The applicant would be asked to provide more information on the final product, demonstrating that no contaminants remain in the final product.** The Group also noted that an MSDS for the final product was not provided, even though it only presents a low hazard. **The applicant would be asked to provide an MSDS for the final product.** Stability studies were deemed to be acceptable as the additive demonstrated good stability, with 95% recovery over 36 months. The stability in premixtures and commercial compound were tested over 3 months and remained stable. Homogeneity was also deemed to be good, as well as the applicant's response regarding particle size distribution.

The Committee evaluated the safety of the additive. The coated formulation was not considered to pose a risk, whereas the high dusting potential of the non-encapsulated preparation may lead to exposure concerns when handled by users. Members agreed with the previous EFSA conclusion that the additive is not a skin irritant or a skin sensitiser, but have indicated that the translated study presented in the application identified the additive as a "slight irritant" for rabbit eyes. As the product is a microorganism-based additive, it should also be regarded as a potential respiratory sensitiser.

Members evaluated the three different efficacy studies presented in the application. Results for study one indicated an improvement both in feed conversion ratio (FCR) and faecal/diarrheic scores. Study two also found an improvement in FCR, but no data on physiological condition of the animals was provided. The third study found a significant improvement in FCR, but this was deemed to be not significant given the study-design. The Committee noted that full experimental protocols were not presented nor had the applicant provided enough information related to quality assurance. **The applicant would be asked to provide full study protocols for the studies, as well as further information on quality assurance.**

14. <u>Previous dossiers' applicant's responses</u>

Adam Smith declared a direct conflict of interest for RP597-600 and an indirect conflict of interest for the other two items. He was asked to leave the room for the discussion on RP597-600.

RP309 (Hostazym® X): The Committee discussed the response by the applicant stating that the extruded form of the additive is expected to float on the water, facilitating consumption by carp rapidly before dissolving in water. Data from three batches on particle size distribution showed a percentage of slightly more than 1% of particles smaller than 50 µm. In an *ad hoc* meeting with toxicologists from ACAF and the Secretariat, it was determined that no acute inhalation studies would be required, as the product would be considered a respiratory sensitiser regardless, applying the principle of precaution.

RP420 (Axtra® Phy Gold): Members evaluated the data presented for stability under conditions of 82ºC for 2 minutes, noting that the background phytase activity measured declined in a very small amount, which is unusual under those conditions. The Committee requested that the raw data from the tests is provided before further evaluation. It was also flagged that the study design for the *in vitro* mammalian cell micronucleus test applicant was inadequate. In an *ad hoc* meeting between toxicologists from ACAF and the Secretariat, it was concluded that the aneugenicity had not been properly evaluated. The applicant would be asked to repeat the test following OECD TG 487.

RP597-600 (Carophyll®): The ACAF discussed the explanation for the disparity in dusting potential, as one batch was significantly different compared to the other two. Given that no active ingredient is found in dust and as the particle size distribution and homogeneity would have been previously evaluated, the Committee felt this did not pose a cause for concern. There was discussion around the potential need to add more safety information to the label, however it was pointed out that under HSE regulations, different categories already exist, therefore risks will be taken into consideration by risk managers. Members were happy with the provided EFSA opinion for the additive's use in breeder hens. The application is ready to move forward to next step of drafting an opinion.

15. Draft opinions

Members were presented with draft opinions for applications RP140, 141, 142, 284 (progressed collectively) and RP641. Feedback was provided to be reviewed by the Secretariat.

The Committee was also presented with the final version of opinions for applications RP16, 24-25-26, 29, 185, 222 and 1059. The Committee provided feedback on final corrections and approved the opinions to be finalised and sent to Risk Managers.

16. Ongoing FSA safety in feed research projects

Colleagues from the Chemical Risk Assessment Unit at the FSA provided two presentations on ongoing research projects at the FSA related to feed. Further updates will be provided in following meetings.

17. Any Other Business

No other business was discussed.

Next ACAF meeting: Friday 9th December 2022 on Microsoft Teams.