Proposed criteria for the assessment of efficacy of feed additives from the functional group of hygiene condition enhancers

Endorsed by the FEEDAP Panel during the 153rd Plenary meeting of 17-18 March 2021[1]

Hygiene condition enhancers are defined by Regulation (EC) No 1831/2003[2] as "substances or, when applicable, microorganisms which favourably affect the hygienic characteristics of feed by reducing a specific microbiological contamination." These additives are intended to have an effect in feed by reducing the contamination with specific microorganism(s) relevant to feed safety (e.g., potential human or animal enteropathogens or harmful or potentially harmful bacteria) (EFSA FEEDAP Panel, 2018).

The target microorganism(s) against which the additive will exert its function should be specified, as well as the feedingstuffs where the additive should exert its function.

Evidence of the efficacy should be demonstrated using laboratory-based studies by means of appropriate criteria as reflected in recognised acceptable methods, under the intended practical conditions of use in comparison with appropriate control feed. The studies (at least three) should be designed to cover a representative range of feed matrices to which the additive will be applied. If the additive is intended for use in water for drinking, specific studies are required. For additives intended to be used in all feedingstuffs, efficacy should be demonstrated in feed matrices covering a range of approximately 10-80% dry matter (DM). The dry matter content and corresponding water activity of each matrix should be provided. The feeds may be naturally or artificially contaminated with the target microorganism(s). In case of artificially contaminated feed, the applicant should describe and justify the selection and inoculation levels of the microbial strain(s) used. Any pre-treatments not routinely used in the feed production/preparation and intended to reduce the background contamination of the experimental feed (e.g., sterilisation of the feeds, use of antimicrobial substances) or to stimulate the growth of the active agent(s) present in the additive (e.g., use of buffers and/or nutrient broths and incubation conditions optimal for the strain(s) but not relevant for the feed) should be avoided.

An appropriate number of replicates of the feed(s) should be stored in conditions mimicking practical use at EU farm level. Samples should be stored in the presence of oxygen (ambient) and at temperature(s) reflecting practical use conditions. Any deviations should be properly justified. Other practical use conditions should be reflected in the study design (e.g., constant mixing). The experimental design should include at least two groups: one group with the experimental feed contaminated with the target microorganism(s) (control) and the other with the same basal contaminated feed treated with the additive for which authorisation is sought at the minimum recommended inclusion level. Other groups with different levels of the additive may be included in the design, if appropriate. The microbial contamination with target microorganisms should be present in the feed at the time the additive is incorporated in the feed, or if not, in case of artificial contamination, both target microorganism(s) and the additive should be added at the same time.

The duration of the study should cover the period for which an effect is claimed according to the proposed conditions of use (e.g., for reconstituted milk replacer, the study should last until time of feeding). Sampling times should reflect real use conditions, allow measurement of the persistence of the effect(s) and include at least measurements at time 0 (treatment with the additive) and at the end of the study. Feed samples should be monitored for the viable counts of the target microorganism(s) using cultivation-based methods. Changes below 0.5 log are considered in the normal variation of the methods and will not be taken as a proof of an effect. Other end-points

[1] https://www.efsa.europa.eu/en/events/event/153rd-plenary-meeting-feedap-panel
[2] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29

intended to monitor the microbial quality of the feed should be included [e.g., total aerobic bacteria, Enterobacteriaceae, yeast and filamentous fungi counts]. For target microorganisms producing toxic compounds, these compounds should also be analysed in the feed samples at the end of the study.

The FEEDAP Panel may review the approach above in view of the experience gained in the assessment of these additives. This material will also be used in the future update of the guidance on the assessment of the efficacy of feed additives.

Reference

EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, Lopez-Alonso M, Lopez Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J, Innocenti ML and Martino L, 2018. Guidance on the assessment of the efficacy of feed additives. EFSA Journal 2018;16 (5):5274, 25 pp. https://doi.org/10.2903/j.efsa.2018.5274