Renewal of approval for many additives

The European Feed Additive Regulation No. 1831/2003 and its Implementing Regulation No. 429/2008 provide for the re-authorization of any feed additive authorization after ten years the so-called Renewal procedure. The reasons for this are clearly described in the Guidance on the renewal of the authorization of feed additives of EFSA (European Food Safety Authority). On the one hand, proof is to be provided that the authorized additive still meets the conditions of the existing authorization. On the other hand, it must be shown that the additive remains safe for the target species, the consumer, the user and the environment under the approved conditions, even according to the current state of knowledge. Such an application for renewal must be submitted to the EU Commission at least one year before the end of the authorization (Regulation (EC) 1831/2003, Article 14), explain Dr. Regina Ohlmann and Dr. Regine Schreiner of the Munich-based consultancy FEED AND ADDITIVES GmbH, which specializes in the European authorization of feed additives.

Essential substances are on the list

According to the experts, this is a particular challenge for non-holder-bound feed additive authorizations. That's because the regulation in Article 14 continues to state, “If an authorization is not issued to a specific holder, any person when the additive is placed on the market or any other interested party may submit the application to the Commission and shall be deemed to be the applicant accordingly.”

Thus, theoretically and in the worst case scenario, it could not be determined by the renewal submission deadline who is actually responsible for the renewal. A particularly large number of renewals are due in the next few years. In 2024 (latest submission 2023), about 20 non-holder approvals will be due, Ohlmann and Schreiner said. The same is true in 2025 (latest submission 2024). These 40-plus additives include vitamins, provitamins and amino acids, essential additives for healthy and sustainable animal nutrition in the EU, as Olmann and Schreiner explain further.

Applications must be submitted in time

The fact that there will be an increase in the number of non-holder-bound authorizations in the near future has to do with the deadline of November 7, 2010. At that time it offered the last possibility to re-evaluate/re-authorize a feed additive with an unlimited authorization according to Directive 82/471/EEC (EU Regulation 1831/2003). Many submitted their re-evaluation applications at the last possible moment. The first approvals were then only granted after 2-3 years, from 2012 or later. Exactly these authorizations are now expiring after ten years.

Authorities make challenging demands

Those who want to submit a renewal must therefore act quickly and compile the application promptly, the consultants recommend. This is currently associated with additional, new high scientific and administrative hurdles. The Transparency Regulation [Regulation (EU) 2019/1381 on the transparency and sustainability of EU risk assessment in the food chain] requires the applicant to pay full attention to study notification, mandatory pre-submission advice and justification of all confidentialities. Also the upload in EC or in the EFSA portal is complex and technically demanding. Highest demands of the authorities for completeness and confidentiality check are a big challenge for the applicant. Scientifically, the topic of nanoparticles is also extremely present and requires full attention in terms of worker and consumer safety, as well as animal welfare.