How will the New Transparency Regulation Impact European Feed Safety?

The EU REGULATION (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain entered into force on 26 September 2019 and will apply from 27 March 2021.

The transparency regulation amends an immense range of legal provisions: general food law, the regulation on genetically modified food and feed, food additives, enzymes and flavours (including smoke flavours), novel foods, food contact materials, plant protection products, GMO crops and the feed additive regulation. In all these areas of food and feed safety, the European Food Safety Authority (EFSA), is the responsible EU risk assessment body.

The objective was to improve the transparency to ensure continuous and inclusive risk communication in the food and feed chain. Its historical trigger was the glyphosate issue, which had generated a lot of attention in 2017 and was the result of a fitness check on general food law in 2018 (REFIT). The legislator had identified the necessity to restore consumers' confidence in the outcome of the risk analysis process. Enhanced transparency of scientific risk assessments and improvement of study standards were chosen as a remedy.

For feed additive applications for authorisation according to Regulation (EC) No 1831/2003 on additives for use in animal nutrition, the transparency regulation (EU) 2019/1381 has several additional consequences:

- Article 32A: The applicant will be able to ask for pre-submission scientific advice;
- Article 32B: There will be an EFSA database of studies commissioned for an application. All planned studies will have to be notified in advance;
- Article 32C: Third parties will be able to submit comments: consultations will be launched on the non-confidential versions of application dossiers to see whether any other scientific data is available;
- Article 32D: In case of doubts, EFSA can commission verification studies;
- Article 38 and 39: More data than before will be public (confidential treatment on request is still possible for IP, personal data of persons involved in animal testing and further well-defined exceptions). EFSA will decide on confidentiality instead of the EC;
- Article 39: There will be standard data formats;
- Article 61A Fact-finding missions of commission experts are foreseen to control laboratories, testing facilities and CROs.

The possibility to obtain pre-submission advice and the EFSA study database is good news for the scientific community: input from the authority for successful study planning is more than welcome for all applicants and listing all current studies regardless of their outcome will reduce bias.

The downside for the applicant is that the preparation of a dossier and dossier evaluation by EFSA will take longer, as soon as transparency obligations will apply. On the EFSA's side, this is due to the extended evaluations of appropriateness of confidentiality requests, consideration of third-party comments and crosschecks with the EFSA study database. On the applicant's side: all studies need to be notified well in advance and extended non-confidential dossier versions need to be prepared after discussions with EFSA. There are concerns that instead of informed consumers, competitors will submit third-party comments to deliberately slow down the process.

The dossier, which is necessary for an application, is just the final, visible result of careful and costly data collection process on identity (quality, purity and analytical methods), safety, efficacy and post-market monitoring of the substance and its use in feed. The structure of the dossier follows EU Regulation 1831/2003 and its implementing rules as established in Regulation 429/2008. Numerous EFSA guidance documents and international standards have to be considered for the compilation of data and composition of a complete application dossier.

After handing in the application dossier to EFSA, the European Commission and EURL-FA, requests for supplementary information by EFSA are rather a rule than an exception. If answering the questions of EFSA experts takes more than four months, a clock-stop during the scientific assessment period (six months) will additionally be necessary. After the completed risk assessment by EFSA, the EFSA issues a scientific opinion: the outcome of the risk assessment. Based on EFSA's scientific opinion, the representatives of the EU Member States are consulted in the Standing Committee on Plants, Animals, Food and Feed, Section Animal Nutrition. If a favourable opinion about the additive is voted for, the European Commission issues an authorisation regulation for each feed additive.

Each regulation specifies the number, the authorisation holder, the name of the additive, its composition, the analytical methods, target species, conditions of use for each feed additive (minimum and maximum content, maximum age, other provisions) and the period of authorisation.

In summary: exceedingly high scientific and formal standards have to be met when applying for a feed additive authorisation according to EU Regulation 1831/2003.

After the entry into force of the Transparency Regulation on 27 March 2021, the formal requirements for the applicant and for EFSA especially will be increased further.

Let us hope that the consumer will make use of their new possibilities and that it will improve the acceptance of EFSA risk assessments, so that risk management decisions by the legislator will in future enjoy a higher level of acceptance in society.

But this new consumer privilege also has a downside, which also affects the consumer:

- Improvement of the transparency of the application process puts a considerable extra workload and

thus costs on the applicants. This will further reduce the possibilities for small, innovative feed additive companies to even start the registration process. Innovative feed additives from smaller companies with beneficial effects on feed and food safety, animal welfare or sustainability may *de facto* be excluded from the EU market. This is a disadvantage for the European consumer who can expect an agricultural practice in Europe according to latest scientific developments.

- Improvement of the transparency of the application process puts a considerable extra workload on EFSA. Even though the authority will be equipped with extra budget and workforce in future, it will take some time until all new systems are up and running. This extra workload comes amiss:

Currently, of around 1400 feed additives present on the EU market, more than 400 have not been fully assessed yet according to EU Regulation 1831/2003 (EU Register of feed additives Annex I, List of additives Edition 284, 06/2020, released 05.08.2020).

In Regulation 1831/2003, it was foreseen that existing products may be placed on the market and used, provided that interested parties would notify their additives to the Commission and that an application for authorisation as feed additive shall be submitted in accordance with Article 7 of Regulation 1831/2003 in a timely manner.

For all "existing products" additives, which are currently in Annex I of the European feed additives register, dossiers have meanwhile been submitted. However, many of these have not been fully assessed yet. This means that these 400 additives are on the market without a duly completed scientific assessment according to legal requirements set 17 years ago in 2003.

Apart from this, the renewal applications have been on top since 2013, as feed additive authorisations have to be renewed every 10 years according to Regulation 1831/2003.

Having a considerable amount of not fully assessed feed additives on the European market impairs feed safety and does not protect the consumer according to the high EU standards set in 2003. Now, further formal requirements for applicants and EFSA to comply with in the application process come on top. Therefore, an undesired effect of the transparency regulation will be, that EFSA scientific assessments – which are currently already behind schedule – will be delayed further. This impairs feed safety.

But then – if not by more transparency - how could feed safety be improved?

Maybe there should be a platform for personal communication for all active contributors in the area of feed: industry, consultants, associations, laboratories, members of EFSA, RASFF and EC, the Member State representatives and those who actually enforce feed law – the officials of the local competent authorities.

Some feed controllers of the local competent authorities seem to have a very vague idea of the problems EU risk assessors and managers identify and discuss.

On the other hand, on the EFSA side: the understanding of the actual problems of local feed control, in the feed mills, in the laboratories and on the farms sometimes seem to drift out of focus.

Apart from this, the national and even the local views on how EU feed law is interpreted and enforced may vary considerably. This is an unfortunate condition for the feed industry.

Both the feed industry and local competent authorities involved in feed control should be proactively addressed and heard by EU risk assessors and managers, as only they have the knowledge to deliver practicable input.

A role model could be the annual AAFCO meeting in the US, where the feed associations, feed industry, federal and national authorities gather to talk.

More feed safety could decrease the incidence of feed and food scandals and this would definitively improve the confidence of the consumer in European regulators, feed control officials and the feed industry.

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