FACTSHEET

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Revision of Regulation (EC) No 429/2008 "The Guidelines"

Applications for assessment and authorisation of feed additives shall be prepared and presented according to details established by Regulation (EC) No 429/2008, also known as The Guidelines. As a result of scientific and legal developments and of experiences gained from almost 10 years of evaluation of feed additives under those requirements, the European Commission is considering proposals for revision of The Guidelines jointly with EFSA, Member States and industry in order to improve adequacy and predictability of the authorisation procedure.
The FEFANA Expert Group on Revision of Guidelines works on proposals that should clarify the application procedure and its requirements and reduce time needed for placing feed additives on the market, particularly innovative ones.

1. The Guidelines

Regularly during the assessment of a feed additive dossier, applicants receive unexpected requests for supplementary data. Also, they have often been faced with an EFSA opinion stating that it was not possible to conclude on the efficacy of the additive. Such situations are cause of serious delays on the timeline set by operators for starting of sales, since authorisations are dependent on the outcome of the assessments.

Considering the experiences acquired after almost 10 years of implementation of Regulation (EC) No 429/2008, FEFANA members have setup a series of principles for improving the assessment and authorisation processes. The FEFANA members that have developed the principles and proposals for the revision have formed the Expert Group on Revision of Guidelines.

The overall purpose of the EG is to achieve a balanced set of requirements to comply with the mandatory scrutiny as defined in Regulation (EC) 1831/2003 with regards to the safety and efficacy of feed additives. Once this objective is accomplished, the authorisation process shall be significantly improved for applicants, risk assessors and risk managers.

In a nutshell, the main aspects set in the *Principles for revision of The Guidelines* are related to:

- Definition and description of the additives (active substance, preparations etc.);
- Assessment of impurities in feed additives;
- Classification of animal species and categories;
- Demonstration of efficacy.

2. EFSA guidance documents

When the European Commission started considering the aspects of The Guidelines that need to be revised, the EFSA was requested to provide their input to the revision. In parallel to this request, the EFSA considered that its guidance documents should also be revised in the light of the experience and issues emerged since their publication in 2008. Hence, EFSA issued a self-task in 2016 to revise its own guidance documents which would then serve as the basis for the EFSA feedback to Commission.

Therefore, during 2017 the EFSA has launched a number of public consultations on revised guidance documents regarding the following aspects:

- Identity, characterisation and conditions of use
- Safety for the target species;
- Safety for the consumer;
- Characterisation of microorganisms used as additives or for the production of additives;
- Efficacy assessment.

The EG Revision of Guidelines has actively provided input to these draft documents. Our feedback to these consultations were mainly based on our objective to obtain a balanced set of requirements, seeking - where applicable - to provide scientific justifications for the proposals.

In the meantime, all of these EFSA Guidance documents have been published with a low rate of uptake of our comments by the FEEDAP. Nevertheless, these revisions are likely to provide improved predictability, clarity and transparency for all interested parties during the assessment.

Nevertheless, Regulation (EC) 429/2008 is the binding document on dossier requirements and classification of animal categories, whereas EFSA guidance documents are intended to assist applicants in preparing dossiers. These Guidance documents shall be in fact based on *The Guidelines* and hence deviations from its recommendations shall be acceptable upon scientific justification.

3. What's next?

Few important pending topics will be followed-up closely during the course of 2018: classification of animal categories, number of efficacy studies per category and use of *in vitro* data supporting the mode of action, and assessment of user safety still need to be thoroughly considered. Members of the EG and of the FEFANA secretariat will approach the Member States representatives to present our proposals and discuss the possible solutions for improving the requirements, assessment and authorisation procedures for feed additives.