Re-evaluation of feed additives: experience from applicants and users

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Who we are / represent

- FEFANA: Specialty Feed Ingredients and their Mixtures
- EMFEMA: Feed minerals
- FEDIAF: Pet food
- FEFAC: Compound feed and premixtures for food producing animals

→We are organisations with different identities but all committed to safe and efficient products

→We welcome the opportunity to speak at the INFO session

General observations on the re-authorisation process

- Huge work …
  - … with limited resources (EFSA, applicants, Commission) …
  - … massive work done until now …
  - … but still challenges in front of us
- Safety must be the focus
- Efficacy requirements are of little added value though demanding for applicants
- Link between identity/characterization of additives and safety is challenging

General observations on the re-authorisation process

→Benefit of this process to the EU

- Process needed to be carried out for confidence purpose
- Proportionality and efficiency of the additional constraints/micro-management measures is questionable
- Exercice getting more and more costly, especially for SMEs, leading in some cases to withdrawal of applications or companies stepping-out from consortia

General aspects of the re-evaluation process

- Complexity underestimated and target not sufficiently clear for operators especially as regards identity and efficacy: learning process for all parties
- Better communication between parties (industry, EU Commission, EFSA) could have helped speeding up the learning process and avoiding unnecessary efforts and delays
- Complex tasks need cooperative approach between applicants and risk assessors

Interaction with EFSA / EU Commission

- Clear understanding of EFSA and EC roles necessary (RA vs RM)
- Clear understanding required of the relevance and impact of information to be provided
- Risk assessment should build the framework for proper risk management

→ EFSA should evaluate management options rather than giving firm recommendations

Content of the dossier

- The basis for dossier preparation should remain the guidelines, Regulation (EC) 429/2008
  - Justification for not providing some studies should be acceptable
- EFSA guidance documents = helping tool but
  - Rationale for certain requirements not clear/justified
  - Long history of safe use: requirements and use of data are missing
  - Inconsistencies of approaches
- Ad-hoc guidance
  - Clear identification of required information in a common agreement process before dossier submission could help to avoid unnecessary efforts and delay
  - Possibility for direct clarifications of requirements/interpretations is needed

Content of the dossier – Inconsistency of guidance

- Example 1: additives produced by fermentation
  - Amino-acids: data from each producers on e.g. stability/homogeneity are requested (even when product specifications are the same/similar)
  - Organic acids: data from one producer only

Content of the dossier – Inconsistency of guidance

- Example 2 : additives for cats and dogs

Tolerance studies are not required for:

- all pets and non food-producing species if three major target species (a monogastric, a ruminant, poultry or a salmonid) showed a comparable and wide margin of safety (at least 10).

Tolerance studies are required for dogs and cats if not otherwise excluded. The safety for other target species can be deduced from tolerance data of three other species or toxicity data from laboratory animals.

Risk assessment

- Rationale of the questions to applicants
  - Clarification of the reason for the request should be provided in the question (SIn) letters
- Risk assessment should not exclusively consider data provided in the application dossier
  - Public data generated in the framework of other evaluation activities (e.g. REACH)
  - Need for closer cooperation with ECHA

Risk assessment

- Establishment of maximum limits must remain a prerogative of risk managers

→Risk assessor must focus on assessing whether the conditions of use proposed by applicants are safe

- For transparency, risk assessment criteria should be consistent and clear to all stakeholders
- Open and direct technical/scientific discussion with FEEDAP Members is missing

Scientific opinion

- All scientific expertise should be appropriately considered and reported in the opinions, including inputs of industry experts
- For transparency, in case some information from applicant is rejected by EFSA experts, explanations should be given
- Need for consistency across opinions for different feed additives (ex. silage additives)

Scientific opinions

- One example of divergent/inconsistent approach: silage additives

The five studies involved a range of forages of differing botanical origin and water-soluble carbohydrate (WSC) content primarily selected to show a wide range of dry matter content (see Table 2). The samples generally represented material easy to ensile (experiments 1 and 3, 4 and probably 5). Only one forage sample considered moderately difficult to ensile (experiment 2) and no samples of difficult to ensile material as defined in Regulation (EC) No 429/2008 were included (see Table 2).

- But no restriction in silage categories… while restrictions are recommended in other opinions

Scientific opinions

- 'Multi-applications'
  - Multi-Opinions for '*single*' additives: undue complexity of the drafting of non-holder specific authorisations
    - Split up of authorisations for same/very similar substances must be avoided (e.g. vitamin A, L-valine)
    - Criteria for grouping different applications into a single opinion / annex entries would be useful (e.g. zinc)
  - Highlight the main conclusions and avoid inconsistencies

Example of multi-opinions: Zinc

- From applications to opinions
  - 5 applications, thereof
    - 2 concerning zinc sulphate monohydrate alone
    - 1 concerning zinc oxide alone
    - 1 concerning zinc chelate of amino acid
    - 1 concerning several compounds including zinc sulphate mono and heptahydrate
  - 1 mandate for all compounds including all applications
  - 5 opinions, thereof 3 concerning zinc sulphate monohydrate

Example of multi-opinions: Zinc

- How to design an authorisation for a single additive (zinc sulphate monohydrate) with 3 opinions, not always consistent?
- What is relevant for user as regards the identity of the additive vs. efficacy (differences between compounds?) and safety (maximum limit set on the element, not on the compound)?

Example of identity: Cobalt

- Different compounds but a single trace-element
  - What is the right information for the market/labelling ?

- Cobalt
- Cobalt carbonate
- Cobalt carbonate x%
- Preparation of Cobalt carbonate x%

Some suggestions

- Value generic information to avoid undermining « non-holder specific » authorisation
  - Need for consolidated opinion (summary) for all opinions related to a single additive or to similar products (e.g. same compounds of trace elements, organic acid and their salts,…)
  - Define criteria for grouped opinion
- Stick to risk assessment
- Agreement on different underlying concepts beyond the concept of feed additives
  - Intended use, active substance, preparations etc…

Thank you for your attention !