FEFANA

19 June 2019

SUSTAINABILITY

INNOVATION

FEED SAFETY

ANIMAL HEALTH AND WELFARE

SAFE FOOD

EFSA ad hoc Stakeholder Meeting

Revision of EFSA Guidance on the renewal of the authorisation of feed additives

Stakeholder's views

Section 2 - Characterisation

It shall confirm whether the product complies with the conditions of the existing authorisation.

For **microorganisms** used as the additive or as production strain: the taxonomic classification and WGS shall suffice to confirm that no change has occurred

- **Antimicrobial resistance/toxigenic potential is part of safety assessment and hence only needed if new information is available or in case of changes**

Safety for the target animals

EFSA Guidance on TAS (2018): all (terrestrial) animal species vs. fish

- Applicants need better understanding and predictability:
  - if no safety data was provided for fish at 1st assessment and the additive is intended for all animal species, data in fish may be requested;
  - Are there other animals that may need to be re-considered? Which ones?
- Decreasing number of animals used for testing: scientific rationale referring to available literature on biotransformation and metabolism of similar compounds should be recommended

Safety for the users

- What if no data was provided at 1st assessment (e.g. skin or eye sensitivity) ?
- Evaluations by ECHA are applicable for all additives for which harmonised classification exist, independently of holder specificity
- Consideration of existing harmonised classification as per CLP
- Decreasing number of animals used for testing: existing products represent no risk for users or precautionary measures have been effective in preventing any possible exposure

Consumer and Environmental safety

- Applicants need to understand the impact of the new FACE tool and of the parameters for calculating exposure:

  ⇒ Will EFSA recommend a change of recently established maximum levels in view of new calculations?

  ⇒ Difficult to predict the effect of these changes for additives intended for all animals species

  ⇒ Which target animals are expected to cause major increase in exposure scenarios?

Efficacy

- New data provided on a voluntary basis shall be accepted for assessment and for eventual revision of its previous opinion on a specific parameter
- Coccidiostats: need for acceptance of studies performed 2 years before submission

Literature

- Clear cut-off dates: oldest and latest relevant studies, considering that renewal dossiers are compiled ~2 years before submission
  - Date of EFSA opinion ?
  - Date of additive authorisation ?
  - Other date ?

EFSA – FEEDAP Open Session – November 2019

Stakeholder's suggestion of topics

Applications under Article 10 and Article 14

- Overview of dossiers for re-authorisation (Art. 10) under assessment and in "frozen" status?
  - reasons for delays
  - expected timeline to start assessment of frozen dossiers
- Renewal of authorisations (Art. 14) - Experiences from EFSA:
  - weaknesses identified in submitted dossiers
  - suggestions for improvement
- 10 years data protection: administrative and scientific aspects to consider when referring to another applicant's evaluation

Revised EFSA Guidance documents

- Assessment of microorganisms (as additives or as production strains): lessons learned from applications after new EFSA guidance document
  - EFSA point of view
  - Applicant point of view
  - Re-authorisations
- FACE calculations – what dataset is expected (statistical considerations)
- Mixtures of chemicals:
  - what is done by the applicant?
  - what is done by the experts?
  - specifically for the component approach?
  - recommendation for reference databases?

THANK YOU!