FEEDAP
Guidance Documents update

Feedback and views from industry

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Regulation (EC) No 429/2008

- Revision of ‘The Guidelines’ is a priority
- Revision of guidance documents ideally following adoption of updated Reg. (EC) No 429/2008 to ensure alignment

Content

- Points of acknowledgement
- Concepts for consideration
- Additional remarks
- Conclusions

Points of acknowledgement

- Clearer definition of active substance/additive
- Identity and characterisation
- Consistency of the assessment of fermentation products
- Reduction in the number of animals/animal studies for safety assessment
- Safety for the user
- Efficacy trials and end-points
- Involvement of stakeholders

Concepts: clearer definition of active substance / additive

- Avoid diverging interpretations by establishing a consistent concept in the Guidelines and related feed legislation
- Foresee the possibility to discuss unclear cases prior to application
- Ensure consistency among application / EFSA assessment / EFSA opinion / authorisation
- Proposed definitions for describing feed additives:

Product descriptors	Definitions	Example
Intended purpose	The active element(s) of the product.	Vitamin A
Active substance	Substance/agent that provides the purpose	Retinol acetate
Characterised substance	Active substance/microorganism as produced and its associated components/constituents (including relevant impurities linked to process, and with safety relevance)	Retinol acetate min. 96%, with impurity 1 at max. 0.02%
Additive	Product as placed on the market (i.e. the characterised substance or a preparation of it)	Preparation of retinol acetate

Concepts: characterisation of the additive

- Specifications/purity of the product with max. levels of impurity(ies) of concern based on manufacturing process nature of the additive and safety
- Consistent approach based on: manufacturing process, HACCP principles and (if applicable) guidelines from other sectors (e.g. biocidal products, food additives, veterinary products, chemicals).
- HACCP information in the dossier linked to quality control and product specifications

Concepts: assessment of fermentation products

- Safe Strain Lineage Concept (Pariza-Johnson, 2001)
- Improve guidance to applicants on methods and thresholds for assessing aspects such as antimicrobial resistant (marker) genes, toxins
- Exemption for tox studies using QPS approach based on the level and identity of active substance and unidentified impurities

Concepts: reduce the number of animal studies

- Avoid the increasing number of species groups while still leaving the option for niche markets
- Target species categories based (mainly) on:
  - Physiological stage (growing vs reproduction)
  - Digestive systems (ruminants, poultry, fish, etc…)
  - Metabolism (ovines vs other ruminants)
- Allow extended extrapolation of efficacy and safety studies across animal categories

Concepts: safety for the user

- User/worker safety: consideration of/alignment with harmonised CLP classification
- Transparency and consistency of the use of physical characteristics for the assessment
- Exposure of user/worker is significantly depending on handling conditions which are not under applicants control
- Endpoint for the risk assessment: determine hazardous properties of the substance(s) and which require risk management measures

Concepts: efficacy

- End-points: list to be included in Reg. 429/2008
- Guidance documents (EFSA or Commission): indicative protocols for testing end-points
- New end-point or function: possibility of tri-partite pre-submission meetings

Concepts: the way forward

- Priority is the revision of The Guidelines
- Involvement of stakeholders as from the early stages of revisions
- Allow valuable inputs for sound and fit for purpose new Regulation (EC) No 429/2008 and associated guidance documents
- Consultation and appropriate timeframe for **each** guidance for comments and possibility to discuss a period for entry into force
- Ensure a harmonised approach for overarching issues with other European Scientific Bodies

Points to be clarified

- Transparency for acceptance and rejection of studies/scientific evidence: consideration of all documents supplied by the applicant
- User safety assessment: differentiation for holder specific authorisations shall not be made
- Reconsideration of the value of meta-analysis in the assessment: need for guidance
- Timing of revision of guidance documents in view of update of Reg. (EC) 429/2008

Conclusions

- Statement is a relevant input for update of Reg. (EC) No 429/2008
- Revision of guidance documents shall be in alignment with updated Reg. (EC) No 429/2008 to avoid inconsistencies
- Involvement of stakeholders is key for fit for purpose revision

Thank you!