Role of EFSA in Feed-related Risk Assessment

Dr. O. Ribó
Senior Scientific Officer
FEED Unit – EFSA

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EFSA FEEDAP PANEL AND FEED UNIT

- The **Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) provides independent scientific advice on the safety and/or efficacy** of additives and products or substances used in animal feed.
- The Panel evaluates their **safety for the target species, the user, the consumer and the environment**.
- The Panel carries out **RAs to produce scientific opinions and advice**, supporting risk managers in taking effective and timely decisions.
- **FEED Unit provides scientific and administrative support to the work of the Panel** and may carry out other projects in the remit of EFSA (e.g. response to urgent requests for scientific advice).

APPLICATION HANDLING

The process

- LEGAL BASIS

REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002
laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

REGULATION (EC) No 1831/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003
on additives for use in animal nutrition

COMMISSION REGULATION (EC) No 429/2008 of 25 April 2008
on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives

MAIN TASKS OF FEEDAP PANEL

- **Assessment/evaluation of new feed additives** (Art. 4(1) of Regulation 1831/2003)
- **Re-evaluation of already authorised additives** pursuant to Directive 70/524 and 82/471 (i.e. technological, colorants, vitamins, trace elements, urea, aminoacids)
- Assessment of **modification to existing authorisations** (Art. 13(3))
- Feed additives **renewal after 10 years of authorisation**
- **Assessment of additional information** following or not inconclusive opinions
- **Generic questions**
- **Administrative Guidance** to guide the applicants to prepare and present the dossier
- **Technical Guidance** for the different categories of additives; but also for aspects that may apply to different categories (safety for the target species, consumer,…)

REGULATION 429/2008 : SAFETY ASSESSMENT

Based on studies intended to demonstrate the safety of the use of the additive in relation to:

- **the target species** at the highest proposed levels of use in feed or water (to establish a margin of safety);
- **consumers ingesting food products from animals that have received the additive**, its residues or its metabolites. When needed, setting of MRLs and withdrawal periods based on an ADI or an UL;
- **users handling the additive**, likely to be exposed by respiratory, mucosal, eye or cutaneous contact when incorporating it into premixtures, complete feed or water;
- **the environment**, as a result of the additive itself or derived products, either directly or excreted by animals.

REGULATION 429/2008: EFSA GUIDANCE DOCUMENTS

Technological

Sensory

Nutritional

Zootechnical

Coccidiostats

Tolerance/efficacy

Consumer/User

Environment

Minor species/Pets

Microbial studies / Antimicrobial resistance

Food additives

Re-evaluation

Compatibility

Bacillus/Enterococcus

Renewal

REGULATION 429/2008 : EFSA GUIDANCE & DOSSIER

- Section I: Summary
- Section II: Characterisation
- Section III: Safety
- Section IV: Efficacy
- Section V: Postmarket monitoring

SAFETY FOR THE TARGET ANIMALS

- **Safety studies for target animals are intended to assess:**
  - the safety of use of the additive in the target species *per se*
  - any risk associated with the selection and/or transfer of resistance to antimicrobials and increased persistence and shedding of enteropathogens

- **Studies to be performed in this section:**
  - Tolerance studies
  - Microbial studies (when a microorganism is involved, e.g. not for chemical synthesis)

TOLERANCE STUDIES

- **Aim**
  - to provide a limited evaluation of short-term toxicity of the additive to the target animals
  - to establish a margin of safety, if the additive is consumed at higher doses than recommended

- **When is it required?**
  - for all zootechnical additives except for micro-organisms considered by EFSA to qualify for QPS approach to safety assessment
  - In all relevant target species / categories
  - Whenever possible use 100-fold overdose
  - Not required for high purity nutritional additives

For details on how to perform and report tolerance studies, see the technical guidance on tolerance and efficacy studies in target animals.

TOLERANCE STUDIES – DURATION

The minimum duration depends on the animal species/category.* Some examples:

Category	Definition of the animal category	Approximate study period (weight/age)	Minimum study duration
		Start, from	**Tolerance**
Piglets (suckling)	Young porcine animals getting milk from sows	Birth	**14 days**
Piglets (weaned)	Young porcine animals having completed the suckling period and being reared for reproduction or meat production	21-42 days of age	**42 days**
Chickens for fattening	Birds raised for fattening	Hatch	**35 days**
Chickens reared for laying	Female birds being reared for consumer egg production or for breeding purposes	Hatch	**35 days**

*Detailed in Appendix B of the Technical Guidance on tolerance and efficacy studies in target animals

SAFETY FOR CONSUMER

- **Aim**

to evaluate the safety of the additive for the consumer and to establish **potential residues of the additive or its metabolites in food derived from animals** given feed or water containing or treated with the additive

- **Studies to be performed in this section:**
  - **Metabolic and residue studies**
    - i) Establish the metabolic pathways of the active substance
    - ii) Identify and quantify residues of toxicological relevance in the edible tissues or products
    - iii) To establish the kinetics of total residues and marker residue in tissues/products
  - **Toxicological studies (ref. to OECD Guidelines)**
    - Genotoxicity (mutagenicity, clastogenicity)
    - Sub-chronic oral toxicity
    - Chronic oral toxicity/carcinogenicity
    - Reproduction toxicity including teratogenicity

SAFETY FOR CONSUMER

Studies are not required if:

- the substance is essentially **not absorbed and excreted unchanged** (or if transformed in the digestive tract, its metabolites can be demonstrated not to be absorbed);
- the substance is absorbed as physiological compound(s);
- the active component(s) of the additive consists only of microorganisms or enzymes.
- if additives are produced by microorganisms considered by EFSA to qualify for the QPS approach;
- enzymes are produced by GMMs for which the recipient strain is considered to qualify for the QPS approach, and its molecular characterisation does not give rise to concern;
- the microorganism is considered by EFSA to qualify for the QPS approach or when its biology is sufficiently well known to allow pathogenic/toxigenic strains to be excluded by direct testing;

For details see the guidance on consumer safety.

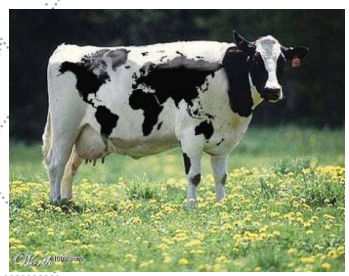
SAFETY FOR THE USERS/WORKERS

- **Workers' exposure**
  - Inhalation
  - Topical exposure
- **Studies to be performed in this section:**
  - final form of the additive
  - studies on skin/eye irritancy
  - allergenic potential/skin sensitisation potential
  - potential systemic toxicity of the additive

For details see the guidance on user safety.

SAFETY FOR THE ENVIRONMENT

- **Why?**
  - use of additives typically occurs over long periods
  - often involves large groups of animals
  - the constitutive active substance(s) may be excreted to a considerable extent either as the parent compound or its metabolites
- **How?**
  - stepwise approach
  - all additives have to be assessed through Phase I to identify those additives which do not need further testing
  - for the other additives a second phase (Phase II) assessment is needed to provide additional information, based upon which further studies may be considered necessary



For details see the guidance on environmental risk assessment.

ADOPTION OF OPINIONS BY THE FEEDAP PANEL

Addressing the Terms of Reference

Feed additive categories and functional groups

- Technological
- Sensory
- Nutritional
- Zootechnical
- Coccidiostats

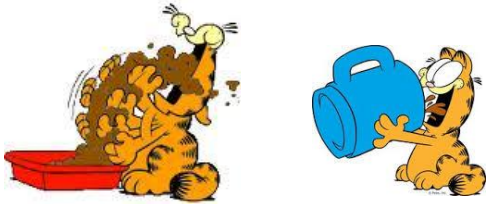
Animal categories

Animal products

- Muscle
- Fat+skin
- Liver
- Kidney
- Milk
- Eggs

Consumer

Intended use



User/Worker

EFFICACY

Environment

FEEDAP PANEL - STANDING WORKING GROUPS*

Amino acids and Vitamins	Genetically modified microorganisms
Coccidiostats & histomonostats	Microorganisms
Colouring agents	Other additives
Enzymes	Trace elements
Feed flavourings	Technological additives
Feed materials	

(from October 2015)

FEEDAP PANEL (2015-2018)

21 Panel Members

Several areas of expertise

Chair FEEDAP Panel 2015-2018
Guido RYCHEN

Vice-chairs:
- Secundino LOPEZ PUENTE
- Maria SAARELA

Gabriele AQUILINA	Boris KOLAR
Vasileios BAMPIDIS	Maryline KOUBA
Maria d. L. BASTOS	Marta LOPEZ ALONSO
Georges BORIES	Alberto MANTOVANI
Andrew CHESSON	Baltasar MAYO
Pier S. COCCONCELLI	Fernando J. RAMOS
Maria FERNANDEZ-CRUZ	Roberto E. VILLA
Gerhard FLACHOWSKY	R. John WALLACE
Jurgen GROPP	Piet WESTER

Expertise covered

- **Animal nutrition/ animal physiology/ production**
- **Toxicology**
- **Pharmacokinetics/ dynamics/ metabolism**
- **Microbiology, antimicrobial resistance**
- **Environmental risk assessment**

Thanks for your attention !