FEED REGULATION IN THE EUROPEAN UNION

Miklós Mézes
Szent István University
Faculty of Agricultural and Environmental Sciences,
Department of Nutrition
Gödöllő, Hungary
Safe feed

Nutritional quality (nutrient content and nutritive value);
Technical quality (physical parameters such as viscosity, density, particle size /distribution, pellet stability, colour etc.);
Safety quality (amount of undesirable substances in the feed);
Ethical quality (presence or animal origin protein sources, GMO plant materials, colorants).
Undesirable substances in feeds

**Chemicals:** residues of pesticides, herbicides, antibiotics, mycotoxins, environmental contaminants (metals, PCBs, dioxins, disinfectants etc.)

**Biologicals:** pathogenic micro-organisms (Salmonella, E. coli, Campylobacter etc.) animal origin proteins, moulds

**Physicals:** glass, plastic, metal and stone particles
The authorisation of Feed Additives in Europe


Additives for use in Animal Nutrition
History of the authorisation of feed additives in Europe

**Before regulation 1831/2003 EC**

Applicant → Member State Rapporteur → Evaluation by Member States → Standing Committee

2-3 years

SCAN / EFSA

European Commission

**After regulation 1831/2003 EC**

Applicant → EFSA → European Commission + Member States

Community Reference Laboratory

< 1 year
Regulation 1831/2003 EC

Definition of Feed Additive

Conditions of Authorisation

Categories and functional groups of additives

Process of Authorisation

Other Measures
Definition of feed additives

Substances, micro-organisms or preparations, other than feed materials and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3)
Conditions for Authorisation

Article 5

Safe
• for the animals, humans and environment
• does not mislead the consumer and user

Efficacious
Conditions for Authorisation

**Efficacy**

Favourably affect the characteristics of feed or animal products
Favourably affect the colour of ornamental fish and birds
Satisfy the nutritional needs of animals
Favourably affect animal production, performance or welfare
Have a coccidiostatic or histomonostatic effect
Categories of Feed Additives

**Technological** (preservatives, antimioxidants, emulsifiers, stabilisers, thickeners, gelling agents, binders, anticaking agents, substances for control radionucleide contamination, acidity regulators, silage additives, denaturants)

**Sensory** (colourants, flavouring compounds)

**Nutritional** (vitamins, pro-vitamins, trace elements, amino acids and analogues, urea and derivatives)

**Zootechnical** (digestibility enhancers, gut flora stabilisers, substances which favourably affect the environment, other zootechnical additives)

**Coccidiostats and Histomonostats**
<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technological/Sensory/Zootechnical</td>
<td>Favourably affect the characteristics of feed or animal products</td>
</tr>
<tr>
<td>Sensory</td>
<td>Favourably affect the colour of ornamental fish and birds</td>
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</table>
Process of Authorisation

Technical dossier preparation

Application

Assessment by EFSA /CRL Analytical Methods

Regulation by EC
Technical Dossier

Guidelines for Dossier preparation

- Chemical Compounds
- Enzymes and micro-organisms
  Opinion of the Scientific Committee on Animal Nutrition (SCAN) 22 October, 1999
Scientific Assessment by EFSA

Assessment on the data presented in the dossier

Verify the CRL report

6 months deadline (extended if more information is needed)
CRL Analytical Methods Evaluation

Regulation 378/2005 EC
Samples of additive (+ premixtures and complete feed)
Assessment of methods of analysis
Testing/validation needed?
CRL is assisted by National Reference Laboratories
Report to EFSA within 3 months (can be extended)
**Procedures for EFSA Opinion Delivery**

1. **Scientific evaluation of the technical dossier**
   - **NO**
   - **Supplementary information?**
     - **NO**
     - Scientific Panel prepares an Opinion
       - **OPINION ADOPTED**
         - Communication to COMMISSION, MEMBER STATES and Applicant
       - **Make Opinion available to public**
     - **YES**
6. **Applicant is requested. Extension of the 6 months time-frame**
Community Authorisation

EFSA Opinion

EC - Draft Regulation authorisation, 3 months
Standing Committee (EC + Member States)
Authorisation of the additive for 10 years
Holder specific/generic
Other Measures

Existing products – Notification
Re-evaluation by 2010
Modification authorisation
Renewal authorisation
Confidentiality/data protection
Other Measures

Phasing out of Coccidiostats and Histomonostats by 31 December 2012

Prohibition of Antibiotics on 31 December 2005
Traceability

Traceability of feed components and complete feeds (178/2002/EC)

All charges of the feed components have to identified according to producer and origin

All complete feed have to identified according to producer and origin even at farm level