FEED REGULATION IN THE EUROPEAN UNION

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Summary

Feed scandals and transmissible prion diseases (e.g. BSE) requires new regulations in the feed production in the European Union. Those regulations cover the whole food chain (from farm to fork) with special attention to feeding stuffs and feed additives. The main purpose of the paper presenting the present feed regulations in the European Union and as an example give some more detailed information about the authorisation of a new feed additive.

Introduction

Food and feed safety are the most important problems of the agriculture all around the world. The food safety based on the using as much as safe feed for feeding farm animals which will produce safe animal products as food materials. The European Union established first the proposals for generally accepted food safety regulations in 2000 (White Paper on Food Safety). It declares that in order to ensure the safety of food, it is necessary to consider all aspects of the food production chain from primary production and the production of animal feed up to sale or supply of food to the consumer. Based on that safety policy declaration the European Council and the European Parliament accepted first food safety regulation (178/2002 EC directive).
The safe food production requires safe feed for farm animals as well which means that the feed of animals, including the feeding stuffs and the feed additives, could not cause undesirable effect or even damage for the animal health, for the health status of consumers and also not for the environment. Those criteria require that all of the feeding stuffs and feed additives have to be authorised by the legislative bodies of the European Union. The process of legislation based on the procedure of authorisation and risk assessment of the particular feeding stuffs and feed additives.
In the case of feeding stuffs the legislative body is the Standing Committee on Food Chain and Animal Health, Animal Nutrition Section of the European Commission and the scientific assessment is given by the European Food Safety Authority, which was established also in 2002 (78/2002 EC directive).

The safe feed also shall to cover the main quality criteria as follows:

- 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 the feed are as follows:

- Chemicals, such as residues (pesticides, herbicides, antibiotics), mycotoxins, and environmental contaminants (metals, PCBs, dioxins, disinfectants, mineral oils);
- Biologicals, such as pathogenic micro-organisms (*Salmonella, E. coli, Campylobacter, Enterobacteria*), animal origin proteins, moulds;
- Physicals, such as glass, plastic, metal and stone particles.

Authorisation and assessment of feed additives in the European Union

The procedure based on the regulation of the European Council and the European Parliament (1831/2003 EC). The directive contains definition of the feed additive, conditions of authorisation, categories and functional groups of additives, process of authorisation and other measures.
Feed additives are dose substances, micro-organisms or preparations, other than feed material and pre-mixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions (Article 5(3).
The conditions of authorisation declared that the feed additive shall be safe for the animals, humans and environment, does not mislead the consumer and user, and last but not least efficacious (Article 5). The term efficacy means that the feed additive has any of the following favourable effects:

- characteristics of feed or animal products;
- colour of ornamental fish and birds;
- satisfy the nutritional needs of animals;
- improve animal production, performance or welfare;
- coccidiostatic or histomonostatic.

The feed additives categorised (and add to any of the functional groups) as follows (Annex I):

- technological additives (preservatives, antioxidants, emulsifiers, stabilisers, thickeners, gelling agents, binders)
- sensory additives (colourings, flavourings)
- nutritional additives (vitamins, trace elements, amino acids and analogues, urea and derivatives
- zootechnical additives (digestibility enhancers, gut flora stabilisers, substances which favourable affect the environment, and other zootechnical additives)

Process of authorisation

1. Application together with send the complete technical dossier to EFSA and samples for analytical evaluation the Community Reference Laboratory.

2. Administrative evaluation by the EFSA and make a summary available to public for comments by the Member States and NGOs.

3. Scientific evaluation of the technical dossier by the relevant Panel(s) of EFSA

3.1. Efficacy of the additive:
   - favourably affect the characteristics of feed or animal products (*Technological/Sensory/Zootechnical*)
   - favourably affect the colour of ornamental fish and birds

(*Sensory*)
- satisfy the nutritional needs of animals (*Nutritional*)
- favourably affect animal production, performance or welfare (*Zootechnical*)
- Have a coccidiostat or histomonostatic effect (*Coccidiostats and histomonostats*)

3.2. Safety of the additive:
- safety for the target animal species – at least 10x of maximum recommended dose level (*Sensory/Nutritional/Zootechnical/Coccidiostats and histomonostats*)
- safety for the consumer – mutagenic, carcinogenic effects of the active substance/metabolites and calculation of maximum residue level (MRL) based on the approximate daily intake (ADI) of the particular animal product(s)
- safety for the user – inhalation of particles during feed processing and potential harmful effects for the users
- safety for the environment (if relevant – negligible if the active substance is physiological/natural: e.g. vitamins, proteins, trace elements) – environmental risk assessment (79/2001 EC)

4. Community Reference Laboratory analytical methods evaluation (378/2005 EC)
- assessment of methods of analysis
- testing and validation of the methods of analysis if requires
- evaluation report send to European Food Safety Authority

5. Authorisation by the European Community
- European Food Safety Authority sent to DG SANCO of the European Commission
- Draft authorisation by the European Commission
- Evaluation and decision of Standing Committee on Food Chain and Animal Health, Section Animal Nutrition
- Authorisation of the additive (brand approval) for 10 years

6. Other measures
- Notification of existing products
- Re-evaluation of existing products by 2010 – partly based on post-market monitoring data
- Modification of authorisation – based on the new requirements and proposals by the producers
- Renewal of authorisation (after 10 years of first authorisation)
- Confidentiality / data protection (producer may declare those data which are confidential)
- Phasing out of coccidiostats and histomonostats by 31. December 2012
- Prohibition of nutritive antibiotics on 31. December 2005

Conclusions

The regulations and requirements for authorisation are under renewal recently because of the special needs of the feed industry, the users and last but not least the consumers. However the main scheme of the process remains as mentioned above but only some minor modifications will be implement in the near future, such as new guideline for assessment procedure and also addition of some new, and more specified functional groups into the category, zootechnical additives.
The process of authorisation is obligatory only for the Member States of the European Union but as example may be useful for other countries and regions of the world.

References

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