Regulatory aspects of the use of herbal products in animal feed

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Regal B.V.

- Especialised in supporting companies on regulatory affairs and taking care of registrations, related to animal nutrition in the European Union
- Founded in 2000
Content

- General information on European Regulations
- Status of herbal products
  - What are herbal products?
  - Differentiation between additives, medicines, feed ingredients and biocides
  - Possible claims
General information on European Regulations

- Veterinary products
- Feed additives
- Feed Ingredients
- (Biocides)
Registration Veterinary products

Central European Procedure (Reg. 726/2004+ 658/2007)

- Application of a dossier to the European Medicines Agency (EMA)
- Committee for Medicinal Products for Veterinary Use (CVMP) evaluates the dossier (210 days)
- European Commission decides
- Fees apply
National Procedure

- According to Directive 2001/82/EC (+ amendments e.g. 2004/28/EC)
- To be evaluated within 210 days
- Application in more than 1 country
  ➔ coordination for evaluation (own rules of procedure)
- National rules in each country
Mutual Recognition / Decentralised procedure

- If product is authorised/under consideration in country A and applications are done in countries B-Z. The applicant informs and country A is asked to make an assessment report, to be sent to countries B-Z.

- Countries B-Z can agree or not to the report statement of reasons. Member states involved agree on actions to be taken. Further details in Directive 2001/82/EC.
Registration as feed additive

- Only central EU registration
- Submit a dossier
- European Food Safety Authority evaluates (6 months)
- European Commission decides (3 months)
- Fee only for CRL/EURL
Registration as feed additive

- European regulations
- EFSA guidances

- Advantage when product is approved for human use
Registration feed additive

- Possibilities to make strong claims
- Decide what claim?
  - preservation
  - flavouring compound
  - zootechnical additive → effect on performance
    (digestibility, gut flora, health, quality of animal product)
Registration feed additive

• Dossier on:
  – Identity of the product (active ingredients, chemical and physiological characteristics, stability, method of analysis)
  – Safety (for the animal, consumer, worker, environment)
  – Efficacy (proof of claim)
Categorisation of the product

- Is product a feed material, feed additive, veterinary product or a biocidal product?
- Non binding guidelines exist!
Definitions

- Feed material: products of vegetable or animal origin, whose principal purpose is to meet animals’ nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures (Regulation (EC) 767/2009)
Definition feed additives

- **Feed additives**: substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more specific functions that are listed in Article 5(3) of Regulation (EC) 1831/2003:
  
  (a) favourably affect the characteristics of feed ... 
  (b) favourably affect the characteristics of animal products ... 
  (e) favourably affect the environmental consequences of animal production 
  (f) favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs ...
Is a product a feed material or feed additive?

- Criteria:
  1. Production and processing method
     - Products of vegetable or animal origin in their natural state, fresh or preserved, and products derived from the simple processing thereof, as well as organic or inorganic substances can be considered feed materials.
  2. Chemical definition and level of standardisation or purification
     - Chemically well-defined substances that are purified and give a certain level of standardisation guaranteed by the manufacturer might qualify as feed additives.
Is a product a feed material or feed additive?

Criteria (continued)

3. Safety and mode of use: If for reasons of animal or human health it is necessary to set a maximum content of the product in the daily ration the products qualify for classification as additive. However, also for certain feed materials maximum inclusion rates apply. Feed additive status might offer improved scope for effective management of the product in terms of stability, homogeneity and with respect to overdosage. **Feed additives are usually used at low incorporation rates.**

4. Functionality: Feed additives are defined by their functions as laid down in Article 5(3) of Regulation (EC) No 1831/2003. However, these functions are **not exclusive to feed additives.** Thus, a feed material can also exert an additive function (e.g. as a thickener) but **this should not be the only intended use**
Feed additives

Some feed additives can be used for organic farming in case of essential technological or zootechnical needs and need to be authorised by the Commission (Regulation (EC) No. 834/2007).
Biocidal products

- Biocidal products: active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means;

- Products that are defined or that fall under the scope of the feed legislation, including processing aids, are no biocidal products but are to be considered as feed (Precedence of the feed legislation over the legislation on biocidal products)
Veterinary products

- Any substance or combination of substances presented as having properties for treating, curing or preventing disease in animals; or
- any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.
- When a product is registered as a feed additive it can not be a veterinary product.
Veterinary products: herbal

Guideline on “quality of herbal medical products/traditional herbal medicinal products” (EMEA 2006): on quality and controls of herbal medicinal products

- In addition to Directive 2001/82 on the Community code relating to veterinary medicinal products
Feed with “particular nutritional purpose” (dietetic feed)

“Particular nutritional purpose” means the purpose of meeting the specific nutritional needs of animals whose process of assimilation, absorption or metabolism is, or could be, temporarily or irreversibly impaired and who can therefore benefit from the ingestion of feed appropriate to their condition (Regulation (EC) 767/2009)
Feed with “particular nutritional purpose” (dietetic feed)

- Certain claims are possible according to Regulation (EC) 767/2009 “products with particular nutritional purpose”, related to nutritional value and physiological role (absorption, metabolism) e.g.:
  - support of liver function in the case of chronic liver insufficiency
  - reduction of urate stones formation
  - reduction of the risk of milk fever, ketosis
  - support of heart function
  - regulation of glucose supply
  - reduction of stress reactions
Claims on feed materials

- Claims: “draw attention to the presence of a substance in the feed, to a specific nutritional characteristic or a specific function...”
- It should not be the only function
- Claims must be scientifically substantiated
- Still a new and developing area
- Therefore a case by case evaluation is necessary.
Labelling

There are strict regulations for labelling. Basis of regulations is different for feed additives, feed materials and veterinary products.
Lists

- List of feed additives is given in the Register
  (http://ec.europa.eu/food/food/animalnutrition/feedadditives/registeradditives_en.htm)
- List of feed materials is given in the Catalogue
  (latest version Regulation (EU) 575/2011, updated)
- European Feed Materials Register
- Veterinary products: Community Register
Thank you for your attention!

Questions?

• Also possibility to contact afterwards: ruud.bremmers@regal-eu.nl or visit website at www.regal-eu.nl