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European Food Safety Authority

New paradigms for the assessment of feed additives

New perspectives for functional feed additives

Georges Bories

member of FEEDAP panel

Consequences of the food crisis in the 90ies

- **New principles enforced by the EU Commission (1998):**

  Separate appraisal of:

  risk assessment (scientific basis)
  risk management

- **Creation of DG SANCO (1999)**

Consequences of the food crisis

- **DG SANCO action:**
  - **“White paper” (2000):**

    to ensure high level of food safety and health and welfare for animals, by coherent measures taken from “farm to table” that would help developing the EU interior market

    and specifically

    a new policy regarding feedingstuffs and feed additives to recast all existing measures on feedingstuffs so as to create a comprehensive legislative tool increasing transparency, consistency and legal security

  - **Creation of EFSA (2002), devoted to risk assessment**

EFSA

- Assessment of food safety dispatched between 10 Scientific Panels
- FEEDAP encharged with feed additives and products and compounds used in animal nutrition

  Co assessment with other Panels where necessary (GMO Panel)
- On request of the Commission, FEEDAP delivers scientific opinions which are used by the risk manager (Commission and Members States) in the decision process
- FEEDAP Panel self tasks scientific questions which appear critical for its assessments

Impact on feed additives legislation

From

Directive 70/524 (1970 to 2004-8)

to

Regulation (EC) 1831/2003

Directive 70/524

Paradigms

- **Article 2. (a) Additives : substances which, when incorporated in feedingstuffs, are likely to affect their characteristics or livestock production**
- **Article 3. The Member States shall provide that, as regards feedingstuffs, only those additives which are listed in Annex I may be incorporated in feedingstuffs (Pre-market approval principle)**
- **Article 6. A substance shall be included in Annex I only if:**

  (a) it has a favourable effect on the characteristics of those feedingstuffs or on livestock production when incorporated in such feedingstuffs;

  (b) at the level permitted in feedingstuffs it does not endanger animal or human health nor harm the consumer by altering the characteristics of livestock products

Directive 70/524

Annex I : **9 categories corresponding to the general charasteristics / properties of the additives**

A. Antioxydants
B. Aromatic substances and appetizers
C. Coccidiostats and other medicinal substances
D. Emulsifiers
E. Colorants
F. Stabilizers
G. Vitamins and pro-vit
H. Oligo-elements
I. Antibiotics

Silage additives and flavourings out of the Directive

Directive 70/524

Paradigms

- **Guidelines for the assessment feed additives (1987), modified (1994) for enzymes/microorganism**
- **Efficacy studies**

  use of appropriate criteria under the intended conditions

  on each target species (no definition of categories of animals)

  duration of studies not specified

  in comparison with negative control (feedingstuffs or animals), possibly with additives of known effectiveness

Regulation (EC) 1831/2003

Paradigms

- **All feed additives (to be included in feed, silage or water; also flavourings) will obtain market authorisation for ten years only if they have complied with and have been approved under the procedures specified in the Regulation**
- **Implementing rules: Regulation (EC)429/2008**
- **Guidance (5) and technical guidance (11) documents (EFSA)**

Regulation 1831/2003

Paradigms

Characteristics of feed additives (Article 5.3):

- favourably affect the characteristics of feed
- favourably affect the characteristics of animal products
- favourably affect the colour of ornamental fish and birds
- satisfy the nutritional needs of animals
- favourably affect the environmental consequences of animal production
- favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs
- have a coccidiostatic or histomonostatic effect

Regulation 1831/2003

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Paradigms

Categories of additives (Article 6)

a) **Technological additives**

b) **Sensory additives**

c) **Nutritional additives**

d) [1] **Zootechnical additives**

e) [1] **Coccidiostats and histomonostats**

[1] *Holder specific approval carrying proprietary rights*

An additive can be allocated to one or more categories

Regulation 1831/2003

Paradigms

Categories of additives (Article 6)

Technological additives: any substance added to feed for a technological purpose

Sensory additives: any substance, the addition of which to feed improves or changes the organoleptic properties of the feed, or the visual characteristics of the food derived from animals

Nutritional additives

Zootechnical additives: additives used to affect favourably the performance of animals in **good health** or the environment

Coccidiostats and histomonostats

Additives/veterinary drugs

- **Legislation attempts a clear distinction between feed additives and veterinary products**
- **Additives should show beneficial effects in animals in "good health"**
- **Most zootechnical additives show (greatest) effects in animals in less than good health**
- **New additive legislation recognises effects on animal welfare as a legitimate characteristic (e.g. reduced morbidity/mortality)**

Regulation 1831/2003

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Paradigms

Functional groups (Annexe I)

FEEDAP Panel

Tasks of the FEEDAP Panel:

- Assess the safety of food from animal origin
- Assess the safety for the users, the target animals and the environment
- Establish whether an additive demonstrates one or more of the attributes listed in the Regulation, defining loosely the efficacy of a feed additive

Regulation 1831/2003

- Completely novel xenobiotic additives assessment needs full requirements
- Specific rules to simplify assessment procedures have been established:
  - Extrapolation from major to minor species
  - Pets and non food producing animals
  - Additives already authorized for food
  - Modification of the authorization
  - Renewal of authorizations
  - Reevaluation of certain additives already authorized under directive 70/524

FEEDAP Panel

- **The operation of Regulation 1831/2003 is critically examined in the light of nearly 100 applications made and experience gained**

Technological	0
Sensory	2
Nutritional	16
Zootechnical (microorganism)	37
Zootechnical (enzymes)	22
Zootechnical (other)	6
Coccidiostats	15

- **The implications for new additives and truly novel additives are considered**

Regulation 1831/2003

Difficulties encountered in selecting categories / functional groups

- most additives fit well within one of the five categories
- in the case of technological, sensory and nutritional additives: efficacy is demonstrated at the level of the functional group
- however, two properties under Article 5.3, e.g. product quality and animal welfare, are not found in any definitions of categories, especially zootechnical additives, and therefore excluded

Regulation (EC) 1831/2003

Approaching Annex I and Article 5.3 ……..

Zootechnical additives:

(a) digestibility enhancers: substances which, when fed to animals, increase the digestibility of the diet through action on target feed materials

(b) gut flora stabilisers: micro-organisms or other chemically defined substances, which, when fed to animals, have a positive effect on the gut flora

favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs

(c) substances which favourably affect the environment

favourably affect the environmental consequences of animal production

(d) **other zootechnical additives**

Regulation 1831/2003

Difficulties encountered in selecting categories / functional groups

- the attributes of zootechnical additives are invariably judged at the level of the category, which is an imperfect solution: requirement for three long term studies in which significant benefit to animal performance is demontrated, is only evidence of a potential
- Until the functional groups (and their definition) included under the zootechnical category more closely relate to mode of action, surrogate measures able to replace the need for animal feeding studies are unlikely to be convincing

Regulation 1831/2003

Categories / Functional groups:

A clear definition is necessary to :

- **more closely define purpose of use**
- **establish a clear link between purpose and value to the user, welfare of livestock or environment**

An increased range and improved definitions would:

- **better reflect current science**
- **encourage and ultimately allow efficacy to be demonstrated at the level of functional groups**
- **could avoid the need for extensive animal trials while still providing the evidence of effectiveness**

Regulation 1831/2003

Advantages of introducing new categories / functional groups

Categories / functional groups based on current knowledge and technological progress would:

- give greater transparency to stakeholders and meaningful labelling
- establish a closer link between Article 5 and Article 6
- facilitate the attribution of new additives by the applicant
- based on the proximity of the mode of action to the definition of FG give greater opportunity to demonstrate efficacy by selection of the most relevant criteria
- facilitate the re-evaluation by offering new potential entries where efficacy cannot be demonstrated in the present category / FG

Future of new vs novel additives

- **A majority of new additives are variants of those already existing and, generally, seek holder-specific authorization as zootechnical additives (better benefits compare to generics if market size adapted)**
- **Novel additives may encounter particular problems:**
  - **potentially greater demand of risk assessor faced with new issues**
  - **difficulty to classify with Regulation definitions**
  - **distinction additives / veterinary drugs**
- **The possibility of introducing new categories / FG :**
  - **is restrospective / applicants needs; recent exception of detoxifying binders following requests to the Commission**
  - **only zootechnical additives leaves open in : « other … »**

Regulation 1831/2003

FEEDAP Panel self task (2008) :

1. **Examined the rationale for existing categories / functional groups within areas which appear to cause difficulties, and considered how this could be improved**
2. **Made short-term proposals for the creation of additional functional groups**
3. **Considered the fact that any change of the definitions of existing categories / functional groups would require revision of the Regulation, and therefore forecasted long-term objectives**

Regulation 1831/2003

Short-term proposal

New categories of additives:

a) **Technological additives**
b) **Sensory additives**
c) **Nutritional additives**
d) **Zootechnical additives**
e) **Coccidiostats and histomonostats**
f) **Welfare additives**
g) **Product quality additives**

Regulation 1831/2003

Short-term proposal

New categories of additives:

f) **Welfare additives:** any additive used to favorably affect the welfare of the animals

g) **Product quality additives:** any additive used to favorably affect the sensory (other than visual appearance), nutritional or hygiene properties of products of animal origin

Regulation 1831/2003

Short-term proposal

New functional groups:

Welfare additives:

a) **Metabolic regulators:** substances which act within the animal to correct undesired consequences of nutritional origin

b) **Immuno-modulators:** agents or substances which influence the immune function to the benefit of the host animal

c) **Detoxifiers:** agents or substances which degrade or otherwise reduce the toxicity of contaminants ingested with feedstuffs [1]

d) **Other welfare additives**

[1] Regulation 386/2009 allocates the **substances for reduction of the contamination of feed by mycotoxins** a new **functional group (m)** of the category **"technological additives"**

Regulation 1831/2003

Long-term proposal: revision of Annex I

Categories of additives:

1. Technological additives
2. Nutritional additives
3. Zootechnical additives
4. Welfare additives
5. Product quality additives

Regulation 1831/2003

Long-term proposal: revision of Annex I

Functional groups :

Technological additives:

- **(a) to (l) becomes (a) to (k),**
- **(h) deleted** (radionucleide contamination controllers)
- **(m) deleted** (detoxifiers)

- **introduction of two new groups:**
- **(l) colourants:** substances that add or restore colour to feedingstuffs
- **(m) flavouring compounds:** substances the inclusion of which in feedingstuffs increases feed smell

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Long-term proposal: revision of Annex I

Functional groups :

Welfare additives:

a) Metabolic regulators
b) Immuno modulators
c) Detoxifiers
d) Coccidiostats and histomonostats
e) Other welfare additives

Regulation 1831/2003

Long term proposal: revision of Annex I

Functional groups :

Product quality additives:

a) **Microbial contamination controllers:** additives intended to reduce the number of zoonotic pathogens in animal products

b) **Nutritional value enhancers:** additives intended to improve nutritional characteristics of the animal products

c) **Radionucleide contamination controllers:** substances that suppress absorption of radionucleides or promote their excretion

d) **Sensory additives:** additives intended to improve the sensory charasteristics and acceptance of animals or animal products

e) **Other product quality additives**

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