

COMMISSION RECOMMENDATION**of 14 January 2011****establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products****(Text with EEA relevance)**

(2011/25/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC ⁽¹⁾, and in particular Article 7(1) thereof,

Whereas:

- (1) The distinction between feed materials, feed additives and other products such as veterinary drugs has implications for the conditions for their placing on the market, depending on the relevant applicable legislation,
- (2) Feed business operators and national competent control authorities are frequently confronted with questions regarding the classification of products, which might jeopardise the marketing of feed throughout the European Union.

- (3) In order to avoid inconsistencies in the treatment of such products, to facilitate the work of the national competent authorities and to help the interested economic operators to act in a framework providing an appropriate level of legal certainty, non-binding guidelines for the distinction between feed materials, feed additives and other kinds of products should be established.
- (4) The measures provided for in this Recommendation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS RECOMMENDATION:

For the distinction between feed materials, feed additives and other kinds of products the guidelines provided in the Annex to this Recommendation should be taken into account.

Done at Brussels, 14 January 2011.

*For the Commission
The President*

José Manuel BARROSO

⁽¹⁾ OJ L 229, 1.9.2009, p. 1.

ANNEX

GUIDELINES FOR THE DISTINCTION BETWEEN FEED MATERIALS, FEED ADDITIVES AND OTHER PRODUCTS

These guidelines are intended to assist the national competent authorities and the feed business operators to enforce and to apply the relevant legislation.

They are based on the provisions laid down in the legislative framework governing the different kinds of products concerned, with a particular view to the definitions of these products provided therein, in order to identify indications for a distinction between the product types.

For any product, the criteria proposed for the distinction between the different kinds of products should not be applied subsequently but simultaneously in order to create a profile of each specific product, taking into account all its characteristics. None of the criteria can be used exclusively or takes precedence over another.

Analogy with other products cannot be used as a discriminatory criterion but may be helpful to review a decision already made based on the application of the established criteria. However, it can also be used to check for consistency.

1. Feed legislation**1.1. Legal texts**

The following definitions can be found in the relevant legislation:

Article 3(4) of Regulation (EC) No 178/2002 ⁽¹⁾:

'feed': any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.

Following on from this broad definition of feed, recital 3 of Regulation (EC) No 767/2009 states that 'feed may take the form of feed materials, compound feed, feed additives, premixtures or medicated feedingstuffs.'

Article 3(2) of Regulation (EC) No 767/2009:

'feed materials': 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;

'carrier': a substance used to dissolve, dilute, disperse or otherwise physically modify a feed additive in order to facilitate its handling, application or use without altering its technological function and without exerting any technological effect itself;

'feed intended for particular nutritional purposes': feed which can satisfy a particular nutritional purpose by virtue of its particular composition or method of manufacture, which clearly distinguishes it from ordinary feed. Feed intended for particular nutritional purposes does not include medicated feedingstuffs within the meaning of Directive 90/167/EEC;

'oral feeding of animals': the introduction of feed into an animal's gastrointestinal tract through the mouth with the aim of meeting the animal's nutritional needs and/or maintaining the productivity of normally healthy animals.

Article 2(2)(a) of Regulation (EC) No 1831/2003 ⁽²⁾:

'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 enumerated in Article 5(3) of the Regulation:

- (a) favourably affect the characteristics of feed;
- (b) favourably affect the characteristics of animal products;

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ OJ L 268, 18.10.2003, p. 29.

- (c) favourably affect the colour of ornamental fish and birds;
- (d) satisfy the nutritional needs of animals;
- (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; or
- (g) have a coccidiostatic or histomonostatic effect.

Article 2(2)(h) of Regulation (EC) No 1831/2003:

'processing aids': any substance not consumed as a feedingstuff by itself, intentionally used in the processing of feedingstuffs or feed materials to fulfil a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not have an adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed.

Moreover, recital 11 of Regulation (EC) No 767/2009 reads as follows: '(...). Feed materials are primarily used to meet animals' needs, for example for energy, nutrients, minerals or dietary fibres. They are usually not chemically well-defined except for basic nutritional constituents. Effects which can be justified by scientific assessment and which are exclusive to feed additives or veterinary drugs should be excluded from the objective uses of feed materials. (...)'

1.2. Consequences for the distinction between feed materials and feed additives

1.2.1. Derivation from the legal texts

- 'Feed additives are substances (...) other than feed material': A product cannot be a feed material and a feed additive at the same time,
- 'Animals' nutritional needs': It is not possible to indicate an exhaustive list of relevant elements but the following characteristics of feed materials can be considered to be the most important:
 - (a) to supply energy, nutrients, minerals or dietary fibre; and
 - (b) to maintain the function of the intestinal tract,
- 'Principal purpose is to meet animals' nutritional needs' and 'primarily used to meet animals' needs': Apart from the usual primary function of delivering nutrients to the animal, feed materials can have other purposes, for example if they are used as carriers or if they are not digestible in the animals' intestinal tract. This is in line with the aims of 'oral feeding' ('meeting the animal's nutritional needs and/or maintaining the productivity of normally healthy animals') which corresponds to the primary intended use according to the 'feed' definition.

1.2.2. Criteria to be simultaneously considered in a case-by-case evaluation

- Production and processing method — chemical definition and level of standardisation or purification: 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 (e.g. fatty acids or calcium carbonate). Chemically well-defined substances that are purified and give a certain level of standardisation guaranteed by the manufacturer might qualify as feed additives (e.g. aromatic oil specifically extracted from plant material). Nonetheless, certain feed materials are chemically well-defined substances and standardised (e.g. sucrose). On the other hand, natural products of whole plants and parts of these or products thereof resulting from a limited physical processing such as crushing, grinding or drying would be feed materials.
- 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 over-dosage. Feed additives are usually used at low incorporation rates. However, many feed materials, such as mineral salts, are also used at low incorporation rates in the feed ration.
- 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.

2. Biocidal products

2.1. Legal texts

The following definitions can be found in the relevant legislation:

Article 2(1) of Directive 98/8/EC ⁽¹⁾:

'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;

'active substance': a substance or micro-organism including a virus or a fungus having general or specific action on or against harmful organisms;

'harmful organism': any organism which has an unwanted presence or a detrimental effect for humans, their activities or the products they use or produce, or for animals or for the environment.

Point 1(a) of Annex I to Regulation (EC) No 1831/2003:

'preservatives': substances or, when applicable, micro-organisms which protect feed against deterioration caused by micro-organisms or their metabolites.

Article 1(2) of Directive 98/8/EC provides for the following:

'This Directive shall apply to biocidal products as defined in Article 2(1)(a) but shall exclude products that are defined or within the scope of the following instruments for the purposes of these Directives:

(...)

(o) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs, Council Directive 82/471/EEC of 30 June 1982 on certain products used in animal nutrition and Council Directive 77/101/EEC of 23 November 1976 on the marketing of straight feedingstuffs,

(...).'

Annex V to Directive 98/8/EC contains an exhaustive list of 23 product types with an indicative set of descriptions within each type, including the following feed related product types:

Product-type 3: Veterinary hygiene biocidal products: Products in this group are biocidal products used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported.

Product-type 4: Food and feed area disinfectants: Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food, feed or drink (including drinking water) for humans and animals.

Product-type 5: Drinking water disinfectants: Products used for the disinfection of drinking water (for both humans and animals).

Product-type 20: Preservatives for food or feedstocks: Products used for the preservation of food or feedstocks by the control of harmful organisms.

2.2. Consequences for the distinction between feed and biocidal products

By virtue of Article 1(2) of Directive 98/8/EC, 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).

Products in products types 3 and 4, as set out in Annex V to Directive 98/8/EC, are not considered to be feed.

However, certain products could qualify for product types 5 or 20 and also be considered as feed, usually feed additives. Due to the above mentioned precedence of feed legislation over biocidal product legislation, such products are to be considered feed. Products to preserve feed or water for animals are not biocidal products. If such products are listed in product type 5 or 20, they are not intended to be administered to animals.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

3. **Veterinary medicinal products (VMPs)**

3.1. *Legal texts*

The following definitions can be found in the relevant legislation:

Article 1 of Directive 2001/82/EC ⁽¹⁾:

'veterinary medicinal product':

- (a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or
- (b) 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;

'medicated feedingstuffs': any mixture of a veterinary medicinal product or products and feed or feeds which is ready prepared for marketing and intended to be fed to animals without further processing, because of its curative or preventive properties or other properties as a medicinal product covered by the definition '*veterinary medicinal product*'.

Article 2(2) of Directive 2001/82/EC provides for the following:

'In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'veterinary medicinal product' and within the definition of a product covered by other Community legislation, the provisions of this Directive shall apply.'

Article 3(1) of the same Directive provides for the following:

'This Directive shall not apply to:

- (a) medicated feedingstuffs as defined in Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community;
- (...)
- (d) any additives covered by Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs, where they are incorporated in animal feedingstuffs and supplementary animal feedingstuffs in accordance with that Directive;
- (...)'.

Article 13(3) of Regulation (EC) No 767/2009 reads as follows:

'The labelling or the presentation of feed materials and compound feed shall not claim that:

- (a) it will prevent, treat or cure a disease, except for coccidiostats and histomonostats as authorised under Regulation (EC) No 1831/2003; this point shall not, however, apply to claims concerning nutritional imbalances provided that there is no pathological symptom associated therewith;
- (...)'.

3.2. *Consequences for the distinction between feed and VMPs*

- If, after consideration of all the characteristics of an unclassified product, the conclusion is that it might be a VMP, it should be considered a VMP (precedence of the VMPs legislation over feed legislation, except for authorised feed additives).
- Medicated feedingstuffs are not VMPs but, according to recital 3 of Regulation (EC) No 767/2009, a form of feed containing medicated pre-mixes and being subject to a prescription by a veterinarian.
- Based on the definition of 'particular nutritional purpose' (see under point 1.1 above), the borderline between feed and veterinary medicinal products is set. The particular nutritional purposes such as 'support of liver function in the case of chronic liver insufficiency', 'reduction of urate stones formation' or 'reduction of the risk of milk fever' can be achieved by feed.

⁽¹⁾ OJ L 311, 28.11.2001, p. 1.