ANNEX

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

1. FEED LEGISLATION

1.1 LEGAL DEFINITIONS

Regulation (EC) No 767/2009 foresees (cfr Article 3(1)(g)) that `feed materials' are primarily meant to meet animals' nutritional needs.

Under certain conditions feed materials can be considered as `feed intended for particular nutritional purposes'. In this case the feed material meets specific nutritional needs of animals whose process of assimilation, absorption or metabolism is, or could be, temporarily or irreversibly impaired. Based on this definition of `particular nutritional purpose' the borderline between feed including feed materials and veterinary medicinal products is set.

According to Regulation (EC) No No 1831/2003, 'feed additives' are substances, micro-organisms or preparations other than feed material and premixtures, which are intentionally added to feed or water in order to perform one or more specific functions. Thus a product cannot be a feed material and a feed additive in the same moment.

Additionally, Regulation (EC) No 1831/2003 defines `processing aids' as 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.

1.2 IMPLICATIONS FOR BORDERLINE BETWEEN FEED MATERIAL AND FEED ADDITIVE

The following criteria are to be simultaneously considered in a case-by-case evaluation:

– Safety: If for reasons of animal or human health a maximum content of the product in the feed exists the products qualifies rather for a classification as additive. This is without prejudice to the general requirement that feed materials have to be sound, genuine and of merchantable quality.

– Production and processing method: Products of vegetable or animal origin in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances can be considered as feed materials.

– Functionality: The additive functions as laid down in Article 5(3) of Regulation (EC) No 1831/2003 are not exclusive for feed additives. Thus, a feed material can exert as well an additive function.

– Chemical definition and level of standardisation: Chemically well-defined substances that are purified and where a certain level of standardisation can be guaranteed by the manufacturer might qualify as feed additives except common substances like sucrose. On the other hand, natural products of whole plants and parts of these or products thereof

resulting from very limited processing such as crushing, grinding or drying would be feed materials.

– Mode of use – maximum incorporation rate: Feed additives are usually administered with low quantities into the feed ration. Some of them have maximum contents and/or recommended incorporation rates. Nonetheless, the mode of use of many feed materials such as mineral salts provides as well for low incorporation rates into the feed ration and thus the inclusion rate can only be considered as an indicative but not an exclusive criteria.

– Analogy: in the sense of consistency, the decision on similar products should be taken into account.

In conclusion, the criteria show a certain precedence of feed materials over feed additives due to the broad definition of feed materials.

2. BIOCIDES

2.1 LEGAL DEFINITIONS

Article 2 of Directive 98/8/EC defines biocidal products as 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.

An exhaustive list of 23 product types with an indicative set of descriptions within each type is given in Annex V of the Directive.

The following is also laid down in Article 2 of the Directive:

"(d) Active substance: A substance or micro-organism including a virus or a fungus having general or specific action on or against harmful organisms."

"(f) 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."

Article 1(2) of the Directive provides in particular 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 (8), Council Directive 82/471/EEC of 30 June 1982 on certain products used in animal nutrition (9) and Council Directive 77/101/EEC of 23 November 1976 on the marketing of straight feedingstuffs".

Annex V (only feed related PTs) of the Directive includes in particular the following:

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 IMPLICATIONS FOR BORDERLINE BETWEEN FEED AND BIOCIDES

Products that are under the scope of the feed legislation including processing aids are no biocides (Precedence of feed over biocides).

3. VETERINARY MEDICINAL PRODUCTS (VMPS)

3.1 LEGAL DEFINITIONS

Article 1 of Directive 2001/82/EC as amended by Directive 2004/28/EC provides notably for the following definitions:

"2. 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;

(…)

6. 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 point 2."

Article 2 of the same Directive provides in particular for the following:

"2. 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 of the same Directive provides in particular for the following:

"1. 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 (1);

(…)

(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."

3.2 IMPLICATIONS FOR BORDERLINE BETWEEN FEED AND VMPS

– If the consideration of all the characteristics of a not yet classified product results in the possibility that it might be a VMP, it is a VMP (precedence of the VMP over feed except for already authorised feed additives).

– Medicated feed is no VMP.