Is the product specified in Annex III, Chapter 1 of Reg. (EC) no. 767/2009 (List of prohibited materials)?

No

Is the product specified in GMP+ BA3: Minimum Requirements for the Negative List? (GMP+)

No

!! THE PRODUCT IS PERMITTED IN PRINCIPLE AS FEED / IN FEEDINGSTUFF !!!

Does the product comply with the following definition in Reg. (EC) no. 767/2009 Article 3 g? *

"Product 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 a carrier in premixes."

No / Don't know

Is the product similar to one of the products in the appendix to Reg. (EU) no. 892/2010 ("grey listed" products of both additives and other products formerly not recognized as feed materials before the implementation of this regulation)? For the answer to this question use:

- The text of consideration 4 of Reg. (EU) no. 892/2010
- Recommendation 2011/25/EU of 14 January 2011 establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products

For the benefit of coherence, products with comparable characteristics must be categorized by analogy. For products for which there were doubts whether they were feed additives, an examination has been carried out taking into account these criteria. *

The product is a feed material

The product is very probably not a feed material.

Go through the FEED and PRODUCTS IN FEEDS decision trees to determine the nature of the product.

!! THE PRODUCT IS A FEED MATERIAL !!!

The feed material may be put on the market on the following conditions:

- The norms for undesirable substances according to Dir. 2002/32/EC and according to GMP+BA1 Specific feed safety limits are not exceeded (if exceeded then in a number of cases detoxification / decontamination is possible (Reg. (EC) no. 767/2009 art. 20, Dir. 2002/32/EC art. 8))
- The norms for residues of crop protection agents according to Reg. (EC) no. 396/2005 are not exceeded.
- If a claim is attached to the feed material then this must comply with the requirements as stated in Reg. (EC) no. 767/2009, Article 13

* In the event of doubt at GMP+ International or in the Technical Committee FSP about the status or purpose of a product, the company will have to obtain an official permit as a feed material in Brussels (EC). GMP+ can handle the risk assessment on the basis of the official permit.
Does the product comply with the following definition in Reg. (EC) no. 767/2009 Article 3 h?

"Mixture of at least 2 feed materials, whether or not containing feed additives, intended for oral animal-feeding, as complete or complementary feed;"

NOTE
If in a mixture of 2 feed materials the level on one feed material is a maximum of 3% and this feed material serves to bind the other feed material and/or to denaturise it, then the mix is still considered to be a feed material (Reg. (EC) no. 767/2009, Appendix I sub 4)

Does the product comply with the following definition in Reg. (EC) no. 1831/2003 Article 2 a?

"Substances, micro-organisms and preparations which are not feed materials or premixes and which are added deliberately to animal feed or water with the intention of achieving one or more of the following functions"

The product favourably influences:
- The characteristics of the feed,
- The characteristics of animal products,
- The environmental consequences of animal production,
- The animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs, or
- Does the substance or the product satisfy the nutritional needs of animals?
- Does the substance or product have a coccidiostatic or histomonostatic effect?

Does the product comply with the following definition in Reg. (EC) no. 1831/2003 Article 2 e?

"Mix of feed additives or mixes of one or more feed additives using a carrier of feed materials or water which are not intended for direct feeding to animals"

The product is a premixture

The product is very probably not a feed.
Go through the PRODUCTS IN FEEDS decision tree to determine the nature of the product.

The feed may be put on the market on the following conditions:
- The norms for undesirable substances according to Dir. 2002/32/EC and according to GMP+ BA1 Specific feed safety limits are not exceeded (if exceeded then in a number of cases detoxification / decontamination is possible (Reg. (EC) no. 767/2009 art. 20, Dir. 2002/32/EC art. 8))
- The norms for residues of crop protection agents according to Reg. (EC) no. 396/2005 are not exceeded.
- If a claim is attached to the compound feed then this must comply with the requirements as stated in Reg. (EC) no. 767/2009, Article 13.
Does the product comply with the following definition in Reg. (EC) no. 1831/2003 Article 2 h?

"substances which are themselves not consumed as animal feed but which are deliberately used in the processing of animal feeds or feed materials in order to meet a particular technical objective"

Yes

The product is a processing aid

NB: the unintentional but technically unavoidable presence of residues of these substances or their derivatives in the end product may have no detrimental effects on animal health, human health or the environment and no technological effect at all on the end product.

The product is a medicated feedingstuff

!! IMPORTANT!!

The marketing and use of medicated feedingstuffs is strictly regulated

Visit the website of the Dutch Medicines Evaluation Board for more information (http://www.cbg-meb.nl/dieren)

The product is a processing aid

Yes

The product is a medicated feedingstuff

!! IMPORTANT!!

The marketing and use of medicated feedingstuffs is strictly regulated

Visit the website of the Dutch Medicines Evaluation Board for more information (http://www.cbg-meb.nl/dieren)

Does the product comply with the following definition in the Veterinary Medicinal Products Act, Article 1?

Substance, or mixture of substances, of human, animal, vegetable or chemical origin, including animals, plants, parts of animals or plants as well as micro-organisms and viruses which are intended whether or not after treatment or processing to be used for - the healing, slimming or prevention of any condition, sign of disease, pain, injury or invalidity in an animal; - the healing, improvement or change to the functions of the organs of the animal; - the detection of a disease or invalidity in animals through use on an animal?

No

The product is a medicated feedingstuff

!! IMPORTANT!!

The marketing and use of medicated feedingstuffs is strictly regulated

Visit the website of the Dutch Medicines Evaluation Board for more information (http://www.cbg-meb.nl/dieren)

Does the product comply with the following definition in Dir. 98/8/EC Article 2.1.a?

*Active substances (chemical elements and their compounds, and micro-organisms) and preparations (mixes or solutions which consist of two or more substances) put up in the form in which they are supplied to the user, contain one or more active substances and are intended to destroy, render harmless, prevent the action of or otherwise to exert a controlling effect on any harmful organism by chemical or biological means

No

!! THE PRODUCT IS VERY PROBABLY NOT PERMITTED FOR USE IN FEEDINGSTUFF!!!

END

DISCLAIMER

These decision trees have been created with the greatest possible care. The decision trees contain references to various relevant elements of the legislation and regulations. Anyone who markets feeds and/or products for processing in feeds is subject to all the applicable legislation and regulations. The user may derive no rights from these decision trees. GMP+ International BV is not liable for any claim or loss of income as a result of the use of these decision trees.