

Pastures new

Changing authorisation for feed additive minerals

New EC regulations on feed additive safety will impact mineral suppliers in this market. Dr Roger Doome, scientific officer of IMA-Europe, explains the issues and how producers have been proactive in this legislative overhaul.



The animal nutrition market represents an annual tonnage of more than 3m. tonnes in Europe. However, access to this market is highly regulated and every candidate mineral must be demonstrably safe for human and animal health, and for the environment.

Apart from the minerals known as feed materials (eg. calcium carbonate and dolomite), there are those authorised as feed additives, ie. a substance that favourably affects the characteristics of feed materials or of compound feeding stuffs.

Today, most mineral feed additives act either as binders or as acidity regulators. Their use is regulated through the old feed additives Council Directive 70/524/EEC¹ which stipulates the type of authorisation granted to these minerals.

Recasting a 32 year old directive

With a view to bringing coherence to European Community legislation in a farm-to-table approach, the Commission announced in its white paper on food safety² that it would propose legislation to

consolidate existing rules on additives in feeding stuffs. It also aimed to clarify certain procedural aspects related to dossier evaluation and the types of authorisation granted to feed additives.

So far, the basic legislation on feed additives has undergone five major amendments and numerous modifications of its annexes. The Directive has never been consolidated and the current legislation is rather complex. The existence of different types of authorisation (provisional for ten years or with no time limit, linked to the applicant company or not) complicates the implementation of EU rules on this matter.

In certain cases, member states may derogate from the common provisions (eg. additive levels in complementary feedstuffs, incorporation rates for additives, and premixtures in feedstuffs).

Consequently, different interpretations are possible, and enforcement of certain decisions adopted at EU level becomes ineffective. The whole procedure is time consuming and confusing for the applicant companies, which sometimes receive similar

questions from different regulatory bodies. This heightened the need for a new, more appropriate legislative instrument and in March 2002 the Commission released a proposal³ for a new regulation that will replace the old Directive 70/524/EEC.

A new regulation for additives

In light of these shortcomings, the general objective of the proposed regulation is to overhaul the entire regulatory process. The regulation will deal with additives in feeding stuffs, premixtures and drinking water, as well as the use of additives in silage.

Only additives that are safe for humans, animals and the environment, and do not mislead the user or impair the distinctive features of animal products, will be authorised. Only processing aids, i.e. products used during the feed production process to achieve a certain technological objective, will fall outside the scope of this regulation. Specifically, the regulation addresses the following elements:

- The borderline between veterinary medicinal products and feed additives is clarified. Thus, the use of antibiotics for growth promotion will be phased out by 2006.
- The use of coccidiostats (i.e. antibiotics for preventing illnesses in poultry) will still be treated as additives rather than medicinal products.
- The procedures for authorising additives will be amended and authorisation will be granted for a ten year period. Companies will have to apply for re-evaluation and re-authorisation of existing additives within four years of the regulation's entry into force.
- Responsibility for evaluation and authorisation will be transferred to the European Food Safety Authority (EFSA). The advantages are that EFSA will have the competency and responsibility to provide a single framework for dossier evaluation for all feed additives, which should bring better clarity, efficiency and transparency to the process.
- Labelling requirements including advice on whether additives are to be used in feed or in drinking water will be detailed.
- The list of authorised additives will be divided into a restricted number of broad additive categories: technological additives (eg. preservatives); sensory additives (eg. flavours and colorants); nutritional additives (eg. vitamins); zootechnical additives (eg. gut flora improvers and non-microbial growth promoters); and coccidiostats. Each category is further divided into functional groups.

Implications for mineral producers

If one has to identify a key change in the newly proposed regulation it would certainly be the requirement for a new mandatory authorisation for all feed additives; even for those products such as industrial minerals that have been in use for many years.

Grandfather's rights will no longer be granted to industrial minerals producers and an application dossier will have to be submitted to the EFSA for evaluation and approval. This dossier will have to be prepared according to guidelines, which have yet to be developed by EFSA on the basis of the recently revised guidelines (Directive 2001/79/EC⁴). In addition, renewal of the authorisation will have to be sought every ten years.

The resulting administrative burden for the industrial minerals sector would obviously depend on the content of these guidelines. Therefore in a proactive approach, the feed additives manufacturers represented by FEFANA⁵ and IMA-Europe decided to work on a proposal for such guidelines. Industry favours a tiered-approach adapted to the various categories of additives, as well as the possibility of limiting studies to major species.

It is considered very important to ensure that feed additive safety be thoroughly evaluated for all feed additives, and that identity



(specifically specifications and control) be a major part of the dossier. In contrast, efficacy should not be a cornerstone of product evaluation.

Should the industry's views be accepted by EFSA, a simplified procedure will be granted for those mineral additives authorised as technological additives; which are simple and natural products.

In the meantime, IMA-Europe's members have taken the opportunity to request the replacement of the current 'binders' group by two more precise and targeted groups, i.e. pelletising aids⁶ and mycotoxin adsorbents⁷, to follow the feedstuff industry's technology development and requirements. Indeed, as technology and feed composition have evolved, a single binder is no longer required by the market.

The final adoption of this legislative proposal is expected by mid-2003 and whatever the outcome, this new regulation will have additional cost implications for those industrial minerals producers active in the feed additives market. **im**

- 1 Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding stuffs.
- 2 Commission white paper on food safety of 12 January 2000 - COM(1999)719 final.
- 3 Proposal of 22 March 2003 for regulation of the European Parliament and of the Council on additives for use in animal nutrition - COM(2002)153 final.
- 4 Commission Directive 2001/79/EC of 17 September 2001 amending Council Directive 87/153/EEC fixing guidelines for the assessment of additives in animal nutrition.
- 5 European Federation of the Animal Feed Additive Manufacturers.
- 6 Substances commonly added before the pelletising process to improve feed particle cohesion giving harder pellets and/or to increase pellet mill performances as the result of lower energy demand and reduced die wear.
- 7 Substances that strongly bind mycotoxins. When added to mycotoxin-contaminated feeding stuffs they adsorb the offending mycotoxin, which then passes through the gut and is excreted as a mycotoxin/sorbent complex.



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