

# European feed additives

## Time to take notice

New EU regulations on feed additives have been approved and, explains *Dr Roger Doome* of IMA-Europe, industrial minerals suppliers must prepare for change.

AS INDICATED in earlier announcements (see *IM June '03*, p. 72), new legislation on additives for use in animal nutrition has been developed by the European Commission (EC), and was adopted by the European Parliament and Council on 22 September 2003.

This Regulation (EC) 1831/2003<sup>1</sup> aims at establishing a Community procedure for authorising the placement on the market and use of feed additives. More so, it lays down rules for the supervision and labelling of feed additives and premixtures.

The impetus for this initiative was the need to provide the basis for the assurance of a high level of protection for human health, animal health and welfare, environment, and users' and consumers' interests in relation to feed additives, while ensuring the effective functioning of the internal market.

As already mentioned, the Regulation covers all feed additives and premixtures, but does not apply to processing aids, i.e. products not consumed as feeding stuffs alone but intentionally used in the processing of feeding stuffs or feed materials to fulfil a technological purpose during treatment or processing.

With this Regulation, the grandfather's rights will no longer be granted and all the industrial minerals used as feed additive (i.e. category L – binders, anti-caking agents and coagulants, and category M – acidity regulators. See *Table 1*) will have to undergo a risk assessment to demonstrate their safety and efficacy in the feedstuffs. Those who fail in this exercise will simply be banned from the EU market (i.e. 25 Members States) as of 7 November 2004.

### Regulation requirements

The new overhauled regulatory procedure states that no person shall place on the market, process or use a feed additive unless it is covered by an authorisation granted in accordance with this Regulation and the conditions on labelling are met.

The authorisation, including the conditions and/or restrictions for use, will be granted by the EC after consultation with the European Food Safety Authority (EFSA), to be located in Parma, Italy. For all existing feed additives, like industrial minerals, a four-step approach has been developed to obtain the mandatory authorisation: notification, registration, re-evaluation, and authorisation.

● A notification dossier should be submitted to the EC and the EFSA by 7 November 2004. This consists of an administrative dossier for the EC and a technical dossier for the EFSA. The technical dossier should contain the following:

- a. name and address of applicant
- b. identification of the feed additive, proposal for its category (eg. technological, nutritional, etc.) and functional group (eg. acidity regulators, anti-caking agent, etc.), and its specifications including purity criteria, where applicable
- c. method of production, intended uses, method of analysis of the feed additive in feed and, if appropriate, residues in food

The notification form for the EC can be downloaded from its website ([www.europa.eu.int/comm/food/food/animalnutrition/feedadditives](http://www.europa.eu.int/comm/food/food/animalnutrition/feedadditives)) and from the EFSA website ([www.efsa.eu.int/notifications](http://www.efsa.eu.int/notifications)).

● For the purposes of registration, the following particulars (in addition to those mentioned above) should be sent to the EFSA by 7 November 2010 at the latest:

- d. the studies demonstrating the products' safety and efficiency
- e. the proposed conditions for use (animal species, levels, etc.)
- f. a written statement that three samples of the feed additive have been sent to the Community Joint Research Centre (JRC)
- g. a summary of the information provided under points (a) to (f)

● Before 2010, the EFSA will re-evaluate all the additives. Within six months of receipt of a valid dossier, the EFSA will give its opinion describing the feed additive assessment and, in particular, the benefits for animal health and welfare on the one hand and for the consumer of animal products on the other.

● Within three months of receipt of EFSA's opinion, the EC will prepare a draft regulation to grant authorisation or to deny it. The authorisation granted will be valid for ten years and shall be renewable. The authorised feed additive will be entered in the Community Register for Feed Additives accessible to the public.

To cope with the authorisation process, IMA-Europe's members have decided to make a joint notification for all the minerals they represent. More so, the feed additives industry represented by five European associations (European Federation of the Animal Feed Additive Manufacturers, FEFANA; European

Feed Manufacturers Association, FEFAC; European Pet Food Industry Federation, FEDIAF; International Association of the European Manufacturers of Major, Trace and Specific Feed Mineral Materials, EMFEMA; and IMA-Europe) decided to set up a common database to facilitate the notification and registration procedures.

The creation of this database started in May 2004 and it is fed through a notification website. Any interested party can consult this website to see the status of a feed additive in the notification procedure.

Although the authorisation

procedure may be seen as another administrative burden for industry it will be insignificant compared to the new requirements on labelling and packaging. Indeed, from 18 October 2004 any additive or premixture of additives put on the market shall be labelled under the responsibility of a producer, packer, importer, seller or distributor established within the Community.

The feed additive should bear a detailed set of information in a conspicuous, clearly legible and indelible manner in at least the national language or languages of the Member State in which it is marketed. More so, additives and premixtures will be marketed only in closed packages or containers which must be closed in such a way that the fastener is damaged on opening and cannot be reused.

In terms of costs, the new labelling and packaging provisions will seriously impact the industrial minerals sector, which sells most of its products in bulk. It is foreseen that the necessary adaptation of industrial minerals companies for complying with this new Regulation will discourage some small producers who will probably withdraw their products from this market.


### What comes next?

For those who believe that the EU legislation decided in Brussels by the Member States creates an unaffordable burden, it may be useful to mention that customers' initiatives may be much more stringent.

To overcome the problem raised by the profusion of national quality schemes obeying the various criteria, FEFANA has introduced a new quality system called FAMI/QS<sup>2</sup>. This voluntary initiative, supported by the animal nutrition business, has been developed to substitute all the existing national systems (eg. PDV, OVOCOM, UKASTA, etc.) with a harmonised European one.

FAMI/QS certification requires feed operators to be successfully audited by an accredited body. This audit consists of an evaluation of the implementation of a Code of Practices based on a HACCP<sup>3</sup> methodology. The entry into force of the FAMI/QS has been set for 1 July 2004 and companies wishing to be certified should contact a certification body duly accredited to deliver the FAMI/QS certification<sup>4</sup>.

Last but not least, an EC proposal for a new regulation on the authorisation of food additives is expected by autumn 2004. The provisions of this new piece of legislation would be very similar to those adopted for the feed additives, and industrial minerals producers will be required to reapply for an authorisation for the same minerals for use as a food additive.

It seems to be an endless story where the new EU Chemical Policy (REACH), to be discussed in the coming months by the European Parliament, will write another chapter. 

**Table 1. Industrial minerals currently authorised as feed additives according to Annex I of Directive 70/524/EEC as amended**

L: Binders, anti-caking agents and coagulants	
EC No.	Additive
E516	Calcium sulphate, dihydrate
E551a	Silicic acid, precipitated and dried
E551c	Kieselgur (diatomaceous earth, purified)
E562	Sepiolite
E558	Bentonite/montmorillonite
E559	Kaolinitic clays, free of asbestos
E560	Natural mixtures of steatite and chlorite
E561	Vermiculite
E563	Sepiolitic clay
E565	Lignosulphonates
E599	Perlite
M: Acidity regulators	
EC No.	Additive
E170	Calcium carbonate
E500(i)	Sodium carbonate
E526	Calcium hydroxide
E529	Calcium oxide

### Notes

1. Official Journal, L 268, 18.10.2003, p. 29
2. FAMI/QS: Feed Additives and Premixtures / Quality System
3. Hazard Analytical Control of Critical Points
4. The list of the certification bodies accredited to deliver the FAMI/QS certification is available on FEFANA's website ([www.fefana.org](http://www.fefana.org))



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