



REGULATION (EC) No. 1831/2003: STATUS OF THE EUROPEAN COMMUNITY REGISTER OF FEED ADDITIVES

ISSUE

Feed additives are authorised for use, processing and or sale in the European Union only if they have complied with, and have been approved under, the procedures specified in Regulation (EC) No. 1831/2003¹. The said procedures specified in the Articles of that Regulation make a number of references to 'Entry in the Community Register of Feed Additives'. This is also repeated in some of the preambles (where-ases) providing some background to the Regulation. The status of the Community Register is not defined in the Regulation but is clearly very important. It is therefore appropriate to explore the provisions in the articles and other texts in Regulation 1831/2003 in order to understand and perhaps lend a specific status to the Register in terms of feed additives listed within it. The following preambles and articles (in the background) are therefore being highlighted for their presumed relevance in elucidating this issue.

The preliminary remarks of the Register of feed additives mention that: 'The Register has only informative purposes and does not replace Community legal acts. The Community legal acts concerning the authorisation of each additive entered in the Register constitute the legal basis for the placing on the market and use of the additives concerned.'

This leads to the potential understanding that the register would not be sensu stricto a positive list of feed additives. The legal analysis below shows that. The Register legally has the value of a proof of legal compliance and as such is to be seen practically equivalent to a positive list.

AUTHORISATIONS UNDER REGULATION (EC) No 1831/2003

Article 1 of Regulation 1831/2003 stipulates that the purpose of Regulation (EC) No 1831/2003 is to provide for a Community procedure for authorising the handling and marketing and use of feed additives and to lay down rules for the post-authorisation monitoring and labelling of feed additives and their premixtures. Article 3 stipulates that no person is authorised to 'place on the market, process or use feed additives unless it is covered by an authorisation granted in accordance with this Regulation'. Article 17 provides that the Commission establishes and keeps up to date a Community Register of Feed Additives.

¹ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition.

CONDITIONS OF AUTHORISATION UNDER REGULATION (EC) No.1831/2003

Article 7 then goes on to specify in greater detail how applications should be made while Articles 8 and 9 provide for the assessment of applications and authorisation processes respectively. The authorisations of the additives in line with this Regulation are valid for 10 years unless otherwise specified. (See products which may fall within the provisions of Article 15 – Urgent Authorisations and those defined below). For ease of reference the products authorised under Article 7 of Regulation (EC) No 1831/2003 will subsequently be referred to as ‘products 1’. A sub-group (products 1b) of this category of products will be those subject to Article 14.4 of Regulation 1831/2003. The other sub-group (products 1c) refer to products (antibiotic growth promoters) now phased out

AUTHORISATION OF PRODUCTS NOW SUBSUMED UNDER REGULATION 1831/2003

As certain products:

- amino acids, salt of an amino acid or analogous substances listed in points 2.1, 3 and 4 of the Annex to Directive 82/471/EEC² (referred to subsequently as ‘**products 2**’) (Article 10.1) and or;
- authorised for use as feed additives (referred to subsequently as ‘**products 3a**’) and or for which a re-application has already been submitted under Article 4 of Directive 70/524/EEC³ and initial comments provided in line with Article 4.4 of Directive 70/524/EEC has been submitted to the Commission (referred to subsequently as ‘**products 3b**’) (Articles 10.1 and 25.1 respectively) and or;
- substances, micro-organisms and preparations used in the Community as silage additives before 18 October 2004 (referred to subsequently as ‘**products 4**’) (Article 10.7),

were used in the Community prior to the emergence of Regulation (EC) No 1831/2003, specific provisions applicable to these products were mandated in order for their authorisation to continue thus avoiding disruption to the use of feed additives in the Community. The requirements are:

- provisions in 70/524/EEC apart from certain labelling provisions, and points 2.1, 3 and 4 in Annex to Directive 82/471/EEC are repealed (Article 23) by Regulation (EC) No 1831/2003. It should however be noted that Article 25 of Regulation (EC) No 1831/2003 still gives effect up to a certain undefined time to Article 4 of Directive 70/524/EEC which allows for certain products (Products 3b described above) to continue to be treated in accordance with that Article 4.
- The authorisation of the products described and referred to as Products 2 and 3a is only given effect if:
 - i. The person(s) first placing the product on the market notifies the Commission and the Authority as provided for in Article 10.1(a) by 7 November 2004; and
 - ii. By 7 November 2005, the Authority after verification that all the necessary information has been submitted will notify the Commission who will in turn enter the products concerned in the Register provided for by the Regulation. Note in particular that preamble 23 foresees an evaluation after notification and prior to entry in the Register.

² Council Directive of 30 June 1982 concerning certain products used in animal nutrition.

³ Council Directive of 23 November 1970 concerning additives in feeding-stuffs.

STATUS OF THE EU COMMUNITY REGISTER WITH REGARDS TO THE ABOVE MENTIONED PRODUCT GROUPS

Products 1a, 1b and 1c

Article 9 provides for a Community Regulation to enact the authorisation of products 1a. And this Regulation should be the first recourse in a situation concerning burden of proof. However, the same can not be said of products subject to Article 14.4 as the only legal evidence of authorisation will be the Register. Similar statement could be made of products caught within the definition in Article 11.2 (phased out antibiotic growth promoters), products 1c, as the only legal recourse to proof of the status of the products is only the Register.

Products 2 and 3a and a new 3c

The terms which continue to provide for these products to remain authorised as per Article 3 of Regulation (EC) No. 1831/2003 are specified above – (i) notification to the Commission and (ii) entry in the Register. These are the acts that continue to enable the authorisation as per Regulation (EC) No.1831/2003 given that Directive 70/524/EEC and the relevant sections of Directive 82/471 are now repealed. Therefore the only evidence to attest to the continued authorisation of these products is the Community Register. This therefore confers on the Register a quasi-legal status in terms of authorisation of the products concerned. The products 3c are those for which a decision on their renewal has not been taken before the expiry date and which will be extended automatically (Article 10.6). The only evidence of their authorisation is the Register.

Products 3b

These are products first authorised under 70/524/EC (now repealed) but retain some elements of the provisions in 70/524/EEC (Article 4). Again the only available document which exists as evidence or proof of the products' authorisation is again the Register.

Products 4

These are products for which the Regulation (EC) No 1831/2003 clearly separates out as '...additives currently marketed and used in the Community without an authorisation pursuant to Directive 70/524/EEC' (preamble 24). Preamble 23 foresees an evaluation of these products after their notification. In fact preamble 24 also foresees '.....safeguard measures to be taken, where appropriate, for those substances that do not fulfil the authorisation criteria mentioned in Article 5 (conditions of authorisation)' of this Regulation. The terms that provide for these products to be sold legally within the Community are similar to those for products 2 and 3a and here it is the Register only that lists the products for the first time. The Register is, therefore, the only evidence of proof of authorisation of products concerned.

CONCLUSION

It can therefore be concluded that even though the Register is not the law, it appears that the only document to be submitted as evidence to prove the authorisation of most of the products used as feed additives (under Regulation (EC) No. 1831/2003) and described above is the Register. This therefore confers on the Register a de facto status of positive list of authorised additives, i.e. any additives not listed in the register is not legally on the market.