# Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (Text with EEA relevance)

## REGULATION (EC) No 1831/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 September 2003

on additives for use in animal nutrition

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37 and 152(4)(b) thereof,

Having regard to the proposal from the Commission[(1)],

Having regard to the opinion of the European Economic and Social Committee[(2)],

Following consultation of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(3)],

Whereas:

(1) Livestock production occupies a very important place in the agriculture of the Community. Satisfactory results depend to a large extent on the use of safe and good-quality feedingstuffs.

(2) The free movement of safe and wholesome food and feed is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(3) A high level of protection of human life and health should be assured in the pursuit of Community policies.

(4) In order to protect human health, animal health and the environment, feed additives should undergo a safety assessment through a Community procedure before being placed on the market, used or processed within the Community. Since pet food is not part of the human food chain and has no environmental impact on arable land, specific provisions for additives in pet food are appropriate.

(5) It is a principle of the Community food law enshrined in Article 11 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[(4)] that food and feed imported for placing on the market within the Community must comply with the relevant requirements of Community legislation or with conditions recognised by the Community to be at least equivalent thereto. It is therefore necessary to subject imports

**Changes to legislation:** *There are outstanding changes not yet made to Regulation (EC) No 1831/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

from third countries of additives for use in animal nutrition to requirements equivalent to those applying to additives produced in the Community.

(6) Action by the Community relating to human health, animal health and the environment should be based on the precautionary principle.

(7) In accordance with Article 153 of the Treaty, the Community is to contribute to promoting the right of consumers to information.

(8) Experience with the application of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs[(5)] has shown that it is necessary to review all the rules on additives in order to take into account the need to ensure a greater degree of protection of animal and human health and of the environment. It is also necessary to take into account the fact that technological progress and scientific developments have made available new types of additives, such as those to be used on silage or in water.

(9) This Regulation should also cover mixtures of additives sold to the end-user, and the marketing and use of those mixtures should comply with the conditions laid down in the authorisation of each single additive.

(10) Premixtures should not be regarded as preparations covered by the definition of additives.

(11) The basic principle in this field should be that only those additives approved under the procedure provided for in this Regulation may be placed on the market, used and processed in animal feeding under conditions set out in the authorisation.

(12) Categories of feed additives should be defined in order to facilitate the assessment procedure with a view to authorisation. Amino acids, their salts and analogues, and urea and its derivatives, which are currently covered by Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition[(6)], should be included as a category of feed additives and therefore transferred from the scope of that Directive to this Regulation.

(13) Implementing rules concerning applications for authorisation of feed additives should take into account different documentation requirements for food-producing and other animals.

(14) In order to ensure a harmonised scientific assessment of feed additives, such assessment should be carried out by the European Food Safety Authority, established by Regulation (EC) No 178/2002. Applications should be supplemented by residue studies in order to assess the establishment of Maximum Residues Limits (MRLs).

(15) The Commission should establish guidelines for the authorisation of feed additives in cooperation with the European Food Safety Authority. In establishing these guidelines, attention should be paid to the possibility of extrapolating the results of the studies carried out on major species to minor species.

(16) It is also necessary to provide for a simplified authorisation procedure for those additives which have successfully undergone the authorisation procedure for food use provided for in Council Directive 89/107/EEC of 21 December 1988 on the

***Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 1831/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption[(7)].

(17) It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account, including societal, economic or environmental factors, feasibility of controls and the benefit for the animal or for the consumer of animal products. Therefore, the authorisation of an additive should be granted by the Commission.

(18) In order to ensure the necessary level of protection for animal welfare and consumer safety, applicants should be encouraged to seek authorisation extensions for minor species by being granted one year's additional data protection in addition to the 10 years' data protection for all species for which the additive is authorised.

(19) Competence for authorising feed additives and establishing conditions for their use and for maintaining and publishing a register of authorised feed additives should be conferred on the Commission in accordance with a procedure by which close collaboration between Member States and the Commission is guaranteed in the framework of the Standing Committee on the Food Chain and Animal Health.

(20) It is necessary to introduce, where appropriate, an obligation for the holder of the authorisation to implement a post-market monitoring plan in order to trace and identify any direct or indirect, immediate, delayed, or unforeseen effect resulting from the use of feed additives on human or animal health or the environment using a product tracing framework similar to that which already exists in other sectors and in line with the traceability requirements laid down in food law.

(21) In order to allow technological progress and scientific development to be taken into account, it is necessary to revise the authorisations of feed additives regularly. Time-limited authorisations should allow this review.

(22) A register of authorised feed additives should be established, including product-specific information and detection methods. Non-confidential data should be made available to the public.

(23) It is necessary to establish transitional rules to take into account additives which are already on the market and which were authorised under Directive 70/524/EEC, and amino acids, their salts and analogues, urea and its derivatives, currently authorised under Directive 82/471/EEC, and silage agents, as well as additives for which the authorisation procedure is in progress. In particular, it is appropriate to provide that such products can remain on the market only insofar as notification with a view to their evaluation has been submitted to the Commission within one year after the entry into force of this Regulation.

(24) A number of silage additives are currently marketed and used in the Community without an authorisation granted pursuant to Directive 70/524/EEC. While it is indispensable to apply the provisions of this Regulation to such substances in view of their nature and use, it is appropriate to apply the same transitional arrangements. In this way it will be possible to obtain information on all the substances currently used and to establish

**Changes to legislation:** *There are outstanding changes not yet made to Regulation (EC) No 1831/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

a list of them, which would allow safeguard measures to be taken, where appropriate, for those substances that do not fulfil the authorisation criteria mentioned in Article 5 of this Regulation.

(25) The Scientific Steering Committee stated in its opinion of 28 May 1999 that: 'regarding the use of antimicrobials as growth promoting agents, the use of agents from classes which are or may be used in human or veterinary medicine (i.e. where there is a risk of selecting for cross-resistance to drugs used to treat bacterial infections) should be phased out as soon as possible and ultimately abolished'. The second opinion of the Scientific Steering Committee on antimicrobial resistance adopted on 10 and 11 May 2001 confirmed the need to provide a sufficient time to replace those antimicrobials by alternative products: 'Thus, the phase-out process must be planned and coordinated since precipitous actions could have repercussions for animal health'.

(26) Therefore, it is necessary to set a date after which the use of the antibiotics still authorised for use as growth promoting agents will be forbidden, while allowing sufficient time for the development of alternative products to replace those antibiotics. Provision should also be made to forbid the authorisation of any further antibiotics for use as feed additives. Within the framework of the phasing out of antibiotics used as growth promoters and in order to ensure a high level of protection of animal health, the European Food Safety Authority will be asked to review the progress achieved in the development of alternative substances and alternative methods of management, feeding, hygiene, etc., before 2005.

(27) Certain substances with coccidiostatic and histomonostatic effects should be considered as feed additives for the purposes of this Regulation.

(28) Detailed labelling of the product should be required since it enables the end-user to make a choice with full knowledge of the facts, creates fewer obstacles to trade and facilitates fairness of transactions. In this respect, it is generally appropriate for requirements applying to feed additives to mirror the ones applying to food additives. It is therefore appropriate to provide for simplified labelling requirements for flavouring compounds similar to the ones applied to food flavourings; this should however be without prejudice to the possibility to provide for specific labelling requirements in the authorisation of individual additives.

(29) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[(8)] provides for an authorisation procedure for the placing on the market of genetically modified food and feed, including feed additives consisting of, containing or produced from genetically modified organisms. Since the objectives of the said Regulation are different from those of this Regulation, feed additives should undergo an authorisation procedure in addition to the authorisation procedure provided for by that Regulation before they are placed on the market.

(30) Articles 53 and 54 of Regulation (EC) No 178/2002 establish procedures for taking emergency measures in relation to feed of Community origin or imported from a third country. They allow such measures to be adopted in situations where feed is likely to constitute a serious risk to human health, animal health or the environment and where

***Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 1831/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

such risk cannot be contained satisfactorily by measures taken by the Member State(s) concerned.

(31) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(9)].

(32) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.

(33) Directive 70/524/EEC should be repealed. However labelling provisions applicable to compound feedingstuffs incorporating additives should be maintained until a revision of Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs[(10)] is completed.

(34) Guidelines addressed to the Member States for the presentation of an application dossier are contained in Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition[(11)]. Verification of the conformity of dossiers is entrusted to the European Food Safety Authority. It is therefore necessary to repeal Directive 87/153/EEC. However, the Annex should remain in force until implementing rules are adopted.

(35) A transitional period is needed to avoid disruptions in the use of feed additives. Therefore, until the rules of this Regulation are applicable, the substances already authorised should be permitted to remain on the market and be used under the conditions of the current legislation,

HAVE ADOPTED THIS REGULATION:

## CHAPTER I

## SCOPE AND DEFINITIONS

### *Article 1*

### Scope

1 The purpose of this Regulation is to establish a Community procedure for authorising the placing on the market and use of feed additives and to lay down rules for the supervision and labelling of feed additives and premixtures in order to provide the basis for the assurance of a high level of protection of human health, animal health and welfare, environment and users' and consumers' interests in relation to feed additives, whilst ensuring the effective functioning of the internal market.

2 This Regulation shall not apply to:

a processing aids;

b veterinary medicinal products as defined in Directive 2001/82/EC[(12)], with the exception of coccidiostats and histomonostats used as feed additives.