Food safety: additive in feedingstuffs and in drinking water for animal nutrition

2002/0073(COD) - 22/09/2003 - Final act

PURPOSE : 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. LEGISLATIVE ACT : Regulation 1831/2003/EC on additives for use in animal nutrition. CONTENT : in order to protect human health, animal health and the environment, this regulation provides that feed additives must undergo a safety assessment through a Community procedure before being placed on the market, used or processed within the Community. The main points of the Regulation are as follows: - imports from third countries of additives for use in animal nutrition are subjected to requirements equivalent to those applying to additives produced in the Community; - mixtures of additives sold to the end-user are covered by this Regulation. The marketing and use of those mixtures must comply with the conditions laid down in the authorisation of each single additive; - premixtures are not regarded as preparations covered by the definition of additives; - the basic principle is 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; - categories of feed additives are 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 are included as a category of feed additives and therefore transferred from the scope of that Directive to this Regulation; - a harmonised scientific assessment of feed additives will be carried out by the European Food Safety Authority. Applications will be supplemented by residue studies in order to assess the establishment of Maximum Residues Limits (MRLs); - the Commission will establish guidelines for the authorisation of feed additives in cooperation with the European Food Safety Authority, paying attention to the possibility of extrapolating the results of the studies carried out on major species to minor species; - there is 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; - the authorisation of an additive will be granted by the Commission; - applicants are 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; - there is an obligation for the holder of the authorisation to implement a post-market monitoring plan in order to trace and identify any unforeseen effect resulting from the use of feed additives on human or animal health or the environment; - a register of authorised feed additives will be established, including product-specific information and detection methods. Non-confidential data will be made available to the public. - there are 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. Such products may 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 the Regulation; - there are transitional provisions for silage additives which are currently marketed and used in the Community without an authorisation granted pursuant to Directive 70/524/EEC; - with a view to a decision on the phasing out of the use of coccidiostats and histomonostats as feed additives by 31 December 2012, the Commission will submit to the European Parliament and the Council before 1 January 2008 a report on the use of these substances as feed additives and available alternatives; - antibiotics, other than coccidiostats and histomonostats, may be marketed and used as feed additives only until 31 December 2005; as from 1 January 2006, those substances will be deleted from the Register; - there are provisions on labeling of the product and for simplified labelling requirements for flavouring compounds; - Directive 70/524/EEC is repealed. However labelling provisions applicable to compound feedingstuffs incorporating additives are maintained until a revision of Council Directive 79/373/EEC; - until the rules of this Regulation are applicable, the substances already authorised may remain on the

market and be used under the conditions of the current legislation. ENTRY INTO FORCE : 07/11/03. DATE OF APPLICATION : 18/10/04.