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(Acts whose publication is obligatory)

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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs [1], as last amended by Directive 2001/46/EC of the European Parliament and of the Council [2], and in particular Article 5 thereof,

Whereas:

(1) Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition [3], as last amended by Directive 95/11/EC [4], should be amended in the light of advances in scientific and technical knowledge.

(2) It has become apparent that the increasing prevalence of antibiotic-resistant bacteria is of major concern to public health. Resistance caused by the use of antibiotics as feed additives contributes to the overall levels of resistance. The guidelines for additives other than micro-organisms and enzymes should therefore be supplemented by the establishment of a requirement for the dossier to include an assessment of the risk of the selection of and/or transfer of resistance to antibiotics and of any increased persistence and shedding of enteropathogens in order to ensure the safety of the use of those additives. For this purpose, the data required for the risk assessment and methodology to be applied should also be established.

(3) They should be supplemented by the establishment of criteria for the assessment of the risk to the consumer which could result from the consumption of food containing residues of the additive or its metabolites. Based on the residue studies maximum residue limits (MRL's) and withdrawal periods should be established, where appropriate.

(4) The environmental impact of feed additives is important since the additives are normally used over a long period, and the abovementioned guidelines should therefore be supplemented by the establishment of criteria for the assessment of the risk of the additive having an adverse effect on the environment, either directly and or as a result of the effect of products derived from it, whether directly or excreted by the animals into the environment. For the determination of this impact a stepwise approach should be followed based on a first and second phase of studies.

(5) The guidelines should be supplemented by more information on how workers and users can be exposed by the additive. An exposure assessment should be provided in order to take adequate measures.

(6) Confidence in the quality and objectivity of dossiers would be improved if they were supplemented by a critical appraisal of an independent person acknowledged to be an expert in the relevant field. The matters to be assessed in this report should be established in the guidelines.

(7) Experience has demonstrated that the guidelines should be supplemented by more specific criteria concerning the efficacy trials.

[1] OJ L 270, 14.12.1970, p. 1.
[2] OJ L 234, 1.9.2001, p. 55.
[3] OJ L 64, 7.3.1987, p. 19.
[4] OJ L 106, 11.5.1995, p. 23.

(8) Article 9b(1) of Council Directive 70/524/EEC provides that an additive referred to in Article 2(aaa) of that Directive shall initially be authorised for 10 years, after which time, the person holding the authorisation for it may seek renewal of the authorisation for a further period of 10 years. It is necessary to establish guidelines indicating the information which must be included in such an application for renewal and its accompanying dossier.

(9) Article 9c(3) of Council Directive 70/524/EEC provides that 10 years after a substance has first been authorised, the findings of all or part of the evaluation of data and information contained in the dossier supplied for initial authorisation may be used for the benefit of other persons seeking authorisation to put that substance into circulation. It is therefore necessary to establish guidelines indicating the information which must nonetheless be included in an application and accompanying dossier.

(10) Scientific and technical knowledge should be taken into account.

(11) For clarity reasons, it is appropriate to divide the guidelines into those applicable to additives other than micro-organisms and enzymes and those applicable to micro-organisms and enzymes.

(12) These guidelines have been established on the basis of the *Report of the Scientific Committee on Animal Nutrition on the revision of the guidelines for the assessment of additives in animal nutrition* (adopted on 22 October 1999).

(13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee for feedingstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annex to Directive 87/153/EEC is amended as follows:

After its title the text set out in the Annex to this Directive shall be inserted.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 January 2002 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 17 September 2001.

For the Commission

David BYRNE

Member of the Commission

ANNEX

PART I

ADDITIVES OTHER THAN MICRO-ORGANISMS AND ENZYMES

GENERAL ASPECTS

This document is intended as a guideline for establishing dossiers on substances and preparations being submitted for authorisation as additives in feedingstuffs or a new usage of an authorised additive. The term 'additive', as used in these guidelines refers to the active chemically specified substances or the preparations containing active substances in the state in which they will be incorporated in premixtures and feedingstuffs. The dossiers must enable an assessment to be made of the additives based on the present state of knowledge and make it possible to ensure their compliance with the fundamental principles laid down for their authorisation, which are the subject of the provisions of Article 3a of Council Directive 70/524/EEC.

Where a dossier concerns an additive consisting of or containing genetically modified organisms within the meaning of Articles 2(1) and (2) of Council Directive 2001/18/EC [1], the dossier must include the additional information specified in Article 7a(1) of Directive 70/524/EEC, in addition to the information required by these guidelines.

The dossiers should include detailed reports of all studies done, presented in the order and with the numbering proposed in these guidelines. They should include references and copies of all published scientific data relevant to the evaluation of the additive. An electronic version of the dossier should be made available. The studies are intended to demonstrate the safety of use of the additive in relation to:

(a) the target species at the proposed levels of incorporation in the feedingstuff;

(b) those likely to be exposed to the additive by respiratory, other mucosal, eye or cutaneous contact while handling the additive as such or incorporated into premixtures or feedingstuffs;

(c) consumers who ingest food products obtained from animals having received the additive, which could contain residues of the additive, or its metabolites; this will generally be ensured by the setting of maximum residue limits (MRLs) and withdrawal periods;

(d) the animals and the human-beings through the selection and spread of antimicrobial resistance genes;

(e) the environment arising from the additive itself or by products derived from the additive, either directly and/or excreted by animals.

As a general rule, studies to establish the identity, conditions of use, physico-chemical properties, methods of determination and efficacy of the additive, and also its metabolic fate and residues, physiological and toxicological effects on target species must be provided. When the additive is intended for a category of animals belonging to a defined species, efficacy and residue studies must be performed on this target category. The studies necessary for the evaluation of risks to human health or the environment will depend essentially on the nature of the additive and the circumstances of its use. In this respect, no strict rule is applicable. If necessary, additional information will be requested. Reasons must be given for the omission from the dossier of any data prescribed in these guidelines. In particular, studies of mutagenicity, carcinogenicity and reproduction toxicity studies may only be dispensed with if the chemical composition, practical experience, or other considerations can reasonably exclude these effects.

The studies should be done and reported according to appropriate quality standards (e.g. good laboratory practice (GLP) pursuant to Council Directive 87/18/EEC of 18 December 1986, on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances [2]).

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[1] OJ L 106, 17.4.2001, p. 1.
[2] OJ L 15, 17.1.1987, p. 29.

Expert reports on quality, efficacy and safety should be provided. Their authors, who should have relevant qualifications and be recognised experts in the field concerned, should not have been personally involved in the conduct of the tests included in the dossier. The reports must provide a critical appraisal of the documentation provided by the applicant; a factual summary is not sufficient.

The determination of physico-chemical, toxicological and eco-toxicological properties shall be performed in accordance with the methods established by Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [1], as last amended by Commission Directive 2000/33/EC [2], or with updated methods recognised by international scientific bodies. The use of methods other than these must be justified.

Each dossier shall contain an adequate summary, an annex proposal and may contain a monograph. The dossiers relating to antibiotics, coccidiostats and other medicinal substances and to growth promoters must be accompanied by a monograph, conforming to the model provided in Section V, enabling the additive concerned to be identified and characterised in accordance with Article 9n of Directive 70/524/EEC. An identification note conforming to the model in Section VI has to be provided for all additives.

For additives intended exclusively for pet food it may not always be necessary to subject additives to an as exhaustive program of chronic toxicity, mutagenicity, reproductive toxicity and carcinogenicity testing as that required for additives intended for feeding to livestock from which products for human consumption are derived. Residue studies in pet animals are not required.

Study of the metabolic fate of the additive in food producing target animals and in laboratory species used for toxicity testing, is required in order to:

(a) ensure that there is adequate data on the toxicity of the parent additive and any metabolites produced in the target species to which the consumer might be exposed. To this end a comparison of the metabolic fates of the additive in the target and laboratory animal species used for the toxicity testing is important;

(b) identify and quantify the appropriate marker residue(s) to be used for setting the MRL for the marker residue and the withdrawal periods for the final product.

[1] OJ L 196, 16.8.1967, p. 1.
[2] OJ L 136, 8.6.2000, p. 90.

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