Council Directive of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community (90/167/EEC)

COUNCIL DIRECTIVE

of 26 March 1990

laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community

(90/167/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

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

Having regard to the opinion of the European Parliament[(2)],

Having regard to the opinion of the Economic and Social Committee[(3)],

Whereas the conditions with which medicated feeding-stuffs should comply, in particular as concerns their preparation, supply, use and administration to animals, have no small influence on the rational development of the keeping and on the rearing of animals and the production of products of animal origin;

Whereas the keeping and rearing of animals constitutes a major portion of the common agricultural policy;

Whereas, to safeguard public health from any dangers arising from the use of medicated feedingstuffs for animals intended for food production, and to prevent distortions in competition in the keeping and rearing of farm animals, conditions should be laid down regarding the preparation, placing on the market and use of medicated feedingstuffs and regarding intra-Community trade in those products;

Whereas Community rules regarding veterinary medicinal products, and in particular Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of Member States relating to veterinary medicinal products[(4)], and Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products[(5)], as amended by Directive 87/20/EEC[(6)], should be taken into account;

Whereas medicated feedingstuffs must, with regard to the medicinal components, comply with the rules applicable to veterinary medicinal products; whereas, however, in the manufacture of medicated feedingstuffs simple mixing is the main process; whereas only authorized medicated pre-mixes may be used and precise instructions must be given for the use of these medicated

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After exit day no further amendments will be applied to this version.

feedingstuffs; whereas, in addition, the person responsible for manufacture must have at his disposal sufficient staff and premises so that can meet the requirements of this Directive;

Whereas it is the manufacturer's responsibility to carry out a quality control on the products placed on the market; whereas, however, the manufacturing unit should be placed under satisfactory official control;

Whereas, for the purposes of this Directive, the rules concerning checks and the safeguard measures laid down by Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market[7] should be used;

Whereas the supply of medicated feedingstuffs to stock-farmers may only be on prescription of a veterinarian, who must himself comply with particular conditions when issuing the prescription;

Whereas, in order for there be to effective control, the persons concerned must be required to keep a register or, where appropriate, to retain the documents for a specified period of time;

Whereas, pending the complete harmonization of the rules authorizing the placing of veterinary medicinal products on the market, the possibility of making national derogations, in particular with respect to the manufacture of intermediate products or certain medicated pre-mixes, should be kept,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive lays down, without prejudice to the adoption of the list laid down in Article 2 (3) of Directive 81/851/EEC, the conditions other than those of animal health, governing the preparation, placing on the market and use of medicated feedingstuffs within the Community.

This Directive shall not affect Community rules applicable to additives used in feedingstuffs, or national rules adopted pursuant to the said rules, and in particular those applicable to the additives entered in Annex II of Directive 70/524/EEC[8], as last amended by Commission Directive 89/583/EEC[9].

Article 2

For the purposes of this Directive the definitions appearing in Article 1 (2) of Directive 81/851/EEC and Article 2 of Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs[10], as last amended by Directive 90/44/EEC[11], shall apply as necessary.

The following definitions shall also apply:

(a) ‘authorized medicated pre-mix’: any pre-mix for the manufacture of medicated feedingstuffs as defined in Article 1 (2) of Directive 81/851/EEC which has been granted an authorization in accordance with Article 4 of that Directive;

(b) ‘placing on the market’: the holding in the territory of the Community for sale or disposal in any other form whatever to third parties, whether or not for consideration, and actual sale or disposal.

Article 3

1 Member States shall prescribe that, as regards the medicinal component, medicated feedingstuffs may be manufactured from authorized medicated pre-mixes only.

By way of derogation from the first subparagraph, Member States may, provided they comply with the requirements of Article 4 (4) of Directive 81/851/EEC:

— subject to any specific conditions laid down in authorizations to place authorized medicated pre-mixes on the market, authorize intermediate products which are prepared from such medicated pre-mixes authorized in accordance with Article 4 of Directive 81/851/EEC and from one or more feedingstuffs and which are intended for the subsequent manufacture of medicated feedingstuffs ready for use.

Member States shall take all necessary steps to ensure that intermediate products are manufactured only by establishments authorized in accordance with Article 4 and that they are the subject of a declaration to the competent authority,

— authorize the veterinarian to have manufactured under the conditions laid down in Article 4 (3) of Directive 81/851/EEC, and under his responsibility and on prescription, medicated feedingstuffs from several authorized medicated pre-mixes, provided that there is no specific authorized therapeutic agent in pre-mix form for the disease to be treated or for the species concerned.

Until the date on which the Member States have to comply with the new rules laid down in Article 4 (3) of Directive 81/851/EEC, national rules governing the above conditions shall remain applicable, with due regard for the general provisions of the Treaty.

2 Products authorized pursuant to paragraph 1 shall be subject to the rules laid down in Articles 24 to 50 of Directive 81/851/EEC.

Article 4

1 Member States shall take all necessary measures to ensure that medicated feedingstuffs are manufactured only under the conditions set out below:

a the manufacturer shall have premises which have been previously approved by the competent national authority, technical equipment and suitable and adequate storage and inspection facilities;

b the medicated feedingstuffs manufacturing plant shall be manned by staff whose knowledge of and qualifications in mixing technology are adequate;

c the producer shall be responsible for ensuring that:

— only feedingstuffs or combinations thereof which comply with Community provisions on feedingstuffs are used,

— the feedingstuff used produces a homogeneous and stable mix with the authorized medicated pre-mix,

— the authorized medicated pre-mix is used during the manufacturing process in accordance with the conditions laid down when authorization for placing on the market was given and, in particular, that:

(i) there is no possibility of any undesirable interaction between veterinary medicinal products, additives and feedingstuffs;

(ii) the medicated feedingstuff will keep for the stipulated period;

Status: *EU Directives are being published on this site to aid cross referencing from UK legislation. After exit day no further amendments will be applied to this version.*

(iii) the feedingstuff to be used for producing the medicated feedingstuff does not contain the same antibiotic or the same coccidiostat as those used as an active substance in the medicated pre-mix;

— the daily dose of medicinal product is contained in a quantity of feedingstuff corresponding to at least half the daily feed ration of the animals treated or, in the case of ruminants, corresponding to at least half the daily requirement of nonmineral supplementary feedingstuffs;

d premises, staff and equipment used and participating in the entire manufacturing process must comply with the manufacturing hygiene rules and principles of the Member State in question; the manufacturing process must conform to the rules of good manufacturing practice;

e the medicated feedingstuffs manufactured shall undergo regular checks — including appropriate laboratory tests of homogeneity — by the manufacturing establishments, under the supervision and periodic control of the official department, to ensure that the medicated feedingstuff complies with the requirements of this Directive, especially in respect of its homogeneity, stability and storability;

f manufacturers shall be obliged to keep daily records of the types and quantities of the authorized medicated pre-mixes and feedingstuffs used and of the medicated feedingstuffs manufactured, held or dispatched, together with the names and addresses of the breeders or holders of the animals, and in the case provided for in Article 10 (2), the name and address of the authorized distributor and, where appropriate, the name and address of the prescribing veterinarian. The records, which must meet the requirements of Article 5 of Directive 81/851/EEC, must be kept for at least three years after the date of the last entry and must be made available at any time to the competent authorities in case of checking;

g pre-mixes and medicated feedingstuffs shall be stored in suitable separate and secured rooms or hermetic containers which are specially designed for the storage of such products.

2 Member States may, by way of derogation from paragraph 1, subject to any additional guarantees appropriate, authorize the manufacture of medicated feedingstuffs on farms provided that the said paragraph is complied with.

Article 5

1 Member States shall prescribe that medicated feedingstuffs may be placed on the market only in packages or containers sealed in such a way that, when the package is opened, the closure or seal is damaged and they cannot be re-used.

2 Where road tankers or similar containers are used to place medicated feedingstuffs on the market, these must be cleaned before any re-use in order to prevent any subsequent undesirable interaction or contamination.

Article 6

1 Member States shall take all necessary measures to ensure that medicated feedingstuffs are not put into circulation unless the labelling complies with the Community provisions in force.

Furthermore, the packages or containers referred to in Article 5 (1) shall be clearly marked ‘Medicated Feedingstuffs’.

2 Where road tankers or similar containers are used to place medicated feedingstuffs on the market, it shall be sufficient for the information referred to in paragraph 1 to be contained in the accompanying documents.

Article 7

1 Member States shall take ail necessary measures to ensure that a medicated feedingstuff cannot be held, placed on the market or used unless it has been manufactured in accordance with this Directive.

2 Subject to the requirements of Article 4 (2) of Directive 81/851/EEC with regard to the tests to be carried out on veterinary medicinal products, Member States may, however, for scientific purposes, provide for derogations from this Directive, provided there is adequate official control.

Article 8

1 Member States shall ensure that medicated feedingstuffs are not supplied to stockfarmers or holders of animals except on presentation of a prescription from a registered veterinarian on the following terms:

a the veterinarian's prescription shall be made out on a form which contains the headings shown on the specimen in Annex A; the original form shall be for the manufacturer or, where appropriate, a distributor approved by the competent authority of the Member State of destination of the medicated feedingstuffs;

b the competent national authorities shall determine the number of copies of the prescription form, the persons who are to receive a copy and the period for which the original and the copies must be kept;

c medicated feedingstuffs may not be used for more than one treatment under the same prescription.

The veterinary prescription shall be valid only for a period determined by the competent national authority which may not exceed three months;

d the veterinarian's prescription may be used only for animals treated by him. He must first satisfy himself that:

(i) the use of this medication is justified for the species concerned on veterinary grounds;

(ii) administration of the medicinal product is not incompatible with a previous treatment or use and that there is no contra-indication or interaction where several pre-mixes are used;

e the veterinarian must:

(i) prescribe the medicated feedingstuffs only in such quantities as, within the maximum limits laid down by the national authorization for placing medicated pre-mixes on the market, are necessary for the purpose of the treatment;

(ii) satisfy himself that the medicated feedingstuff and the feedingstuff currently used to feed treated animals do not contain the same antibiotic or the same coccidiostat as active substances.

2 However, in the case of anthelmintic medicinal products (vermifuges), Member States may, pending the review to be carried out under Directive 81/851/EEC of the risks associated with the use of these groups of substances, derogate for five years after the adoption of this Directive from the obligation laid down in paragraph 1 not to supply medicated