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)

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[(1)], as last amended by Commission Directive 89/583/EEC[(2)].

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[(3)], as last amended by Directive 90/44/EEC[(4)], 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;

(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 feedingstuffs obtained from authorized medicated pre-mixes except on presentation of a veterinary prescription, provided that:

— the medicated pre-mixes used do not contain active substances which belong to the chemical groups used, in their territory, on medical prescription for human medicine,

— the medicated feedingstuffs accorded such authorization are used in their territory only prophylactically and in the dosages necessary for the purpose in question.

Member States applying such a derogation shall inform the Commission and the other Member States thereof within the Standing Veterinary Committee, before the date provided for in the first indent of the first subparagraph of Article 15, specifying in particular the nature of the medicinal products and animal species that it covers.

Not more than six months before the expiry of the five-year period laid down in the first subparagraph the Commission shall report to the Council on the risks associated with the use of these groups of substances and may include proposals on which the Council will decide by a qualified majority.

3 Where medicated feedingstuffs are administered to animals whose meat, flesh, offal or products are intended for human consumption, the stockfarmer or holder of the animals concerned must ensure that treated animals are not slaughtered in order to be offered for consumption before the end of the withdrawal period and that products obtained from a treated animal before the end of such a withdrawal period are not disposed of with a view to their being offered for human consumption.

Article 9

1 Member States shall take all necessary measures to ensure that medicated feedingstuffs are issued directly to the stockfarmer or holder of the animals only by the manufacturer or distributor specially approved by the competent authority of the Member State of destination.

Furthermore, medicated feedingstuffs for the treatment of animals whose meat, flesh, offal or products are intended for human consumption may not be issued unless:

— they do not exceed the quantities prescribed for the treatment, in accordance with the veterinary prescription where this is provided for,

— they are not issued in quantities greater than one month's requirements as established in accordance with the stipulations of the first indent.

2 However, notwithstanding paragraph 1, Member States may in special cases authorize distributors specifically approved for that purpose to issue, on the basis of a veterinary prescription, medicated feedingstuffs in small quantities, prepacked and ready for use, and prepared, without prejudice to Article 8 (2) in accordance with the requirements of this Directive, provided that these distributors:

— comply with the same conditions as the manufacturer regarding the keeping of registers and the storage, transport and issue of the products concerned,

— are subject to special checking for the purpose, under the supervision of the competent veterinary authority,

— may supply only prepacked or prepackaged medicated feedingstuffs ready for use by the holder or stock-farmer that have on the packaging or containers instructions for the use of the said medicated feedingstuffs and, in particular, an indication of the withdrawal period.

3 The provisions of paragraph 2 shall not affect national rules on the legal ownership of the medicated feedingstuffs.

Article 10

1 Member States shall ensure that, without prejudice to animal-health rules, there are no prohibitions, limitations or obstacles in respect of intra-Community trade

— in medicated feedingstuffs which have been manufactured in accordance with the requirements of this Directive, and in particular Article 4 thereof, with authorized pre-mixes which have the same active substances as pre-mixes authorized by the Member State of destination, in accordance with the criteria of Directive 81/852/EEC, and a quantitative and qualitative composition similar thereto,

— subject to the specific provisions of Council Directive 86/469/EEC of 16 September 1986 concerning the examination of animals and fresh meat for the presence of residues[(5)] and Council Directive 88/299/EEC of 17 May 1988 on trade in animals treated with certain substances having a hormonal action and their meat, as referred to in Article 7 of Directive 88/146/EEC[(6)], in animals to which those medicated feedingstuffs except those produced pursuant to the second subparagraph of Article 3 (1), have been administered, or in meat, flesh, offal or their products from such animals.

2 Where the application of paragraph 1 gives rise to dispute, in particular as concerns recognition of the similar nature of the pre-mix, the Member States concerned or the Commission may submit the dispute to assessment by an expert appearing on a list of Community experts to be drawn up by the Commission on a proposal from the Member States.

If the two Member States so agree beforehand, the parties shall abide by the opinion of the expert, in compliance with Community legislation.

3 The Member State of destination may require that each consignment of a medicated feedingstuff be accompanied by a certificate issued by the competent authority, corresponding to the specimen form in Annex B.

Article 11

1 The safeguard measures laid down by Directive 89/662/EEC shall apply to trade in authorized medicated pre-mixes or medicated feedingstuffs.

2 The rules laid down concerning veterinary control and, in particular, the requirements laid down in Article 5 (2) and Article 20 of Directive 89/662/EEC shall apply to trade in authorized pre-mixes or medicated feedingstuffs to the extent that they are subject to veterinary control.

Article 12

The Council, acting by a qualified majority on proposals from the Commission, shall adopt any amendments and additions to be made to this Directive.

Article 13

Member States shall take all necessary measures to ensure that their competent authorities satisfy themselves:

(i) by making sampling checks at all stages of the production and marketing of the products referred to by this Directive, that the provisions of this Directive are complied with;

(ii) in particular, by making sampling checks on farms and slaughterhouses, that medicated feedingstuffs are used in compliance with the conditions of use, and that withdrawal periods have been complied with.

Article 14

Pending the implementation of Community measures relating to imports of medicated feedingstuffs from third countries, Member States shall apply to those imports measures which are at least equivalent to those of this Directive.

Article 15

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply:

— with the requirements of Article 11 (2) on the date on which they must conform with the Community rules on the protection of feedingstuffs against pathogenic agents, but at the latest by 31 December 1992,

— before 1 October 1991, with the other provisions of this Directive.

They shall forthwith inform the Commission thereof.

Article 16

This Directive is addressed to the Member States.

(**1**) OJ No L 270, 14. 12. 1970, p. 1.

(**2**) OJ No L 325, 10. 11. 1989, p. 33.

(**3**) OJ No L 86, 6. 4. 1979, p. 30.

(**4**) OJ No L 27, 31. 1. 1990, p. 35.

(**5**) OJ No L 275, 26. 9. 1986, p. 36.

(**6**) OJ No L 128, 21. 5. 1988, p. 36.