COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 14 January 1982.

Proposal for a

COUNCIL DIRECTIVE

on the manufacture, putting into circulation and supply of medicated feeding-stuffs in the Community

(submitted to the Council by the Commission)

Explanatory Memorandum

Medicated feedingstuffs are not covered by the Council Directive on the approximation of the laws of Member States relating to veterinary medicinal products and the Council Directive on the approximation of the law of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products of 28 September 1981 (1). Specific Community provisions must therefore be laid down for them.

This proposal is closely linked with the Directive on veterinary medicinal products and sets out conditions for the manufacture, putting into circulation and supply of medicated feedingstuffs for animals.

This manufacture must, in principle, be carried out by mixing animal feeds, in accordance with current legislation, with medicinal substances which must be authorised pre-mixes conforming to the legislation on veterinary medicinal products. In addition, the manufacturing process is subject to certain requirements concerning buildings, equipment, personnel and procedures.

Putting into circulation of medicated feedingstuffs for animals is limited to those which are manufactured in conformity with the Directive, and which are packaged and identified in an appropriate manner.

They may only be supplied to the farmer on a veterinary prescription, and the veterinarian may only prescribe medicated feedingstuffs for animals under this treatment, and in the quantity necessary for that treatment.

In order to guarantee compliance with the requirements of this Directive, control measures in particular the strict obligation for those persons involved to keep records, have been provided for.

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(1) OJ No L 317, 6.11.1981

Provision has also been made for the free circulation within the Community of medicated feedingstuffs. To this end it is necessary, in particular, to draw up a Community procedure regulating the approval of standard prescriptions, which will assure a close collaboration between the Commission and the Member States.

The abovementioned proposal for a Directive thus both gives a guarantee of protection of human health against the risks of uncontrolled use of medicated feedingstuffs in animals and avoids distortion of competition in animal production.

PROPOSAL FOR A
COUNCIL DIRECTIVE

on the manufacture, putting into circulation and supply of medicated feeding-stuffs in the Community

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,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

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 manufacture, putting into circulation and supply of medicated feedingstuffs;

Whereas Community rules regarding medicinal products, in the form of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products(1), the second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (2), Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of Member States relating to veterinary medicinal products (3) 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 (4), should be taken into account;

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(1) OJ No 22, 9.2.1965, p. 369
(2) OJ No L 147, 9.6.1975, p. 13
(3) OJ No L 317, 6.11.1981, p. 1
(4) OJ No L 317, 6.11.1981, p. 16
(5) OJ No L 270, 14.12.1970, p. 1
(6) OJ No L 231, 15.8.1981, p. 30
(7) OJ No L 86, 6.4.1979, p. 30

Whereas account must also be taken of Community rules on feedingstuffs in the form of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (5), as last amended by the 38th Commission Directive 81/632/EEC (6), and of Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs (7);

Whereas medicated feedingstuffs must in principle be manufactured under the same conditions as those applying to veterinary medicinal products; whereas, however, since in the manufacture of medicated feedingstuffs simple mixing is usually the main process, only authorized pre-mixes may be used and precise instructions are given in a prescription or standard prescription, the person responsible for manufacture required by the rules on medicinal products may be replaced by a person with adequate knowledge of mixing techniques;

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

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

Whereas, for the authorization of medicated feedingstuffs from standard prescriptions in intra-Community trade, a procedure should be chosen which ensures close cooperation between the Commission and the Member States,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Definitions and scope

Article 1

This Directive covers the manufacture and putting in circulation of medicated feedingstuffs and their supply to livestock farmers within the Community, as well as intra-Community trade in these products.

Article 2

For the purposes of this Directive the following definitions shall apply:

(a) medicated feedingstuff: any mixture of one or more veterinary medicinal products and one or more feedingstuffs which is prepared prior to being put into circulation and which, because of its prophylactic or therapeutic properties or other properties as referred to in Article 1(2) of Directive 65/65/EEC is intended to be fed to animals without alteration;

(b) pre-mix for medicated feedingstuffs: any veterinary medicinal product prepared in advance with a view to the subsequent manufacture of medicated feedingstuffs;

(c) authorised pre-mix: any pre-mix for medicated feedingstuffs for which an authorisation has been granted in accordance with Article 4 of Directive .81/851/EEC on the approximation of the laws of Member States relating to veterinary medicinal products;

(d) intermediate product: any mixture of one or more pre-mixes for medicated feedingstuffs and one or more feedingstuffs which is prepared in advance with a view to the subsequent manufacture of medicated feedingstuffs;

(e) veterinary medicinal product: any medicinal product intended for animals;

(f) putting into circulation: the holding for sale or any other disposal, and any kind of disposal to others, whether or not for consideration;

(g) additives: substances which, when incorporated in feedingstuffs, are likely to affect their characteristics or livestock production;

(h) feedingstuffs: organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding;

(i) daily ration: the average total quantity of feedingstuffs, calculated on a moisture content of 12%, required daily by an animal of a given species, age category and performance to satisfy all its nutritional requirements;

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(j) complete feedingstuffs: mixtures of feedingstuffs which, by reason of their composition, are sufficient for a daily ration;

(k) supplementary feedingstuffs: mixtures of feedingstuffs which have a high content of certain substances and which, by reason of their composition, are sufficient for a daily ration only if they are used in combination with other feedingstuffs;

(l) mineral feedingstuffs: supplementary feedingstuffs which are composed mainly of minerals and contain at least 40% crude ash;

(m) standard prescription: officially recognised prescription for the manufacture of a medicated feedingstuff.

Article 3

1. This Directive shall be without prejudice to other Community provisions on feedingstuffs.

2. The provisions of this Directive shall not apply to medicated feedingstuffs shown, at least by appropriate markings, to be intended for export to non-member countries.

CHAPTER II

Manufacture of medicated feedingstuffs

Article 4

1. As regards the content of medicinal products, medicated feedingstuffs may be manufactured only from pre-mixes authorized for that purpose.

2. Medicated feedingstuffs may be manufactured only from a veterinary prescription or from a standard prescription authorized in accordance with Article 14(2).

3. By way of derogation from paragraph 2, however, Member States may authorize other standard prescriptions for the manufacture of medicated feedingstuffs. Such standard prescriptions shall require the approval of the competent central authority of the Member State.

Article 5

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

1. The manufacturer must have suitable and adequate premises, technical equipment, storage and inspection facilities.

2. The manufacturer must have available the services of proficient staff to comply with the conditions regarding manufacture. In particular, staff with an adequate knowledge of mixing techniques must be present in the manufacturing plant.

3. Only complete or supplementary feedingstuffs, not including mineral feeds, which comply with the Community provisions on feedingstuffs may be used. The feedingstuff used must demonstrably allow of homogeneous and stable mixing with the veterinary medicinal product and it must be possible to store it for an appropriate period. In particular, the feedingstuff used may not contain any additives which affect the action of the veterinary medicinal product.

4. In respect of premises, staff and equipment the entire manufacturing process must comply with provisions of the Member State ensuring the observance of recognized principles of hygiene, with a view, in particular, to avoiding contamination between veterinary medicinal products or feedingstuffs.

5. The medicated feedingstuffs manufactured must be checked regularly in accordance with national provisions, especially in respect of homogeneity and stability of the mixture and storability.

6. Manufacturers must keep records, on the basis of immediate entries, of the types and quantities of pre-mixes and feedingstuffs used and of medicated feedingstuffs manufactured, put into storage or dispatched, the names and addresses of recipients and, where delivery is direct to stockfarmers, the name and address of the prescribing veterinarian. The record must be retained for at least one year after the date of the last entry and be made available at any time to the inspection authorities.

7. Pre-mixes, intermediate products and medicated feedingstuffs must be stored in suitable separate rooms or containers which are specially designed for the purpose and which can be locked.

Article 6

By way of derogation from Article 4(1), medicated feedingstuffs may be manufactured without the use of an authorized pre-mix if appropriate measures are taken to ensure that in addition to the provisions of this Directive, in particular Article 5, the provisions of Directive 81/851/EEC and Directive 81/852/EEC are complied with, and that in particular the manufacturer disposes of the services ov a qualified person as defined in Article 31 of Directive 81/851/EEC.

In such cases the medicated feedingstuff shall require authorization under Article 4 of the abovementioned Directive 81/851/EEC.

Article 7

Member States may provide that medicated feedingstuffs may be manufactured from intermediate products and that these intermediate products may be put into circulation.

Such intermediate products may be manufactured only from authorized pre-mixes with the addition of feedingstuffs.

Member States shall ensure that intermediate products are subject to the supervision of the competent authorities, that they may be used only for the manufacture of medicated feedingstuffs and that their use is subject to the conditions governing the putting into circulation of the pre-mix used.

CHAPTER III

Packaging and labelling

Article 8

Member States shall prescribe that medicated feedingstuffs may be supplied only in containers which ensure that their condition is not impaired.

Whenever medicated feedingstuffs are put into circulation in road tankers or similar containers, these must be thoroughly cleaned before any re-use in order to prevent contamination.

Article 9

1. Member States shall take all appropriate measures to ensure that medicated feedingstuffs are not put into circulation unless the labelling fulfils the requirements:

   - Chapter VII of Directive ..../81/851/..../EEC, in respect of the medicinal products used, and

   - Council Directive 70/524/EEC and Council Directive 79/373/EEC, in respect of the feedingstuffs used.

Medicated feedingstuffs must further bear the clearly visible words "Medicated feedingstuff" and an indication as to what proportion of the daily ration they are intended to represent.

2. Whenever medicated feedingstuffs are put into circulation in road tankers or similar containers, it shall be sufficient for the indications referred to in paragraph 1 to be contained in the accompanying documents.

CHAPTER IV

Putting into circulation and supply of medicated feedingstuffs

Article 10

1. Member States shall take all appropriate measures to ensure that a medicated feedingstuff is put into circulation only if it has been manufactured in accordance with the provisions of this Directive and, in cases as referred to in Article 6, the authorization provided for has been granted.

2. Except in cases of tests of medicinal products carried out pursuant to Article 5(10) of Directive 81/851/EEC, a medicated feedingstuff may not be administered to animals unless the conditions laid down in paragraph 1 are fulfilled.

3. Articles 5, 6 and 7 of Directive 81/851/EEC shall apply to applications for authorization to put into circulation a medicated feedingstuff manufactured in accordance with Article 6 of this Directive.

   As regards indication of the components of the medicated feedingstuff, however, it shall be sufficient to indicate the main components of the feedingstuff used.

   As regards examination of applications for authorization, Chapter III of Directive 81/851/EEC and Directive 81/852/EEC sahll apply.

Article 11

Member States shall ensure that medicated feedingstuffs are put into circulation only if 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, half the daily requirements of non-mineral supplementary feedingstuffs.

Article 12

1. Member States shall prescribe that medicated feedingstuffs may be supplied to stockfarmers only on presentation of a prescription from a registered veterinarian.

   The veterinarian's prescription shall be made out in at least triplicate, at one impression, on a form based on the model in Annex 1.

   The original shall be kept by the manufacturer or dealer; the first copy shall be kept by the stockfarmer and when the medicated feedingstuff is supplied the manufacturer or dealer shall enter the additional particulars provided for on the form.

   The second copy shall be kept by the prescribing veterinarian.

   Prescriptions shall be retained by the veterinarian, manufacturer or merchant and stockfarmer for at least one year from the date of issue and shall be made available to the competent supervisory authorities at any time on request.

2. The veterinarian may prescribe medicated feedingstuffs only for animals treated by him, only if their use is justified on veterinary grounds and only in such quantities as are necessary for the purpose of the treatment.

3. Member States shall lay down that medicated feedingstuffs may not be supplied more than once on the same prescription.

4. Member States may limit the period of validity of the veterinary prescription.

Article 13

Member States shall take all appropriate measures to ensure that medicated feedingstuffs are supplied directly by the manufacturer or merchant to the stockfarmer.

CHAPTER V

Intra-Community trade

Article 14

1. Member States shall ensure that there are no prohibitions, limitations or obstacles in respect of intra-Community trade in medicated feedingstuffs which have been manufactured:

   - in accordance with a standard prescription authorized by the Community,
   - in accordance with a prescription from a veterinarian, provided that the pre-mix used had been authorized by the Community according to Directive 81/851/EEC,

   or

   - in accordance with Article 6 provided that the medicated feedingstuff had been authorized by the Community, in accordance with the abovementioned Directive.

2. The Community authorizations referred to in the first indent of paragraph 1 shall be granted by the Commission in accordance with the procedure laid dow in Article 16. The criteria for the Community authorization of standard prescriptions shall be determined in accordance with the same procedure.

   A list of such standard prescriptions and all amendments thereto shall be published in the Official Journal of the European Communities.

3. Each consignment of a medicated feedingstuff must be accompanied by a certificate issued by the competent veterinary authority, in accordance with the model in Annex II. In the event of manufacture as referred to in the second indent of paragraph 1 a veterinary prescription in accordance with Annex 1 shall suffice.

CHAPTER VI

Supervision and sanctions

Article 15

1. Member States shall take all appropriate measures to ensure that their competent authorities satisfy themselves through inspection visits that the provisions of this Directive are complied with.

2. Such inspections shall be carried out by employees of the competent authorities of the Member States, who shall be empowered as a minimum to:

   (1) inspect manufacturing and commercial establishments and, in cases where the veterinarian is authorized to supply medicated feedingstuffs direct, the laboratories and work premises of veterinary practices;

   (2) inspect the stock farms where medicated feedingstuffs are used;

   (3) take samples;

   (4) examine and have at their disposal any documents relevant to the object of the inspection;

   (5) require all necessary particulars from the interested parties.

3. Member States shall take all appropriate measures to ensure that infringements of this Directive are penalized.

CHAPTER VII

Final provisions

Article 16

1. Where the procedure laid down in this Article is to be used, matters shall be referred by the Chairman, either on his own initiative or at the request of a Member State, to the Standing Veterinary Committee (hereinafter called the 'Committee') set up by Council Decision 68/361/EEC.

2. Within the Committee, the votes of Member States shall be weighted as provided in Article 148(2) of the Treaty. The Chairman shall not vote.

3. The representative of the Commission shall submit a draft of the measures to be adopted. The Committee shall deliver its opinion on such measures within two days. Opinions shall be delivered by a majority of 45 votes.

4. The Commission shall adopt the measures and shall apply them immediately where they are in accordance with the opinion of the Committee. Where they are not in accordance with the opinion of the Committee or if no opinion is delivered, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall adopt the measures by a qualified majority.

   If, within three months from the date on which the proposal was submitted to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and shall apply them immediately.

Article 17

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 January 1984. They shall forthwith inform the Commission thereof.

Article 18

This Directive is addressed to the Member States.

Surname, forename and address of the prescribing veterinarian:

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ANNEX 1

Date: .....

Copy intended for manufacturer or dealer* (to be retained for at least one year)

PRESCRIPTION FOR A MEDICATED FEEDINGSTUFF

This prescription may not be re-used

Name or business name and address of the manufacturer or dealer:

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Name and address of the stockfarmer: .....

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Identification and number of animals: .....

Indication**: .....

.....

Designation or composition of the medicated feedingstuff : .....

Rp.....

.....

Total quantity of medicated feedingstuff: ..... Kg

Special instructions for the stockfarmer:

Percentage of medicated feedingstuff in the daily ration, frequency and duration of treatment: .....

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Withdrawal time before slaughtering, or waiting time before marketing products from treated animals: .....

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Personal signature of veterinarian

To be completed by the manufacturer or dealer:

Date of delivery: .....

To be used before: .....

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Signature of manufacturer or dealer

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* The following shall be inserted instead of "the manufacturer or dealer"
  (a) on the first copy the words: "the stockfarmer"
  (b) on the second copy the words: "the veterinarian"

** To be entered only on the copy for the veterinarian

ANNEX II

CERTIFICATE OF MANUFACTURE OF A MEDICATED FEEDINGSTUFF FOR THE PURPOSES OF INTRA-COMMUNITY TRADE

(pursuant to Article 14 (3) of Directive .../.../EEC on the manufacture, putting into circulation and supply of medicated feedingstuffs)

Name and address of manufacturer or dealer: .....

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Designation of the medicated feedingstuff: .....

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Quantity of medicated feedingstuff : .....

Name and address of the recipient : .....

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This is to certify that the abovementioned consignment of medicated feedingstuffs was manufactured in accordance with the provisions of the abovementioned Directive.

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Place and date

.....
(Signature)
Name and position

Stamp
of the competent veterinary authority