European Communities

EUROPEAN PARLIAMENT

Working Documents

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DOCUMENT 1-79/83

Report

drawn up on behalf of the Committee on the Environment, Public Health and Consumer Protection

on the proposal from the Commission of the European Communities to the Council (Doc. 1-987/81 - COM(81) 795 final) for a directive on the manufacture, putting into circulation and supply of medicated feedingstuffs in the Community

Rapporteur: Mrs V. SQUARCIALUPI

PE 82.304/fin.

English Edition

By letter of 1 February 1982, the President of the Council requested the European Parliament to deliver an opinion on the proposal for a Council directive on the manufacture, putting into circulation and supply of medicated feedingstuffs in the Community.

On 15 February 1982, the President of the European Parliament referred this proposal to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Agriculture for an opinion.

On 24 February 1982, the Committee on the Environment, Public Health and Consumer Protection appointed Mrs SQUARCIALUPI rapporteur.

The committee considered the proposal at its meetings of 1 October 1982, 3 December 1982, 20 January 1983 and 16 March 1983. At the last meeting, the committee decided unanimously to recommend to Parliament that it approve the Commission's proposal with the following amendments.

The committee subsequently decided to propose to Parliament the application of Rule 36(2) of the Rules of Procedure.

The motion for a resolution as a whole was adopted unanimously.

The following took part in the vote: Mr Ryan, vice-chairman; Mr Weber, vice-chairman; Mrs Squarcialupi, rapporteur; Mr Alber, Mr Bombard, Mr Del Duca, Mr Ghergo, Mrs Van Hemeldonck, Mrs Krouwel-Vlam, Mrs Lentz-Cornette, Mr Mertens (deputizing for Mrs Schleicher), Mr Muntingh, Mr Pantazi, Mr Provan (deputizing for Mr Forth), Mr Remilly and Mrs Seibel-Emmerling.

The report was submitted on 21 March 1983.

The opinion of the Committee on Agriculture is attached.

C O N T E N T S

The Committee on the Environment, Public Health and Consumer Protection hereby submits to the European Parliament the following amendments to the Commission's proposal and the following motion for a resolution together with explanatory statement:

Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection	Text proposed by the Commission of the European Communities

Proposal for a Council directive on the manufacture, putting into circulation and supply of medicated feedingstuffs in the Community (COM(81) 795 final)

Amendment No. 1

Article 4 (3)	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 authority of the Member State.
Delete	

Amendment No. 2

Article 5(1)	1. The manufacturer must have suitable and adequate premises, technical equipment, storage and inspection facilities.
At the end of the paragraph, add the words:	
'for the various stages in the manufacture of the medicated feedingstuffs'	

Amendment No. 3

Article 5(6)
Replace the word 'immediate' by the word 'daily'.

6. Manufacturers must keep records, on the basis of immediate entries, of the types and quantities (rest unchanged)

Amendment No. 4

After Article 5(7) insert a new paragraph 5(8):

'8. Member States shall report to the Commission annually on the measures they have adopted in the context of this article of the directive.'

Amendment No. 5

Article 6
Delete

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 of 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.

Amendment No. 6

Article 7, second paragraph
The text to read as follows:

'Such intermediate products must be manufactured only from authorized pre-mixes with the addition of feedingstuffs and must bear the name of the manufacturer of the intermediate product.

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

Amendment No. 7

Article 8, second paragraph
The text to read as follows:

'... these must be thoroughly and demonstrably cleaned before ...'
(rest unchanged)

2. 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.

Amendment No. 8

Article 9(1)
Add a third indent as follows:

' - Directive 74/63/EEC of 17 December 1973 on the fixing of maximum permitted levels for undesirable substances and products in feedingstuffs'

Delete the word 'and' at the end of the first indent.

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.

(rest unchanged)

Amendment No. 9

Article 12(1), second paragraph
The text to read as follows:

'The veterinarian's prescription shall be made out in at least quadruplicate, at one impression,

1. The veterinarian's prescription shall be made out in at least triplicate, at one impression, on

on a form based on the model in Annex I.'	a form based on the model in Annex I.
After the fourth paragraph, add the following:	
'The third copy shall be forwarded to the competent supervisory atuhorities.'	
Amendment No. 10	
Article 15	
Add a new paragraph 4 as follows:	
'Member States shall report to the Commission annually on the number of infringements recorded and the penalties imposed.'	

A

MOTION FOR A RESOLUTION

closing the procedure for consultation of the European Parliament on the proposal from the Commission of the European Communities to the Council for a directive on the manufacture, putting into circulation and supply of medicated feedingstuffs in the Community

The European Parliament,

- having regard to the proposal from the Commission to the Council (COM(81) 795 final)[1],

- having been consulted by the Council (Doc. 1-987/81),
- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinion of the Committee on Agriculture (Doc.1-79/83),
- having regard to the result of the vote on the Commission's proposal,

A whereas European consumers are concerned at the dangers to their health arising from the use of antibiotics, hormones and anabolic substances in livestock raising,

1. Welcomes the proposal for a Council directive, which can make the intra-Community market in medicated feedingstuffs more transparent, to the benefit of both consumers and meat, milk and egg producers;

2. Calls on the Commission to establish more precise rules as soon as possible concerning:
   (a) production conditions for medicated feedingstuffs;
   (b) quality standards for the mixing and combination of medicinal products and feedingstuffs;

3. Considers it urgent, moreover, that the Commission take prompt initiatives on the following points:
   (a) reduction of medicinal products intended for animals;
   (b) uniform rules on the control and monitoring of the observance of withdrawal periods, from the withdrawal of medication or medicated feedingstuffs to slaughter;
   (c) abolition of medicinal products and medicated feedingstuffs for auxinic purposes;
   (d) the illegal marketing of veterinary medicinal products and medicated feedingstuffs must be prevented;
   (e) uniform methods of analysis are a prerequisite for monitoring and implementation of the directives. Much greater efforts must therefore be made in this area;

[1] OJ No. C 41, 16.2.1982, p. 3

(f) control of residues of vegetable, animal and synthetic origin in foodstuffs intended for animal and human consumption (meat, eggs, milk);

4. Calls on the Commission to provide a more detailed definition of the term 'manufacturer' in Article 5(2);

5. Asks the Commission to provide in Article 7 for precise marking of the products concerned, incorporating not only the name of the manufacturer but also a reference number for easy identification of the product, to ensure that control can actually be carried out;

6. Requests the Commission to provide uniform rules on the duration of the validity of the veterinarian's prescription in Article 12(4);

7. Urges the Council to take prompt decisions concerning hormonal and antibiotic residues in meat for human consumption;

8. Calls on the Commission to harmonize the provisions for the marketing and sale of medicated feedingstuffs;

9. Approves the proposal for a Council directive, subject to these remarks and the amendments requested;

10. Instructs its President to forward to the Council and the Commission the text of the Commission's proposal as voted by Parliament, and the corresponding resolution as Parliament's opinion.

B

EXPLANATORY STATEMENT

1. The proposal for a directive on medicated feedingstuffs

1.1 The Commission's present proposal is designed to approximate the laws of the individual Member States on medicated feedingstuffs in order to make the intra-Community market in this sector more transparent, to the benefit of both consumers and producers of meat and milk products.

1.2. The principle that only feedingstuffs and veterinary medicinal products authorized by the relevant Community provisions (Articles 4, 5 and 6) may be used for the manufacture of medicated feedingstuffs, provides both meat and milk producers and consumers with a guarantee that the effects, and any possible side effects, of the medicated feedingstuffs have been recognized as harmless in respect of the consumption of products obtained from the animals to which these feedingstuffs have been given.

1.3. With the aim of preventing the abusive use of medicated feedingstuffs without veterinary prescription, the directive stipulates that medicated feedingstuffs may be supplied to stockfarmers only by prescription of a registered veterinarian and that the veterinarian may prescribe them only for animals treated by him and only in such quantities as are necessary for the purposes of the treatment (Article 12).

1.4. The exclusive use of authorized veterinary medicinal products and feedingstuffs and the prevention of improper use of medicated feedingstuffs manufactured from these will improve the intra-Community conditions of competition for meat and milk producers.

1.5. The introduction of a standard prescription for the preparation of medicated feedingstuffs (Article 14), authorized at Community level with the assistance of the Standing Veterinary Committee, will help improve intra-Community trade in these products.

1.6. In view of the fact that public opinion is still justifiably alarmed at certain past practices involving the use of additives in feedingstuffs, the proposed directive will help restore consumers' confidence by removing all the suspicion from products of this food sector, - to the considerable benefit of producers.

2. The need for this directive

2.1. This proposal is necessary because there are as yet no rules governing the manufacture of medicated feedingstuffs in the Community. The main aim of the directive is to provide common rules for the Member States which do not penalize or favour any one country.

2.2. In fact, Article 2(2) of Directive 81/851 of 28 September 1981 on veterinary medicinal products states that the provisions of the directive are not applicable to medicated feedingstuffs. However, Article 1(3) states that: 'Until Community rules are adopted for medicated feedingstuffs, Member States may lay down that this term shall include semi-finished products which are manufactured from a pre-mix for medicated feedingstuffs for which an authorization pursuant to Article 4 of this Directive has been issued and feedingstuffs, where such semi-finished products are intended to be processed by further mixing with feedingstuffs to become medicated feedingstuffs ready for use.'

2.3. This clarification is necessary because Directive 81/851 applies to all veterinary medicinal products in the form of proprietary medicinal products or pre-mixes intended for the manufacutre of medicated feedingstuffs.

2.4. The directive is therefore essential because it supplements other directives such as Directive 81/851 of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products.

3. Medicated feedingstuffs

3.1. The need to adopt rules on the manufacture and putting into circulation of medicated feedingstuffs is due to the spread in intensive farming methods under which animals are subjected to stressful conditions, making them more vulnerable to large-scale outbreaks of disease.

3.2. Treatment with proprietary medicines has limited scope, the results being unsatisfactory because the diseases are mainly environmental in origin. It is therefore more convenient and less expensive to administer medicinal products directly in feedingstuffs. Moreover, not only do the stock-raising techniques promote disease, but the animals themselves are also weaker.

3.3. The genetic selection of chickens and turkeys, to produce animals with more developed hind quarters, has resulted in under-development of the thorax and under-oxygenation. A direct result of this is a susceptibility to diseases affecting the skeletal muscles and the cardiac muscle in addition to serious deficiencies in the digestive apparatus. The anti-stress factors are also

reduced as a result of induced hormone imbalances. In general, the anatomical, physical and endocrinal changes produced render the animals more prone to attacks of infectious diseases.

3.4. The use of medicated feedingstuffs based on active elements such as antibiotics and coccidiostats requires special care and control as the dangers to human and animal health are very real. The problem created by residues from medicinal products in foodstuffs, particularly the risk from antibiotics, which interfere with the microflora of the digestive apparatus and, by altering it, produce bacterial resistance, remains still unresolved.

3.5. Thus, while medicated feedingstuffs have to be used for prophylactic and therapeutic purposes, it is advisable - in order to restrict dangers to health - to avoid using them for auxinic purposes, i.e. to increase the weight of the animal. In any event, abuses such as excessive dosages or failure to respect the withdrawal period prior to slaughter, must be avoided.

4. Analysis of the directive

4.1. The directive does not apply to products for export to third countries (Article 3), yet it would be advisable for the feedingstuffs industry to adopt the same production standards regardless of the destination of the products, to avoid anomalies and loopholes which could rebound also on the European consumer.

4.2. Article 4(2) states that medicated feedingstuffs may be manufactured only from a veterinary prescription or from an authorized standard prescription. However, rather than a prescription, it would be better to speak of a formulation, because medicated feedingstuffs are a combination of one or more medicaments with feedingstuffs, both elements being important to the animal's health. The term 'prescription', on the other hand, refers only to the active (or formulated) medicinal element.

4.3. Article 4(3) allows any Member State to lay down other standard prescriptions for medicated feedingstuffs, in addition to those authorized by the Community. This derogation seems neither necessary nor appropriate; regulations should be introduced which at the very least are compatible with Community rules and the possibility for Member States to authorize standard prescriptions which do not comply with the principles laid down, should be withdrawn.

4.4. With regard to production conditions (Article 5(1) and (4)), more specific rules are required, along the lines of those laid down by the Italian law on the subject (D.M. 4.8.69). This would ensure adequate health and hygiene conditions, uniform at Community level.

4.5. Article 5 (paragraphs 3 and 5) stipulates that the feedingstuff used must be shown to form a homogeneous and stable mix with the veterinary medicinal product and be able to be stored for an adequate period of time. It would therefore be advisable to lay down more precise quality standards in respect of both the mixing and combination of feedingstuffs and medicinal products, in order to present unnecessary inequalities and investigations which would probably occur at the marketing and authorization stage.

4.6. The directive is very precise as regards measures to control the production and use of medicated feedingstuffs and it stipulates that records must be kept of all persons involved and of the quantity and types of feedingstuffs dispatched. In Article 5(6) it would be more appropriate to replace the word 'immediate' by the word 'daily'.

4.7. Article 7 authorizes the manufacture of medicated feedingstuffs from intermediate products. However, this would involve additional manufacturing stages and possibly additional sites, which would make the control system less effective.

4.8. All in all, the provisions of the directive are satisfactory, including those relating to packaging and the conditions to be met for obtaining production authorizations.

4.9. Nevertheless, a number of important problems remain unresolved, and the Commission should take these into consideration as soon as possible. They include, in particular:

- reduction of the medicinal products given to animals;
- respect of withdrawal periods;
- abolition of medicinal products and medicated feedingstuffs for auxinic purposes;
- illegal marketing of veterinary medicinal products;
- methods of analysis;
- control of residues in foodstuffs intended for animals (vegetable, animal, synthetic) and for consumers (meat, eggs, milk).

OPINION OF THE COMMITTEE ON AGRICULTURE

Letter from Sir Henry PLUMB, Chairman of the Committee on Agriculture, to Mr COLLINS, Chairman of the Committee on the Environment, Public Health and Consumer Protection.

Luxembourg, 1.4.1982

Dear Mr Chairman,

At its meeting of 1 April 1982 the Committee on Agriculture considered the proposal for a Council directive on the manufacture, putting into circulation and supply of medicated feeding-stuffs in the Community (COM(81) 795 final).

It welcomes the intention expressed in the Commission proposal to approximate the provisions of the Member States relating to medicated feeding-stuffs. The proposed directive is likely to make the internal Community market in medicated feeding-stuffs more transparent, to the benefit of both meat and milk producers and of the consumer

The principle that medicated feeding-stuffs may be manufactured only from authorized feeding-stuffs and veterinary medicinal products which comply with Community provisions (Articles 4, 5 and 6) provides a guarantee to meat and milk producers and to consumers that the effects and any side-effects of the medicated feeding-stuffs have been recognized as harmless to consumers of animal products from the treated animals.

The proposal prevents any misuse of medicated feeding-stuffs without consultation of a veterinarian by stipulating that they may be supplied only on the prescription of a registered veterinarian and that the veterinarian may prescribe them only for animals treated by him and only in such quantities as are necessary for the purpose of the treatment (Article 12).

The assurance that only authorized veterinary medical products and feeding-stuffs will be used and the prevention of any misuse of the medicated feeding-stuffs manufactured from them will improve the competitiveness of meat and milk producers within the Community.

The introduction of a standard prescription for the manufacture of medicated feeding-stuffs (Article 14) and the involvement of the Standing Veterinary Committee will promote trade in medicated feeding-stuffs within the Community.

Given that the general public is rightly disturbed by past evidence of certain practices involving the use of additives in feeding-stuffs, the proposed directive will be a means of restoring consumer confidence in the fact that animal products are being manufactured in an entirely acceptable manner. This will also be of great benefit to the producers of these products.

The Committee on Agriculture therefore approves the Commission's proposal for a directive.

Yours sincerely,
(sgd) Sir Henry PLUMB

I Present:

Mr Früh (Vice-Chairman and acting Chairman), Mr Colleselli (Vice-Chairman), Mr Clinton, Mr Dalsass, Mr Gatto, Mr Jürgens (deputizing for Mrs Martin), Mr Herklotz, Mr Kaloyannis, Mr Maher, Mr Marck, Mr Newton-Dunn (deputizing for Mr Curry), Mr Papapietro, Mr Provan, Mr Stella (deputizing for Mr Ligios) and Mr Wettig.