COMMISSION OF THE EUROPEAN COMMUNITIES

COM(93) 587 final

Brussels, 26 November 1993

Proposal for a

COUNCIL REGULATION (EEC)

laying down the conditions and arrangements
for approving certain establishments
operating in the animal feed sector
and amending Directives 70/524/EEC and 74/63/EEC

(presented by the Commission)

Explanatory Memorandum

The draft Council Regulation forms part of the general Community rules and regulations on animal feed and, more particularly, the scheme to register manufacturers and their representatives.

At matters currently stand, various directives lay down the minimum conditions that manufacturers of additives, premixtures and compound feedingstuffs must observe.

Thus, Council Directives 70/524/EEC on additives in feedingstuffs and 74/63/EEC on undesirable substances and products in feedingstuffs restrict the use and handling of certain materials and products only to those persons with the qualifications, facilities and equipment deemed necessary for general safety.

In the light of the experience gained, and in the context of the operation of the single market, it is proposed:

- to ensure legal clarity and to improve transparency by setting out the conditions and arrangements applying to the approval of the establishments in question;

- to update and supplement the criteria that manufacturers, intermediaries and their possible representatives must meet;

- to amend Directives 70/524/EEC and 74/63/EEC in accordance with the provisions of this draft Regulation.

As regards subsidiarity, it should be noted that the Member States are required to manage the procedures for granting and withdrawing approval and to ensure that the obligations laid down are met.

As in other cases where highly scientific or technical annexes relating to animal or human health are updated, provision should be made for close cooperation between the Member States and the Commission in the Standing Committee on animal feed established by the Council Decision 70/372/EEC of 20 July 1970, so that the annex can be amended in line with scientific and technical progress.

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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 Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs(4), as last amended by Directive 93/ /EEC(5), lays down the minimum conditions to be met by manufacturers of additives, premixtures and compound feedingstuffs containing such products;

Whereas this legislation restricts the manufacture and use of certain categories of additives, premixtures and compound feedingstuffs containing such additives and premixtures to those manufacturers who are included on a national list;

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(1)

(2)

(3)

(4) OJ No L 270, 14.12.1970, p. 1.

(5)

Whereas with the operation of the single market in mind, some optional provisions which still allow the Member States to derogate from the Community provisions applying to the sector in question and to specify the criteria for approving manufacturers should be abolished so as to avoid distortions of competition caused by the Member States' different applications and interpretations of already existing approval conditions and to prevent any potentially adverse effects on animals, humans or the environment, given the risks inherent in using certain additives.

Whereas, to govern the presence of certain particularly undesirable substances in feedingstuffs, Council Directive 74/63/EEC of 17 December 1973 on the fixing of maximum permitted levels for undesirable substances and products in feedingstuffs[6], as last amended by Directive 93/../EEC[7], limits their presence in raw materials to an acceptable level; whereas this Directive also restricts the use of these raw materials to those persons who have the necessary qualifications, facilities and equipment for the dilution operations which ensure that the maximum levels laid down in the Directive as regards the various types of compound feedingstuffs are complied with;

Whereas, in the light of the experience gained, additional rules should be laid down relating to the registration of establishments engaged in the manufacture, storage or packaging of the products in question, and the recording of other persons in an official register;

Whereas, with a view to ensuring the quality of the product and preventing the risk of residues of certain additives in animal products or of high levels of heavy metals or pesticides which might result in the defective manufacture of the additives, premixtures or compound feedingstuffs, the intention is to approve all manufacturers of additives, premixtures and compound feedingstuffs on the basis of standard, specific criteria;

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(6) OJ No L 38, 11.2.1974, p. 31.

(7)

Whereas the obligation on all manufacturers to obtain approval will provide the Member States with the opportunity to monitor them and possibly uncover and act against those making illegal use of authorized substances or employing banned substances such as hormones or β-agonists;

Whereas the standard obligations which must be complied with to qualify for approval should be laid down; whereas it is also necessary to give the Commission the task of adopting detailed rules for the application of this Regulation, including the imposition of appropriate penalties;

Whereas, should the Council confer on the Commission responsibility for implementing the rules laid down on the conditions and arrangements for approving the establishments in question, provision should be made for close cooperation between the Member States and the Commission within the Standing Committee for Feedingstuffs established by Council Decision 70/372/EEC(8);

Whereas to ensure greater transparency the conditions and arrangements relating to approval in the animal feed sector should be brought together in a single text; whereas this entails adapting existing legislations;

Whereas the Member States are responsible for ensuring that the minimum conditions for national authorities to grant approval as set out in this Regulation are met and that the establishments subsequently continue to comply with the said conditions; whereas, however, these provisions must apply without prejudice to the Community rules governing the organization of official checks on animal feed;

Whereas it is necessary to adopt these measures at Community level in order to better achieve the objectives of guaranteeing the quality and safety of animal feedingstuffs,

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(8) OJ No L 170, 3.8.1970, p. 1.

HAS ADOPTED THIS REGULATION:

Article 1

1. This Regulation lays down the conditions and arrangements for approving certain categories of establishments in the animal feed sector, hereinafter referred to as "establishments", which must meet the conditions laid down in Article 3 below with a view to the marketing of the products in question.

2. This Regulation shall apply without prejudice to the Community provisions concerning the organization of official checks on animal feed.

3. For the purposes of this Regulation, the definitions laid down in Community legislation on animal feed shall apply where necessary.

Article 2

From .../.../19..., the establishments shall apply for inclusion in an official register held by the competent national authority with a view to being approved by the Member State.

Article 3

1. To be approved by the competent national authorities an establishment
   (a) manufacturing additives must meet the conditions listed in Chapter I of the Annex;
   (b) engaged in the manufacture, storage or packaging of premixtures must meet the conditions listed in Chapter II of the Annex;
   (c) engaged in the manufacture, storage or packaging of compound feedingstuffs containing premixtures must meet the conditions listed in Chapter III A of the Annex;
   (d) manufacturing compound feedingstuffs from raw materials (ingredients) containing high levels of undesirable products or substances must meet the conditions listed in Chapter III B of the Annex;

(e) manufacturing compound feedingstuffs must meet the conditions listed in Chapter III C of the Annex.

2. The amendments that need to be made to the Annex by virtue of scientific and technological progress shall be adopted in accordance with the procedure laid down in Article 11.

Article 4

Article 1 notwithstanding, manufacturers of compound feedingstuffs who use premixtures or raw materials containing high levels of undesirable substances and products with a view to their proper consumption may apply for approval in accordance with this Regulation. To be eligible for such approval, they must meet the conditions laid down in Article 3(1)(c) or (d) and set out in Chapters IIIA or IIIB, with the exception however of the requirements laid down in point 7.

Article 5

Where the additive is an antibiotic, coccidiostat or another medicinal substance listed in Groups A or D of the Annexes to Directive 70/524/EEC and already authorized for manufacture as a veterinary medication within the meaning of Article 24 of Directive 81/851/EEC, the conditions laid down in Article 3(1)(a) and contained in Chapter I of the Annex to this Regulation shall not apply, with the exception however of the requirements stipulated in points 3, 5, 6.2 and 7.

Article 6

1. For each activity, the competent national authority shall enter the establishments in the official register referred to in Article 2 under an individual registration number which identifies them, once it has established that they satisfy the conditions laid down by this Regulation.

2. The Member States shall update the official register and correct or replace, where necessary, any entry where an establishment decides to engage in activities which are in addition to or replace those for which it was initially registered.

Article 7

The practical arrangements for approving establishments located in a non-member country and putting animal feedingstuffs, additives or premixtures into circulation within the Community shall be adopted in accordance with the procedure laid down in Article 11.

Article 8

Each Member State shall publish each year, and by 30 November at the latest, a list of the establishments and representatives approved in accordance with Articles 3 and 7 which it has found to comply with the requirements listed in the Annexes hereto.

The Member State shall send the list to the other Member States and to the Commission before 31 December of each year.

Any amendments made to the lists after 30 November shall be separately notified to the other Member States and to the Commission.

Article 9

Detailed rules for the application of this Regulation shall be adopted in accordance with the procedure laid down in Article 11.

Article 10

The Commission shall be assisted by the Standing Committee for Feedingstuffs, established by Council Decision 70/372/EEC of 20 July 1970, hereinafter referred to as "the Committee".

Article 11

Where the procedure laid down in this Article is to be followed, the following provisions shall apply:

The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down depending on the urgency of the matter, with a vote being taken, where appropriate.

The opinion shall be recorded in the summary record. Each Member State shall also have the right to request that its position be recorded in the summary record.

The Commission shall take full note of the Committee's opinion. It shall inform the Committee of the way in which it took account thereof.

Article 12

Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs is hereby amended as follows:

1. Article 13(1) is replaced by the following:

"1. Member States shall require that antibiotics, coccidiostats and other medicinal substances, growth promoters, trace elements and vitamins listed in Annex I or Annex II, premixtures prepared from these additives with a view to being incorporated in compound feedingstuffs and compound feedingstuffs containing these premixtures may only be put on the market under the conditions referred to in the Annex to Regulation (EEC) No .../... and in particular only if they have been produced by manufacturers who have been approved in accordance with the provisions of the said Regulation."

2. The reference to Annex III in Article 13(2) is replaced by a reference to the Annex to Regulation (EEC) No .../...

3. Article 13(3) is deleted.

4. Paragraph 4 of Article 13 becomes paragraph 3.

5 Article 13(5) is deleted.

6. Annex III is deleted.

Article 13

Council Directive 74/63/EEC of 17 December 1973 on the fixing of maximum permitted levels for undesirable substances and products in feedingstuffs is hereby amended as follows:

Point (a) of Article 3a(2) is replaced by the following:

"(a) it is intended for use by manufacturers of compound feedingstuffs entered on a national list in accordance with the provisions of Regulation (EEC) No .../... and meeting the requirements set out in Chapter III B of the Annex and"

Article 14

This Regulation shall enter into force twelve months following its publication in the Official Journal of the European Communities.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at

For the Council

The President

ANNEX

Chapter I. Conditions which must be fulfilled by establishments manufacturing additives in order to obtain approval

1. Facilities and Equipment

Facilities and manufacturing equipment shall be located, designed, constructed, adapted and maintained to suit the manufacture of additives. The lay-out, design and operation of the facilities and equipment must minimize the risk of error and permit effective cleaning and maintenance in order to avoid contamination, cross-contamination by other products and any adverse effects generally on the quality of the products.

Facilities and equipment to be used for manufacturing operations which are essential for the quality of the products shall undergo appropriate and regular checks, in accordance with the written procedures.

2. Personnel

The manufacturer or his staff must possess the knowledge and experience necessary for the manufacture of additives.

3. Production

The manufacturer must ensure that the additives conform to Directive 70/524/EEC and that all manufacturing operations are carried out in accordance with the information given in the application. A qualified person responsible for production must be designated.

The different stages in production shall be carried out according to pre-established written instructions and procedures. Measures shall be taken to avoid cross-contamination and errors. The critical stages in the manufacturing process shall be regularly checked, in accordance with the written procedures.

4. **Quality control**

The manufacturer shall establish and maintain a quality control laboratory to carry out the necessary examination and analysis of raw materials, packaging materials and intermediate and finished products testing. A qualified person responsible for quality control shall be designated.

Before releasing the finished products for sale or distribution, their compliance with the specifications as supplied with the application for authorization must be checked and guaranteed.

Samples of the active substance and of each batch of finished product shall be retained in order to ensure traceability.

5. **Storage**

Additives shall be stored in such a way as to to be easily identified and to avoid any confusion with other products. They shall be stored in suitable places to which only authorized persons have access.

6. **Documentation**

6.1 Documentation of manufacturing process and controls

The manufacturer must have a system of documentation based upon specifications, manufacturing formulae, processing and packaging instructions, procedures and the various summary sheets and records covering the different manufacturing operations performed. This set of documents shall make it possible to trace the manufacturing history of each batch produced and to establish responsibility when complaints arise.

6.2 **Commercial register**

The manufacturer must record the following information to facilitate traceability : the nature and quantity of the additives produced, the respective dates of manufacture and batch number if appropriate and the names and addresses of the approved manufacturers of premixtures or approved intermediaries to whom the additives have been delivered, along with an indication of the nature and quantity of additives delivered and batch number, if appropriate.

7. Commercial Intermediaries

Where the manufacturer delivers additives to a person other than an approved manufacturer of premixtures, that person and any subsequent intermediary shall be equally bound by the obligations laid down in points 5 and 6.2.

8. **Complaints and product recall**

The manufacturer shall implement a system for recording and dealing with complaints, together with an effective system for recalling promptly and at any time the products in the distribution network. Where there is a risk to human health, the authorities must be informed. Any goods returned must be reassessed and approved by quality control before being resold, where appropriate.

Chapter II. Conditions which must be fulfilled by establishments manufacturing premixtures in order to obtain approval

1. **Facilities and Equipment**

Facilities and manufacturing equipment shall be located, designed, constructed, adapted and maintained to suit the manufacture of premixtures. The lay-out, design and operation of both facilities and equipment must minimize the risk of error and permit effective cleaning and maintenance in order to avoid contamination, cross-contamination and any adverse effects generally on the quality of the products. Facilities and equipment to be used for manufacturing operations which are essential for the quality of the products shall undergo appropriate and regular checks, in accordance with the written procedures.

There must be a prevention scheme and regular control measures must be applied to prevent the entrance of rodents, insects, birds and domestic animals as far as possible.

2. **Personnel**

The manufacturer or his staff must possess the knowledge and experience necessary for the manufacture of premixtures.

3. **Production**

A qualified person responsible for production must be designated. The different stages in production shall be carried out according to pre-established written instructions and procedures. Measures shall be taken to avoid cross-contamination and errors. The critical stages in the manufacturing process shall be regularly checked in accordance with the written procedures: incorporation, chronological order of production, meters and weighing apparatus, mixer, returns.

4. **Quality control**

The manufacturer must guarantee and verify the nature, content, uniformity and stability of the additives in the premixture. A quality control plan must be established and implemented with a view to achieving this goal. A qualified person responsible for quality control must be designated.

Samples of the finished product shall be kept in order to ensure traceability.

5. **Storage**

The additives and premixtures shall be stored in such a way as to be identifiable and to avoid confusion with other products. They shall be stored in suitable places to which only authorized persons have access.

There must be a prevention scheme and regular control measures must be applied to prevent the entrance of rodents, insects, birds and domestic animals as far as possible.

6. **Documentation**

6.1 Documentation of manufacturing process and controls

The manufacturer must have a system of documentation based on specifications, manufacturing formulae, processing and packaging instructions, procedures and the various summary sheets and records covering the different manufacturing operations performed. This set of documents shall make it possible to trace the manufacturing history of each batch produced and to establish responsibility when complaints arise.

6.2 Commercial register

The manufacturer must record the following information in order to ensure traceability : the name of the approved manufacturers and suppliers, the nature and quantity of the additives used and batch number if appropriate, the date of manufacture, the name and address of the approved compound feedingstuff manufacturers or intermediaries for whom the premixture is intended and the nature and quantity of the premixture delivered.

7. **Commercial intermediaries**

Where the manufacturer delivers premixtures to a person other than an approved manufacturer of compound feedingstuffs, that person and any subsequent intermediary shall be equally bound by the obligations laid down in points 5 and 6.2.

8. **Complaints and product recall**

The manufacturer shall implement a system for recording and dealing with complaints, together with an effective system for recalling promptly and at any time the products in the distribution network. Where there is a risk to human health, the authorities must be informed. Any goods returned must be reassessed and approved by quality control before being resold, where appropriate.

Chapter III. Conditions which must be fulfilled by establishments manufacturing compound feedingstuffs in order to obtain approval

III.A : Conditions which must be fulfilled by establishments manufacturing compound feedingstuffs containing the premixtures referred to in chapter II, in order to obtain approval.

1. **Facilities and Equipment**

Facilities and manufacturing equipment shall be located, designed, constructed, adapted and maintained to suit the manufacture of compound feedingstuffs containing premixtures. The lay-out, design and operation of the facilities and equipment must be such as to minimize the risk of error and permit effective cleaning and maintenance in order to avoid contamination, cross-contamination and any adverse effects generally on the quality of the products.

Facilities and equipment to be used for manufacturing operations which are essential for the quality of the products shall undergo the appropriate checks in accordance with the written procedures.

There must be a prevention scheme and regular control measures must be applied to prevent the entrance of rodents, insects, birds and domestic animals as far as possible.

2. **Personnel**

The manufacturer or his staff must possess the knowledge and have the appropriate experience for the manufacture of compound feedingstuffs containing premixtures.

3. **Production**

A qualified person responsible for production must be designated. The different stages in production shall be carried out according to pre-established written instructions and procedures. Measures shall be taken to avoid cross-contamination and errors. Critical stages in the manufacturing process shall be regularly checked in accordance with the written procedures: incorporation, chronological order of production, meters and weighing apparatus, mixer, returns.

4. **Quality control**

The manufacturer must guarantee and verify the nature, content, uniform mix of the additives in the premixture. A quality control plan must be established and implemented with a view to achieving this goal. A qualified person responsible for quality control must be designated.

The various analytical components must be checked for conformity with Directive 79/373/EEC by means of a quality control plan and appropriate methods.

Samples of the finished product shall be kept in order to ensure traceability.

5. **Storage**

The premixtures and/or additives shall be stored in such a way as to be identifiable and to avoid confusion with other products. They shall be stored in suitable places to which only authorized persons have access.

There must be a prevention scheme and regular control measures must be applied to prevent the entrance of rodents, insects, birds and domestic animals as far as possible.

6. **Documentation**

6.1 Documentation of the manufacturing process and controls

The manufacturer shall have a system of documentation based on specifications, manufacturing formulae, processing and packaging instructions, procedures and the various summary sheets and records covering the different manufacturing operations performed. This set of documents shall make it possible to trace the manufacturing history of each batch processed and establish responsibility when complaints arise.

6.2 Commercial register

The manufacturer must record the following information in order to ensure traceability : the name of the approved premixture supplier and approved manufacturer if he is not the supplier, the batch number if appropriate, the nature and quantity of the premixture and the use to which it will be put.

7. Complaints and product recall

The manufacturer shall implement a system for recording and dealing with complaints, together with an effective system for recalling promptly and at any time the products in the distribution network. Where there is a risk to human health, the authorities must be informed. Any goods returned must be reassessed and approved by quality control before being resold, where appropriate.

III B. Conditions which must be fulfilled by establishments manufacturing compound feedingstuffs from raw materials containing high levels of undesirable substances and products

1. Facilities and Equipment

Facilities and manufacturing equipment shall be located, designed, constructed, adapted and maintained to suit the manufacture of compound feedingstuffs from raw materials containing high levels of undesirable substances and products. The lay-out, design and operation of the facilities and equipment must be such as to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid contamination, cross-contamination and any adverse effects generally on the quality of the products.

Facilities and equipment to be used for manufacturing operations which are essential for the quality of the products shall undergo the appropriate checks in accordance with the written procedures.

There must be a prevention scheme and regular control measures must be applied to prevent the entrance of rodents, insects, birds and domestic animals as far as possible.

2. **Personnel**

The manufacturer or his staff must possess the knowledge and have the necessary experience for the manufacture of compound feedingstuffs from raw materials containing high levels of undesirable substances and products.

3. **Production**

A qualified person responsible for production must be designated. The different stages in production shall be carried out according to pre-established written instructions and procedures. Measures shall be taken to avoid cross-contamination and errors. The critical stages in the manufacturing process shall be regularly checked in accordance with the written procedures: incorporation, chronological order of production, meters and weighing apparatus, mixer, returns.

4. **Quality control**

The manufacturer must guarantee and verify the nature, content, and uniform mix of the undesirable products and substances in the compound feedingstuff. A quality control plan must be established and implemented to achieve this goal and to comply with the maximum limits permitted in compound feedingstuffs. A qualified person responsible for quality control must be designated.

The various analytical components must be checked for conformity with Directive 79/373/EEC by means of a quality control plan and appropriate methods.

Samples of the finished product shall be kept in order to ensure traceability.

5. **Storage**

The raw materials and the compound feedingstuffs shall be stored in such a way as to be identifiable and to avoid confusion with other products. They shall be stored in suitable places to which only authorized persons have access.

There must be a prevention scheme and regular control measures must be applied to prevent the entrance of rodents, insects, birds and domestic animals as far as possible.

6. Documentation

6.1 Documentation of the manufacturing process and controls

The manufacturer shall have a system of documentation based on specifications, manufacturing formulae, processing and packaging instructions, procedures and the various summary sheets and records covering the different manufacturing operations performed. This set of documents shall make it possible to trace the manufacturing history of each batch produced and establish responsibility when complaints arise.

6.2 Commercial register

The manufacturer must record the following information in order to ensure traceability : the name of the supplier of raw materials containing high levels of undesirable substances and products and the name of the manufacturer if he is not the supplier, the nature and quantity of undesirable substances and products and the use to which they will be put.

7. Complaints and product recall

The manufacturer shall implement a system for recording and dealing with complaints, together with an effective system for recalling promptly and at any time the products in the distribution network. Where there is a risk to human health, the authorities must be informed. Any goods returned must be reassessed and approved by quality control before being resold, where appropriate.

III C. Conditions which must be fulfilled by establishments manufacturing compound feedingstuffs in order to obtain approval

1. **Facilities and Equipment**

Facilities and manufacturing equipment shall be located, designed, constructed, adapted and maintained to suit the manufacture of compound feedingstuffs. The lay-out, design and operation of the facilities and equipment must be such as to minimize the risk of error and permit effective cleaning and maintenance in order to avoid contamination, cross-contamination and any adverse effects generally on the quality of the products.

Facilities and equipment to be used for manufacturing operations which are essential for the quality of the products shall undergo the appropriate checks.

There must be a prevention scheme and regular control measures must be applied to prevent the entrance of rodents, insects, birds and domestic animals as far as possible.

2. **Personnel**

The manufacturer or his staff must possess the knowledge and have the appropriate experience for the manufacture of compound feedingstuffs.

3. **Production**

A qualified person responsible for production must be designated. The different stages in production shall be carried out according to pre-established written instructions and procedures. The critical stages in the manufacturing process must be checked: incorporation, meters and weighing apparatus, mixer.

4. **Quality control**

The manufacturer must have the means to guarantee and verify the uniform mix of the ingredients in the compound feedingstuff. The various analytical components must be checked for conformity with Directive 79/373/EEC by means of a quality control plan and appropriate methods. A qualified person responsible for quality control must be designated.

5. **Storage**

The raw materials and the compound feedingstuffs shall be stored in such a way as to be identifiable and to avoid confusion with other products. They shall be stored in suitable places.

There must be a prevention scheme and regular control measures must be applied to prevent the entrance of rodents, insects, birds and domestic animals as far as possible.

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