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PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
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To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
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EUROPEAN
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2014/0255 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on the manufacture, placing on the market and use of medicated feed and repealing
Council Directive 90/167/EEC

(Text with EEA relevance)

{SWD(2014) 271 final}
{SWD(2014) 272 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Farmed animals in the EU are fed with roughage, feed materials and compound feed (mixture of feed materials). If animals are sick and need a treatment, veterinary medicinal products may be administered on the basis of a veterinary prescription. The vast majority of medicated feed for farmed animals contains antimicrobials or anti-parasites.

As regards the oral administration of medicines to animals, the animal holders can either add medicines themselves to the animal feed or drinking water or use medicated feed into which the medicine is incorporated by themselves or by another approved manufacturer.

Medicated feed is generally used to treat animal diseases in large groups of animals, in particular pigs and poultry. There is a clear correlation between the level of manufacture standards and the quality of the treatment via medicated feed. High standards mean good homogenous distribution of the medicine in the feed, good compatibility of the medicine with the feed and as a result good dosage and efficient treatment of the animal and low carry-over of the medicine into non-target animal feed.

There are 13.7 million animal holdings in the EU. The value of livestock farming output in the EU is €57 billion. The value of the EU's aquaculture which includes production of crustaceans, molluscs, and finfish is estimated to be €3.3 billion. Pet animals represent the second largest type of animals kept in the EU. There are around 64 million cats, 60 million dogs, 40 million pet birds, 25 million small mammals and many millions of ornamental fishes. All these farmed animals, aquaculture species and pets, depending on their health condition, may need medication.

The aim of the review of the medicated feed rules is to harmonise at a high safety level the manufacture, marketing and use of medicated feed and intermediate products in the EU and to reflect technical progress in this field. The draft proposal updates the current legislation on medicated feed by repealing Directive 90/167/EEC which sets out the conditions under which medicated animal feed may be manufactured, placed on the market and used within the EU. The Directive has been established before the creation of the internal market and it has never been adapted in substance. The national transposition of this legal instrument has given freedom to Member States regarding interpretation and implementation of the legal provisions, but this flexibility has contributed to some problems. The Directive gives no indication on what standards to apply in approving plants or the acceptable techniques to produce medicated feed, whether standards should be technology-based or results-based, it does not provide for homogeneity criteria, it is totally silent on the concept of carry-over of medicated feed between batches, on the specific labelling of medicated feed and on medicated feed for pets and it is vague on whether feed may be prepared in advance of prescription in the feed mill, allowing Member States to arrive with different interpretations.

Furthermore, the existing legislation is likely to perpetuate existing discrepancies in its implementation between the Member States. This creates an uneven playing field for professional operators on the single market. There is a need to harmonise implementation of the legislation, reduce financial and administrative burdens and support innovation.

The draft proposal will allow the anticipated medicated feed production, mobile and on-farm mixing, while simultaneously establishing the parameters for these schemes. The provisions include measures for disposal of not used medicated feed on farm. EU wide limits will be set for the carry-over of veterinary medicines in feed that should be adapted based on an assessment of the risk for the animals and the humans with regard to the different types of active substances.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENT

The impact assessment builds on the results of an external study entitled "Evaluation of the EU Legislative Framework in the Field of Medicated Feed" carried out in 2009/2010 by the Food Chain Evaluation Consortium (FCEC).

It is furthermore based on a wide stakeholders' consultation in the context of the evaluation conducted in 2009/2010, following which internal consultations and discussion with the Member States took place. In addition, during the whole process consultations with the stakeholders were done in the margins of the Advisory Group on the Food Chain and Animal and Plant Health, the Animal Health Advisory Committee and the Advisory Committee on Fisheries and Aquaculture working group on aquaculture. Furthermore, targeted consultations of the International Federation for Animal Health Europe, the European Feed Manufacturers' Federation, the Federation of Veterinarians in Europe and the EU Farmers and Agri-Cooperatives were undertaken.

Following the stakeholders' consultation in the margins of the FCEC evaluation, a new web-based stakeholders' survey was organised from 30 March to 31 May 2011, using an Interactive Policy Making questionnaire to collect comments on the policy options.

Finally, focussed interviews with experts from the industry and competent authorities were undertaken mainly to collect data for the assessment of the different options.

In June 2009 a questionnaire was sent to the Member States plus Norway and Switzerland to gather information from the competent authorities on the status quo in the field of medicated feed.

In addition, the Commission has consulted and reported regularly to the working party of Chief Veterinary Officers, the Standing Committee on the Food Chain and Animal Health (Section Animal Nutrition) and the Veterinary Pharmaceutical Committee.

The purpose of the impact assessment was to support the changes proposed to the medicated feed legislation (Directive 90/167/EEC) in line with the principles set out in the Commission's Work programme. This is related to similar on-going work in

the field of veterinary medical products. The Health and Consumers Directorate-General has taken the initiative to revise Directive 90/167/EEC at the same time as the revision of the veterinary medicinal products legislation.

Member States and the different stakeholders involved in this field have on several times indicated the importance of ensuring that the revision of the medicated feed legislation takes the specificities of the sector into account. This can only be done by an independent approach which builds on the links with the feed legislation and the veterinary medicinal products legislation.

The impact assessment identified the following main axes along which the system has to change in order to answer the stakeholders concerns: residues of veterinary medicines in feed, imprecise dosage of veterinary medicines, impossible market access to medicated feed for pets and barriers to intra EU trade of medicated feed.

The impact assessment concluded that an EU Regulation with detailed rules would have the most positive impacts and would provide for the best way forward to achieve the objectives for the EU. It should have a significant positive impact on cost efficiency and economic growth of the medicated feed manufacturing sector, also considering innovative applications of veterinary medicines. Animal and public health can be expected to be improved both in Member States with currently lax standards for medicated feed and those with prohibitive standards. Safe tolerance levels for the unavoidable carry-over of veterinary medicines in feed would lead to a pragmatic and solid level playing field for the industry and the control authorities.

3. LEGAL ELEMENTS OF THE PROPOSAL

The aim of this proposal is to repeal Directive 90/167/EEC by the proposed Regulation.

General provisions

The scope of the proposed Regulation covers the manufacture, placing on the market and use of medicated feed for use in pets and in food-producing animals within the Union. It does not apply to veterinary medicinal products used as the medicinal component of medicated feed (previously called "medicated premixes"), which are dealt with under the veterinary medicinal products legislation.

The Regulation lays down rules for the manufacture, composition, placing on the market and use of medicated feed. The general manufacture requirements laid down in Regulation (EC) No 183/2005 apply. Furthermore, medicated feed may only be manufactured from veterinary medicinal products authorised under the veterinary medicinal products legislation. It also sets rules for the approval of feed business operators and rules they need to comply with in order to manufacture medicated feed. The Regulation lays down rules for the homogenous incorporation of the veterinary medicinal products into the medicated feed and requirements in order to avoid carry-over of active substances from veterinary medicinal products into non target feed.

With respect to labelling, the general provisions laid down in Regulation (EC) No 767/2009 apply. Specific rules for the prescription, the validity of the prescription, the use of medicated feed containing antimicrobials in food-producing animals and

the quantities required for the treatment of animals with medicated feed are laid down. Manufacturers, distributors and users of medicated feed must keep daily records for the effective tracing of medicated feed. For veterinary medicinal products authorised at national level, the Regulation sets Intra-Union rules for trade of medicated feed in order to prevent distortions in competition.

Rules for the adoption of delegated acts and of implementing acts on the basis of the Regulation are laid down in the proposal.

Legal basis

Articles 43 and 168(4)(b) of the TFEU provide for the legal basis of the proposal.

Directive 90/167/EEC was based on Article 43 of the Treaty establishing the European Economic Community (now Article 43 of the TFEU), implementing the Common Agricultural Policy. The objectives of that policy are to increase agricultural productivity, to ensure a fair standard of living for the agricultural community, to stabilise markets, to assure the availability of supplies and to ensure that supplies reach consumers at reasonable prices. To aim for harmonised and adequate production conditions for the EU livestock farmers can be also derived from this Article.

Article 168(4)(b) of the TFEU covers measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health.

The proposal takes the form of a Regulation of the European Parliament and of the Council. Other means would not be appropriate because the objectives of the measure can be achieved most efficiently by fully harmonised requirements throughout the Union.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**on the manufacture, placing on the market and use of medicated feed and repealing
Council Directive 90/167/EEC**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43 and 168(4)(b) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Council Directive 90/167/EEC³ constitutes the Union's regulatory framework for the manufacture, placing on the market and use of medicated feed.
- (2) Livestock production occupies a very important place in the agriculture of the Union. The rules concerning medicated feed have significant influence on the keeping and on the rearing of animals, including non-food producing animals, and on the production of products of animal origin.
- (3) The pursuit of a high level of protection of human health is one of the fundamental objectives of food law, as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council⁴, and the general principles laid down in that Regulation should apply to the placing on the market and use of feed without prejudice to more

¹ OJ C , , p. .

² OJ C , , p. .

³ Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community (OJ L 92, 7.4.1990, p. 42).

⁴ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

specific Union legislation. In addition, the protection of animal health constitutes one of the general objectives of EU food law.

- (4) Experience with the application of Directive 90/167/EEC has shown that further measures should be taken to strengthen the effective functioning of the Internal Market and to explicitly give and improve the possibility to treat non-food producing animals by medicated feed.
- (5) Medicated feed is one of the routes for the administration of veterinary medicinal products, which are incorporated into feed. The authorisation for use in feed, the manufacture, distribution, advertising and supervision of those veterinary medicinal products are governed by Directive 2001/82/EC of the European Parliament and of the Council⁵.
- (6) As a type of feed, medicated feed falls within the scope of Regulation (EC) No 1831/2005 of the European Parliament and of the Council⁶, of Regulation (EC) No 767/2009 of the European Parliament and of the Council⁷, of Regulation (EC) No 1831/2003 of the European Parliament and of the Council⁸ and of Directive 2002/32/EC of the European Parliament and of the Council⁹. Specific provisions for medicated feed and intermediate products should be established concerning facilities and equipment, personnel, manufacture quality control, storage and transport, record-keeping, complaints and product recalls, the application of procedures based on the hazard analysis and critical control points (HACCP) principles and labelling.
- (7) Medicated feed imported into the Union must satisfy the general obligations laid down in Article 11 of Regulation (EC) No 178/2002 and the import conditions laid down in Regulation (EC) No 183/2005 and in Regulation (EC) No 882/2004 of the European Parliament and of the Council¹⁰. Within this framework, medicated feed imported into the Union is to be considered as falling within the scope of this Regulation.
- (8) Without prejudice to the general obligations laid down in Article 12 of Regulation (EC) No 178/2002 concerning exports of feed to third countries, the provisions of this Regulation should apply to medicated feed and intermediate products which are manufactured, stored, transported or placed on the market within the Union with the intention to be exported. However, the specific requirements concerning labelling, prescription and use of medicated feed and intermediate products should not apply to products intended to be exported.

⁵ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

⁶ Regulation (EC) No 1831/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1).

⁷ Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed (OJ L 229, 1.9.2009, p. 1).

⁸ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

⁹ Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).

¹⁰ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules (OJ L 165, 30.4.2004, p. 1) (Corrigendum : OJ L 191, 28.5.2004, p. 1).

- (9) Medicated feed should be manufactured only with authorised veterinary medicinal products and the compatibility of all compounds used should be ensured for the purpose of safety and efficacy of the product. Additional specific requirements or instructions for the inclusion of the veterinary medicinal products into feed should be foreseen to ensure a safe and efficient treatment of the animals.
- (10) Homogeneous incorporation of the veterinary medicinal product into the feed is also crucial for the manufacture of a safe and efficient medicated feed. Therefore, the possibility to establish criteria, such as target values, for the homogeneity of the medicated feed should be provided for.
- (11) Feed business operators may produce within one establishment a broad range of feeds for different target animals and containing different types of compounds such as feed additives or veterinary medicinal products. The manufacture of different types of feed after each other in the same production line may result in the presence of traces of a substance in the line, which ends up in the beginning of the production of another feed. This transfer of traces of a substance from one production lot to another is called "carry-over".
- (12) Carry-over may occur during production, processing, storage and transport of feed where the same production and processing equipment, storage facilities or means of transport are used for feed with different components. For the purposes of this Regulation, the concept of "carry-over" is used specifically to designate the transfer of traces of an active substance contained in a medicated feed to a non-target feed, while the term "cross-contamination" is to be considered as a contamination resulting from a carry-over or from the transfer in feed of any unintended substance. Carry-over of active substances contained in medicated feed to non-target feed should be avoided or kept as low as possible. In order to protect animal health, human health and the environment, maximum levels of carry-over for active substances contained in medicated feed should be established, based on a scientific risk assessment performed by the European Food Safety Authority and taking into account the application of good manufacturing practice and the ALARA (As Low As Reasonably Achievable) principle. General limits should be set out in this Regulation, taking into account the unavoidable carry-over and the risk caused by the active substances concerned.
- (13) Labelling of medicated feed should comply with the general principles laid down in Regulation (EC) No 767/2009 and be subject to specific labelling requirements in order to provide the user with the information necessary to correctly administer the medicated feed. Similarly, limits for the deviations of the labelled content of medicated feed from the actual content should be established.
- (14) Medicated feed should be marketed in sealed containers for safety reasons and to protect user's interest.
- (15) For intra Union trade of medicated feed, it should be ensured that the veterinary medicinal product contained therein has been duly authorised in the Member State of destination according to Directive 2001/82/EC.
- (16) Feed business operators manufacturing, whether they operate in a feed mill, with a specially equipped lorry or on-farm, storing, transporting or placing on the market medicated feed and intermediate products, should be approved by the competent

authority, in line with the approval system laid down in Regulation (EC) No 183/2005, in order to ensure both feed safety and product traceability. Provision should be made for a transition procedure concerning establishments already approved under Directive 90/167/EEC.

- (17) In order to ensure the safe use of medicated feed, its supply and use should be subject to presentation of a valid veterinary prescription which has been issued after examination of the animals to be treated. However, the possibility to manufacture medicated feed before a prescription is presented to the manufacturer should not be excluded.
- (18) In order to ensure a particularly prudent use of medicated feed for food-producing animals and therefore provide the basis for the assurance of a high level of protection of public health, specific conditions concerning the use and the validity of the prescription, compliance with the withdrawal period and record-keeping by the animal holder should be provided for.
- (19) Taking into account the serious public health risk posed by resistance to antimicrobials, it is appropriate to limit the use of medicated feed containing antimicrobials for food-producing animals. Preventive use or use to enhance the performance of food-producing animals should in particular not be allowed.
- (20) A system for the collection of unused or expired products should be put in place in order to control any risk that such products might raise with regard to the protection of animal, human health or the environment.
- (21) In order to comply with the objective of this Regulation and to take into account technical progress and scientific developments, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the establishment of specific carry-over limits and of the amendment to the Annexes to this Regulation. Those Annexes concern provisions on feed business operators obligations related to the manufacture, storage, transport and placing on the market of medicated feed and intermediate products, the incorporation of the veterinary medicinal product into feed, the labelling particulars for medicated feed and intermediate products, the permitted tolerances for the compositional labelling of medicated feed or intermediate products and the specimen form to be used for the veterinary prescription. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.
- (22) In order to ensure uniform conditions for the implementation of this Regulation regarding the establishment of homogeneity criteria for medicated feed, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers¹¹.

¹¹ OJ L 55, 28.2.2011, p. 13.

- (23) Member States should lay down penalties for infringement to the provisions of this Regulation and should take all measures necessary to ensure that they are implemented. Such penalties should be effective, proportionate and dissuasive.
- (24) Since the objective of this Regulation, namely ensuring a high level of protection of human and animal health, providing adequate information for users and strengthening the effective functioning of the internal market, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

Chapter I

Scope and definitions

Article 1 *Scope*

This Regulation shall apply to:

- (a) the manufacture, storage and transport of medicated feed and intermediate products;
- (b) the placing on the market, including import, and use of medicated feed and intermediate products;
- (c) the export to third countries of medicated feed and intermediate products. However, Articles 9, 15, 16 and 17 shall not apply to medicated feed and intermediate products whose label indicates that they are intended for export to third countries.

Article 2 *Definitions*

1. For the purposes of this Regulation, the following definitions shall apply:
 - (a) the definitions of 'feed', 'feed business' and 'placing on the market' as laid down in Article 3 of Regulation (EC) No 178/2002;
 - (b) the definitions of 'feed additive' and 'daily ration' as laid down in Article 2(2) of Regulation (EC) No 1831/2003;
 - (c) the definitions of 'food-producing animal', 'feed materials', 'compound feed', 'complementary feed', 'mineral feed', 'labelling', 'label', 'minimum storage life' and 'batch' as laid down in Article 3(2) of Regulation (EC) No 767/2009;

- (d) the definition of 'establishment' as laid down in Article 3 of Regulation (EC) No 183/2005;
- (e) the definitions of 'official control' and 'competent authority' as laid down in Article 2 of Regulation (EC) No 882/2004;
- (f) the definitions of 'veterinary medicinal product', 'withdrawal period', 'strength' and 'veterinary prescription' as laid down in Article 1 of Directive 2001/82/EC.

2. The following definitions shall also apply:

- (a) 'medicated feed': a mixture of one or more veterinary medicinal products or intermediate products with one or more feeds which is ready to be directly fed to animals without further processing;
- (b) 'intermediate product': a mixture of one or more veterinary medicinal products with one or more feeds, intended to be used for the manufacture of medicated feed;
- (c) 'active substance': a substance with a pharmacological activity;
- (d) 'non-target feed': feed which is not intended to contain a specific veterinary medicinal product;
- (e) 'carry-over': the transfer of traces of an active substance into non-target feed;
- (f) 'feed business operator': any natural or legal person responsible for ensuring that the requirements of this Regulation are met within the feed business under their control;
- (g) 'distributor': any feed business operator that supplies medicated feed, packaged and ready for use, to the animal holder;
- (h) 'mobile mixer': a feed business operator with a feed establishment consisting of a specifically equipped lorry for the manufacture of medicated feed;
- (i) 'on-farm mixer': a feed business operator manufacturing medicated feed on the farm of use.

Chapter II

Manufacture, storage, transport and placing on the market

Article 3 *General obligations*

Feed business operators shall manufacture, store, transport and place on the market medicated feed and intermediate products in compliance with Annex I.

Article 4
Hazard analysis and critical control points system

Feed business operators manufacturing, storing, transporting and placing on the market medicated feed and intermediate products shall put in place, implement and maintain a permanent written procedure or procedures based on the hazard analysis and critical control points (hereinafter: 'HACCP') system as provided for in Regulation (EC) No 1831/2003.

Article 5
Composition

1. Medicated feed and intermediate products shall only be manufactured from veterinary medicinal products authorised for the purpose of the manufacture of medicated feed in accordance with the conditions laid down in Directive 2001/82/EC.
2. The manufacturer of medicated feed shall ensure the following:
 - (a) the veterinary medicinal product is incorporated into the feed in accordance with Annex II;
 - (b) the medicated feed is manufactured in compliance with the relevant conditions laid down in the summary of the product characteristics referred to in Article 14 of Directive 2001/82/EC, related to the veterinary medicinal products to be incorporated in the medicated feed;
 - (c) there is no possibility of an interaction between the veterinary medicinal products and the feed impairing the safety or the efficacy of the medicated feed;
 - (d) a feed additive for which a maximum content is set in the respective authorisation act is not incorporated in the medicated feed if it is already used as active substance in the veterinary medicinal product.

Article 6
Homogeneity

1. Feed business operators manufacturing medicated feed shall ensure the homogeneous incorporation of the veterinary medicinal product or the intermediate product into the feed.
2. The Commission may, by means of implementing acts, establish criteria for the homogenous incorporation of the veterinary medicinal product into the medicated feed or into the intermediate product, taking into account the specific properties of the veterinary medicinal products and of the mixing technology. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 20(2).

Article 7
Carry-over

1. Feed business operators manufacturing, storing, transporting and placing on the market medicated feed and intermediate products shall apply measures in accordance with Article 3 and 4 to avoid carry-over.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 19 concerning the establishment of specific carry-over limits for active substances.

Where no specific carry-over limits have been set for an active substance, the following carry-over limits shall apply:

- (a) for antimicrobial active substances, 1% of the active substance in the last batch of medicated feed or of intermediate product produced before the production of non-target feed;
- (b) for the other active substances, 3% of the active substance in the last batch of medicated feed or of intermediate product produced before the production of non-target feed.

Article 8
Anticipated production

Medicated feed and intermediate products may be manufactured and stored before the prescription referred to in Article 15 is issued. This provision shall not apply to on-farm mixers or in case of manufacture of medicated feed or intermediate products from veterinary medicinal products in accordance with Articles 10 or 11 of Directive 2001/82/EC.

Article 9
Labelling

1. In addition to Article 11(1), Articles 12 and 14 of Regulation (EC) No 767/2009, the labelling of medicated feed and intermediate products shall comply with Annex III to this Regulation.
2. Where containers are used instead of packaging material, they shall be accompanied by documents complying with paragraph 1.
3. Permitted tolerances for discrepancies between the labelled compositional values of a medicated feed or an intermediate product and the values analysed in official controls performed in accordance with Regulation (EC) No 882/2004 are as set out in Annex IV.

Article 10
Packaging

Medicated feed and intermediate products shall be placed on the market only in sealed packages or containers. Packages or containers shall be sealed in such a way that, when the package or container is opened, the seal is damaged and cannot be reused.

Article 11
Intra Union trade

Where the Member State of manufacture of medicated feed is not the same as the Member State where it is used by the animal holder, the veterinary medicinal product shall be authorised in accordance with Directive 2001/82/EC in the Member State of use.

Chapter III

Approval of establishments

Article 12
Approval obligation

Feed business operators manufacturing, storing, transporting or placing on the market medicated feed or intermediate products shall ensure that establishments under their control are approved by the competent authority.

Article 13
Approval procedure and lists of approved establishments

1. The competent authority shall approve establishments only where an on-site visit, prior to start-up of any activity, has demonstrated that the system put in place for the manufacture, storage, transport and placing on the market of medicated feed and intermediate products meets the requirements of Chapter II.
2. The procedure for the granting, suspension, revocation of, or amendment to the approval of establishments shall be subject to Article 13(2) and Articles 14, 15, 16 and 17 of Regulation (EC) No 183/2005.
3. The establishments shall be recorded in the national list as referred to in Article 19(2) of Regulation (EC) No 183/2005 under an individual identifying number which has been attributed in the form set out in Annex V, Chapter II, to that Regulation.

Article 14
Establishments approved in accordance with Directive 90/167/EEC

1. Establishments falling under the scope of this Regulation which have already been approved in accordance with Directive 90/167/EEC may continue their activities subject to the submission, by [Office of Publications, please insert date counting

18 months from the date of entry into force of this Regulation], of a declaration to the relevant competent authority in whose area their facilities are located, in a form decided upon by this competent authority, that they meet the requirements for approval referred to in Article 13(1).

2. The competent authorities shall renew, suspend, revoke or amend the approval of those establishments in accordance with the relevant rules and procedures referred to in Article 13(1) of this Regulation and in Articles 13(2), 14, 15 and 16 of Regulation (EC) No 183/2005. Where the declaration referred to in paragraph 1 is not submitted within the period specified, the competent authority shall suspend the existing approval in accordance with Article 14 of Regulation (EC) No 183/2005.

Chapter IV

Prescription and use

Article 15 *Prescription*

1. The supply of medicated feed to animal holders shall be subject to the presentation and, in case of manufacturing by on-farm mixers, the possession of a veterinary prescription and to the conditions laid down in paragraphs 2 to 6.
2. The prescription shall contain the information set out in Annex V. The original prescription shall be kept by the manufacturer or, where appropriate, the distributor. The person issuing the prescription and the animal holder shall keep a copy of the prescription. The original and copies shall be kept for three years from the date of issuance.
3. With the exception of medicated feed for non-food producing animals, medicated feed shall not be used for more than one treatment under the same prescription.
4. The prescription shall be valid for a maximum period of six months for non-food producing animals and three weeks for food-producing animals.
5. The prescribed medicated feed may be used only for animals examined by the person who issued the prescription and only for a diagnosed disease. The person who issued the prescription shall verify that this medication is justified for the target animals on veterinary grounds. Furthermore he shall ensure that the administration of the veterinary medicinal product concerned is not incompatible with another treatment or use and that there is no contra-indication or interaction where several medicinal products are used.
6. The prescription shall, in line with the summary of the product characteristics of the veterinary medicinal product, indicate the inclusion rate of the veterinary medicinal product calculated on the basis of the relevant parameters.

Article 16
Use in food-producing animals

1. Feed business operators supplying medicated feed to the holder of food-producing animals, or on-farm mixers of medicated feed for food-producing animals shall ensure that the quantities supplied or mixed do not exceed:
 - (a) the quantities provided in the prescription and
 - (b) the quantities required for one month's treatment or two weeks in case of medicated feed containing antimicrobial veterinary medicinal products.
2. Medicated feed containing antimicrobial veterinary medicinal products shall not be used to prevent diseases in food-producing animals or to enhance their performance.
3. When administering medicated feed, the holder of food-producing animals shall ensure compliance with the withdrawal period provided for in the veterinary prescription.
4. Feed business operators feeding food-producing animals with medicated feed shall keep records in accordance with Article 69 of Directive 2001/82/EC. Those records shall be kept for five years after the date of administration of medicated feed, including when the animal is slaughtered during the five-year period.

Article 17
Collection systems of unused or expired products

Member States shall ensure that appropriate collection systems are in place for medicated feed and intermediate products that are expired or in case the animal holder has received a bigger quantity of medicated feed than he actually uses for the treatment referred to in the veterinary prescription.

Chapter V **Procedural and final provisions**

Article 18
Amendment of Annexes

The Commission shall be empowered to adopt delegated acts in accordance with Article 19 concerning amendments to Annexes I to V, in order to take into account technical progress and scientific developments.

Article 19
Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Articles 7 and 18 shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.
3. The delegation of powers referred to in Articles 7 and 18 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Articles 7 and 18 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

Article 20 *Committee procedure*

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002, hereinafter referred to as the ‘Committee’. That Committee is a Committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
3. Where the opinion of the Committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the Committee so decides or a simple majority of Committee members so request.

Article 21 *Penalties*

1. Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.
2. Member States shall notify those provisions to the Commission by [Office of Publications, please insert date counting [12] months from the date of entry into force of this Regulation] at the latest and shall notify it without delay of any subsequent amendment affecting them.

Article 22
Repeal

Directive 90/167/EEC is repealed.

References to the repealed Directive shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex VI.

Article 23
Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from [*Office of Publications, please insert date counting [12] months from the date of entry into force of this Regulation*].

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President