AMENDMENTS 001-093
by the Committee on Agriculture and Rural Development

Report
Clara Eugenia Aguilera García **A8-0075/2016**
Manufacture, placing on the market and use of medicated feed

Proposal for a regulation (COM(2014)0556 – C8-0143/2014 – 2014/0255(COD))

Amendment 1

Proposal for a regulation
Citation 1

Text proposed by the Commission	*Amendment*
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 Treaty on the Functioning of the European Union, and in particular ***Article*** 43***(2)*** and ***Article*** 168(4)(b) thereof,

Justification

The legal basis for this proposal is Article 43(2) whereby the ordinary legislative procedure is used for legislation necessary for the pursuit of the objectives of the common agricultural policy.

Amendment 2

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) Prevention of disease is better than

	cure. Medicinal treatments, especially with antimicrobials, should never replace good husbandry, bio-security and management practices.

Amendment 3

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) As ***a type*** of feed, medicated feed ***falls*** within the scope of Regulation (EC) No 183/2005 of the European Parliament and of the Council[6], of Regulation (EC) No 767/2009 of the European Parliament and of the Council[7], of Regulation (EC) No 1831/2003 of the European Parliament and of the Council[8] and of Directive 2002/32/EC of the European Parliament and of the Council[9]. 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.	(6) As ***types*** of feed, medicated feed ***and intermediate products fall*** within the scope of Regulation (EC) No 183/2005 of the European Parliament and of the Council[6], of Regulation (EC) No 767/2009 of the European Parliament and of the Council[7], of Regulation (EC) No 1831/2003 of the European Parliament and of the Council[8] and of Directive 2002/32/EC of the European Parliament and of the Council[9]. 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.
[6] Regulation (EC) No 183/2005 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).	[6] Regulation (EC) No 183/2005 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).	[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).	[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).

[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).

Amendment 4

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(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.	(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. ***The holder of the authorisation of the veterinary medicinal products should be responsible for compatibility assessment.*** 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. ***The inclusion rates set should as a matter of principle be geared to a farm's average needs. To take account of the specific features of the small-scale farming sector, and in particular to enable small or remote farms to optimise livestock care, it should be permissible to retain established control systems provided that it is ensured that the prescription, production and use of medicated feed take place under the instructions and supervision of a veterinarian and are subject to an external process control.***

Amendment 5

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(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.	(10) Homogeneous ***distribution*** of the veterinary medicinal product ***in*** 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.

Justification

The objective is to ensure that the veterinary medicinal product is evenly distributed in the feed. 'Distribution' is a term used in the pharmaceutical sector.

Amendment 6

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(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	(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 kept as low as possible. In order to protect animal health, human health and the environment, maximum ***limits for*** levels of carry-over for active substances contained in ***non-target*** 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

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.	(As Low As Reasonably Achievable) principle. ***In the interim period, a*** general ***maximum limit*** should be set out in this Regulation, taking into account the unavoidable carry-over and the risk caused by the active substances concerned.

Amendment 7

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) Medicated feed should be marketed in sealed containers for safety reasons and to protect user's interest.	(14) Medicated feed should be marketed in sealed containers for safety reasons and to protect user's interest. ***However, appropriate derogations should be provided for where the application of that requirement is not necessary to protect human or animal health or consumer interests, and would represent an excessive administrative and technical burden.***

Justification

Existing derogations under Article 23 of Regulation (EC) No 767/2009 for the transport of feed should be included in this regulation to ensure consistency with current transport arrangements for medicated feed in certain Member States.

Amendment 8

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(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***.	(15) For intra-Union trade of medicated feed, it should be ensured that the veterinary medicinal product contained therein***, or another veterinary medicinal product with equivalent active substances or composition,*** has been duly authorised in the Member State of destination ***in accordance with Regulation (EU) 2016/... (Veterinary Medicinal Products)***.

Justification

It is important not to hamper intra-Community trade in medicated feed, in particular to help farmers in Member States with small markets. In some cases, a veterinary medicinal product may not be authorised in a Member State for commercial reasons.

Amendment 9

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(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.	(16) Feed business operators manufacturing, whether they operate in a feed mill, with a specially equipped ***mobile infrastructure*** 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. ***The approval and registration procedure under Regulation (EC) No 183/2005 should take account of the specific features of primary production with a view to ensuring that in particular small or remote farms can optimise livestock care through the use of medicated feed.***

Amendment 10

Proposal for a regulation
Recital 16 a (new)

Text proposed by the Commission	*Amendment*
	(16a) Care should be taken to ensure that the medicated feed handling requirements imposed by this Regulation and delegated and implementing acts adopted pursuant to this Regulation on feed business

	operators, in particular on-farm mixers, are feasible and practical.

Amendment 11

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(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	(17) In order to ensure the safe use of medicated feed, its supply and use should be subject to presentation of a valid ***written or electronic*** veterinary prescription which has been issued ***by a veterinarian or another professional person qualified to do so in accordance with applicable national law*** after examination of the animals to be treated ***or, if appropriate under applicable national law, following a proper assessment of the health status of the animals concerned***. However, the possibility to manufacture medicated feed before a prescription is presented to the manufacturer should not be excluded.

Amendment 12

Proposal for a regulation
Recital 17 a (new)

Text proposed by the Commission	*Amendment*
	(17a) In order to ensure that the lines of distribution and the supply of veterinary medicines are not restricted, where Member States have a legally defined, professionally qualified animal medicines advisor, they shall continue to prescribe and supply certain veterinary medicines.

Justification

The persons authorised to prescribe certain veterinary medicines should be determined by the relevant national authorities. Those with suitable qualifications, recognised by the Member State in which they reside, shall not be prohibited from prescribing and supplying certain veterinary medicines.

Amendment 13

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(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.	(18) In order to ensure a particularly prudent use***, which means appropriate use of medicines in accordance with the prescription,*** of medicated feed for food-producing ***and non-food producing*** animals and therefore provide the basis for the assurance of a high level of protection of ***animal health and*** 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.

Amendment 14

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(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***.	(19) Taking into account the serious public health risk posed by resistance to ***antibiotics***, it is appropriate to limit the use of medicated feed containing ***antibiotics*** for animals. ***Prophylactic*** use ***of medicated feed containing antibiotics should not be allowed unless such use is permitted under Regulation (EU) 2016/... (Veterinary Medicinal Products). The use of antibiotics*** to enhance the performance of food-producing animals should ***be prohibited***.

Justification

See justification for the amendment on Article 16 - paragraph 2.

Amendment 15

Proposal for a regulation
Recital 19 a (new)

Text proposed by the Commission	*Amendment*
	(19a) In accordance with Regulation (EC) No 1831/2003, the ban on the use of antibiotics as growth promoting agents as from 1 January 2006 should be strictly adhered to and properly enforced.

Amendment 16

Proposal for a regulation
Recital 19 b (new)

Text proposed by the Commission	*Amendment*
	(19b) The 'One Health' concept, endorsed by the World Health Organisation (WHO) and the World Organisation for Animal Health (OIE), recognises that human health, animal health and ecosystems are interconnected and it is therefore essential for both animal and human health to ensure prudent use of antimicrobial medicines in food-producing animals.

Amendment 17

Proposal for a regulation
Recital 19 c (new)

Text proposed by the Commission	*Amendment*
	(19c) On 19 May 2015 the European Parliament adopted a resolution on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance.

Amendment 18

Proposal for a regulation
Article 1

Text proposed by the Commission	*Amendment*
This Regulation shall apply to:	This Regulation shall apply to:
(a) the manufacture, storage and transport of medicated feed and intermediate products;	(a) the manufacture, storage and transport of medicated feed and intermediate products ***intended for both food-producing and non-food producing animals***;
(b) the placing on the market, including import, and use of medicated feed and intermediate products;	(b) the placing on the market, including import ***from third countries***, and use of medicated feed and intermediate products ***intended for both food-producing and non-food producing animals***;
(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.	(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.

Amendment 19

Proposal for a regulation
Article 1 – paragraph 1a (new)

Text proposed by the Commission	*Amendment*
	1a. This Regulation shall not apply to finished veterinary medicinal products to be orally administered that have been approved for use via feed as oral powders (via 'top dressing') or in drinking water. The Commission shall, by ... [12 months after the date of entry into force of this Regulation], propose a specific legislative proposal on the administration of veterinary medicinal products for use via feed or in drinking water.

Amendment 20

Proposal for a regulation
Article 2 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(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;	(c) the definitions of 'food-producing animal', ***'non-food producing animal', 'fur 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;

Amendment 21

Proposal for a regulation
Article 2 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) the definition of 'establishment' as laid down in Article 3 of Regulation (EC) No 183/2005;	(d) the definition of 'establishment' ***and 'feed business operator'*** as laid down in Article 3 of Regulation (EC) No 183/2005;

Amendment 22

Proposal for a regulation
Article 2 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) the definitions of 'veterinary medicinal product', 'withdrawal period', 'strength***' and*** 'veterinary prescription' as laid down in Article 1 of Directive 2001/82/EC.	(f) the definitions of 'veterinary medicinal product', 'withdrawal period', 'strength***´,*** 'veterinary prescription' ***and ´premix for medicated feedingstuffs´*** as laid down in Article 1 of Directive 2001/82/EC.

Justification

The definition of the ´premix for medicated feedingstuffs´ should be amended, as the medicated premix is the veterinary medicinal product, which is an appropriate pharmaceutical form primarily authorised to be used incorporated in medicated feedingstuffs in conditions fully in compliance with the conditions of the marketing authorisation.

Amendment 23

Proposal for a regulation
Article 2 – paragraph 1 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) the definitions of 'antimicrobials'and 'antibiotics' / 'antibacterials' as laid down in Regulation (EU) 2016/... (Veterinary Medicinal Products);

Amendment 24

Proposal for a regulation
Article 2 – paragraph 1 – point f b (new)

Text proposed by the Commission	*Amendment*
	(fb) the definition of 'preventive treatment (prophylaxis' as laid down in Regulation (EU) 2016/... (Veterinary Medicinal Products);

Amendment 25

Proposal for a regulation
Article 2 – paragraph 1 – point f c (new)

Text proposed by the Commission	*Amendment*
	(fc) the definition of 'control treatment (metaphylaxis)' as laid down in Regulation (EU) 2016/... (Veterinary Medicinal Products);

Amendment 26

Proposal for a regulation
Article 2 – paragraph 1 – point f d (new)

Text proposed by the Commission	*Amendment*
	(fd) the definition of 'curative (therapeutic) treatment' as laid down in Regulation (EU) 2016/... (Veterinary

Medicinal Products);

Amendment 27

Proposal for a regulation
Article 2 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(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;	(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, ***owing to the properties brought by the medicinal part of the mixture for treating or preventing disease and owing to the properties brought by the feed part of the mixture for providing nutrition***;

Amendment 28

Proposal for a regulation
Article 2 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(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;	(b) 'intermediate ***medicated feed***': a mixture of one or more veterinary medicinal products with ***one or more raw materials***, intended to be used for the manufacture of medicated feed; *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)*

Amendment 29

Proposal for a regulation
Article 2 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) 'non-target feed': feed which is not intended to contain a ***specific*** veterinary	(d) 'non-target feed': feed which is not intended to contain a veterinary medicinal

medicinal product;	product;

Justification

This definition is currently ambiguous and needs to be clarified. A non-target feed should be defined as an ordinary feed containing no veterinary medicinal products.

Amendment 30

Proposal for a regulation
Article 2 – paragraph 2 – point f

Text proposed by the Commission	*Amendment*
(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;	***deleted***

Amendment 31

Proposal for a regulation
Article 2 – paragraph 2 – point g

Text proposed by the Commission	*Amendment*
(g) 'distributor': any feed business operator that supplies medicated feed, packaged and ready for use, to the animal holder;	(g) 'distributor': any feed business operator that supplies medicated feed, packaged and ready for use, to the animal holder ***or, in the case of medicated feed supplied for non-food producing animals, another operator authorised to distribute veterinary medicines***;

Amendment 32

Proposal for a regulation
Article 2 – paragraph 2 – point h

Text proposed by the Commission	*Amendment*
(h) 'mobile mixer': a feed business operator with a feed establishment consisting of a specifically equipped ***lorry*** for the manufacture of medicated feed;	(h) 'mobile mixer': a feed business operator with a feed establishment consisting of a ***mobile infrastructure*** specifically equipped for the manufacture of medicated feed ***which moves from farm***

	to farm for the purpose of providing its services;

Justification

It is important to distinguish more clearly between the mobile mixer, which moves from farm to farm in order to produce medicated feed, and the on-farm mixer.

Amendment 33

Proposal for a regulation
Article 2 – paragraph 2 – point i

Text proposed by the Commission	*Amendment*
(i) 'on-farm mixer': a feed business operator manufacturing medicated feed on the farm ***of use***.	(i) 'on-farm mixer': a feed business operator manufacturing medicated feed ***for exclusive use*** on the farm ***on which it is produced for food-producing animals in his or her possession;***

Amendment 34

Proposal for a regulation
Article 2 – paragraph 2 – point i a (new)

Text proposed by the Commission	*Amendment*
	(ia) 'cross-contamination': a contamination resulting from a carry-over or from the transfer in feed of any unintended substance;

Amendment 35

Proposal for a regulation
Article 2 – paragraph 2 – point i b (new)

Text proposed by the Commission	*Amendment*
	(ib) 'anti-parasites': medicinal substance used in the treatment of parasitic diseases of varied aetiology;

Amendment 36

Proposal for a regulation
Article 2 – paragraph 2 – point i c(new)

Text proposed by the Commission	*Amendment*
	(ic) 'broker': any person active in the buying or selling of medicated feed, excluding the distribution of medicated feed, which operations do not involve the physical handling of medicated feed but rather the trading thereof, independently and in the name of a physical or legal person;

Justification

A definition should be added, namely that of broker.

Amendment 37

Proposal for a regulation
Article 3

Text proposed by the Commission	*Amendment*
Feed business operators shall manufacture, store, transport and place on the market medicated feed and intermediate products in compliance with Annex I.	Feed business operators shall manufacture, store, transport and place on the market medicated feed and intermediate products in compliance with ***the requirements of Regulation 183/2005 and Regulation 767/2009 and the provisions of*** Annex I ***to this Regulation, where relevant for the operations carried out, and of Annex III***. ***The requirements for the placing on the market of medicated feed shall not be applicable to on-farm mixers, including rules on labelling particulars as set out in Annex III***.

Amendment 38

Proposal for a regulation
Article 3 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. A Member State may impose restrictions in order to prohibit or regulate the use of mobile mixers in its territory.

Justification

Performing checks on livestock farmers is a very complicated process, especially when they are operating in the territories of several Member States (cross-border operations).

Amendment 39

Proposal for a regulation
Article 3 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. Distributors who supply medicated feed solely for non-food producing animals, which is manufactured and distributed in sealed bags and supplied under prescription directly to the animal holders, shall be exempt from the obligations of feed business operators.

Justification

The exemption proposed facilitates wholesale and retail (veterinary and pharmacist) distribution solely of medicated feed for pets without imposing unnecessary administrative burdens which are taken care of by the 'feed business operator' that actually manufactures the medicated feed. Feed business operators rules (designed to protect human food safety) would be unnecessary and over burdensome.

Amendment 40

Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission	*Amendment*
1. 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	1. 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 183/2005.	procedures based on the hazard analysis and critical control points (hereinafter: ' HACCP ') system as provided for in Regulation (EC) No 183/2005. ***Established control systems for on-farm mixers may be retained, provided it is ensured that the HACCP principles are complied with.***

Justification

In implementing Regulation (EC) No 183/2005, primary feed producers already comply with the principles of the HACCP in the records they keep. It should remain possible to use these records.

Amendment 41

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The manufacturer of medicated feed shall ensure the following:	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;	(a) the veterinary medicinal product is incorporated into the feed in accordance with ***Article 15(6) and*** 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;	(b) the medicated feed is manufactured in compliance with the relevant conditions laid down in ***the prescription or, in the cases referred to in Article 8 of this Regulation, in*** the summary of the product characteristics referred to in Article ***30 of Regulation (EU) 2016/... (Veterinary Medicinal Products)*** related to the veterinary medicinal products to be incorporated in the medicated feed; ***this includes in particular provisions regarding known interactions between the veterinary medicinal products and the feed that may impair the safety or the efficacy of 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**.**	(d) a feed additive ***authorised as coccidiostats or histomonostats*** 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;
	(da) where the active substance in the veterinary medicinal product is the same as a substance in a feed additive contained in the feed concerned, the total content of that substance in the medicated feed shall not exceed the maximum content set out in the prescription for the veterinary medicinal product or, in the cases referred to in Article 8, in the summary of product characteristics.

Amendment 42

Proposal for a regulation
Article 5 – paragraph 2 – point d b (new)

Text proposed by the Commission	*Amendment*
	(db) the feed used for the production of medicated feed complies with all relevant provisions of Union legislation concerning animal feedingstuffs;

Justification

The feed used for incorporation of the medicated premix - veterinary medicinal product- should have appropriate quality and conditions complying with the valid legal provisions within this area should be followed.

Amendment 43

Proposal for a regulation
Article 6 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Feed business operators manufacturing medicated feed shall ensure the homogeneous ***incorporation*** of the	1. Feed business operators manufacturing medicated feed shall ensure the homogeneous ***distribution*** of the veterinary

veterinary medicinal product or the intermediate product ***into*** the feed.	medicinal product or the intermediate product ***in*** the feed.

Justification

It is important to underline that the objective here is to ensure that the veterinary medicinal product is evenly distributed in the feed. 'Distribution' is a term used in the pharmaceutical sector.

Amendment 44

Proposal for a regulation
Article 6 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Feed business operators manufacturing intermediate products shall ensure the homogeneous distribution of the veterinary medicinal product in the feed.

Amendment 45

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*
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).	2. The Commission may, by means of implementing acts, establish criteria for the homogenous ***distribution*** of the veterinary medicinal product ***in*** the medicated feed or into the intermediate product, taking into account the specific properties of the veterinary medicinal products and of the ***manufacturing*** technology ***(such as mixing or spraying)***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 20(2).

Amendment 46

Proposal for a regulation
Article 7

Text proposed by the Commission	*Amendment*
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.	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 ***minimise*** carry-over ***in accordance with the ALARA principle, in order to avoid risk to animal health, human health or the environment.***
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.	2. The Commission ***is*** empowered to adopt delegated acts in accordance with Article 19 concerning the establishment of specific carry-over limits for active substances ***in non-target feed on the basis of scientific risk assessments carried out by the European Food Safety Authority (EFSA).***
Where no specific carry-over limits have been set for an active substance, the ***following*** carry-over ***limits*** shall ***apply***:	Where no specific carry-over limits have been set for an active substance, the ***general*** carry-over ***limit*** shall ***be set at 3 % of the active substance in the last batch of medicated feed or of intermediate product produced before the production of the next batch of non-target feed.***
(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.	
	2a. The Commission shall, by means of implementing acts, establish a detailed schedule listing, in order of priority, the different active substances for which specific carry-over limits must be adopted. EFSA and the European Medicines Agency (EMA) shall be consulted as the list is being compiled. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 20(2).

By ... [two years after the date of entry into force of this Regulation], the Commission shall submit a report to the European Parliament and to the Council indicating the specific carry-over limits adopted.

Amendment 47

Proposal for a regulation
Article 7 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. The Commission shall be empowered to adopt implementing acts in order to establish criteria in respect of:
	(a) the definition of the batch, pursuant to this Article;
	(b) the analytical methods that must be employed by medicated feed business operators;
	(c) the sampling methods and analytical methods that must be employed by medicated feed business operators and the competent authorities in order to check that the specific carry-over limits have been complied with.
	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 20(2).

Justification

It is very important to define the term « batch » in order to ensure a harmonised application of the legislation.

Amendment 48

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission	*Amendment*
Medicated feed and intermediate products	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.***	may be manufactured and stored ***for production-related reasons*** before the prescription referred to in Article 15 is issued. ***In such cases the nature and quantity of the medicated feed which is manufactured or stored shall be notified to the competent authority.*** This provision shall not apply to ***mobile*** mixers.

Amendment 49

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. In addition to ***Article 11(1) and (4), Articles 12 and 14, points (b), (d), (e) and (f) of Article 15, points (a), (d), (e), and (f) of Article 17(1), and Article 17(2) and (3)*** of Regulation (EC) No 767/2009, the labelling of medicated feed and intermediate products, ***where these are not fed directly to livestock,*** shall comply with Annex III to this Regulation.

Amendment 50

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where containers are used instead of ***packaging material***, they shall be accompanied by ***documents*** complying with paragraph 1.	2. Where containers are used instead of ***packages***, they shall be accompanied by ***a document*** complying with paragraph 1.

Justification

We are proposing that all labelling information should be included in a single document (in a manner similar to that specified in Regulation (EC) No 767/2009). If the reference to various documents is maintained, it would make it difficult for the competent authorities to check compliance with labelling rules, and could also make it difficult to monitor the traceability of medicated feed.

Amendment 51

Proposal for a regulation
Article 9 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	3. ***In addition to the tolerances listed in Annex IV to Regulation (EC) No 767/2009, the permitted*** tolerances for discrepancies between the labelled ***active ingredient content*** 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.

Amendment 52

Proposal for a regulation
Article 10

Text proposed by the Commission	*Amendment*
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.	Medicated feed and intermediate products shall be placed on the market only in ***properly labelled and*** sealed packages***, including sack packaging,*** 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. ***Appropriate derogations should be provided for those instances where the application of that requirement is not necessary to protect human or animal health or consumer interests, and would represent an excessive administrative and technical burden.***

Amendment 53

Proposal for a regulation
Article 11

Text proposed by the Commission	*Amendment*
Where the Member State of manufacture of	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.	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 ***Regulation (EU) 2016/... (Veterinary Medicinal Products)*** in the Member State of use ***or contain the same active substances and a composition, in quantitative and qualitative terms, equivalent to a veterinary medicinal product already authorised under Directive 2001/82/EC***.

Justification

It is important not to hamper intra-Community trade in medicated feed, in particular to help farmers in Member States with small markets. In some cases, a veterinary medicinal product may not be authorised in a Member State for commercial reasons.

Amendment 54

Proposal for a regulation
Article 11 a (new)

Text proposed by the Commission	*Amendment*
	Article 11a
	Trade with third countries
	Imports, from third countries, of food-producing animals which have been administered medicated feed containing antimicrobial veterinary medicinal products in order to prevent disease shall be prohibited. Similarly, imports of foodstuffs derived from those animals shall be prohibited.

Amendment 55

Proposal for a regulation
Article 12 – paragraph 1

Text proposed by the Commission	*Amendment*
Feed business operators manufacturing, storing, transporting or placing on the market medicated feed or intermediate	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.	products shall ensure that establishments under their control are approved by the competent ***public*** authority. ***This shall not apply to agricultural establishments which feed on-farm manufactured medicated feed to their own animals.***

Amendment 56

Proposal for a regulation
Article 15

Text proposed by the Commission	*Amendment*
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.***	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 ***issued by a veterinarian or another professional person qualified to do so in accordance with applicable national law, following a proper assessment of the health status of the animals concerned.***
	Prescriptions for medicated feed containing veterinary medicinal products which have anabolic, anti-inflammatory, anti-infectious (other than anthelmintic), anti-cancer, hormonal or psychotropic properties or substances shall only be issued by a veterinarian after a clinical examination and diagnosis.
	For medicated feed containing antibiotics, a physical examination and diagnosis shall be carried out for every prescription issued.
	Veterinarians or other professional persons qualified to do so in accordance with applicable national law issuing follow-up prescriptions prolonging or modifying a treatment after an initial prescription may, in exceptional cases and based on their epidemiological and clinical knowledge, decide that an additional clinical examination of the animals is not necessary.

	The supply of medicated feed to animal holders shall also be subject 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.	2. The prescription shall contain the information set out in ***Article 110 of Regulation (EU) 2016/... (Veterinary Medicinal Products), supplemented by*** Annex V ***to this Regulation***. The original prescription shall be kept by the manufacturer or, where appropriate, the distributor. The ***veterinarian or another professional person qualified to do so in accordance with applicable national law*** 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.	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.
	3a. The duration of the treatment should follow the valid summary of product characteristics (SPC) of the authorised veterinary medicinal product incorporated into the medicated feed and should not exceed three weeks in the case of medicated feed with incorporated veterinary medicinal products containing active substances with the potential to select resistance.
	3b. In the event of the occurrence of a diagnosed disease as referred to in paragraph 5, if part of the medicated feed is left unused, it may be re-used under a new prescription, provided that it is stored in accordance with the conditions set out in the SPC.
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.	4. The prescription shall be valid ***from the date of issuance*** 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	5. The prescribed medicated feed may be used only for ***individual animals or a group of*** animals examined ***or assessed*** by

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.	the ***veterinarian or another professional*** person ***qualified to do so in accordance with applicable national law issuing*** the prescription and only for a diagnosed disease. ***Significant and imminent health risks may be grounds for the limited and non-routine prophylactic use of vaccines and anti-parasitical treatments***. The ***veterinarian or another professional person qualified to do so in accordance with applicable national law*** who issued the prescription shall verify, ***based on knowledge of the feeding systems in use, the possibilities of mixing and other relevant farm specificities,*** that ***the*** 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***.	6. The prescription shall, in line with the summary of the product characteristics of the veterinary medicinal product, indicate the inclusion rate of the ***active substance of the*** veterinary medicinal product ***per kilogram of medicated feed taking into account the product characteristics and, where appropriate, the geographical or season-related circumstances. The daily dose of the veterinary medicinal product shall be incorporated into that quantity of medicated feed that ensures the uptake of the daily dose by the target animal taking into consideration that the feed uptake of diseased animals might differ from a normal daily ration.***

Amendment 57

Proposal for a regulation
Article 16 – title

Text proposed by the Commission	*Amendment*
Use ***in food-producing animals***	Use

Amendment 58

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission	*Amendment*
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***:***	1. Feed business operators supplying medicated feed to the ***holders*** of food-producing ***and non-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 ***the quantities provided for in the prescription.***
(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.	
	The quantities required for a treatment shall be determined in accordance with the SPC included in the marketing authorisation of the veterinary medicinal product included in the prescription.

Amendment 59

Proposal for a regulation
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Medicated feed containing ***antimicrobial*** veterinary medicinal products shall not be used to ***prevent diseases in food-producing animals or to enhance their performance***.	2. Medicated feed containing ***antibiotic*** veterinary medicinal products shall not be used to ***enhance the performance of animals. Prophylaxis with antibiotics shall not be applied routinely nor to***

	compensate for poor hygiene or for inadequate husbandry conditions. However, such prophylaxis may be permitted in very exceptional cases before a disease is diagnosed or clinical signs of disease are present on the basis of the epidemiological and clinical knowledge of the veterinarian when such use is permitted under Article 111 of Regulation (EU) 2016/... (Veterinary Medicinal Products). Metaphylaxis shall be allowed to minimise the spread of an infection within a group of animals ***where the presence of an infectious agent has been confirmed***.

Amendment 60

Proposal for a regulation
Article 16 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	4. Feed business operators feeding food-producing animals with medicated feed shall keep records in accordance with ***Article 112 of Regulation (EU) 2016/…(Veterinary Medicinal Products).*** Those records shall be kept for ***three*** years after the date of administration of medicated feed, including when the animal is slaughtered during the ***three-***year period. ***Member States shall ensure that the data in those records are collected and transferred to the Union database on veterinary medicinal products as provided for in Articles 51 and 54 of Regulation (EU) 2016/…(Veterinary Medicinal Products).***

Amendment 61

Proposal for a regulation
Article 16 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Packaged medicated feed to be fed to food-producing animals shall be stored separately. Silos that once contained medicated feed shall be emptied before being loaded with other types of feed, and cleaned regularly.

Amendment 62

Proposal for a regulation
Article 17 – title

Text proposed by the Commission	*Amendment*
Collection systems of ***unused or*** expired products	Collection systems of expired products

Amendment 63

Proposal for a regulation
Article 17

Text proposed by the Commission	*Amendment*
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.	Member States shall ***develop*** appropriate collection systems ***in cooperation with the operators of the sector*** 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 ***and is unable to store it in effective conditions for re-use as set out in the SPC. The collected material shall be disposed of in accordance with existing national or Union legislation. Member States shall ensure that manufacturers of medicated feed and farmers are informed as regards where to find collection points for expired products and how to get their expired medicated feed to those collection points.***

Amendment 64

Proposal for a regulation
Article 17 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Business operators shall provide data needed for calculation of the volume of the sales of veterinary medicinal products incorporated into the final medicated feed to the competent national authority of the Member State.
	Member States shall collect relevant and comparable data on the volume of sales of medicated feed containing antimicrobial active substances.
	Member States shall send data on the volume of sales of medicated feed containing antimicrobial active substances to the competent European authority.
	That European authority shall analyse the data and publish an annual report.

Justification

According to the Action Plan of the European Commission, monitoring of the sales/use of antimicrobials containing products is highly recommended. It is therefore considered as beneficial to define rules for such monitoring in the case of medicated feedingstuffs, which contains antimicrobials creating huge part of the total consumption of veterinary antimicrobials.

Amendment 65

Proposal for a regulation
Article 19 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. The power ***to adopt delegated acts*** referred to in Articles 7 and 18 shall be conferred on the Commission for ***a*** period of ***five years*** from the date of entry into force of this Regulation. ***The Commission shall draw up a report in respect of the***

	delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

Justification

The European Parliament, in all legislative acts, follows the principle that delegation of powers is conferred on the European Commission for a fixed time period.

Amendment 66

Proposal for a regulation
Annex 1 – section 2 – point 1 – paragraph 2

Text proposed by the Commission	*Amendment*
A qualified ***person*** responsible for the manufacture ***of medicated feed and intermediate products and a qualified person responsible for*** quality control ***shall be delegated***.	***The*** qualified ***persons*** responsible for the manufacture ***and quality control operations shall have qualifications or specific skills in the field of veterinary medicine. The qualified persons responsible for the manufacture and*** quality control ***operations shall not prescribe medicated feed intended to be manufactured or inspected in the establishments in which they work***.

Amendment 67

Proposal for a regulation
Annex 1 – section 2 – point 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Any person entering a manufacturing area shall wear protective equipment that is appropriate for the operations performed therein. Operators shall ensure that their hands do not come into direct contact with unprotected products or with any machinery that has come into contact with such products.

Amendment 68

Proposal for a regulation
Annex 1 – section 3 – point 2

Text proposed by the Commission	*Amendment*
2. Technical or organisational measures shall be taken to ***avoid*** any cross-contamination and errors, to carry out checks in the course of manufacture and to ensure effective tracing of the products used for the manufacture of medicated feed and intermediate products.	2. Technical or organisational measures shall be taken to ***minimise*** any cross-contamination and errors, to carry out checks in the course of manufacture and to ensure effective tracing of the products used for the manufacture of medicated feed and intermediate products.

Amendment 69

Proposal for a regulation
Annex 1 – section 3 – point 3

Text proposed by the Commission	*Amendment*
3. The presence of undesirable substances within the meaning of Directive 2002/32/EC ***and of other contaminants*** in relation to human and animal health shall be monitored, and appropriate measures to minimise this presence shall be taken.	3. The presence of undesirable substances within the meaning of Directive 2002/32/EC in relation to human and animal health shall be monitored, and appropriate measures to minimise this presence shall be taken.

Justification

The reference to 'other contaminants' is very unclear. Those contaminants are not identified.

Amendment 70

Proposal for a regulation
Annex I – section 3 – point 4

Text proposed by the Commission	*Amendment*
4. The products used for the manufacture and unprocessed feed shall be stored separately from medicated feed and intermediate products in order to avoid any ***cross-contamination***.	4. The products used for the manufacture and unprocessed feed shall be stored separately from medicated feed and intermediate products in order to avoid ***or minimise*** any ***carry-over***.

Amendment 71

Proposal for a regulation
Annex I – section 6 – point 2 – point i

Text proposed by the Commission	*Amendment*
(i) information on the person who has issued the prescription, including at least his name and address.	(i) ***for the distributor who supplies to the animal holder*** information on the ***veterinarian or another professional*** person ***qualified to do so in accordance with applicable national law*** who has issued the prescription, including at least his name and address.

Amendment 72

Proposal for a regulation
Annex 1 – section 7 a (new)

Text proposed by the Commission	*Amendment*
	Section 7a
	OPERATIONS CARRIED OUT BY THIRD PARTIES
	1. Any subcontracted activity shall be covered by an appropriately defined, agreed upon and monitored contract so as to avoid any misunderstandings that could lead to work or products of an insufficient quality. A written contract shall be drawn up between the subcontracting party and the subcontractor in order to clearly establish each party's obligations. The contract shall clearly set out the ways in which the qualified persons responsible for manufacture, transport and quality control operations are to fulfil their responsibilities.
	2. A written contract shall cover the manufacturing, nalytical or transport activities assigned by the subcontracting party, and all the technical provisions taken in relation thereto. All the provisions contained in the contract, including any proposed technical modifications or other provisions, shall

	comply with the provisions of this Regulation.

Amendment 73

Proposal for a regulation
Annex 2 – point 2

Text proposed by the Commission	*Amendment*
2. The daily dose of the veterinary medicinal product shall be incorporated in ***a quantity of medicated feed that ensures the uptake of the daily dose by the target animal considering that the feed uptake of diseased animals might differ from a normal daily ration***.	2. The daily dose of the veterinary medicinal product shall be incorporated in ***accordance with the prescription***.

Amendment 74

Proposal for a regulation
Annex 3 – introductory part

Text proposed by the Commission	*Amendment*
The label of medicated feed and intermediary products shall include the following particulars:	The label of medicated feed and intermediary products shall include, ***in accordance with the requirements of this Annex and of Regulation (EC) No 767/2009,*** the following particulars***, in a simple, clear and easily understandable manner for the end users***:

Amendment 75

Proposal for a regulation
Annex 3 – point 1

Text proposed by the Commission	*Amendment*
(1) the expression ‘Medicated feed’ or ‘Intermediate product for medicated feed’ supplemented by the expression ‘complete’ or ‘complementary’, as appropriate, and the target species;	(1) the expression ‘Medicated feed’ or ‘Intermediate product for medicated feed’ supplemented by the expression ‘complete’ or ***‘complete dietetic’ or*** ‘complementary’ ***or ‘complementary dietetic’***, as appropriate, and the target species;

Justification

It may be appropriate to modify the nutritional content of the diet to complement the medicated feed. This is particularly important for the treatment of chronic conditions in pets. In this case, it should be possible to provide information on the label in relation to nutritional content as well as medicinal content.

Amendment 76

Proposal for a regulation
Annex 3 – point 2

Text proposed by the Commission	*Amendment*
(2) the name or business name and the address of the feed business operator responsible for the labelling;	***deleted***

Amendment 77

Proposal for a regulation
Annex 3 – point 3

Text proposed by the Commission	*Amendment*
(3) the approval number of the person responsible for the labelling in accordance with Article 12;	(3) the approval number of the person responsible for the labelling ***and of the manufacturer if different from the person responsible for labelling,*** in accordance with Article 12;

Amendment 78

Proposal for a regulation
Annex 3 – point 4

Text proposed by the Commission	*Amendment*
(4) the batch reference number of the medicated feed or intermediate product;	***deleted***

Amendment 79

Proposal for a regulation
Annex 3 – point 5

Text proposed by the Commission	*Amendment*
(5) the net quantity of medicated feed expressed in units of mass in the case of solid feed, and in units of mass or volume in the case of liquid feed;	***deleted***

Amendment 80

Proposal for a regulation
Annex 3 – point 6

Text proposed by the Commission	*Amendment*
(6) the veterinary medicinal products with name, active substance, ***strength,*** added amount***, marketing authorisation holder and marketing authorisation number***, preceded by the heading 'medication';	(6) the veterinary medicinal products with name, active substance, added amount ***of active substance***, preceded by the heading 'medication';

Justification

The reason for mentioning on the label the amount of the veterinary medicinal substance and its strength is to allow the user to calculate the amount of active substance. It is therefore much more useful to provide directly the amount of active substance. The indication of the authorisation holder and authorisation number is superfluous for the user. For the sake of legibility of the label, these particulars should not be required.

Amendment 81

Proposal for a regulation
Annex 3 – point 7

Text proposed by the Commission	*Amendment*
(7) ***therapeutic indications of the veterinary medicinal products,*** any contra-indications and adverse events in so far as these particulars are necessary for the use;	(7) any contra-indications and adverse events in so far as these particulars are necessary for the use;

Justification

Therapeutic indications are superfluous since the medicated feed shall be used in accordance with the prescription where the animals and the disease to be treated are already mentioned.

Amendment 82

Proposal for a regulation
Annex 3 – point 9

Text proposed by the Commission	*Amendment*
(9) a recommendation to read the package leaflet of the veterinary medicinal products, including a hyperlink where it can be found, a warning that the product is only for the treatment of animals, ***as well as another*** warning that the product must be kept out of the sight and reach of children***;***	(9) a recommendation to read the package leaflet of the veterinary medicinal products, including a hyperlink where it can be found, a warning that the product is only for the treatment of animals, ***a*** warning that the product must be kept out of the sight and reach of children***, as well as another warning that persons in the proximity of animals treated with medicated feed may be contaminated.***

Amendment 83

Proposal for a regulation
Annex 3 – point 10

Text proposed by the Commission	*Amendment*
(10) the list of feed additives, preceded by the heading 'additives', contained in medicated feed for food-producing animals in accordance with Chapter I of Annex VI to Regulation (EC) No 767/2009 or in case of medicated feed for non-food producing animals in accordance with Chapter I of Annex VII to that Regulation and, if applicable, the labelling requirements laid down in the respective feed additive authorisation act;	***deleted***

Amendment 84

Proposal for a regulation
Annex 3 – point 11

Text proposed by the Commission	*Amendment*
(11) the name(s) of the feed materials as listed in the Catalogue referred to in Article 24(1) of Regulation (EC) No 767/2009 or in the register referred to in	***deleted***

Article 24(6) of that Regulation. Where several feed materials are used for the manufacture, they shall be listed in accordance with the provisions laid down in Article 17(1)(e) and (2) of Regulation (EC) No 767/2009;

Amendment 85

Proposal for a regulation
Annex 3 – point 12

Text proposed by the Commission	*Amendment*
(12) the analytical constituents of medicated feed for food-producing animals in accordance with Chapter II of Annex VI to Regulation (EC) No 767/2009 or in accordance with Chapter II of Annex VII to that Regulation in case of medicated feed for non-food producing animals;	***deleted***

Amendment 86

Proposal for a regulation
Annex 3 – point 13

Text proposed by the Commission	*Amendment*
(13) in case of medicated feed for non-food producing animals, a free telephone number or other appropriate means of communication in order to allow the purchaser to obtain, in addition to the mandatory particulars, information on the feed additives contained in the medicated feed or on the feed materials contained in the medicated feed where they are designated by category as provided for in Article 17(2)(c) of Regulation (EC) No 767/2009;	***deleted***

Amendment 87

Proposal for a regulation

Annex 3 – point 14

Text proposed by the Commission	*Amendment*
(14) the moisture content if it exceeds 14 %;	***deleted***

Amendment 88

Proposal for a regulation
Annex 3 – point 15

Text proposed by the Commission	*Amendment*
(15) the instructions for use, in accordance with ***the veterinary prescription and with*** the summary of product characteristics referred to in Article 14 of Directive 2001/82/EC***;***	(15) the instructions for use, in accordance with the summary of product characteristics referred to in Article 14 of Directive 2001/82/EC***, or with the veterinary prescription, if available at the time of manufacture.***

Amendment 89

Proposal for a regulation
Annex III – point 16 a (new)

Text proposed by the Commission	*Amendment*
	(16a) information that inappropriate disposal of medicated feed poses serious threats to the environment and may contribute to antimicrobial resistance, and information on where and how to appropriately dispose of unused material.

Justification

Information on where and how to appropriately dispose of unused material can be provided by a hyperlink.

Amendment 90

Proposal for a regulation
Annex 4 – point 1

Text proposed by the Commission

1. The tolerances laid down in this point shall include technical ***and analytical*** deviations.

Where the composition of a medicated feed or an intermediate product is found to deviate from the amount of an ***antimicrobial*** active substance indicated on the label, ***a tolerance of 10% shall apply. For the other active substances,*** the following tolerances shall apply:

Active substance per kg of medicated feed	Tolerance
> 500 mg	± ***10***%
> ***10*** mg and ≤ 500 mg	± ***20***%
> ***0,5*** mg and ≤ ***10*** mg	± 30%
≤ ***0,5*** mg	± ***40***%

Amendment

1. The tolerances laid down in this point shall include technical deviations

Where the composition of a medicated feed or an intermediate product is found to deviate from the amount of an active substance indicated on the label, the following tolerances shall apply:

Active substance per kg of medicated feed	Tolerance
> 500 mg	± ***20*** %
> ***100*** mg and ≤ 500 mg	± ***25*** %
> ***10*** mg and ≤ ***100*** mg	± 30 %
≤ ***10*** mg	± ***35***%

Amendment 91

Proposal for a regulation
Annex 4 – point 2

Text proposed by the Commission	*Amendment*
2. For the labelling particulars referred to in points 10 and 12 of Annex III to this Regulation, the tolerances laid down in Annex IV to Regulation (EC) No 767/2009 shall apply, as appropriate.	***deleted***

Justification

Respecting tolerances by taking account of both technical and analytical deviations does not appear to be applicable in practice, since none of the analytical methods have been validated. Consequently, only the technical deviations should be considered and a single tolerance limit of +/- 10% imposed, regardless of the content and the active substance in question.

Amendment 92

Proposal for a regulation
Annex V – point 1

Text proposed by the Commission	*Amendment*
1. Surname, forename, address and professional membership number of the person ***allowed*** to prescribe a veterinary medicinal product.	1. Surname, forename, address and professional membership number of the ***veterinarian or another professional*** person ***qualified*** to prescribe a veterinary medicinal product ***in accordance with applicable national law***.

Amendment 93

Proposal for a regulation
Annex V – point 2

Text proposed by the Commission	*Amendment*
2. Issue date and signature or electronic identification of the person ***allowed*** to prescribe a veterinary medicinal product.	2. Issue date and signature or electronic identification of the ***veterinarian or another professional*** person ***qualified*** to prescribe a veterinary medicinal product ***in accordance with applicable national law***.