EUROPEAN PARLIAMENT 2014 - 2019

Committee on the Environment, Public Health and Food Safety

2014/0255(COD)

28.4.2015

AMENDMENTS
18 - 251

Draft opinion
Norbert Lins
(PE546.581v01-00)

on the 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

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

AM_Com_LegOpinion

Amendment 18
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Title

Text proposed by the Commission	*Amendment*
Proposal for a	Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	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	on the ***import,*** manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC
(Text with EEA relevance)	(Text with EEA relevance)

Or. fr

Amendment 19
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Title

Text proposed by the Commission	*Amendment*
Proposal for a	Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	***DIRECTIVE*** 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	on the manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC
(Text with EEA relevance)	(Text with EEA relevance)

Or. fr

Justification

In view of the liberties which the Commission is taking to negotiate the transatlantic

agreement, and the impenetrable nature of the negotiations themselves, its proposals for legislation likely to lay the groundwork for regulatory convergence with the US on subjects as essential as food, health, animal welfare or the environment cannot be adopted in the form of regulations. This amendment to switch from a regulation to a directive applies throughout the text; adopting it will necessitate corresponding changes throughout.

Amendment 20
Michèle Rivasi, Martin Häusling

Proposal for a regulation
Title

Text proposed by the Commission	*Amendment*
Proposal for a	Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	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	on the manufacture, placing on the market***,*** use of medicated feed ***and traceability of active substances in the ecosystems*** and repealing Council Directive 90/167/EEC
(Text with EEA relevance)	(Text with EEA relevance)

Or. en

Amendment 21
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Proposal for a regulation
Citation 5 a (new)

Text proposed by the Commission	*Amendment*
	Having regard to the European Parliament's own initiative report entitled 'Safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance' (A8-9999/2015 of XX/yy/2015),

Or. it

Amendment 22
Stefan Eck

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(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.	(2) Livestock production***, animal health and welfare, occupy*** 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.

Or. en

Amendment 23
Aldo Patriciello

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(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.	(2) Livestock production occupies ***an*** 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.

Or. it

Amendment 24
Aldo Patriciello

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(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 Council[4], 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 specific Union legislation. In addition, the protection of animal health constitutes one of the general objectives of EU food law.	(3) The pursuit of a high level of protection of human health is one of the fundamental objectives of food law, as ***confirmed*** in Regulation (EC) No 178/2002 of the European Parliament and of the Council, 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 specific Union legislation. In addition, the protection of animal health constitutes one of the general objectives of EU food law.
[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).	[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).

Or. it

Amendment 25
Martin Häusling

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.

Or. en

Amendment 26
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) Given that objective, and in view of the current negotiations between the Union and the United States of America (US) on, in particular, animals farmed for the production of food intended for human consumption, information should be available on the practices of the Union's potential partner. In that context, on 10 April 2015 the US Food and Drug Administration (FDA) published a report[1a] on the use of antimicrobials in food-producing animals over the period 2009-2013. The report provides statistics on antimicrobials used in food-producing animals and regarded as medically important in human medical therapy. The following points are made:
	(1) 99% of antimicrobials sold and distributed in the US are used in domestic livestock farming;
	(2) antimicrobials medically important in human medical therapy account for 62% of antimicrobials sold;
	(3) 74% of antimicrobials medically important in human medical therapy are administered in medicated feed;
	(4) only 28% of antimicrobials sold are sold solely for therapeutic purposes; the FDA declines, on confidentiality grounds, to give figures for the volume for production purposes only; accordingly, 72% of antimicrobials are sold either solely for production indications or for both production and therapeutic indications;
	(5) 98% of antimicrobials medically important in human medical therapy are

sold over the counter;

(6) tetracycline is an antibiotic on the World Health Organisation's schedule of essential medicines and, in the form administered in medicated feed, alone accounts for 39% of all antimicrobials sold and 62% of antimicrobials medically important in human medical therapy; its use increased by 24% between 2009 and 2013;

(7) administration, in medicated feed, of antimicrobials medically important in human medical therapy increased by 20% between 2009 and 2012 and by 9% between 2012 and 2013.

1a

http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM440584.pdf

Or. fr

Justification

The US Food and Drug Administration's data are particularly alarming and must be brought to elected representatives' attention because this proposal may be part of a process of regulatory convergence with the United States without being expressly presented as such.

Amendment 27
Stefan Eck

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(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***	(4) ***Pet animals should be excluded from the general scope of this Regulation. However, there should be the possibility to adopt clearly defined conditions under which medicated feed may be used*** to treat ***pet*** animals ***as a delegated act***.

producing animals ***by medicated feed***.

Or. en

Justification

There are currently very few medicated feeds available on the market for pet animals. As pet animals generally live in households under the care of their owner, and often with other pet animals, there would be certain risks associated with treatment with medicated feed. It would be difficult to ensure that other pets in the household do not have access to the medicated feed and that the correct amount of food is consumed by the target animal.

Amendment 28
Nicola Caputo

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(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.	(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 the possibility to treat non-food producing animals by medicated feed ***under clearly defined conditions***.

Or. en

Amendment 29
Stefan Eck

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	(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.

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, ***animal welfare,*** 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.

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[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).

[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).

[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).

[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).

Or. en

Amendment 30
Aldo Patriciello

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(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 Council[10]. Within this framework, medicated feed imported into the Union is to be considered as falling within the scope of this Regulation.	*(Does not affect English version.)*
[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)..	

Or. it

Amendment 31
Michèle Rivasi, Martin Häusling

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(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,***	(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 prescription and

prescription and use of medicated feed and intermediate products should not apply to products intended to be exported.	use of medicated feed and intermediate products should not apply to products intended to be exported. ***Requirements concerning labelling should not apply where the requirements for labelling are more stringent in the export country than in the EU.***

Or. en

Amendment 32
Aldo Patriciello

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 ***exclusively*** 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.

Or. it

Amendment 33
Elisabeth Köstinger

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	(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.

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. ***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 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.***

Or. de

Amendment 34
Sirpa Pietikäinen

Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) Flock medication in feed and water often increases the unnecessary use of antibiotics and therefore individual injections of antibiotics should be preferred.

Or. en

Amendment 35
Sirpa Pietikäinen

Proposal for a regulation
Recital 9 b (new)

Text proposed by the Commission	*Amendment*
	(9b) Effects of the use of medicated feed on the medicalisation of the environment should be further studied.

Or. en

Amendment 36
Tomáš Zdechovský

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 and the ALARA (As Low As Reasonably Achievable) principle. General limits should be set out in this***	(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.

Regulation, taking into account the unavoidable carry-over and the risk caused by the active substances concerned.

Or. en

Justification

Each article should contain a single provision or rule. Its structure must be as simple as possible.

Amendment 37
Stefan Eck

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***	(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 ***prohibited*** in order to protect animal health, human health and the environment.

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.

Or. en

Amendment 38
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

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 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.

and the ALARA (As Low As Reasonably Achievable) principle. General limits should be set out in this ***Directive***, taking into account the unavoidable carry-over and the risk caused by the active substances concerned.

Or. fr

Amendment 39
James Nicholson

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 and the ALARA (As Low As Reasonably Achievable) principle. General ***limits*** should be set out in this Regulation, taking	(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 ***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 (As Low As Reasonably Achievable) principle. ***In the interim, a*** general ***maximum limit*** should be set out

into account the unavoidable carry-over and the risk caused by the active substances concerned.

in this Regulation, taking into account the unavoidable carry-over and the risk caused by the active substances concerned.

Or. en

Justification

The maximum level of active substances in non-target feed depends on the dosage of the Veterinary Medicinal Product in the previous batch of Medicated Feed. This would increase the administrative burden for the manufacturing plant in ensuring the control of compliance with the lawful level of active substances. It is more appropriate to establish a harmonised limit for the presence of active substances in non-target feed, independent of the dosage of the previous batch of Medicated Feed.

Amendment 40
Martin Häusling

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,	(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 should be avoided or ***reduced to an absolute minimum***. 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

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.	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**.**

Or. en

Amendment 41
Tomáš Zdechovský

Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission	*Amendment*
	(12a) 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.

Or. en

Amendment 42
Michèle Rivasi

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(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.***	(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.

Or. en

Justification

Deviations of the labelled content automatically lead to misleading information for the user. Therefore, the labelling itself should be as precise as possible.

Amendment 43
Stefan Eck

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(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***.	(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. Deviations of the labelled content of medicated feed from the actual content should be ***prohibited***.

Or. en

Amendment 44
Ivan Jakovčić

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 ***specially labelled*** sealed containers for safety reasons and to protect ***the*** user's interest.

Or. hr

Amendment 45
James Nicholson

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***, but appropriate derogations should be provided for in so far as the application of that requirement is not necessary to protect human or animal health or consumer interests and would represent excessive burden for the feed business operators***.

Or. en

Justification

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

Amendment 46
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) Although it could, potentially, resolve the administration problems encountered by pet owners, the administration of medicated feed to pets should be the subject of further research, in particular in order to assess the risks of over-administration and under-administration;

Or. it

Amendment 47
James Nicholson, Richard Ashworth, Julie Girling

Proposal for a regulation
Recital 16 a (new)

Text proposed by the Commission	*Amendment*
	(16a) 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.

Or. en

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 48
Tibor Szanyi

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 veterinary prescription which has been issued after examination of the animals to be treated. ***The prescription can only be issued by a veterinarian after he/she has examined the animal and made a diagnosis. A written or electronic*** prescription is ***always required to be*** presented to the manufacturer ***or the feed business operator***.

Or. en

Amendment 49
Annie Schreijer-Pierik

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 veterinary prescription***. The prescription can only be given by a veterinarian*** after examination of the ***animal and when a diagnosis is made, or if the veterinarian has personal knowledge of the condition of the animal. A written or electronic prescription is always required when the medicine is dispensed by anyone other than the veterinarian***. However, the possibility to manufacture medicated feed before a prescription is presented to the manufacturer should not be excluded.

Or. en

Amendment 50
Stefan Eck

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 veterinary prescription which has been issued after examination of the animals to be treated.

Or. en

Amendment 51
Aldo Patriciello

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 ***must*** 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.

Or. it

Amendment 52
Sirpa Pietikäinen

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 veterinary prescription which has been issued ***for a limited period of time*** 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.

Or. en

Amendment 53
James Nicholson

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 veterinary prescription. However, the possibility to manufacture medicated feed before a prescription is presented to the manufacturer should not be excluded.

Or. en

Justification

In conjunction with Article 15(5), the Commission's proposals as currently drafted imply a physical examination of the animals by the person issuing the prescriptions. Such an

arrangement is often impracticable, given the rapid and severe nature of some animal diseases.

Amendment 54
Michèle Rivasi, Martin Häusling

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 veterinary prescription which has been issued after examination of the animals to be treated.

Or. en

Justification

Such a provision can lead to harmful loopholes in access to the market of active substances.

Amendment 55
Stefan Eck

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	(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, ***including animal health,*** specific conditions concerning the use and the validity of the prescription, compliance with the withdrawal period and record-keeping by

provided for.

the animal holder should be provided for.

Or. en

Amendment 56
Annie Schreijer-Pierik

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 ***prudent use, by which is meant appropriate*** use of ***medicines according to 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 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.

Or. en

Amendment 57
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

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 antimicrobials, it is appropriate to limit the use of medicated feed containing antimicrobials for food-producing animals. ***In particular,*** preventive use or use to enhance the performance of food-producing animals should not be allowed

and the necessary measures should be taken to prevent the import of any live animals, carcases, meat, and prepared meals and dishes based on meat which have been treated for such purposes.

Or. fr

Amendment 58
Biljana Borzan

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 antimicrobials, it is appropriate to limit ***or prohibit*** the use of medicated feed containing antimicrobials for food-producing animals***, especially in the case of certain new or antimicrobials critically important for humans***. Preventive use or use to enhance the performance of food-producing animals should in particular not be allowed.

Or. en

Amendment 59
Nicola Caputo

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	(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. Preventive use or use to enhance the performance of food-

the performance of food-producing animals should in particular not be allowed.	producing animals should in particular not be allowed.

Or. en

Amendment 60
Iratxe García Pérez

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 antimicrobials, it is appropriate to limit the use of medicated feed containing antimicrobials for food-producing animals. ***The prophylactic use of antibiotics should not be authorised except in cases where there is a high risk of infection and it is allowed under the conditions of use already defined in the authorisation for the same medicinal product***.

Or. es

Justification

The use of medicated feed as a route for administering a veterinary medicinal product should be subject to the same conditions as any other veterinary medicinal product. The regulation on feed must not introduce a restriction that contradicts an authorisation under the regulation on veterinary medicinal products.

Amendment 61
Tibor Szanyi

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) Taking into account the serious public	(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.	health risk posed by resistance to antimicrobials, it is appropriate to limit the use of medicated feed containing antimicrobials. Preventive use or use to enhance the performance of animals should in particular not be allowed**.**

Or. en

Amendment 62
Fredrick Federley, Marit Paulsen

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 antimicrobials, it is appropriate to limit the use of medicated feed containing antimicrobials for food-producing animals. ***Group treatment with medicated feed containing antimicrobial veterinary medicinal products should only be used in justifiable cases where individual treatment is not appropriate.*** Preventive ***(prophylactic)*** use or use to enhance the performance of animals should in particular not be allowed.

Or. en

Justification

Medicated feed is often used for treating groups of animals. Individual treatment should always be considered before treatment with medicated feed containing antimicrobial veterinary medicine is conducted.

Amendment 63
Piernicola Pedicini, Marco Affronte, Eleonora Evi

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 antimicrobials, it is appropriate to limit the use of medicated feed containing antimicrobials for food-producing animals. ***In particular, the ban on the use of antibiotics as growth promoters should be confirmed,*** preventive use or use to enhance the performance of food-producing animals should not be allowed***, and all economic incentives that could result in over-use of antibiotics administered through feed should be removed***.

Or. it

Amendment 64
James Nicholson

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 antimicrobials, it is appropriate to limit the use of medicated feed containing antimicrobials for food-producing animals. ***The use of antimicrobials in medicated feed*** to enhance the performance of animals should ***never be allowed. The use of antimicrobials in medicated feed before a disease is diagnosed or clinical signs are present should only*** be allowed ***in very exceptional circumstances and under prescription on the basis of the epidemiological and clinical knowledge of the person who issued the prescription***. ***It***

should never be applied routinely nor to compensate for poor hygiene or for inadequate husbandry conditions

Or. en

Justification

A total ban on preventative use could have adverse implications on animal health and welfare, particularly in cases where diseases emerge and spread rapidly. Preventative use should however only be allowed in precise and defined conditions, under the auspices of the epidemiological and clinical knowledge of the person who issued the prescription.

Amendment 65
Martin Häusling

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 antimicrobials, it is appropriate to limit the use of medicated feed containing antimicrobials for food-producing animals. ***Antibiotics critically important for human use should not be used at all.*** Preventive use or use to enhance the performance of food-producing animals should in particular not be allowed. ***Metaphylaxis for large animals such as pigs and cows should not be allowed, as they should be treated individually.***

Or. en

Amendment 66
Stefan Eck

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 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 ***be prohibited***.

Or. en

Amendment 67
Lynn Boylan, Stefan Eck

Proposal for a regulation
Recital 19 a (new)

Text proposed by the Commission	*Amendment*
	(19a) The One Health concept, endorsed by the World Health Organisation, 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.

Or. en

Amendment 68
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Proposal for a regulation
Recital 19 a (new)

Text proposed by the Commission	*Amendment*
	(19a) Notes with great concern the high number of animals infected with bacteria that are resistant to antibiotics, and the

risk of carry-over of these bacteria from infected meat to consumers.

Or. en

Amendment 69
Lynn Boylan, Stefan Eck

Proposal for a regulation
Recital 19 b (new)

Text proposed by the Commission	*Amendment*
	(19b) The WHO has identified food products of animal origin as the main potential route of contamination for transmission of resistant bacteria and resistant genes from food-producing animals to humans.

Or. en

Amendment 70
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Proposal for a regulation
Recital 19 b (new)

Text proposed by the Commission	*Amendment*
	(19b) The issue of off-label use of antibiotics is a concern for animal medicine as well as human medicine.

Or. en

Amendment 71
Ivan Jakovčić

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(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.	(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 ***health***, human health or the environment. ***Member States should set up such a system as and where necessary, in cooperation with regional and local authorities.***

Or. hr

Amendment 72
Martin Häusling

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(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.	(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. ***Collection points should keep records on the return of unconsumed medicated feed containing antimicrobial veterinary medicinal products.***

Or. en

Amendment 73
Michèle Rivasi, Martin Häusling

Proposal for a regulation
Recital 20 a (new)

Text proposed by the Commission	*Amendment*
	(20a) A register of the prescriptions of active substances should be kept up to date at the level of competent authorities for water management, for the sake of traceability of the dissemination of chemicals in the ecosystems.

Or. en

Amendment 74
Nicola Caputo

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(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	(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***, the conditions under which medicated feed may be used to treat non-food producing animals*** 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

documents to the European Parliament and Council.

acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

Or. en

Amendment 75
Stefan Eck

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(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.	(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 amendment to the Annexes to this Regulation. Those Annexes concern provisions on feed business operators obligations related to ***animal health and welfare,*** 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.

Or. en

Amendment 76
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 24

Text proposed by the Commission	*Amendment*
(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,	(24) Since ***the Union is conducting negotiations with a partner whose practices are far removed from the Union's objectives,*** the objective of this ***Directive***, 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, ***can*** be sufficiently achieved by the Member States ***only***. In accordance with the principle of proportionality as set out in Article ***5 of the Treaty on European Union***, this ***Directive*** does not go beyond what is necessary to achieve that objective.

Or. fr

Justification

The second part of the amendment follows on from the amendment to recital 3.

Amendment 77
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 1 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
This ***Regulation*** shall apply to:	This ***Directive*** shall apply to:

Or. fr

Amendment 78
Annie Schreijer-Pierik

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

Text proposed by the Commission	*Amendment*
(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 pets, non-food producing animals and food-producing animals;***

Or. en

Amendment 79
Annie Schreijer-Pierik

Proposal for a regulation
Article 1 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the placing on the market, including import, and use of medicated feed and intermediate products;	(b) the placing on the market, including import, and use of medicated feed and intermediate products ***intended for pets, non-food producing animals and food-producing animals***;

Or. en

Amendment 80
Michèle Rivasi, Martin Häusling

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

Text proposed by the Commission	*Amendment*
(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 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 9 shall not apply where the requirements for labelling are more stringent in the export country than in the EU.***

Or. en

Amendment 81
Pilar Ayuso, Esther Herranz García

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

Text proposed by the Commission	*Amendment*
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, ***the following articles*** shall not apply to medicated feed and intermediate products whose label indicates that they are intended for export to third countries***:*** ***- Article 9, except as provided for in Annex III, point 1, and*** ***- Articles 15, 16 and 17***.

Or. es

Justification

Certain labelling requirements such as the obligation to include the phrase 'medicated feed'

should also be mandatory where the feed is intended for export. This obligation will make it easier for the competent authorities to carry out their monitoring tasks in order to guarantee the proper functioning of the internal market and correct controls on products intended for export to third countries.

Amendment 82
Stefan Eck

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

Text proposed by the Commission	*Amendment*
	This Regulation shall not apply to pet animals unless a delegated act is adopted in accordance with Articles 16a and 19.

Or. en

Justification

Risks associated with the use of medicated feed to treat pet animals include: consumption of and over dosing if pet animals are able to access supplies of medicated feed which is not securely stored. In addition, if the animal does not eat the required portion of medicated feed within a certain amount of time, the active ingredient may never reach the appropriate therapeutic level. The Commission should be empowered to adopt delegated acts with respect to clearly defined conditions under which medicated feed may be used to treat pet animals, medicated feed by non-target animals in multi-pet households; over or under dosing if the correct amount of food is not given by owners; under dosing if animals which are ill eat less than normal

Amendment 83
Pavel Poc

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

Text proposed by the Commission	*Amendment*
	This Regulation shall not apply to finished veterinary medicinal products to be orally administered that have been approved for use via feed or drinking

water.

Or. en

Justification

It is important to mention explicitly the scope of the present proposal for a regulation distinct to the proposal of the Regulation on Veterinary Medicinal Product.

Amendment 84
Ulrike Müller

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

Text proposed by the Commission	*Amendment*
	This Regulation shall not apply to finished medicinal products to be orally administered that have been approved for use via feed or drinking water. Accordingly, the approval requirement set out in Recital 16 shall not apply to farms which use such medicinal products for their own herd.

Or. de

Justification

It is important to mention explicitly that the scope of the present proposal for a regulation is distinct from the proposal for a Regulation on Veterinary Medicinal Products, and that it will not entail any extra costs for small and medium-sized farms.

Amendment 85
Piernicola Pedicini, Marco Affronte, Eleonora Evi

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

Text proposed by the Commission	*Amendment*
	Without prejudice to the adoption of delegated acts under Article 16a and Article 19, this Regulation shall not apply to pets.

Or. it

Amendment 86
Pavel Poc, Daciana Octavia Sârbu

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 animals',*** '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;

Or. en

Justification

Medicated feed will also be used for non-food producing animals, (such as fur and pet animals) so it is important to clarify that, in both the scope of the regulation and the definitions that apply.

Amendment 87
Piernicola Pedicini, Marco Affronte, Eleonora Evi

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

Text proposed by the Commission	*Amendment*
	(ca) the definition of 'pet': the species listed in Annex I to Regulation (EU) No

576/2013 of 12 June 2013;

Or. it

Amendment 88
Tibor Szanyi

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;

Or. en

Amendment 89
Iratxe García Pérez

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

Text proposed by the Commission	*Amendment*
	fa) the definition of 'antimicrobial' as laid down in Article 4 of Regulation XXXX/201X of the European Parliament and of the Council on veterinary medicinal products.

Or. es

Amendment 90
Iratxe García Pérez

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

Text proposed by the Commission	*Amendment*
	fb) the definition of 'antibiotic' as laid down in Article 4 of Regulation XXXX/201X of the European Parliament and of the Council on veterinary medicinal products.

Or. es

Amendment 91
Pilar Ayuso, Esther Herranz García

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 ***feed materials***, intended to be used for the manufacture of medicated feed;

Or. es

Justification

To tighten up the definition and avoid possible confusion in practice. The term 'intermediate medicated feed' is more appropriate than 'product', since it concerns a feed rather than a medicinal product.

Amendment 92
Pilar Ayuso, Esther Herranz García

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

Text proposed by the Commission	*Amendment*
c) ' active substance ' : a substance with a pharmacological activity;	***deleted***

Or. es

Justification

We are proposing that this definition be deleted from the proposal for a regulation under review and included in the regulation on veterinary medicinal products, since the concept of 'active substance' applies to all medicinal products.

Amendment 93
Pilar Ayuso, Esther Herranz García

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 medicinal product;	d) ' non-target feed ' : ***medicated*** feed which is not intended to contain a specific veterinary medicinal product;

Or. es

Justification

It should be made clear that non-target feed is a medicated feed which contains traces of other medicinal products resulting from technically unavoidable carry-over. The definition as it stands would create uncertainties in application. The definition needs to be improved to ensure the correct application of Article 7 on carry-over limits and cross contamination.

Amendment 94
Tibor Szanyi

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***

Or. en

Amendment 95
Annie Schreijer-Pierik

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 ***other distributors and directly to*** the animal holder;

Or. en

Amendment 96
Pilar Ayuso, Esther Herranz García

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 non-food producing animals, to other distributors who are authorised to distribute veterinary medicinal products***;

Or. es

Justification

Medicated feed for pets is a recent innovation, and account must be taken of the possible existence of different distribution channels in addition to those distributing medicated feed for livestock.

Amendment 97
Iratxe García Pérez

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 specifically equipped ***mobile system*** for the manufacture of medicated feed***, who travels in order to provide services to different animal holdings.***

Or. es

Amendment 98
Pilar Ayuso, Esther Herranz García

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 specifically equipped ***mobile system*** for the manufacture of medicated feed***, who travels in order to provide services to different animal holdings***;

Or. es

Justification

To differentiate mobile mixers, which travel to various animal holdings to provide a service, from mixers owned by farmers who manufacture feed for use on their own farms, dealt with in Article 2(2)(i).

Amendment 99
Iratxe García Pérez

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 ***intended exclusively for animals on his or her*** farm.

Or. es

Amendment 100
Pilar Ayuso, Esther Herranz García

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 ***intended exclusively for animals on his or her*** farm.

Or. es

Justification

To differentiate between farmers who manufacture their own feed and mobile mixers which travel between farms to manufacture medicated feed at the farmers' request.

Amendment 101
James Nicholson

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

Text proposed by the Commission	*Amendment*
	(ia) 'antimicrobials': an active substance of synthetic or natural origin which destroys microorganisms, suppresses their growth or their ability to reproduce in animals or humans.

Or. en

Justification

The introduced definition is used by the European Medicines Agency in their paper entitled "Answers to the requests for scientific advice on the impact on public health and animal health of the use of antibiotics in animals", reference number EMA/381884/2014.

Amendment 102
Pavel Poc, Claudiu Ciprian Tănăsescu, Daciana Octavia Sârbu

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

Text proposed by the Commission	*Amendment*
	(ia) „antimicrobials" mean any compound with a direct action on microorganisms used for treatment or prevention of infections. Antimicrobials include anti-bacterials, anti-virals, antifungals and anti-protozoals.

Or. en

Justification

Definition of the ´antimicrobials´ should be amended to clearly express and clarify the extent and coverage of this important category (keeping also in mind the fact that resistance development is an issue not only for anti-bacterials, but also for other substances as listed in the above mentioned definition). The introduced definition was adopted by HMA (Heads of Medicines Agencies) in October 2012.

Amendment 103
Tibor Szanyi

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

Text proposed by the Commission	*Amendment*
	(ia) 'antimicrobials: any compound with a direct action on microorganisms used for treatment or prevention of infections. Antimicrobials include anti-bacterials/antibiotics, anti-virals, antifungals and anti-protozoals.

Or. en

Amendment 104
Martin Häusling

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

Text proposed by the Commission	*Amendment*
	(ia) 'group treatment (metaphylaxis)': treatment of a group of animals, after a diagnosis of a clinical disease in part of the group has been made, with the aim of treating the clinically sick animals and controlling the spread of disease to animals in close contact and at risk which may already be (sub-clinically) infected.

Or. en

Justification

A definition for metaphylaxis ('group treatment', instead of 'control treatment') is needed.

Amendment 105
Pavel Poc, Claudiu Ciprian Tănăsescu, Daciana Octavia Sârbu

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

Text proposed by the Commission	*Amendment*
	(ib) 'curative (therapeutic) treatment': treatment of an ill animal or group of animals, when a diagnosis of a disease or an infection has been made;

Or. en

Justification

It should be clearly defined the claimed use of the medicated feed as ´treatment´ (curative/therapeutic use) or the ´metaphylaxis´ (control treatment). Proposed definition was adopted by EPRUMA (European Platform for the Responsible Use of Medicines in Animals) in May 2013. (In the case that the definition will be introduced in the regulation related veterinary medicinal products, cross link to this regulation might be appropriate to be introduced.)

Amendment 106
Tibor Szanyi

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

Text proposed by the Commission	*Amendment*
	(ib) 'curative (therapeutic) treatment': treatment of an ill animal or group of animals, when a diagnosis of a disease or an infection has been made;

Or. en

Amendment 107
Pavel Poc, Claudiu Ciprian Tănăsescu, Daciana Octavia Sârbu

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

Text proposed by the Commission	*Amendment*
	(ic) 'control treatment (metaphylaxis)': treatment of a group of animals, after a diagnosis of a clinical disease in part of the group has been made, with the aim of treating the clinically sick animals and controlling the spread of disease to animals in close contact and at risk which may already be (sub-clinically) infected;

Or. en

Justification

In order to clarify the term "preventive use", a precise distinction between the different forms of treatment was added. The introduced definition was adopted by EPRUMA (European Platform for the Responsible Use of Medicines in Animals) in May 2013. (In the case that the definition will be introduced in the regulation related veterinary medicinal products, cross link to this regulation might be appropriate to be introduced.)

Amendment 108
Tibor Szanyi

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

Text proposed by the Commission	*Amendment*
	(ic) 'control treatment (metaphylaxis)': treatment of a group of animals, after a diagnosis of a clinical disease in part of the group has been made, with the aim of treating the clinically sick animals and controlling the spread of disease to animals in close contact and at risk which may already be (sub-clinically) infected;

Or. en

Amendment 109
Pavel Poc, Claudiu Ciprian Tănăsescu, Daciana Octavia Sârbu

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

Text proposed by the Commission	*Amendment*
	(id) 'preventive treatment (prophylaxis)': treatment of an animal or a group of animals before the emergence of clinical signs of a disease, in order to prevent the occurrence of a disease or an infection.

Or. en

Justification

In order to clarify the term "preventive use", a precise distinction between the different forms of treatment was added. The introduced definition was adopted by EPRUMA (European Platform for the Responsible Use of Medicines in Animals) in May 2013. (In the case that the definition will be introduced in the regulation related veterinary medicinal products, cross link to this regulation might be appropriate to be introduced.)

Amendment 110
Tibor Szanyi

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

Text proposed by the Commission	*Amendment*
	(id) 'preventive treatment (prophylaxis)': treatment of an animal or a group of animals before the emergence of clinical signs of a disease, in order to prevent the occurrence of a disease or an infection;

Or. en

Amendment 111
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Chapter 2 – title

Text proposed by the Commission	*Amendment*
Manufacture, storage, transport and placing on the market	Manufacture, storage, transport***, import*** and placing on the market

Or. fr

Amendment 112
Michèle Rivasi, Martin Häusling

Proposal for a regulation
Chapter 2 – title

Text proposed by the Commission	*Amendment*
Manufacture, storage, transport ***and*** placing on the market	Manufacture, storage, transport**,** placing on the market***, traceability of the active substances in the ecosystems***

Or. en

Amendment 113
Sylvie Goddyn, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau, Jean-François Jalkh

Proposal for a regulation
Article 3 – paragraph 1

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 ***established in the Union or in third countries trading with Union Member States*** shall manufacture, store, transport and place on the market medicated feed and intermediate products in compliance with Annex I. ***Live animals, carcases, meat and prepared meals and dishes based on meat shall not be imported unless the provisions of this Directive are strictly***

complied with.

Or. fr

Amendment 114
Martin Häusling

Proposal for a regulation
Article 3 – paragraph 1

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 Annex I. ***Holders of food-producing animals shall not be allowed to prepare their own medicated feed containing antimicrobial veterinary medicinal products.***

Or. en

Justification

On-farm mixing of medicated feed containing antimicrobial veterinary medicinal products should not be allowed.

Amendment 115
Pilar Ayuso, Esther Herranz García

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

Text proposed by the Commission	*Amendment*
	1a. Distributors who supply medicated feed solely for non-food producing animals, distributed in sealed bags on prescription and sent to the holders of the animals, shall be exempt from the requirements applying to feed business operators.

Or. es

Justification

To facilitate the distribution of feed intended for pets so that this can be done through veterinarians or pharmacies authorised to distribute veterinary medicinal products, without imposing an unnecessary administrative burden on this type of distributor and on administrations resulting from an obligation to meet the same requirements as feed business operators.

Amendment 116
Elisabeth Köstinger

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

Or. de

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 117
James Nicholson

Proposal for a regulation
Article 7 – 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 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 avoid ***or minimise*** carry-over ***in accordance with the ALARA principle***.

Or. en

Justification

It is not technically possible to avoid carry-over absolutely in a multi-purpose feed mill. Therefore Article 7(1) should restate the importance of minimising carry-over in accordance with the ALARA principle.

Amendment 118
Pilar Ayuso, Esther Herranz García

Proposal for a regulation
Article 7 – 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 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.

Or. es

Justification

The amendment adopts the term used in Regulation No 183/2005 on feed hygiene.

Amendment 119
Iratxe García Pérez

Proposal for a regulation
Article 7 – 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 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 avoid ***or minimise*** carry-over.

Or. es

Justification

In keeping with recital 12, which states that carry-over 'should be avoided or kept as low as possible'.

Amendment 120
Stefan Eck

Proposal for a regulation
Article 7 – 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 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 ***prevent*** carry-over.

Or. en

Amendment 121
Stefan Eck

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. en

Amendment 122
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
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.	The Commission shall ***submit proposals to the European Parliament for*** the establishment of specific carry-over limits for active substances.

Or. fr

Amendment 123
Pilar Ayuso, Esther Herranz García

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
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.	The Commission shall be empowered to adopt ***implementing*** acts in accordance with Article 19 concerning the establishment of specific carry-over limits for active substances.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 20(2).

Or. es

Justification

The implementing act procedure should be used, as is the case in Article 6(2).

Amendment 124
James Nicholson

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
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.	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 ***in non-target feed on the basis of a scientific risk assessment by the European Food Safety Authority (EFSA)***.

Or. en

Amendment 125
Paul Brannen

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
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.	The Commission shall be empowered to adopt delegated acts in accordance with Article 19 concerning the establishment of carry-over limits for ***specific*** active substances ***in order to avoid risk for animal health, human health or the environment***.

Or. en

Amendment 126
Tibor Szanyi

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
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.	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 ***to avoid risk for animal health, human health or the environment***.

Or. en

Amendment 127
Stefan Eck

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Where no specific carry-over limits have been set for an active substance, the following carry-over limits shall apply:	***deleted***
(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.	

Or. en

Amendment 128
Paul Brannen

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2 – introductory part

Text proposed by the Commission	*Amendment*
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 ***carry-over limit of 3% of the active substance in the last batch of medicated feed or of intermediate product produced before the production of non-target feed*** shall apply***.***

Or. en

Justification

The proposed 1% carry-over limit goes beyond the principle of proportionality and technical feasibility.

Amendment 129
Pilar Ayuso, Esther Herranz García

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2 – introductory part

Text proposed by the Commission	*Amendment*
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, ***a*** carry-over ***limit of 3% of the active substance in medicated feed to non-target feed*** shall apply***.***

Or. es

Justification

The maximum percentage of carry-over should be set on the basis of scientific data in keeping with the proportionality principle, in line with good manufacturing practice. It is technologically difficult to achieve a 1% limit.

Amendment 130
James Nicholson

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2 – introductory part

Text proposed by the Commission	*Amendment*
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 ***in non-target feed, a general maximum limit of 3% of the active substance in the last batch of medicated feed or intermediate product produced*** shall apply***.***

Or. en

Justification

Current laboratory methods for medicines are not sufficiently developed to measure low level contamination at the carry-over thresholds proposed for antimicrobial active substances. Therefore, it is more appropriate for a general maximum limit for the presence of active substances in non-target feed, until specific carry-over limits are established after a scientific risk assessment by EFSA.

Amendment 131
Paul Brannen

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2 – point a

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

Or. en

Justification

The proposed 1% carry-over limit goes beyond the principle of proportionality and technical feasibility.

Amendment 132
James Nicholson

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2 – point a

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

Or. en

Amendment 133
Stefan Eck

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2 – point a

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

Or. en

Amendment 134
Pilar Ayuso, Esther Herranz García

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2 – point a

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

Or. es

Justification

The maximum percentage of carry-over should be set on the basis of scientific data in keeping with the proportionality principle, in line with good manufacturing practice. It is technologically difficult to achieve a 1% limit.

Amendment 135
Iratxe García Pérez

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2 – point a

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

Or. es

Amendment 136
Martin Häusling

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) for antimicrobial active substances, ***1%*** of the active substance in the last batch of	(a) for antimicrobial active substances, ***0.1%*** of the active substance in the last

medicated feed or of intermediate product produced before the production of non-target feed;	batch of medicated feed or of intermediate product produced before the production of non-target feed;

Or. en

Justification

The carry-over limit should be reduced to 0,1% of the active substance to ensure that unneeded exposure to antimicrobials is reduced as far as technically feasible. Thorough cleaning of production lines, separation of production lines into antimicrobial and non-antimicrobial ones, and pre-packaging doses and packs of doses for transport will help achieve this target.

Amendment 137
Annie Schreijer-Pierik

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2 – point a

Text proposed by the Commission	*Amendment*
(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;	(a) for antimicrobial active substances, ***2%*** of the active substance in the last batch of medicated feed or of intermediate product produced before the production of non-target feed;

Or. en

Justification

The average carry over in the feed industry is around 5%

Amendment 138
Paul Brannen

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2 – point b

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

Or. en

Justification

The proposed 1% carry-over limit goes beyond the principle of proportionality and technical feasibility.

Amendment 139
James Nicholson

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2 – point b

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

Or. en

Amendment 140
Stefan Eck

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2 – point b

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

target feed.

Or. en

Amendment 141
Pilar Ayuso, Esther Herranz García

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2 – point b

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. es

Justification

The maximum percentage of carry-over should be set on the basis of scientific data in keeping with the proportionality principle, in line with good manufacturing practice. It is technologically difficult to achieve a 1% limit.

Amendment 142
Annie Schreijer-Pierik

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2 – point b

Text proposed by the Commission	*Amendment*
(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.	(b) for the other active substances, ***4%*** of the active substance in the last batch of medicated feed or of intermediate product produced before the production of non-target feed.

Or. en

Amendment 143
Iratxe García Pérez

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 2 – point b

Text proposed by the Commission	*Amendment*
(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.	(b) for ***all*** 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.

Or. es

Amendment 144
Michèle Rivasi, Martin Häusling

Proposal for a regulation
Article 8

Text proposed by the Commission	*Amendment*
Article 8	***deleted***
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.	

Or. en

Justification

Such a provision can lead to harmful loopholes in access to the market of active substances.

Amendment 145
Pilar Ayuso, Esther Herranz García

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission	*Amendment*
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***.	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 ***mobile*** mixers.

Or. es

Justification

Medicated feed needs to be made available for minor species and aquaculture, because exceptional prescriptions are often used owing to the fact that not enough authorised medicines are available for them. The original wording prohibits the prior manufacture of medicated feed prescribed under the 'exceptional prescription system' used for minor species (rabbits, goats, sheep and fish) and minor uses.

Amendment 146
Stefan Eck

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission	*Amendment*
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.***	Medicated feed and intermediate products may ***not*** be manufactured and stored before the prescription referred to in Article 15 is issued.

Or. en

Amendment 147
Iratxe García Pérez

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission	*Amendment*
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.***	Medicated feed and intermediate products may be manufactured and stored before the prescription referred to in Article 15 is issued.

Or. es

Justification

Prior manufacture allows manufacturers to plan ahead and thereby avoid 'carry-over'. We cannot deprive minor species of this method of treatment.

Amendment 148
Elisabeth Köstinger

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), Articles 12 and 14 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.

Or. de

Justification

Medicated feed which is fed directly to the animals by an on-farm mixer does not need to be specially and additionally labelled.

Amendment 149
Pilar Ayuso, Esther Herranz García

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*** Articles 12**,** 14***, 15 and 17*** of Regulation (EC) No 767/2009, the labelling of medicated feed and intermediate products shall comply with Annex III to this Regulation.

Or. es

Justification

Many of the requirements laid down in Annex III to this proposal are already established in Articles 15 and 17 of Regulation (EC) No 767/2009. We are proposing that this article should include a reference to the provisions in that regulation that relate to the labelling and circulation of feed.

Amendment 150
Pilar Ayuso, Esther Herranz García

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 ***a document*** complying with paragraph 1.

Or. es

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 151
Michèle Rivasi

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.	***deleted***

Or. en

Justification

Deviations of the labelled content automatically lead to misleading information for the user. Therefore, the labelling itself should be as precise as possible.

Amendment 152
Stefan Eck

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***	3. Discrepancies between the labelled compositional values of a medicated feed or an intermediate product and the values analysed in official controls ***won't be***

Regulation (EC) No 882/2004 are as set out in Annex IV.	***permitted***.

Or. en

Amendment 153
Ivan Jakovčić

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 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.

Or. hr

Amendment 154
James Nicholson

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 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. ***Appropriate derogations should be provided for in so far as the application of that requirement is not necessary to protect human or animal health or consumer interests and would represent excessive burden for the feed business operators.***

Or. en

Justification

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

Amendment 155
Pilar Ayuso, Esther Herranz García

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.	*(Does not affect the English version.)*

Or. es

Justification

(Does not affect the English version.)

Amendment 156
Pilar Ayuso, Esther Herranz García

Proposal for a regulation
Article 11

Text proposed by the Commission	*Amendment*
Article 11	***deleted***
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.

Or. es

Justification

The requirements of Council Directive 90/167/EEC ought to be maintained. This proposal needs to be in line with Article 114 of the new proposal for a regulation on veterinary medicinal products.

Amendment 157
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 11 – title

Text proposed by the Commission	*Amendment*
Intra Union trade	Intra-Union trade ***and trade with third countries***

Or. fr

Amendment 158
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 11 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Where medicated feed is manufactured in a third country, the veterinary medicinal product shall be authorised by the Member State of use and by any Member State in which the products derived from the animals treated are consumed,

including in instances where the manufacturer's head office is established in a Member State.

Or. fr

Amendment 159
Michèle Rivasi, Martin Häusling

Proposal for a regulation
Article 11 a (new)

Text proposed by the Commission	*Amendment*
	Article 11a
	Traceability of the active substances disseminated in the ecosystems
	The prescription givers shall fill in a register of the prescriptions of active substances. The register shall be kept up to date at the level of competent authorities for water management, for the sake of traceability of the dissemination of chemicals in the ecosystems.

Or. en

Justification

In order to improve the efficiency of water management, the competent authorities need to know which active substances are disseminated into water.

Amendment 160
Stefan Eck

Proposal for a regulation
Article 12

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.

Or. en

Amendment 161
Elisabeth Köstinger

Proposal for a regulation
Article 12

Text proposed by the Commission	*Amendment*
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.	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. ***Where on-farm mixers include medicinal products solely for use on their own farms, they shall notify their activity to the competent authority.***

Or. de

Justification

On-farm mixers are already registered with the authorities. An additional approval procedure goes against the principle of administrative simplification and cost saving for businesses.

Amendment 162
Fredrick Federley, Marit Paulsen

Proposal for a regulation
Article 15 – paragraph 1

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	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.	mixers, the possession of a veterinary prescription ***issued by a veterinarian*** and to the conditions laid down in paragraphs 2 to 6.

Or. en

Amendment 163
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission	*Amendment*
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 Annex V. The original prescription shall be kept by the manufacturer or, where appropriate, the distributor. The ***veterinarian*** 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.

Or. fr

Justification

Only duly qualified veterinarians must be authorised to produce diagnoses and issue prescriptions.

Amendment 164
Tibor Szanyi

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The prescription shall contain the information set out in Annex V. The	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.	original prescription shall be kept by the manufacturer or, where appropriate, the distributor. The ***veterinarian*** 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.

Or. en

Amendment 165
Stefan Eck

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission	*Amendment*
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 Annex V. The original prescription shall be kept by the manufacturer or, where appropriate, the distributor. The ***veterinary agent*** 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.

Or. en

Amendment 166
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission	*Amendment*
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	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 ***veterinarian*** 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.	keep a copy of the prescription. The original and copies shall be kept for three years from the date of issuance.

Or. it

Amendment 167
Elisabeth Köstinger

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission	*Amendment*
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 the Regulation of the European Parliament and the Council on veterinary medicinal products[1 a]*** . 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.
	_____
	[1 a] Commission proposal COM(2014)558 final

Or. en

Justification

A veterinary prescription shall contain the elements as suggested in the current Commission proposal on veterinary medicinal products.

Amendment 168
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Proposal for a regulation
Article 15 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Metaphylactic use of medicated feed shall be duly justified by the veterinarian issuing the prescription. To that end, prescribing veterinarians shall assess the health and hygiene conditions at animal holdings, including aquaculture holdings, and the preventive bio-safety measures taken there.

Or. it

Amendment 169
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Proposal for a regulation
Article 15 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Prescribing veterinarians may not sell medicated feed.

Or. it

Amendment 170
Pilar Ayuso, Esther Herranz García

Proposal for a regulation
Article 15 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. es

Justification

This regulation needs to be fully in line with the legislation on veterinary medicinal products and should under no circumstances place one way of administering veterinary medicated products above another. That is why we are proposing that the paragraph should be deleted.

Amendment 171
Elisabeth Köstinger

Proposal for a regulation
Article 15 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. en

Amendment 172
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 15 – paragraph 4

Text proposed by the Commission	*Amendment*
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 for a maximum period of six months for non-food-producing animals ***in the case of medicated feed not containing antimicrobials,*** and three weeks for food-producing animals ***and antimicrobial-containing feed prescribed for non-food-producing animals***.

Or. fr

Amendment 173
James Nicholson

Proposal for a regulation
Article 15 – paragraph 4

Text proposed by the Commission	*Amendment*
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 ***only for the*** period ***determined by the person who issued the prescription***.

Or. en

Justification

Persons issuing the prescriptions should retain the capability to determine the validity of the prescription on the basis of their clinical and epidemiological knowledge. Restricting the period of prescription and the amount of medicated feed that can be supplied in one order may cause an excessive administrative burden to both the persons issuing the prescription and those using the feed.

Amendment 174
Annie Schreijer-Pierik

Proposal for a regulation
Article 15 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	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 ***and after having knowledge of the feeding systems the possibilities of mixing and other relevant farm specificities***. 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.

Or. en

Amendment 175
Nicola Caputo

Proposal for a regulation
Article 15 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	5. The prescribed medicated feed may be used only for animals examined by the ***veterinarian*** who issued the prescription and only for a diagnosed disease. The ***veterinarian*** 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.

Or. en

Amendment 176
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 15 – paragraph 5

Text proposed by the Commission	*Amendment*
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	5. The prescribed medicated feed may be used only for animals examined by the ***veterinarian*** who issued the prescription and only for a diagnosed disease. The ***veterinarian*** who issued the prescription

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.	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.

Or. fr

Amendment 177
Pilar Ayuso, Esther Herranz García

Proposal for a regulation
Article 15 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	5. The prescribed medicated feed may be used only for animals examined by the person who issued the prescription. 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.

Or. es

Justification

Medicated feed can be used to administer any kind of veterinary medicinal product, including vaccines and anti-parasite treatments. It is in any case up to the vet to choose the best treatment for animals among the various existing routes of administration.

Amendment 178
Stefan Eck

Proposal for a regulation
Article 15 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	5. The prescribed medicated feed may be used only for animals examined by the ***veterinary agent*** who issued the prescription and only for a diagnosed disease. The ***veterinary agent*** 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.

Or. en

Amendment 179
Fredrick Federley, Marit Paulsen

Proposal for a regulation
Article 15 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	5. The prescribed medicated feed may be used only for animals examined by the ***veterinarian*** who issued the prescription and only for a diagnosed disease. The ***veterinarian*** 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.

Or. en

Amendment 180
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Proposal for a regulation
Article 15 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	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. ***The off-label use of medicated feed with antimicrobials authorised for human use only shall be forbidden.***

Or. it

Amendment 181
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Proposal for a regulation
Article 15 – paragraph 5

Text proposed by the Commission	*Amendment*
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	5. The prescribed medicated feed may be used only for animals examined by the ***veterinarian*** who issued the prescription and only for a diagnosed disease. The ***veterinarian*** who issued the prescription

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.	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.

Or. it

Amendment 182
James Nicholson

Proposal for a regulation
Article 15 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	5. The prescribed medicated feed may be used only for ***a group of animals under the care of*** the person who issued the prescription and only for ***the*** 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.

Or. en

Justification

In conjunction with Recital 17, the Commission's proposals as currently drafted imply a physical examination of the animals by the person issuing the prescription. Such an arrangement is often impracticable, given the rapid and severe nature of some animal diseases, and furthermore would undermine the clinical and epidemiological knowledge of the person issuing the prescription.

Amendment 183
Elisabeth Köstinger

Proposal for a regulation
Article 15 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	5. The prescribed medicated feed may be used only for ***the group of*** animals ***inspected*** by the person who issued the prescription. 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.

Or. en

Amendment 184
Nicola Caputo

Proposal for a regulation
Article 15 – paragraph 5 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Veterinarians qualified to prescribe medicated feed in accordance with applicable national law shall not retail medicated feed.

Or. en

Amendment 185
Pilar Ayuso, Esther Herranz García

Proposal for a regulation
Article 15 – paragraph 6

Text proposed by the Commission	*Amendment*
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 kg of medicated feed***.

Or. es

Justification

We are proposing that the wording of the proposal should be made more concise so that it is easier to understand.

Amendment 186
Martin Häusling

Proposal for a regulation
Article 16 – paragraph 1 – introductory part

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. ***For*** medicated feed ***containing antimicrobial veterinary medicinal products, feed business operators supplying such*** medicated feed ***to the holder of*** food-producing animals shall ensure that the quantities supplied or mixed do not exceed:

Or. en

Justification

There is a need to distinguish between feed containing antimicrobial veterinary medicinal products or not. There should be no on-farm mixing of medicated feed with antimicrobial veterinary medicinal products.

Amendment 187
Iratxe García Pérez

Proposal for a regulation
Article 16 – paragraph 1 – introductory part

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 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 ***the quantities determined in the prescription.***
	The quantities required for treatment shall be determined in accordance with the conditions of use established in the authorisation to place on the market the veterinary medicinal products included in the prescription.

Or. es

Justification

In this paragraph, the Commission gives feed business operators a responsibility that should actually be that of the vet alone, as he or she is the professional who must decide on the length of the treatment and the quantity to supply on the basis of the conditions of use established in the authorisation.

Amendment 188
James Nicholson

Proposal for a regulation
Article 16 – paragraph 1 – introductory part

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 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 ***the quantities***

provided for in the prescription.

Or. en

Justification

Currently, some antimicrobial products are prescribed for a period longer than two weeks. Not only would a two week limit increase the administrative burden for those using medicated feed, but finishing the treatment course early may increase the possibility of antimicrobial resistance. Feed business operators should supply medicated feed on the basis of the prescription issued by the person assessing the clinical condition.

Amendment 189
Pilar Ayuso, Esther Herranz García

Proposal for a regulation
Article 16 – paragraph 1 – introductory part

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 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 ***the quantities required for treatment, which shall be determined in accordance with the conditions of use established in the authorisation to place on the market the veterinary medicinal products included in the prescription.***

Or. es

Justification

It must be for the vet to determine the length of treatment, and therefore also the quantity that is to be supplied, on the basis of the authorised conditions of use set out in the notice accompanying the veterinary medicinal products that must be included in the corresponding veterinary prescription. The length of treatment cannot be established by means of legislation, given the differences between species, their physiological conditions, the conditions of administration, etc.

Amendment 190
James Nicholson

Proposal for a regulation
Article 16 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the quantities provided in the prescription and	***deleted***

Or. en

Amendment 191
Iratxe García Pérez

Proposal for a regulation
Article 16 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the quantities provided in the prescription and	***deleted***

Or. es

Amendment 192
Pilar Ayuso, Esther Herranz García

Proposal for a regulation
Article 16 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the quantities provided in the prescription and	***deleted***

Or. es

Amendment 193
James Nicholson

Proposal for a regulation
Article 16 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the quantities required for one month's treatment or two weeks in case of medicated feed containing antimicrobial veterinary medicinal products.	***deleted***

Or. en

Amendment 194
Elisabeth Köstinger

Proposal for a regulation
Article 16 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the quantities required for one month's treatment or two weeks in case of medicated feed containing antimicrobial veterinary medicinal products.	***deleted***

Or. en

Amendment 195
Iratxe García Pérez

Proposal for a regulation
Article 16 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the quantities required for one month’s treatment or two weeks in case of medicated feed containing antimicrobial veterinary medicinal products.	***deleted***

Or. es

Justification

Restricting the quantity of medicated feed to be supplied for the treatment, and establishing the length of that treatment, should be the sole responsibility of the vet.

Amendment 196
Pilar Ayuso, Esther Herranz García

Proposal for a regulation
Article 16 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the quantities required for one month's treatment or two weeks in case of medicated feed containing antimicrobial veterinary medicinal products.	***deleted***

Or. es

Amendment 197
Annie Schreijer-Pierik

Proposal for a regulation
Article 16 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the quantities required for one month's treatment or ***two weeks*** in case of medicated feed containing antimicrobial veterinary medicinal products**.**	(b) the quantities required for one month's treatment or in case of medicated feed containing antimicrobial veterinary medicinal products ***the quantities required for a duration mentioned in the summary of the product characteristics, unless specifically licensed otherwise under COM(2014) 556 final, 2014/0255 (COD).***

Or. en

Justification

The Regulation on Medicated Feed and Regulation on Veterinary Medicinal Products are linked. It is therefore important to reference the conditions for use and duration as indicated in the VMP Regulation in this proposal. There are instances in which a treatment with an

antimicrobial takes longer than two weeks, the MF regulation needs to take that into account

Amendment 198
Paul Brannen

Proposal for a regulation
Article 16 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the quantities required for one month's treatment or ***two*** weeks in case of medicated feed containing antimicrobial veterinary medicinal products.	(b) the quantities required for one month's treatment or ***three*** weeks in case of medicated feed containing antimicrobial veterinary medicinal products.

Or. en

Justification

Some antimicrobial products are prescribed for a period of up to three weeks. Premature finishing of the treatment may exacerbate antimicrobial resistance.

Amendment 199
Tibor Szanyi

Proposal for a regulation
Article 16 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Before repeated prescription, it is necessary for the veterinarian to evaluate how the effected animals reacted to the treatment and whether or not the treatment can be stopped or needs to be continued or changed.

Or. en

Amendment 200
Annie Schreijer-Pierik

Proposal for a regulation
Article 16 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Before a repeated prescription, it is necessary for the veterinarian to do a sensitivity check and to evaluate if the treatment can be stopped or needs to be continued or changed.

Or. en

Amendment 201
Martin Häusling

Proposal for a regulation
Article 16 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. For medicated feed not containing antimicrobial veterinary medicinal products, 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 the quantities provided in the prescription.

Or. en

Justification

Need to introduce a separate paragraph for medicated feed not containing antimicrobial veterinary medicinal products (where on farm-mixing is tolerable).

Amendment 202
Martin Häusling

Proposal for a regulation
Article 16 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. Member States shall ensure that holders of food-producing animals apply the preventive measures listed in Annex Va before resorting to the use of medicated feed containing antimicrobials for metaphylaxis.

Or. en

(This amendment is linked to the amendment introducing a new Annex Va.)

Justification

Clear conditions should be set with regard to metaphylaxis.

Amendment 203
Stefan Eck

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. ***Since there is a direct link between good animal husbandry and a responsible use of veterinary medicines,*** medicated feed containing antimicrobial veterinary medicinal products shall ***never*** be used to prevent diseases in food-producing animals or to enhance their performance

Or. en

Amendment 204
Iratxe García Pérez

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 ***for*** food-producing animals***, except in prophylactic uses where there is a high risk of infection and they are allowed under the conditions of use already defined in the authorisation for the same medicinal product***.

Or. es

Amendment 205
Fredrick Federley, Marit Paulsen

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 antimicrobial veterinary medicinal products shall be used ***in accordance with good animal husbandry standards and not be used for preventive treatment (prophylactic use)***.

Or. en

Justification

Prophylactic use of medicated feed containing antimicrobial veterinary medicine contributes heavily to the risk of developing antimicrobial resistance.

Amendment 206
Elisabeth Köstinger

Proposal for a regulation
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Medicated feed containing antimicrobial	2. Medicated feed containing antimicrobial

veterinary medicinal products shall not be used to prevent diseases in food-producing animals ***or to enhance their performance***.	veterinary medicinal products shall not be used ***routinely*** to prevent diseases in food-producing animals***. It shall only be used in limited and precise circumstances prescribed by the veterinarian***.

Or. en

Amendment 207
Pilar Ayuso, Esther Herranz García

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 antimicrobial veterinary medicinal products shall not be used to enhance performance.

Or. es

Justification

Preventive use is justified when there is a high risk of a group of animals contracting a disease. It should be allowed, but restricted to specific situations, and should also always be subject to a veterinary prescription based on clinical and epidemiological knowledge. Routine use for prevention purposes, or to compensate for poor hygiene or husbandry, must not be authorised under any circumstances.

Amendment 208
Lynn Boylan

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	2. Medicated feed containing antimicrobial veterinary medicinal products shall not be used to prevent diseases in food-producing animals or to enhance their performance

animals or to enhance their performance.	***and should be strictly restricted to therapeutic use and individual treatment***.

Or. en

Amendment 209
James Nicholson

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 antimicrobial veterinary medicinal products shall not be used to ***enhance the performance of*** food-producing animals***. The use of antimicrobials in medicated feed before a disease is diagnosed or clinical signs are present should only be allowed in very exceptional circumstances and under prescription on the basis of the epidemiological and clinical knowledge of the person who issued the prescription***.

Or. en

Justification

A total ban on preventative use could have adverse implications on animal health and welfare, particularly in cases where diseases emerge and spread rapidly. Preventative use should only be allowed in precise and defined conditions, under the auspices of the epidemiological and clinical knowledge of the person who issued the prescription.

Amendment 210
Pavel Poc, Daciana Octavia Sârbu

Proposal for a regulation
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Medicated feed containing antimicrobial	2. Medicated feed containing antimicrobial

veterinary medicinal products shall not be used ***to prevent diseases in food-producing animals or to enhance their performance***.	veterinary medicinal products shall not be used ***for preventive treatment (prophylaxis) or to enhance performance of animals. Prophylaxis with antimicrobials shall never be applied routinely nor to compensate for poor hygiene or for inadequate husbandry conditions***.

Or. en

Justification

A clarification based on the EPRUMA definitions was introduced. The ban on growth promotion was already mentioned in the recitals. It is important that preventive treatment is not used in neither food nor non-food producing animals.

Amendment 211
Zoltán Balczó

Proposal for a regulation
Article 16 – paragraph 3

Text proposed by the Commission	*Amendment*
(3) When administering medicated feed, the holder of food-producing animals ***shall*** ensure compliance with the withdrawal period provided for in the veterinary prescription.	(3) When administering medicated feed, the holder of food-producing animals ***must*** ensure compliance with the withdrawal period provided for in the veterinary prescription.

Or. hu

Amendment 212
Fredrick Federley, Jan Huitema, Marit Paulsen

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	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 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. ***Member States shall ensure that the data in those records is collected and transferred to the Union database on veterinary medicinal products (referring to Article 51 and 54 in the Regulation on veterinary medicinal products 2014/0257 (COD)).***

Or. en

Amendment 213
Martin Häusling

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 ***of medicated feed and holders of food-producing animals*** 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.

Or. en

Justification

Both feed businesses as well as farmers should keep records.

Amendment 214
Nicola Caputo

Proposal for a regulation
Article 16 a (new)

Text proposed by the Commission	*Amendment*
	Article 16a
	Use in non-food producing animals
	The Commission shall be empowered to adopt delegated acts in accordance with Article 19 concerning the establishment of specific conditions in which medicated feed may be used to treat non-food producing animals. Such conditions shall be based on scientific evidence and shall define the species of non-food producing animals as well as the specific health conditions which may be treated with medicated feed.

Or. en

Amendment 215
Stefan Eck

Proposal for a regulation
Article 16 a (new)

Text proposed by the Commission	*Amendment*
	Article 16a
	Use in pet animals
	The Commission shall be empowered to adopt delegated acts in accordance with Article 19 concerning the establishment of specific conditions in which medicated feed may be used to treat pet animals.

Or. en

Amendment 216
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Proposal for a regulation
Article 16 a (new)

Text proposed by the Commission	*Amendment*
	Article 16
	Authorisation of the use of medicated feed for pets
	The Commission may adopt delegated acts authorising the production and placing on the market of medicated feed for pets provided that there is sound scientific evidence of the benefits of this method for administering veterinary medicines and the risks of over-administration and under-administration are taken into account. The Commission shall stipulate the species of pet that may be treated with medicated feed.

Or. it

Amendment 217
Ivan Jakovčić

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***, in cooperation with regional and local authorities,*** 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.

Or. hr

Amendment 218
Pilar Ayuso, Esther Herranz García

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.	***Feed business operators*** shall ensure that appropriate collection systems are in place for medicated feed and intermediate products that ***have*** 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.

Or. es

Justification

It is up to the operators to establish procedures for the recall and disposal of the medicated feed referred to in Article 17: this echoes the obligation relating to non-medicated feed laid down in the section on complaints and product recall in Annex II to Regulation (EC) No 183/2005 laying down requirements for feed hygiene.

Amendment 219
Martin Häusling

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 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 ensure that manufacturers of medicated feed and farmers are informed where to find these collections systems and how to get their unused leftovers of medicated feed to these collection points. Member States shall ensure that operators of collection points keep records of the medicated feed collected. Those records shall be kept for***

five years after collection.

Or. en

Justification

It is important to know how much medicated feed is returned.

Amendment 220
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 18

Text proposed by the Commission	*Amendment*
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.	The Commission shall submit amendments to Annexes I to V ***to the European Parliament*** in order to take into account technical progress and scientific developments.

Or. fr

Amendment 221
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 19 – title

Text proposed by the Commission	*Amendment*
Exercise of the delegation	***Transposition***

Or. fr

Amendment 222
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe

Loiseau

Proposal for a regulation
Article 19 – paragraph 1

Text proposed by the Commission	*Amendment*
1. ***The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article***.	1. ***Member States shall adopt and publish, by ... [one year after entry into force of this Directive] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall immediately communicate to the Commission the text of those provisions. They shall apply those provisions from … [two years after the entry into force of this Directive].*** ***When Member States adopt these measures, they shall contain a reference to this Directive or shall be*** ***accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.***

Or. fr

Amendment 223
Nicola Caputo

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 delegation of power referred to in Articles 7***, 16a*** and 18 shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

Or. en

Amendment 224
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

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. ***Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive***.

Or. fr

Amendment 225
Stefan Eck

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 delegation of power referred to in Articles 7***, 16a*** and 18 shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

Or. en

Amendment 226
Nicola Caputo

Proposal for a regulation
Article 19 – paragraph 3

Text proposed by the Commission	*Amendment*
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	3. The delegation of powers referred to in Articles 7***, 16a*** and 18 may be revoked at any time by the European Parliament or by

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.	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.

Or. en

Amendment 227
Stefan Eck

Proposal for a regulation
Article 19 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	3. The delegation of powers referred to in Articles 7***, 16a*** 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.

Or. en

Amendment 228
Nicola Caputo

Proposal for a regulation
Article 19 – paragraph 5

Text proposed by the Commission	*Amendment*
5. A delegated act adopted pursuant to Articles 7 and 18 shall enter into force only if no objection has been expressed either	5. A delegated act adopted pursuant to Articles 7***, 16a*** and 18 shall enter into force only if no objection has been expressed

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.	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.

Or. en

Amendment 229
Stefan Eck

Proposal for a regulation
Article 19 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	5. A delegated act adopted pursuant to Articles 7***, 16a*** 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.

Or. en

Amendment 230
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 23

Text proposed by the Commission	*Amendment*
This ***Regulation*** shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	This ***Directive*** shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

Or. fr

Amendment 231
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Annex I – section 1 – point 5

Text proposed by the Commission	*Amendment*
5. Drainage facilities shall be adequate for the purpose intended; they shall be designed and constructed to avoid the risk of contamination of feed.	5. Drainage facilities shall be adequate for the purpose intended; they shall be designed and constructed to avoid the risk of contamination of feed ***and of the environment; in particular, they shall prevent water contamination by antimicrobials, especially antibiotics and anti-parasites or substances classifiable as endocrine disruptors in animals and humans***.

Or. fr

Justification

Water is a key vector for exposure of animals and humans to hazardous products. Exposure to them must be drastically reduced throughout their manufacturing and utilisation chain.

Amendment 232
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Annex I – section 1 – point 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. Feed used as the basis for medicated feed shall not be derived from genetically modified organisms.

Or. fr

Amendment 233
James Nicholson

Proposal for a regulation
Annex I – 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 avoid ***or 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.

Or. en

Justification

Consistent with Article 7(1).

Amendment 234
Stefan Eck

Proposal for a regulation
Annex I – 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	2. Technical or organisational measures shall be taken to ***prevent*** 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.	used for the manufacture of medicated feed and intermediate products.

Or. en

Amendment 235
Stefan Eck

Proposal for a regulation
Annex I – 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 and of other contaminants in relation to human and animal health shall ***not be permitted***, and appropriate measures to ***prevent*** this presence shall be taken.

Or. en

Amendment 236
Stefan Eck

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 ***prevent*** any cross-contamination.

Or. en

Amendment 237
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

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) information on the ***veterinarian*** who has issued the prescription, including at least his name and address.

Or. fr

Amendment 238
Tibor Szanyi

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) information on the ***veterinarian*** who has issued the prescription, including at least his name and address.

Or. en

Amendment 239
Stefan Eck

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) information on the ***veterinary agent*** who has issued the prescription, including at least his name and address.

Or. en

Amendment 240
Stefan Eck

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

Text proposed by the Commission	*Amendment*
Apart from the documents that are permanent in nature, the documents shall be kept for ***three*** years in the register after their date of issuance.	Apart from the documents that are permanent in nature, the documents shall be kept for ***six*** years in the register after their date of issuance.

Or. en

Amendment 241
Elisabeth Köstinger

Proposal for a regulation
Annex II – point 1

Text proposed by the Commission	*Amendment*
1. Mobile mixers or on-farm mixers shall only use veterinary medicinal products at inclusion rates above 2 kg/t of feed.	1. Mobile mixers or on-farm mixers shall only use veterinary medicinal products at inclusion rates above 2 kg/t of feed. ***By way of derogation, smaller inclusion rates may be specified in the veterinary prescription:*** ***- to adjust the quantity of medicated feed produced to the size of the herd;*** ***- if the prescription, production and use take place under the supervision of the veterinarian monitoring the herd; and*** ***- if the farmer and the veterinarian monitoring the herd are subject to an external process control.***

Or. de

Amendment 242
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Annex III – paragraph 1 – point 4

Text proposed by the Commission	*Amendment*
4. the batch reference number of the medicated feed or intermediate product;	4. the batch reference number of the medicated feed or intermediate product ***and the country of manufacture***;

Or. fr

Amendment 243
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Annex III – paragraph 1 – 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 ***and*** a 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***, and a warning concerning authorisation to administer the product to organically farmed animals in accordance with the regulations and directives in force and with any special conditions of use***;

Or. fr

Justification

To make it easier for veterinarians to do their job and for farmers who make the effort to use organic production methods to do their work, authorised medicinal products must be clearly identifiable.

Amendment 244
Martin Häusling

Proposal for a regulation
Annex III – paragraph 1 – 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. Information on where and how to appropriately dispose of unused material.

Or. en

Justification

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

Amendment 245
Martin Häusling

Proposal for a regulation
Annex III – paragraph 1 – point 16 a (new)

Text proposed by the Commission	*Amendment*
	For medicated feed containing antibiotics: the request to use antibiotics only as a last resort and in a most prudent and responsible manner

Or. en

Amendment 246
Michèle Rivasi

Proposal for a regulation
Annex 4

Text proposed by the Commission	*Amendment*
Annex IV	***deleted***

Permitted tolerances for the compositional labelling of medicated feed or intermediate products as referred to in Article 9(3)

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%***

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.

Or. en

Amendment 247
Stefan Eck

Proposal for a regulation
Annex IV – heading 1

Text proposed by the Commission	*Amendment*
Permitted tolerances for the compositional labelling of medicated feed or intermediate products ***as referred to in Article 9(3)***	Tolerances for the compositional labelling of medicated feed or intermediate products ***won't be permitted***

Or. en

Amendment 248
Martin Häusling

Proposal for a regulation
Annex IV – point 1 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
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:	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 ***3%*** shall apply. For the other active substances, the following tolerances shall apply:

Or. en

Justification

Given the potency of antimicrobial active substances, a tolerance of 10% is far too high.

Amendment 249
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe Loiseau

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. fr

Amendment 250
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano, Edouard Ferrand, Philippe

Loiseau

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. fr

Amendment 251
Martin Häusling

Proposal for a regulation
Annex V a (new)

Text proposed by the Commission	*Amendment*
	Annex Va
	Preventive measures
	Preventive measures to be used before resorting to antimicrobial treatment of entire groups (metaphylaxis):
	- using good healthy breeding stock that grows naturally, with suitable genetic diversity
	- conditions that respect the behavioural needs of the species, including social interactions/ hierarchies
	- stocking densities that do not increase risk of disease transmission
	- isolation of sick animals away from the rest of the group
	- (for chickens and smaller animals) subdivision of flocks into smaller, physically separated groups
	- Implementation of existing animal welfare rules pursuant to Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes (OJ L 221, 8.8.1998,

p. 23),

Council Directive 91/630/EEC of 19 November 1991 laying down minimum standards for the protection of pigs (OJ L 340, 11.12.1991, p. 33), Council Directive 91/629/EEC of 19 November 1991 laying down minimum standards for the protection of calves (OJ L 340, 11.12.1991, p. 28).

Or. en

Justification

These preventative measures include regularly checking the welfare of individual animals, which would not be possible in many mass rearing operations for chickens for example.