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NOTE

From: General Secretariat of the Council
To: Delegations

Subject: 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
- Confirmation of the final compromise text with a view to agreement

Delegations will find in Annex to this document the compromise text as provisionally agreed with the European Parliament at the trilogue on 19 June 2018.

Changes compared to the Commission's proposal are marked in **bold underlined** (added text) and in [...] (deleted text).

Commission Proposal Cion(2014) 556 final - 2014/0255 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article[.]43(2) and **Article** 168(4)(b) thereof,

Having regard to the proposal from the European Commission,

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

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

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

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Council Directive 90/167/EEC³ constitutes the Union's regulatory framework for the manufacture, placing on the market and use of medicated feed.

¹ OJ C , , p. .

² OJ C , , p. .

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

(2) Livestock production occupies a very important place in the agriculture of the Union. The rules concerning medicated feed have significant influence on the keeping and on the rearing of animals, including non-food producing animals, and on the production of products of animal origin.

(3) The pursuit of a high level of protection of human health is one of the fundamental objectives of food law, as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council⁴, and the general principles laid down in that Regulation should apply to the placing on the market and use of feed without prejudice to more specific Union legislation. In addition, the protection of animal health constitutes one of the general objectives of EU food law.

(3a) Prevention of disease is better than cure. Medicinal treatments, especially with antimicrobials, should never replace good husbandry, bio-security and management practices.

(4) Experience with the application of Directive 90/167/EEC has shown that further measures should be taken to strengthen the effective functioning of the Internal Market and to explicitly give and improve the possibility to treat non-food producing animals by medicated feed.

(5) Medicated feed is one of the routes for the **oral** administration of veterinary medicinal products [...]. **Medicated feed is a homogenous mixture of feed and veterinary medicinal product(s). Other alternative routes for oral administration, such as mixing of water for drinking with a veterinary medicinal product or as manual mixing of a veterinary medicinal product into feed are not part of the scope of this Regulation.** The authorisation for use in feed, the manufacture, distribution, advertising and supervision of those veterinary medicinal products are governed by [...] **Regulation (EU) .../... [VMP]** of the European Parliament and of the Council⁵.

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).

⁵ [...]

5a) Regulation (EU) .../... (VMP) applies to veterinary medicinal products for the time up until these products are included in medicated feed or intermediate products including for the purpose of what in Directive 90/167/EEC was referred to as 'pre-mixes', after which this Regulation applies to the exclusion of Regulation (EU) .../... (VMP).

(6) As [...] type[...] of feed, medicated feed **and intermediate products** fall[...] within the scope of Regulation (EC) No 183/2005 of the European Parliament and of the Council⁶, of Regulation (EC) No 767/2009 of the European Parliament and of the Council⁷, of Regulation (EC) No 1831/2003 of the European Parliament and of the Council⁸ and of Directive 2002/32/EC of the European Parliament and of the Council⁹.

Thus, whenever medicated feed is produced from a compound feed all relevant legislation on compound feed applies and whenever medicated feed is produced from a feed material, all relevant legislation on feed material applies. This applies to feed business operators, whether they operate in a feed mill, with a specially equipped vehicle (mobile mixers) or being on-farm mixers, as well as by feed business operators storing, transporting or placing on the market medicated feed and intermediate products.

(6a) 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 [...] and labelling.

⁶ Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1).

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).

(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 [...] **(EU) No 2017/625** of the European Parliament and of the Council¹⁰. Within this framework, medicated feed imported into the Union is to be considered as falling within the scope of this Regulation.

(8) Without prejudice to the general obligations laid down in Article 12 of Regulation (EC) No 178/2002 concerning exports of feed to third countries, the provisions of this Regulation should apply to medicated feed and intermediate products which are manufactured, stored, transported or placed on the market within the Union with the intention to be exported. However, the specific requirements concerning labelling, prescription and use of medicated feed and intermediate products should not apply to products intended to be exported.

(8a) While veterinary medicinal products and the supply thereof are regulated in Regulation (EU) .../... (VMP), intermediate products are not and should therefore be specifically regulated in this Regulation in a corresponding way.

(9) Medicated feed should be manufactured only with [...] veterinary medicinal products **authorised for the purpose of the manufacture of medicated feed** and the compatibility of all compounds used should be ensured for the purpose of safety and efficacy of the product. Additional specific requirements or instructions for the inclusion of the veterinary medicinal products into feed should be foreseen to ensure a safe and efficient treatment of the animals.

¹⁰ [...] **Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).**

(10) Homogeneous [...] **dispersion** of the veterinary medicinal product into the feed is also crucial for the manufacture of a safe and efficient medicated feed. Therefore, the possibility to establish criteria, such as target values, for the homogeneity of the medicated feed should be provided for.

(11) Feed business operators may produce within one establishment a broad range of feeds for different target animals and containing different types of compounds such as feed additives or veterinary medicinal products. The manufacture of different types of feed after each other in the same production line may result in the presence of traces of an **active** substance in the line, which ends up in the beginning of the production of another feed. This transfer of traces of an **active** substance from one production [...] **batch** to another is called "[...] **cross-contamination**".

(12) [...] **Cross-contamination** may occur during production, processing, storage and transport of feed where the same production and processing equipment, **including mobile mixers**, storage facilities or means of transport are used for feed with different components. For the purposes of this Regulation, the concept of "[...] **cross-contamination** " is used specifically to designate the transfer of traces of an active substance contained in a medicated feed to a non-target feed [...]. [...] **Contamination** of **non-target feed with** active substances contained in medicated feed [...] should be avoided or kept as low as possible.

In order to protect animal health, human health and the environment, maximum levels of **cross-contamination for active substances in non-target feed** [...] should be established, based on a scientific risk assessment performed by the European Food Safety Authority **and in cooperation with the European Medicines Agency** and taking into account the application of good manufacturing practice and the ALARA (As Low As Reasonably Achievable) principle. [...] **Until the completion of abovementioned risk assessment, national maximum levels of cross-contamination for active substances in non-target feed, regardless of its origin**, should **apply** [...], taking into account the unavoidable [...] **cross-contamination** and the risk caused by the active substances concerned.

(13) Labelling of medicated feed should comply with the general principles laid down in Regulation (EC) No 767/2009 and be subject to specific labelling requirements in order to provide the user with the information necessary to correctly administer the medicated feed. Similarly, limits for the deviations of the labelled content of medicated feed from the actual content should be established.

(14) Medicated feed **and intermediate products** should be marketed in sealed **packages or** containers for safety reasons and to protect user's interest. **This should not apply to mobile mixers that supply medicated feed directly to the animal keeper.**

(14a) The advertising of medicated feed could affect public and animal health and distort competition. Therefore, advertising of medicated feed should satisfy certain criteria. Veterinarian can properly evaluate the information available in advertising because of their knowledge and experience in animal health. The advertising of medicated feed to persons who cannot properly appreciate the risk associated with their use may lead to medicine misuse or overconsumption which is liable to harm public or animal health, or the environment.

(15) For intra Union trade **and import** of medicated feed, it should be ensured that the veterinary medicinal products contained therein [...] **are** allowed for use in the Member State of destination according to [...] **Regulation (EU) .../... (VMP).**

(15a): It is important to consider the international dimension of the development of antimicrobial resistance. Antimicrobial resistant organisms can spread to humans and animals in the Union and third countries through consumption of products of animal origin, from direct contact with animals or humans or by other means. This has been recognized in Article 122a of the Regulation on veterinary medicinal products where it is provided that operators in third countries respect certain conditions relating to antimicrobial resistance for animals and products of animal origin exported to the Union; this is to be considered also in respect of the use of antimicrobial medicinal products concerned if they are administered via medicated feed. Furthermore, in the context of international cooperation and in line with activities and policies of international organisations such as the WHO Global Action Plan and the Strategy on Antimicrobial Resistance and the Prudent use of Antimicrobials of the World Organisation for Animal Health, steps restricting the use of medicated feed containing antimicrobials in order to prevent a disease should be considered worldwide for animals and products of animal origin exported from third countries to the Union.

(16) Feed business operators manufacturing, whether they operate in a feed mill, with a specially equipped [...] **vehicle** or on-farm, storing, transporting or placing on the market medicated feed and intermediate products, should be approved by the competent authority, in line with the approval system laid down in Regulation (EC) No 183/2005, in order to ensure both feed safety and product traceability. **Feed business operators dealing with some lower risk activities such as certain types of transport, storage and retail, should be exempted from the approval obligation, however this does not exempt them from the registration obligation under the registration system laid down in Regulation (EC) No 183/2005. To ensure appropriate use and full traceability for medicated feed, it is appropriate that retailers of medicated feed for pets and keepers of fur animals feeding animals with medicated feed, not being subject to the approval obligations, provide information to competent authorities.** Provision should be made for a transition procedure concerning establishments already approved under Directive 90/167/EEC.

(16a) Care should be taken to ensure that the medicated feed handling requirements imposed by this Regulation and delegated and implementing acts adopted pursuant to this Regulation on feed business operators, in particular on-farm mixers, are feasible and practical.

(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 **for medicated feed** which has been issued **by the veterinarian** after examination **or any other proper assessment of the health status** of the animals to be treated. However, the possibility to manufacture medicated feed before a **veterinary prescription for medicated feed** is presented to the manufacturer should not be excluded.

Where medicated feed has been prescribed in a Member State by a veterinarian, it should in principle be possible for that veterinary prescription to be recognised and for the medicated feed to be dispensed in another Member State. As a derogation, a Member State could allow that a prescription for medicated feed is issued by a professional person qualified to do so, other than a veterinarian, in accordance with applicable national law at the time of entry into force of this Regulation, to be valid only in that Member State. Such a prescription issued by that professional person other than a veterinarian should exclude the prescription of medicated feed containing antimicrobial veterinary medicinal products and of any other veterinary medicinal products where a diagnosis by a veterinarian is necessary.

(18) In order to ensure a particularly prudent use, **which means appropriate use of medicines in accordance with the veterinary prescription for medicated feed and the summary of product characteristics,** of medicated feed for food-producing animals **and fur animals** and therefore provide the basis for the assurance of a high level of protection of **animal health and** public health, specific conditions concerning the use and the validity of the **veterinary prescription for medicated feed,** compliance with the withdrawal period and record-keeping by the animal **[...] keeper, where appropriate,** should be provided for.

(19) Taking into account the serious public health risk posed by resistance to antimicrobials, it is appropriate to limit the use of medicated feed containing antimicrobials for [...] animals.

Prophylaxis or use to enhance the performance of [...] animals should [...] not be allowed, **except , in certain cases, as regards antiparasitics and immunological veterinary medicinal products.**
The use of antimicrobials for metaphylaxis should only be allowed when the risk of spread of an infection is high, in line with the Regulation on veterinary medicinal products.

(19a) The use of medicated feed containing some antiparasitics should be based on the knowledge of the parasite infestation status in the animal or group of animals. Despite the measures that farmers take on good hygiene and biosecurity, animals may suffer of diseases which need to be prevented by medicated feed for both animal health and welfare reasons. Animal diseases transmissible to humans may also have a significant impact on public health. Therefore the use of medicated feed containing immunological veterinary medicinal products or some antiparasitics should be allowed in the absence of a diagnosed disease.

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

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

(19c) On 17 June 2016 the Council adopted conclusions on the next steps under a One Health approach to combat antimicrobial resistance.
On xx xx 2018 the European Parliament adopted a resolution on a European One Health Action Plan against Antimicrobial Resistance.

(20) A system for the collection **or discard** of unused or expired **intermediate** products **and medicated feed** should be [...] in place, **including through existing systems and when managed by feed business operators** in order to control any risk that such products might raise with regard to the protection of animal, human health or the environment. **The decision on who is responsible for such collection or discard system should remain under national competence. Member States should take measures to ensure that appropriate consultations with relevant stakeholders are carried out to ensure the fitness for purpose of such systems.**

(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 **maximum levels of cross-contamination for active substances** [...] 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 list of antimicrobial active substances which are most commonly used in medicated 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 **mandatory information** [...] to be **included in** [...] the veterinary prescription for medicated feed. [...]

(22) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making¹¹. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. In order to ensure uniform conditions for the implementation of this Regulation regarding the establishment of homogeneity criteria for medicated feed, **as well as a model format for the veterinary prescription for medicated feed,** implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers¹².

(23) Member States should lay down penalties for infringement to the provisions of this Regulation and should take all measures necessary to ensure that they are implemented. Such penalties should be effective, proportionate and dissuasive.

(23a) In order to ensure that all manufactures of medicated feed, including on farm mixers, apply Annex II of Regulation (EU) 183/2005, that Regulation should be amended accordingly.

(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.

¹¹ OJ L 123, 12.5.2016, p. 1.

¹² OJ L 55, 28.2.2011, p. 13.

HAVE ADOPTED THIS REGULATION:

Chapter I

Subject matter, [.]scope and definitions

Article 0

Subject matter

This Regulation lays down specific provisions regarding medicated feed and intermediate products, which are additional to Union legislation on feed and shall apply without prejudice in particular to Regulation (EC) No 183/2005 of the European Parliament and of the Council, Regulation (EC) No 767/2009 of the European Parliament and of the Council, Regulation (EC) No 1831/2003 of the European Parliament and of the Council and Directive 2002/32/EC of the European Parliament and of the Council.

Article 1

Scope

1. This Regulation shall apply to:

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

2. This Regulation shall not apply to veterinary medicinal products, referred to in Regulation (EU) .../... (VMP) other than when included in a medicated feed or an intermediate product.

Article 2

Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

(a) the definitions of 'feed', 'feed business' and 'placing on the market' as laid down in Article 3 of Regulation (EC) No 178/2002;

(b) the definitions of 'feed additive' and 'daily ration' as laid down in Article 2(2) of Regulation (EC) No 1831/2003;

(c) the definitions of 'food-producing animal', '**non-food producing animals**', '**fur 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;

(d) the definition of 'establishment' as laid down in Article 3 of Regulation (EC) No 183/2005;

(e) the definitions of 'official control' and 'competent authority' as laid down in Article 2 **(1) and 3(3)** of Regulation [...] **(EU) No 2017/625**;

(f) the definitions of 'veterinary medicinal product', 'withdrawal period', [...] '**antimicrobial**', '**antibiotic**', '**active substance**', '**metaphylaxis**', '**antiparasitic**', '**immunological veterinary medicinal product**' and '**prophylaxis**' as laid down in Article [...] **4 of [...] Regulation (EU) .../... (VMP)** , '**summary of the product characteristics**' as laid down in Article 30 of **Regulation (EU) .../... (VMP)**.

2. The following definitions shall also apply:

(a) 'medicated feed': **a feed, which is ready to be directly fed to animals without further processing, consisting of a homogenous** mixture of one or more veterinary medicinal products or intermediate products with **feed materials or compound feed** [...];

(b) 'intermediate product': **a feed, which is not ready to be directly fed to animals without further processing, consisting of a homogenous** mixture of one or more veterinary medicinal products, with **feed materials or compound feed** [...], **exclusively** intended to be used for the manufacture of medicated feed;

[...]

(d) 'non-target feed': feed, **whether medicated or not**, which is not intended to contain a specific **active substance** [...];

[...]

(ea) 'cross-contamination': contamination of a non target feed with an active substance originating from the previous use of the facilities or equipment;

(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;

[...]

(h) 'mobile mixer': a feed business operator with a feed establishment consisting of a specifically equipped [...] **vehicle** for the manufacture of medicated feed;

(i) 'on-farm mixer': a feed business operator manufacturing medicated feed **for the exclusive use** on [...] **its** farm [...].

(j) 'veterinary prescription for medicated feed': a document issued by a veterinarian for a medicated feed;

(k) 'advertising': the making of a representation in any form in connection with medicated feed and intermediate products in order to promote prescription or use of medicated feed comprising also the supply of samples and sponsorships.

(l) 'animal keeper': any natural or legal person responsible for animals, whether on a permanent or on a temporary basis.

Chapter II

Manufacture, storage, transport and placing on the market

Article 3

General obligations

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

2. This Article shall not apply to farmers that only buy, store and transport medicated feed for the exclusive use on their farm, except as regards Section 5 of Annex I.

3. Article 105a(2) and Article 110(6) of Regulation (EU) .../...(VMP) shall apply, mutatis mutandis, to the supply of intermediate products.

4. Article 54 and Section 6, of Chapter IV of Regulation (EU) .../...(VMP) shall apply, mutatis mutandis, to medicated feed and intermediate products.

[...]

Article 5
Composition

1. Medicated feed and intermediate products shall only be manufactured from veterinary medicinal products, **including veterinary medicinal products intended to be used in accordance with Articles 115, 116 or 116a of Regulation (EU) .../... (VMP),** authorised for the purpose of the manufacture of medicated feed in accordance with the conditions laid down in [...] **Regulation (EU) .../... (VMP).**

2. The [...] **feed business operator manufacturing** medicated feed **or intermediate product** shall ensure **that** [...]:

[...]

(b) the medicated feed **or intermediate product** is manufactured in compliance with the relevant conditions laid down in **the veterinary prescription for medicated feed or, in the cases referred to in Article 8 of this Regulation, in** the summary of the product characteristics referred to in Article [...] **30 of Regulation (EU) .../... (VMP),** related to the veterinary medicinal products to be incorporated in the medicated feed. **These conditions include particular provisions regarding known interactions between the veterinary medicinal products and the feed that may impair the safety or the efficacy of the medicated feed or intermediate product;**

[...]

(d) a feed additive **authorised as coccidiostats or histomonostats** for which a maximum content is set in the respective authorisation act is not incorporated in the medicated feed **or intermediate product** if it is already used as active substance in the veterinary medicinal product;

(da) where the active substance in the veterinary medicinal product is the same as a substance in a feed additive contained in the feed concerned, the total content of that active substance in the medicated feed shall not exceed the maximum content set out in the veterinary prescription for the medicated feed or, in the cases referred to in Article 8, in the summary of product characteristics.

(e) the veterinary medicinal products incorporated in the feed shall combine with it to form a stable mixture for the entire storage life of the medicated feed, and shall respect the expiry date of the veterinary medicinal product, as referred to in point (f) of Article 9 (1) of Regulation (EU) .../... (VMP), provided that the medicated feed or intermediate product is properly stored and handled;

3. Feed business operators supplying medicated feed to the animal keeper shall ensure that the medicated feed complies with the prescription referred to in Article 15.

Article 6

Homogeneity

1. Feed business operators manufacturing medicated feed **or intermediate products** shall ensure **that** [...] the veterinary medicinal product **is homogeneously dispersed** [...] in[...] the **intermediate product and in the medicated** feed.

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

Article 7

*[...] **Cross-contamination***

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 [...] to avoid [...] **cross-contamination**.

2. The Commission [...] **is** empowered to adopt delegated acts in accordance with Article 19 [...] **supplementing this Regulation by establishing** specific [...] **maximum levels of cross-contamination** for active substances **in non-target feed, unless such levels are already established in accordance with Directive 2002/32/EC. Those delegated acts may also set out analytical detection methods for active substances in feed.**

Regarding maximum levels of cross contamination, those delegated acts shall be based on a scientific risk assessment carried out by the European Food Safety Authority (EFSA).

2a0. The Commission shall, at the latest one year after the date of application of this Regulation, adopt delegated acts in accordance with Article 19 supplementing this Regulation by establishing, as regards the active substances listed in Annex IIA, specific maximum levels of cross-contamination for active substances in non-target feed and analytical detection methods for the active substances.

Regarding maximum levels of cross contamination, those delegated acts shall be based on a scientific risk assessment carried out by the European Food Safety Authority (EFSA).

[...]

[...]

[...]

2b. For active substances in the veterinary medicinal product which are the same as a substance in a feed additive, the respective maximum level of cross contamination in non target feed shall be the maximum content of feed additive in complete feed established in the respective Union act regulating the feed additive authorisations.

2c. Until maximum levels of cross contamination are established in accordance with paragraphs 2 and 2a0, Member States may apply national maximum levels of cross contamination.

Article 8

Anticipated production

Medicated feed and intermediate products may be manufactured and **placed on the market, except as regards the supply to the animal keeper**, [...] before the prescription referred to in Article 15 is issued.

This provision shall not apply to:

(a) on-farm mixers **and mobile mixers**; [...]

(b) [...] manufacture of medicated feed or intermediate products **incorporating** [...] veterinary medicinal products **intended to be used** in accordance with Articles [...] **115 or 116 of Regulation (EU) .../... (VMP)**.

Article 9

Specific [.]Labelling requirements

1. [...] **The labelling of medicated feed and intermediate products shall comply with Annex III to this Regulation. In addition, the specific requirements provided for in Regulation (EC) No 767/2009 for the labelling of feed materials and compound feed shall apply to medicated feed and intermediate products containing respectively feed materials or compound feed.**

2. Where containers are used instead of packages [...], they shall be accompanied by **a** document[.] complying with paragraph 1.

3. Permitted tolerances for discrepancies between the labelled [...] **content of an active substance in** a medicated feed or an intermediate product and the [...] **content** analysed in official controls performed in accordance with Regulation [...] **(EU) No 2017/625 shall be** as set out in Annex IV.

Article 10

Packaging

- 1.** 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. **Packages shall not be reused.**

- 2. Paragraph 1 shall not apply to mobile mixers that supply medicated feed directly to the animal keeper.**

Article 10a

Advertising of medicated feed and intermediate products

- 1. The advertising of medicated feed and intermediate products shall be prohibited. That prohibition shall not apply to advertising made exclusively to veterinarians.**

- 2. The advertising shall not include information in any form which could be misleading or lead to incorrect use of the medicated feed.**

- 3. Medicated feed shall not be distributed for promotional purposes except for small quantities of samples.**

- 4. Medicated feed containing antimicrobial veterinary medicinal products shall not be distributed for promotional purposes as samples or in any other presentation.**

- 5. The samples referred to in paragraph 3 shall be appropriately labelled indicating that they are samples and given directly to veterinarians during sponsored events or by sales representatives during their visits.**

Article 11

*Intra Union trade **and import***

[...]

- 1. The feed business operator distributing medicated feed or intermediate products in a Member State which is different from the Member State where it was produced shall ensure that the veterinary medicinal products used for the manufacturing of that medicated feed are allowed for use, in accordance with Regulation (EU) .../... (VMP), in the Member State of use.**

2. The feed business operator importing medicated feed or intermediate products into the Union shall ensure that the veterinary medicinal products used for the manufacturing of that medicated feed are allowed for use in accordance with Regulation (EU) .../... (VMP) in the Member State of use.

Chapter III

Approval of establishments

Article 12

Approval obligations

1. 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

1a. Paragraph 1 shall not apply to the following feed business operators:

(a) those who only buy, store and transport medicated feed for the exclusive use on their farm;

(b) those who act solely as traders, without holding the medicated feed or intermediate products in their premises;

(c) those who only transport or store medicated feed or intermediate products exclusively in sealed packages or containers;

2. The competent authority shall approve establishments only where an on-site visit, prior to start-up of the relevant activity, has demonstrated that the system put in place for the manufacture, storage, transport and placing on the market of medicated feed and intermediate products meets the specific requirements of Chapter II.

3. In case mobile mixers place medicated feed on the market in a Member State different from the one where they are approved, such mobile mixers shall notify this activity to the competent authority in the Member State where the medicated feed is placed on the market.

4. In respect of retailers of medicated feed for pets and keepers of fur animals feeding animals with medicated feed, Member States shall have in place national procedures to ensure that relevant information regarding their activities is available to the competent authorities, while avoiding duplication and unnecessary administrative burden.

Article 13

[...] Lists of approved establishments

The establishments approved in accordance with Article 12 (1) shall be recorded in a national list, as referred to in Article 19(2) of Regulation (EC) No 183/2005, under an individual identifying number attributed in the form set out in Annex V, Chapter II, to that Regulation.

[...]

[...]

[...]

Article 14

[...] Transitional measures concerning the implementation of the requirements for approval and registration

1. Establishments falling under the scope of this Regulation which have already been approved in accordance with Directive 90/167/EEC **or otherwise authorised by the competent authority for activities under the scope of this Regulation** may continue their activities subject to the submission, by [Office of Publications, please insert date counting [...] **6**-months from the date of [...] **application** of this Regulation], of a declaration to the relevant competent authority in whose area their facilities are located, in a form decided upon by this competent authority, that they meet the requirements for approval referred to in Article 1[.]**2**([.]**2**).

2. [...] **Where the declaration referred to in paragraph 1 is not submitted within the period specified, the competent authority shall suspend the existing approval in accordance with the procedure referred to in Article 14 of Regulation (EC) No 183/2005.**

Chapter IV

Prescription and use

Article 15

Prescription

1. The supply of medicated feed to animal [...] **keepers** shall be subject to the presentation and, in case of manufacturing by on-farm mixers, the possession of a veterinary prescription **for medicated feed** and to the conditions laid down in paragraphs [.] **1a** to 6.

1a. A veterinary prescription for medicated feed shall be issued only after a clinical examination or any other proper assessment of the health status of the animal or group of animals by a veterinarian and only for a diagnosed disease.

1b. By way of derogation from paragraph 1a, a veterinary prescription for medicated feed containing immunological veterinary medicinal products may be issued also in the absence of a diagnosed disease.

1c. By way of derogation from paragraph 1a, if it is not possible to confirm the presence of a diagnosed disease, a veterinary prescription for medicated feed containing antiparasitics without antimicrobial effects may be issued based on the knowledge of the parasite infestation status in the animal or group of animals.

1d. By way of derogation from Article 2 (2) (i) and paragraph 1a of this Article, a Member State may allow that a veterinary prescription for medicated feed is issued by a professional person qualified to do so in accordance with applicable national law at the time of entry into force of this Regulation. Such prescriptions shall exclude prescription of medicated feed containing antimicrobial veterinary medicinal products and any other veterinary medicinal products where a diagnosis by a veterinarian is necessary and shall be valid only in that Member State. The person referred to in this paragraph shall, when issuing such a prescription, make any necessary verifications in accordance with national law. Paragraphs 2, 3, 4, 6 shall apply, mutatis mutandis, to such prescriptions.

2. The **veterinary** prescription **for medicated feed** shall contain the information set out in Annex V. The original **veterinary** prescription **for medicated feed** shall be kept by the manufacturer or, where appropriate, the [...] **feed business operator supplying the medicated feed to the animal keeper**. The [...] **veterinarian, or the professional person referred to in paragraph 1d,** issuing the prescription and the **keeper of food producing or fur** animal[...] shall keep a copy of the **veterinary** prescription **for medicated feed**. The original and copies shall be kept for [...] **five** years from the date of issuance.

3. With the exception of medicated feed for non-food producing animals, **other than fur animals**, medicated feed shall not be used for more than one treatment under the same **veterinary** prescription **for medicated feed**. **The duration of a treatment shall comply with the summary of product characteristics of the veterinary medicinal product incorporated in the feed and, where not specified, shall not exceed one month, or two weeks in case of a medicated feed containing antibiotic veterinary medicinal products.**

4. The **veterinary** prescription **for medicated feed** shall be valid **from the date of issuance** for a maximum period of six months for non-food producing animals **other than fur animals** and three weeks for food-producing animals **and fur animals**. **In case of medicated feed containing antimicrobial veterinary medicinal products, the prescription shall be valid from the date of issuance for a maximum period of 5 days.**

[...]

5a. The [...] **veterinarian** [...] **issuing**[...] the **veterinary** prescription **for medicated feed** 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. **In particular, he shall not prescribe medicated feed with more than one veterinary medicinal product containing antimicrobial veterinary medicinal products.**

6. The **veterinary** prescription **for medicated feed** shall [...]:

(a) comply with the summary of the product characteristics of the veterinary medicinal product, except for veterinary medicinal products intended to be used in accordance with Articles 115, 116 or 116a of Regulation (EU) .../... (VMP);

(b) indicate the daily dose of the veterinary medicinal product which shall be incorporated in a quantity of medicated feed that ensures the uptake of the dosage by the target animal considering that the feed uptake of diseased animals might differ from a normal daily ration.

(c) ensure that the medicated feed containing the dosage of the veterinary medicinal product corresponds to at least 50% of the daily feed ration on a dry matter basis. For ruminants, the daily dose of the veterinary medicinal product shall be contained in at least 50% of the complementary feed except for mineral feed.

(d) indicate the inclusion rate of the active substances, calculated on the basis of the relevant parameters.

7. Veterinary prescriptions for medicated feed issued in accordance with paragraphs 1a, 1b, and 1c shall be recognised throughout the Union.

8. The Commission may, by means of implementing acts, set a model format for the information set out in Annex V, which model format shall also be made available in electronic version. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 20(2).

Article 16

Use [...] of medicated feed

1. [...] **The prescribed medicated feed shall be used only for animals for which the veterinary prescription for medicated feed has been issued in accordance with Article 15.**

[...]

[...]

1a. Animal keepers shall use medicated feed only in accordance with the veterinary prescription for medicated feed, take measures to avoid cross contamination and ensure that only the identified animals in the veterinary prescription for medicated feed get the medicated feed. Animal keepers shall ensure that expired medicated feed is not used.

2. Medicated feed containing antimicrobial veterinary medicinal products **shall be used in accordance with Article 111a of Regulation (EU) .../... (VMP), except as regards paragraph (2), and** shall not be used [...] **for prophylaxis.**

2a. Medicated feed containing immunological veterinary medicinal products shall be used in accordance with Article 113 of Regulation (EU) .../... (VMP) and shall be used on the basis of a prescription in accordance with Article 15 (1b) of this Regulation.

2b. Medicated feed containing antiparasitics shall be used on the basis of a prescription in accordance with article 15 (1c) of this Regulation.

3. When administering medicated feed, the [...] **keeper** of food-producing animals shall ensure compliance with the withdrawal period provided for in the veterinary prescription **for medicated feed.**

4. [...] **The keeper of** food-producing animals **feeding them** with medicated feed shall keep records in accordance with Article [...] **112 of Regulation (EU) .../... (VMP).** Those records shall be kept for five years after the date of administration of medicated feed, including when the **food-producing** animal is slaughtered during the five-year period.

Article 17

Collection systems of unused or expired products

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

Member States shall take measures to ensure that relevant stakeholders are consulted as regards such systems.

Member States shall take measures to ensure that the location of collection points as well as other relevant information is made available to farmers, animal keepers, veterinarians and other relevant persons.

Chapter V

Procedural and final provisions

Article 18

Amendment of Annexes

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

Article 19

Exercise of the delegation

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

2. The delegation of power referred to in Articles 7 and 18 shall be conferred on the Commission for [...] **a period of 5 years** from the date of entry into force of this Regulation. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the 5 year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

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.

3a. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Articles 7 and 18 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

Article 20

Committee procedure

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002, hereinafter referred to as the ‘Committee’. That Committee is a Committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where the opinion of the Committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the Committee so decides or a simple majority of Committee members so request.

Article 21

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.

2. Member States shall notify those provisions to the Commission by [*Office of Publications, please insert date counting [[...] 36] months from the date of entry into force of this Regulation*] at the latest and shall notify it without delay of any subsequent amendment affecting them.

Article 21a

Amendment to Regulation 183/2005

1. In paragraph 1 of Article 5 of Regulation (EC) No 183/2005 point (c) is replaced by the following:

'(c) mixing of feed, for the exclusive requirements of their own holdings, without using veterinary medicinal products or intermediate products as defined in [Regulation (EU) .../... (Medicated Feed)] or additives or premixtures of additives, with the exception of silage additives.'

2. Paragraph 2 of Article 5 of Regulation (EC) No 183/2005 is replaced by the following:

'2. For operations other than those referred to in paragraph 1, including mixing of feed for the exclusive requirements of their own holdings when using veterinary medicinal products or intermediate products as defined in [Regulation (EU) .../... (Medicated Feed)] or additives or premixtures of additives with the exception of silage additives, feed business operators shall comply with the provisions in Annex II, where relevant for the operations carried out.'

Article 21b

Transitional measures

1. Without prejudice to the date of application referred to in Article 23, the Commission is empowered to adopt the delegated acts provided for in Article 7 (2a0) as from [the date of entry into force of this Regulation].

Article 22

Repeal

Directive 90/167/EEC is repealed.

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

Article 23

Entry into force

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

It shall apply from [Office of Publications, please insert date counting [[..]**36**] months from the date of entry into force of this Regulation].

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

Done at Brussels,

For the European Parliament

The President

For the Council

The President

ANNEXES

to 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**

SWD(2014) 271 final

SWD(2014) 272 final

ANNEX I

Specific [...] requirements for feed business operators, as referred to in Article 3

SECTION 1

FACILITIES AND EQUIPMENT

[...]

1. [...] **Feed business operators shall ensure that facilities and equipment and their immediate surroundings are kept clean.** Cleaning [...] **plans** shall be introduced **and be drawn up in writing,** [...] **in order to** ensure that any contamination, including [...] cross-contamination, [...] **is** minimised.

1a. Feed business operators shall ensure that access to all facilities shall be restricted to authorised personnel.

[...]

[...]

[...]

[...]

[...]

[...]

[...]

[...]

[...]

[...]

SECTION 2
PERSONNEL

[...]

2. An [...] **adequately trained** person responsible for the manufacture, **placing on the market and supply to the animal keeper** of medicated feed and intermediate products and an [...] **adequately trained** person responsible for quality control shall be designated.

[...]

4. With the exception of mobile mixers and on-farm mixers, the functions of person responsible for manufacture and person responsible for quality control shall be independent of each other and therefore shall not be carried out by the same person.

SECTION 3
MANUFACTURE

01. Feed business operators should take account of requirements under relevant systems of quality assurance and good manufacturing practices, developed in accordance with Article 20 of Regulation (EC) No 183/2005.

[...]

[...]

[...]

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.

4a. Veterinary medicinal products shall be stored in a separate secured room and in such a way that their characteristics are not altered.

4b. The material used for cleaning the production line after the manufacturing of medicated feed or intermediate products, shall be identified, stored and managed in such a way to not affect the safety and quality of the feed.

[...]

SECTION 4
QUALITY CONTROL

[...]

2. A quality control plan shall be drawn up in writing and implemented. It shall include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications [...] **for the final products of medicated feed and intermediate products** and the measures to be taken in the event of non-compliance.

The quality control plan should define rules regarding sequencing or incompatibilities of manufacturing operations and, where applicable, define the need of dedicated production lines.

3. Specific regular own checks **as well as stability tests** shall ensure compliance with the homogeneity criteria as laid down in accordance with Article 6(2), the [...] **maximum levels of cross-contamination for active substance in non-target feed** as laid down in accordance with Article 7(2) and the minimum storage life of the medicated feed **and the intermediate products**.

[...]

SECTION 5 STORAGE AND TRANSPORT

1. Medicated feed and intermediate products shall be stored in suitable separate and secured [...] **facilities** [...] or sealed in hermetic containers which are specially designed for the storage of such products. They shall be stored in places designed, adapted and maintained in order to ensure good storage conditions.

2. Veterinary medicinal products shall be stored in separate, safe and secure areas. These areas shall be of sufficient capacity and properly identified to allow orderly storage of the various veterinary medicinal products. Medicated feed and intermediate products shall be stored and transported in such a way as to be easily identifiable. Medicated feed and intermediate products shall be transported in suitable means of transport.

3. Specific facilities shall be identified for the storage of expired, withdrawn or returned medicated feed and intermediate products.

4. Containers in vehicles used for the transport of medicated feed shall be cleaned after each use to avoid any risk of cross-contamination.

SECTION 6 RECORD-KEEPING

1. Feed business operators manufacturing, storing, transporting or placing on the market medicated feed and intermediate products shall keep in a [...] **record** relevant data, comprising details of purchase, manufacturing, storage, transport and placing on the market for effective tracing from receipt to delivery, including export to the final destination.

2. The [...] **record** referred to in paragraph 1 shall contain:

(a) the HACCP documentation referred to in Article 6(2)(g) **and 7 (1)** of Regulation (EC) No 1831/2003,

(b) the quality control plan and the results of the relevant controls,

(c) specifications and quantities of veterinary medicinal products **with batch number**, feed materials, compound feed, feed additives, intermediate products and medicated feed which have been purchased,

(d) specifications and quantities of the batches of medicated feed and intermediate products which have been manufactured, including the veterinary medicinal products **with batch number**, feed materials, compound feed, feed additives and intermediate products which have been used,

(e) specifications and quantities of the batches of medicated feed and intermediate products which have been stored or transported,

(f) specifications and quantities of medicated feed and intermediate products which have been placed on the market or exported to third countries **including the unique prescription number**,

(g) information on the manufacturers or suppliers of the medicated feed and intermediate products or of the products used for the manufacture of medicated feed and intermediate products, including at least their name, address and, where applicable, their approval identifying number,

(h) information on the recipients of the medicated feed and intermediate products, including at least their name, address and, where applicable, their approval identifying number and

(i) information on the [...] **veterinarian, or the professional person referred to in Article 15(1d)**, who has issued the **veterinary** prescription **for medicated feed**, including at least [...] **the person's** name and address.

[...] **T**he documents shall be kept for [...] **five**-years in the [...] **record** after their date of issuance.

SECTION 7

COMPLAINTS AND PRODUCT RECALL

1. Feed business operators placing medicated feed and intermediate products on the market shall implement a system for registering and processing complaints.

2. [...] Feed business operators shall put in place, a system for the prompt withdrawal from the market of medicated feed or intermediate products and, if necessary, for the recall from the distribution network of products in case they prove not to satisfy the requirements of this Regulation. [...] **Feed business operators** shall define by means of written procedures the destination of any recalled products, and before such products are put back into circulation [...] **the feed business operators** shall [...] **carry out** a quality-control reassessment **to ensure that the Union feed safety requirements are fulfilled.**

SECTION 8

ADDITIONAL REQUIREMENTS FOR MOBILE MIXERS

1. Mobile mixers shall have a copy of the following documents available in the vehicle, in the official language of the Member State where the manufacture of medicated feed takes place:

(a) the approval of the designated mobile mixer for the manufacture of medicated feed from the competent authority from the Member State where the mobile mixer is approved,

(b) the HACCP documentation referred to in Article 6(2)(g), and 7 (1) of Regulation (EC) No 183/2005,

(c) the quality control plan, foreseen in Section 4 of this Annex,

(d) the cleaning plan referred to in Section 1 of this Annex,

(e) the list of the authorized persons for the manufacture of medicated feed, referred to in Section 2 of this Annex

2. Mobile mixers shall take all the appropriate precautionary measures to prevent the spread of diseases. Vehicles used for the production of medicated feed shall be cleaned after each use for the production of medicated feed to avoid any risk of cross-contamination.

3. Where vehicle registration plate numbers are available, mobile mixers shall use only those vehicles whose vehicle registration plate numbers have been notified to the competent authority.

[...]

ANNEX IIA

List of antimicrobial active substances as referred to in Article 7(2a0)

Active substance
1. Amoxicillin
2. Amprolium
3. Apramycin
4. Chlortetracycline
5. Colistin
6. Doxycycline
7. Florfenicol
8. Flumequine
9. Lincomycin
10. Neomycin
11. Spectinomycin
12. Sulfonamides
13. Tetracycline
14. Oxytetracycline
15. Oxolinic Acid
16. Paromomycin

17. Penicillin V
18. Tiamulin
19. Tiamfenicol
20. Tilmicosin
21. Trimethoprim
22. Tylosin
23. Valnemulin
24. Tylvalosin

ANNEX III

Specific [.]labelling particulars as referred to in Article 9(1)

The label of medicated feed and intermediate products shall include the following particulars, **in a simple, clear and easily understandable manner for the end users:**

(1) the expression 'Medicated feed' or 'Intermediate product for **the manufacturing of** medicated feed' [...], as appropriate [...];

[...]

(3) the approval number of the [...] **feed business operator** responsible for the labelling in accordance with Article 12;

In cases where the manufacturer is not the feed business operator responsible for the labelling, the following shall be provided:

(a) the name or business name and address of the manufacturer, or

(b) the approval number of the manufacturer;

[...]

[...]

(6) the [...] **active substances** with name, [...] added amount (**mg/kg**), **and the veterinary medicinal products with** [...] **its** marketing authorisation number **and the marketing authorisation holder**, preceded by the heading ‘medication’;

(7) [...] any contra-indications **of the veterinary medicinal products** and adverse events in so far as these particulars are necessary for the use;

(8) in the case of a medicated feed or of intermediate product intended for food-producing animals, the withdrawal period or the indication ‘no [...] **withdrawal period**’;

(9) [...] **in the case of medicated feed for non food producing animals, except fur animals**, a warning that the [...] **medicated feed** is only for the treatment of animals and a warning that [...] **it** must be kept out of the sight and reach of children;

[...]

[...]

[...]

(13) [...] a free telephone number or other appropriate means of communication in order to allow the [...] **animal keeper** to obtain, in addition to the mandatory particulars, **the package leaflet of the veterinary medicinal products**. [...]

[...]

(15) the instructions for use in line with the veterinary prescription **for medicated feed** [...] **or** the summary of the product characteristics [...];

(16) the minimum storage life, **which shall take into account the expiry dates of the veterinary medicinal products and shall be expressed as ‘use before...’, followed by the date,** [...] and special storage precautions, if appropriate.

(16a) information that inappropriate disposal of medicated feed poses serious threats to the environment and may, where relevant, contribute to antimicrobial resistance.

(17) Points (1) to (16) shall not apply to mobile mixers exclusively manufacturing the medicated feed without supplying any components.

ANNEX IV

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 **only** include technical [...] 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 <u>or</u> <u>intermediate products</u>	Tolerance
> 500 mg	± 10%
[...] ≤ 500 mg	± 20%
[...]	[...]
[...]	[...]

[...]

ANNEX V

Information to be included in the veterinary [...] prescription for medicated feed [...] as referred to in Article 15(2)

"VETERINARY PRESCRIPTION FOR MEDICATED FEED

1. [...] **Full name and contact details of the veterinarian including, if available, the** professional [...] number [...].
2. Issue date, **unique number of prescription, expiry date of prescription (if the validity is shorter than that referred to in Article 15 (4))** and signature or **an equivalent** electronic **form of** identification of the [...] **veterinarian**.
3. **Full** [...] **name and** [...] **contact details** of the animal [...] **keeper, and identification number of the establishment, if existing**.
4. Identification (including category, species and age) and number of animals **or, where appropriate, the weight of the animals**.
5. Diagnosed disease to be treated. **In the case of immunological veterinary medicinal products or antiparasitics without antimicrobial effects, disease to be prevented**.
6. Designation (**name and marketing authorisation number**) of the veterinary medicinal product(s), including the name of the active substance(s).
7. If **the veterinary medicinal product is** prescribed under Articles [...] **111a(3), 115, 116 or 116a of Regulation (EU) .../... (VMP)**, a statement to this effect.
8. Inclusion rate of the veterinary medicinal product(s) **and active substance** (quantity per weight unit of medicated feed).

9. Quantity of medicated feed.

10. Instructions for use for the animal [...] **keeper**, including the duration of the treatment.

11. Percentage of medicated feed in the daily ration or quantity of medicated feed per animal and day.

12.[...]-**For food-producing animals**, withdrawal period, **even if zero days** [...].

13. Any [...] warnings **necessary to ensure the proper use including, where relevant, to ensure prudent use of antimicrobials.**

14. For food-producing animals **and fur animals**, the mention 'this prescription shall not be re-used'.

15. The following mentions to be completed by the supplier of the medicated feed or the on-farm mixer, as appropriate:

– name or business name and address;

– date of delivery or of on-farm mixing.

– **batch number of medicated feed delivered for the prescription, except for on-farm mixers.**

16. Signature of supplier **to the animal keeper** or of on-farm mixer."

ANNEX VI

Correlation table referred to in Article 22

Directive 90/167/EEC	This Regulation
Article 1	Article 1
Article 2	Article 2
Article 3(1)	Article 5(1)
Article 3(2)	-
Article 4(1)	Articles 3, 4, 5(2), 6, Annexes I and II
Article 4(2)	-
Article 5(1)	Article 10
Article 5(2)	Articles 3, 7 and Annex I
-	Article 8
Article 6	Article 9 and Annex III
Article 7	-
Article 8(1)	Article 15
Article 8(2)	-
Article 8(3)	Article 16(3)
Article 9(1)	Article 12 and 16(1)
Article 9(2)	-
Article 9(3)	-
Article 10	Article 11
-	Article 13
-	Article 14
-	Article 16(2)
-	Article 16(4)
-	Article 17
Article 11	-
Article 12	Article 18

-	Article 19
-	Article 20
-	Article 21
-	Article 22
-	Article 23
Article 13	-
Article 14	-
Article 15	-
Article 16	-
Annex A	Annex V
Annex B	-
-	Annex IV