Council of the European Union

Brussels, 15 September 2014
(OR. en)

13196/14
ADD 1

Interinstitutional File:
2014/0255 (COD)

AGRILEG 179
VETER 84
CODEC 1813

PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	15 September 2014
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2014) 556 final
Subject:	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

Delegations will find attached document COM(2014) 556 final - Annexes 1 to 6.

Encl.: COM(2014) 556 final - Annexes 1 to 6.

EUROPEAN
COMMISSION

Brussels, 10.9.2014
COM(2014) 556 final

ANNEXES 1 to 6

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

Requirements for feed business operators, as referred to in Article 3

SECTION 1
FACILITIES AND EQUIPMENT

Feed business operators shall use facilities and equipment that satisfy the following requirements.

1. Facilities and equipment and their immediate surroundings shall be kept clean and effective pest control programmes shall be implemented. Cleaning programmes shall be introduced. Those programmes shall ensure that any contamination, including from residues of detergents and biocides, and any cross-contamination, including resulting from carry-over, are minimised.

2. The lay-out, design, construction and size of the facilities and equipment shall be such as to:

   (a) minimise the risk of errors and to avoid any adverse effects generally on the safety and quality of the products;

   (b) allow adequate cleaning and disinfection;

   (c) allow the machinery coming into contact with feed to be dried following any wet cleaning process.

3. Facilities and equipment to be used for manufacturing shall undergo appropriate and regular checks, in accordance with written procedures pre-established by the manufacturers of the equipment.

   All scales and metering devices shall be appropriate for the range of weights or volumes to be measured and shall be tested for accuracy regularly.

   All mixers shall be appropriate for the range of weights or volumes being mixed, and shall be capable of manufacturing suitable homogeneous mixtures. Operators shall demonstrate the effectiveness of mixers with regard to homogeneity.

4. Facilities shall have adequate natural or artificial lighting.

5. Drainage facilities shall be adequate for the purpose intended; they shall be designed and constructed to avoid the risk of contamination of feed.

6. Water used in manufacture shall be of suitable quality for animals; the conduits for water shall be of an inert nature.

7. Sewage, waste and rainwater shall be disposed of in a manner which ensures that equipment and the safety and quality of medicated feed and intermediate products is not affected.

8. Where appropriate, temperatures shall be kept as low as possible to avoid condensation and spoilage.

9. Spoilage and dust shall be controlled to prevent pest invasion.

10. Windows and other openings shall, where necessary, be proven against pests. Doors shall be close-fitting and proven against pests when closed.

11. Where necessary, ceilings and overhead fixtures shall be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable moulds and the shedding of particles that can affect the safety and quality of medicated feed and intermediate products.

SECTION 2
PERSONNEL

1. Feed business operators shall have sufficient staff possessing the skills and qualifications necessary for the manufacture of the products concerned. All the staff shall be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired product quality.

   A qualified person responsible for the manufacture of medicated feed and intermediate products and a qualified person responsible for quality control shall be designated.

2. An organisation chart setting out the qualifications and responsibilities of the supervisory staff shall be drawn up and made available to the competent authorities in case of an inspection.

SECTION 3
MANUFACTURE

1. Feed business operators shall ensure that the different stages of production are carried out in accordance with pre-established written procedures.

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.

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.

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.

5. Waste and other materials not intended for feed use should be separated, adequately labelled and used or disposed of in an appropriate way and not used as feed.

SECTION 4
QUALITY CONTROL

1. Feed business operators shall, as part of a quality control system, have access to a laboratory with adequate staff and equipment.

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 from processed materials to final products and the measures to be taken in the event of non-compliance.

3. Specific regular own checks shall ensure compliance with the homogeneity criteria as laid down in accordance with Article 6(2), the limits for carry-over as laid down in accordance with Article 7(2) and the minimum storage life of the medicated feed.

4. Samples of the products used for manufacturing medicated feed and intermediate products and of each batch of medicated feed and intermediate products shall be taken in sufficient quantity in accordance with a pre-established sampling plan in order to ensure traceability. The samples shall be sealed and labelled for easy identification and stored under conditions which prevent any abnormal change in the composition of the sample or any adulteration. They shall be kept at the disposal of the competent authorities for a period appropriate to the use for which the medicated feed or intermediate product is placed on the market.

SECTION 5
STORAGE AND TRANSPORT

Medicated feed and intermediate products shall be stored in suitable separate and secured rooms to which only persons authorised by the feed business operators have access, 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.

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.

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 register 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 register referred to in paragraph 1 shall contain:

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

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

(c) specifications and quantities of veterinary medicinal products, 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, 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,

(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 person who has issued the prescription, including at least his name and address.

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.

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. They 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. They shall define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they shall undergo a quality-control reassessment.

ANNEX II

Incorporation of the veterinary medicinal product into the feed as referred to in Article 5(2)(a)

1. Mobile mixers or on-farm mixers shall only use veterinary medicinal products at inclusion rates above 2 kg/t of feed.

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

3. Medicated feed containing the daily dose of the veterinary medicinal product shall correspond 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.

ANNEX III

Labelling particulars as referred to in Article 9(1)

The label of medicated feed and intermediate products shall include the following particulars:

(1) the expression 'Medicated feed' or 'Intermediate product for medicated feed' supplemented by the expression 'complete' or 'complementary', as appropriate, and the target species;

(2) the name or business name and the address of the feed business operator responsible for the labelling;

(3) the approval number of the person responsible for the labelling in accordance with Article 12;

(4) the batch reference number of the medicated feed or intermediate product;

(5) the net quantity of medicated feed expressed in units of mass in the case of solid feed, and in units of mass or volume in the case of liquid feed;

(6) the veterinary medicinal products with name, active substance, strength, added amount, marketing authorisation holder and marketing authorisation number, preceded by the heading ‘medication’;

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

(8) in the case of a medicated feed or of intermediate product intended for food-producing animals, the withdrawal period or the indication ‘none’;

(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;

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

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

(12) the analytical constituents of medicated feed for food-producing animals in accordance with Chapter II of Annex VI to Regulation (EC) No 767/2009 or in

accordance with Chapter II of Annex VII to that Regulation in case of medicated feed for non-food producing animals;

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

(14) the moisture content if it exceeds 14 %;

(15) the instructions for use in line with the veterinary prescription and the summary of the product characteristics referred to in Article 14 of Directive 2001/82/EC;

(16) the minimum storage life considering the stability of the feed additives and the veterinary medicinal products and special storage precautions, if appropriate.

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 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.

ANNEX V

Prescription form as referred to in Article 15(2)

"PRESCRIPTION FOR MEDICATED FEED

1. Surname, forename, address and professional membership number of the person allowed to prescribe a veterinary medicinal product.

2. Issue date and signature or electronic identification of the person allowed to prescribe a veterinary medicinal product.

3. Name and address of the animal holder.

4. Identification and number of animals.

5. Diagnosed disease to be treated.

6. Designation of the veterinary medicinal product(s), including the name of the active substance(s).

7. If prescribed under Articles 10 and 11 of Directive 2001/82/EC, a statement to this effect.

8. Inclusion rate of the veterinary medicinal product(s) (quantity per weight unit of medicated feed).

9. Quantity of medicated feed.

10. Instructions for use for the animal holder, 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. If applicable, withdrawal period before placing on the market products from treated animals.

13. Any appropriate warnings.

14. For food-producing 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.

16. Signature of supplier 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