ANNEX I

SPECIFIC REQUIREMENTS FOR FEED BUSINESS OPERATORS IN ACCORDANCE WITH ARTICLE 4

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.

2. Feed business operators shall ensure that access to all facilities is restricted to authorised personnel.

SECTION 2

Personnel

1. 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.

2. With the exception of mobile mixers and on-farm mixers, the functions of the 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

1. Feed business operators shall 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.

2. Medicated feed and intermediate products shall be stored separately from any other feed in order to avoid any cross-contamination.

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

4. 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 as not to affect the safety and quality of the feed.

SECTION 4

Quality control

1. 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 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 for dedicated production lines.

2. 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. Those 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 or intermediate products 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 of this Section shall contain:

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

(b) the quality control plan provided for in Section 4 of this Annex 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 number of the veterinary prescription for medicated feed;

(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 16(5), who has issued the veterinary prescription for medicated feed, including at least that veterinarian's or that professional person's name and address.

The documents listed in this paragraph shall be kept for at least 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 of medicated feed or intermediate products from the distribution network in case they fail to comply with 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 complied with.

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 point (g) of Article 6(2) and in Article 7(1) of Regulation (EC) No 183/2005;

(c) the quality control plan provided for in Section 4 of this Annex;

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

(e) the list of persons responsible 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 manufacture of medicated feed shall be cleaned after each use for the manufacture 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 II

LIST OF ANTIMICROBIAL ACTIVE SUBSTANCES
AS REFERRED TO IN ARTICLE 7(3)

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

ANNEX III

SPECIFIC LABELLING REQUIREMENTS 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;

(2) the approval number of the feed business operator responsible for the labelling. 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;

(3) 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';

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

(5) 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';

(6) 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;

(7) 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 each veterinary medicinal product;

(8) the instructions for use in line with the veterinary prescription for medicated feed or the summary of the product characteristics;

(9) 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;

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

Points 1 to 10 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)

The tolerances laid down in this Annex 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 or intermediate products	**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 16(6)

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 16(8)) 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 or products, including the name of the active substance or substances.

7. If the veterinary medicinal product is prescribed under Article 107(4), Article 112, Article 113 or Article 114, of Regulation (EU) 2019/6, a statement to that effect.

8. Inclusion rate of the veterinary medicinal product or products and active substance or substances (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 such period is zero.

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 under the veterinary prescription for medicated feed, 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 25

Directive 90/167/EEC	**This Regulation**
Article 1	Article 2
Article 2	Article 3
Article 3(1)	Article 5(1)
Article 3(2)	—
Article 4(1)	Articles 4, 5(2), 6, 7(1), 13, 16 and Annex I
Article 4(2)	—
Article 5(1)	Article 10
Article 5(2)	Articles 4, 7 and Annex I
—	Article 8
Article 6	Article 9 and Annex III
Article 7	—
Article 8(1) and (2)	Article 16
Article 8(3)	Article 17(6)
Article 9(1)	Articles 13.17(1) and (2)
Article 9(2)	—
Article 9(3)	—
—	Article 11
Article 10	Article 12(1)
—	Article 14
—	Article 15
—	Article 17(3), (4) and (5)
—	Article 17(7)
—	Article 18
Article 11	—
Article 12	Article 19
—	Article 20
—	Article 21
—	Article 22
—	Article 25
—	Article 26

Article 13	—
Article 14	Article 12(2)
Article 15	—
Article 16	—
Annex A	Annex V
Annex B	—
—	Annex II
—	Annex IV

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2019/4 of the European Parliament and of the Council.