II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2019/2090

of 19 June 2019

supplementing Regulation (EU) 2017/625 of the European Parliament and Council regarding cases of suspected or established non-compliance with Union rules applicable to the use or residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or with Union rules applicable to the use or residues of prohibited or unauthorised pharmacologically active substances

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/625 of the European Parliament and 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) ([1]), and in particular Articles 19(2)(a) and 19(2)(b), thereof,

Whereas:

(1) Regulation (EU) 2017/625 lays down rules for the performance of official controls and other official activities by the competent authorities of the Member States to verify compliance with Union legislation, inter alia, in the area of food safety at all stages of production, processing and distribution. It provides for specific rules on official controls in relation to substances whose use may result in residues in food and feed.

(2) Articles 137 and 138 of Regulation (EU) 2017/625 respectively lay down obligations of the competent authorities as regards actions to be taken in case of suspicion of non-compliance and list actions and measures to be taken in the event of established non-compliance.

(3) Regulation (EU) 2017/625 repeals Directive 96/23/EC ([2]) with effect from 14 December 2019. That Directive currently lays down measures to monitor certain substances and residues thereof in live animals and animal products and specifically defines the enforcement measures to be taken by the competent authorities in cases of suspected or established non-compliance related to substances and residues within its scope.

([1]) OJ L 95, 7.4.2017, p. 1.

([2]) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

(4) The rules set out in Directive 96/23/EC ensure the harmonised enforcement of the EU food safety legislation related to the use and residues of pharmacologically active substances. In order to rationalise and simplify the overall legislative framework, the rules applicable to official controls in specific areas of the agri-food chain legislation have been integrated into the framework for official controls defined by Regulation (EU) 2017/625. In order to ensure a continued and harmonised enforcement, the rules of Directive 96/23/EC related to the follow-up to non-compliances, should be integrated in the new legal framework under Regulation (EU) 2017/625.

(5) The rules laid down in this Regulation should ensure, within the framework of Regulation (EU) 2017/625, a continuation of the requirements on the follow-up of suspected or established non-compliance with the rules applicable to the use or residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or with Union rules applicable to the use or residues of prohibited or unauthorised pharmacologically active substances, in particular as laid down in:

— Regulation (EC) No 470/2009 of the European Parliament and of the Council ([3]) laying down rules for the establishment of residue limits of pharmacologically active substances in food of animal origin and for placing on the market food of animal origin containing residues of pharmacologically active substances;

— Commission Regulation (EU) No 37/2010 ([4]), which classifies pharmacologically active substances in light of their prohibition or the maximum residue limits applicable to them;

— Regulation (EC) No 1831/2003 of the European Parliament and of the Council ([5]), which lays down rules for the authorisation of certain veterinary medicinal products as feed additives and the legal acts adopted on this basis, define the authorisations of specific substances and their maximum residue limits in food of animal origin;

— Commission Regulation (EC) No 1950/2006 ([6]), which lays down a list of substances essential for the treatment of equidae;

— Commission Regulation (EC) No 124/2009 ([7]), which sets maximum levels for the presence of coccidiostats or histomonostats in foods resulting from the unavoidable carry-over of these substances in non-target feed ([8]) on the basis of Council Regulation (EEC) No 315/93 laying down Community procedures for contaminants in food ([9]).

— Council Directive 96/22/EC ([10]), which prohibits the use in stockfarming of certain substances having a hormonal or thyreostatic action and of ß-agonists.

(6) Where, on the basis of the Union rules referred to Recital 5, prohibited or unauthorised substances are discovered in the possession of non-authorised persons, thereby creating a suspicion of illegal treatment and a possible impact on food safety, the measures for official detention and investigations, as provided for in Regulation (EU) 2017/625 and in this Regulation should apply.

([3]) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

([4]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

([5]) 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).

([6]) Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae and of substances bringing added clinical benefit use (OJ L 367, 22.12.2006, p. 33).

([7]) Commission Regulation (EC) No 124/2009 of 10 February 2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed (OJ L 40, 11.2.2009, p. 7).

([8]) Non-compliance with these maximum levels is considered to be non-compliance with the rules applicable to the use and residues of veterinary medicinal products.

([9]) Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1).

([10]) Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ L 125, 23.5.1996, p. 3).

(7) Directive 2001/82/EC of the European Parliament and of the Council ([11]) establishes the regulatory framework for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and the use of veterinary medicinal products. Pharmacologically active substances, which are not authorised in veterinary medicinal products, are not to be used on food-producing animals, with the exception of the use of substances essential for the treatment of equidae, as laid down in Regulation (EC) No 1950/2006. Follow-up on established or suspected non-compliances related to the use of veterinary medicinal products which have a suspected or established impact on food safety falls within the scope of Regulation (EU) 2017/625 and of this Regulation. Directive 2001/82/EC has been repealed and replaced by Regulation (EU) 2019/6 of the European Parliament and the Council on veterinary medicinal products (the new VMP Regulation) ([12]) which is to apply from 28 January 2022 and which amongst others provides for restrictions on the use in animals of antimicrobial veterinary medicinal products.

(8) In light of the fact that diverging enforcement practices could lead to an uneven protection of human and animal health, to disruptions of the internal market and to distortions of competition, Regulation (EU) 2017/625 should be supplemented by specific rules for the performance of official controls on animals and goods at any stage of production, processing, distribution and use in relation to suspected or established non-compliances related to the relevant substances and for action to be taken following those official controls.

(9) In view of the specificities of the actions and controls to be taken in case of suspected or established non-compliance with Union rules applicable to the use of pharmacologically active substances on food-producing animals and to their residues, and in order to ensure an Union-wide uniform application of enforcement actions, the cases where the measures listed in Articles 137 and 138 of Regulation (EU) 2017/625 are to be taken should be specified to tailor them to this sector.

(10) Pursuant to Article 79(2)(c) of Regulation (EU) 2017/625, costs generated by mandatory fees or charges for official controls taken under this Regulation, should be borne by the operator responsible for the animals and goods.

(11) Article 50 of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([13]) requires Member States to notify a direct or indirect risk to human health deriving from food or feed via the network, which has been put in place for this purpose. Non-compliances related to residues of pharmacologically active substances and constituting such risks should therefore be notified accordingly. In addition, where the non-compliances are identified in relation to animals or products of animal origin originating from another Member State, the authorities of the Member State having identified the non-compliance and the Member State of origin should make use of the provisions on assistance set out in Regulation (EU) 2017/625 and take the appropriate follow-up measures, as defined in the present Regulation.

(12) As the rules laid down in Directive 96/23/EC for the follow-up of specific cases of established non-compliance or suspected non-compliance related to the substances and residues within its scope are repealed with effect from 14 December 2019, this Regulation should apply from that date onwards.

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down rules on specific requirements for official controls and applicable measures for cases of non-compliance or suspected non-compliance with Union rules applicable to the use of authorised, unauthorised or prohibited pharmacologically active substances on food-producing animals and to their residues.

([11]) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

([12]) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

([13]) 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).

Article 2

Definitions

For the purposes of this Regulation, the definitions in Regulation (EU) 2017/625, Directive 2001/82/EC and Regulation (EC) No 470/2009 shall apply. The following definitions shall also apply:

(a) 'pharmacologically active substance' means any substance or mixture of substances intended to be used in the manufacture of a veterinary medicinal product that, when used in its production, becomes an active ingredient of that product;

(b) 'unauthorised substances' means pharmacologically active substances, which are not included in Table 1 of the Annex to Regulation (EU) No 37/2010 or substances that are not authorised as a feed additive under Regulation (EC) No 1831/2003, with the exception of substances essential for the treatment of equidae and substances bringing added clinical benefit compared to other treatment options available for equidae, as laid down in Regulation (EC) No 1950/2006.

(c) 'illegal treatment' means the use in food producing animals of

— prohibited or unauthorised substances or products, or

— substances or veterinary medicinal products authorised under Union legislation for purposes or under conditions other than those laid down in the said legislation or, where appropriate, in national legislation.

For the purpose of this Regulation for substances or veterinary medicinal products authorised under Union legislation, non-compliance with the withdrawal period or residues of pharmacologically active substances exceeding the maximum residue limit or maximum level shall not be considered as an illegal treatment, provided that all other conditions on the use of the substance or veterinary medicinal product, laid down in Union or national legislation, are complied with.

(d) 'residues of pharmacologically active substances exceeding the maximum residue limit' means the presence of residues of authorised pharmacologically active substances in products of animal origin in a concentration, exceeding the maximum residue limits set under Union legislation;

(e) 'residues of pharmacologically active substances exceeding the maximum level' means the presence of residues of pharmacologically active substances in products of animal origin, resulting from the unavoidable carry-over of these substances in non-target feed, in a concentration, exceeding the maximum levels set under Union legislation;

(f) 'batch of animals' means a group of animals of the same species, in the same age range, reared on the same holding, at the same time and under the same conditions of rearing.

Article 3

Actions to be taken at the slaughterhouse in case of non-compliance or suspected non-compliance

1. If the official veterinarian performing official controls in a slaughterhouse or the official auxiliary performing certain tasks in the framework of these controls suspect or has evidence that animals have been subject to illegal treatment, the official veterinarian shall ensure that the following actions are taken:

(a) order that the operator keeps the concerned animals separated from other batches of animals present or arriving at the slaughterhouse under the conditions to be established by the competent authority;

(b) arrange for the animals to be slaughtered separately from other batches of animals present at the slaughterhouse;

(c) order that the operator separates the carcases, meat, offal and by-products from the concerned animals, to be immediately identified and kept separated from other products of animal origin, and order such products not to be moved, processed or disposed without prior authorisation by the competent authority;

(d) order that samples necessary to detect the presence of prohibited or unauthorised substances or of authorised substances, in case of a suspected or established use under conditions other than those laid down in the legislation, are taken.

2. If the illegal treatment is established, the competent authority shall order the operator to dispose the carcasses, meat, offal and by-products as laid down in Regulation (EC) No 1069/2009 of the European Parliament and of the Council ([14]), without indemnity or compensation.

3. If the official veterinarian performing official controls in a slaughterhouse or the official auxiliary performing certain tasks in the framework of these controls suspects that the animals present in the slaughterhouse have been treated with an authorised veterinary medicinal product, but that the withdrawal period referred to in Directive 2001/82/EC has not been respected, the official veterinarian shall order that the concerned animals are separated from other batches of animals present or arriving at the slaughterhouse, under conditions to be established by the competent authority. The official veterinarian shall also:

— postpone the slaughter at the expense of the operator, until the withdrawal period has been respected, or;

— issue an order to slaughter the animals separately and, pending the outcome of an investigation, order for the carcases, meat, offal and by-products from the concerned animals, to be immediately identified and kept separated from other products of animal origin.

The slaughter may only be postponed temporarily, provided that the official veterinarian has verified that the Union legislation on animal welfare is respected and that the concerned animals can be kept separated from the other animals.

4. When the slaughter is postponed in accordance with paragraph (3), the withdrawal period shall in no circumstances be shorter than:

— the withdrawal period provided for in the summary of products characteristics of the marketing authorisation for veterinary medicinal products;

— the withdrawal period established under the Regulation authorising the use of a certain pharmacologically active substance as a feed additive in accordance with Regulation (EC) No 1831/2003.

— the withdrawal period prescribed by the veterinarian for uses in accordance Article 11 of Directive 2001/82/EC or, if no withdrawal period is prescribed for such uses, the minimum withdrawal period laid down in Article 11 of Directive 2001/82/EC;

Following the postponement of the slaughter, the competent authority may take samples at the expense of the operator to verify compliance with the maximum residue limits once the animals have been slaughtered after the expiry of the withdrawal period.

5. If the official veterinarian performing official controls in a slaughterhouse or the official auxiliary performing certain tasks in the framework of these controls has evidence that the animals present in the slaughterhouse have been treated with an authorised veterinary medicinal product, but that the withdrawal period referred to in Directive 2001/82/EC has not been respected, the official veterinarian shall order that the concerned animals are separated from other batches of animals present or arriving at the slaughterhouse, under conditions to be established by the competent authority. The official veterinarian shall also:

— postpone the slaughter at the expense of the operator under the conditions laid down in the second subparagraph of Article 3(3) and in Article 3(4) until the withdrawal period has been respected, or;

— issue an order that the operator kills the animals separately. In this case the official veterinarian shall declare them unfit for human consumption, whilst taking all necessary precautions to safeguard animal and public health.

6. If the operator fails to take all necessary measures to comply with the orders of the official veterinarian or competent authority in accordance with Article 3(1), 3(2), 3(3), 3(4), 3(5) and 3(6) of this Regulation, the official veterinarian or the competent authority shall take measures having the same effect, at the expense of the operator.

Article 4

Investigation

1. Where the maximum residue limits for pharmacologically active substances authorised in veterinary medicinal products or as feed additives, set on the basis of Regulation (EC) No 470/2009 and Regulation (EC) No 1831/2003, or, where the maximum levels for residues of pharmacologically active substances resulting from the unavoidable carry-over of these substances in non-target feed, set on the basis of Regulation (EC) No 315/93, have been exceeded, thereby establishing non-compliance, the competent authority, shall:

([14]) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

(a) carry out any necessary measure or investigation, which it deems appropriate in relation to the finding in question. This may include any investigation in the farm of origin or departure of the animals, including controls on animals or batches of animals on their farms of origin or place of departure, to determine the extent and origin of non-compliance and to establish the extent of the operator's responsibilities;

(b) request the animal keeper or the responsible veterinarian to provide the prescription and treatment records and any documentation, justifying the nature of the treatment.

2. Where residues are identified at concentrations below the maximum residue limits for pharmacologically active substances authorised in veterinary medicinal products or as feed additives, but where the presence of those residues is inconsistent with the food chain information, thereby creating a suspicion of non-compliance or illegal treatment, the competent authority shall carry out any measure of investigation which it deems appropriate for investigating the source of these residues or the deficiencies in the food chain information.

3. Where residues are suspected at levels exceeding the maximum residue limits or maximum levels for pharmacologically active substances authorised in veterinary medicinal products or as feed additives, set under Union legislation, the competent authority shall carry out any measure of investigation which it deems appropriate.

4. Where illegal treatment is suspected or established, or where substances falling under the scope of Directive 96/22/EC are discovered in the possession of non-authorised persons or operators, or where prohibited or unauthorised substances or products are discovered in the possession of non-authorised persons or operators, the competent authority shall:

(a) immediately place the livestock and products concerned by the investigation under official detention.

(b) during official detention the competent authority shall:

— order that the animals concerned by the investigation are not moved without prior authorisation by the competent authority and this for the duration of the investigation;

— order that carcases, meat, offal, by-products, milk, eggs and honey from those animals do not leave the farm or establishment of origin and are not handed over to any other person without prior authorisation of the competent authority;

— order that, where relevant, feed, water or any other products concerned, are kept separate and are not moved from the farm or establishment of origin;

— ensure that the animals concerned by the investigation bear an official mark or other means of identification, or, in the case of poultry, fishes and bees, that they are kept in a marked space or hive;

— take appropriate precautionary measures in accordance with the nature of the substance or substances identified;

(c) request the animal keeper and the responsible veterinarian to provide any documentation justifying the nature of the treatment;

(d) carry out any other official controls on animals or batches of animals at the farm of origin or place of departure of the animals, necessary to ascertain such use;

(e) carry out any other official controls necessary to ascertain the acquisition and presence of unauthorised or prohibited substances;

(f) carry out any other official controls deemed necessary to clarify the origin of the prohibited or unauthorised substances or products or of the treated animals.

5. The official controls referred to in this Article may also include controls on manufacturers, distributors, transporters, production sites of pharmacologically active substances and veterinary medicinal products, pharmacies, all relevant actors in the supply-chain and any other site concerned by the investigation.

6. The official controls referred to in this Article may also include official sampling, including of water, feed, meat, offal, blood, animal by-products, hair, urine, faeces and other animal matrices. The competent authority shall take any number of samples it considers necessary for investigating the suspected or established non-compliance or illegal treatment. In case of aquaculture animals, samples from the waters in which they are grown or caught and in the case of honey bees, samples of the hives may be required.

Article 5

Follow-up on residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives, exceeding the applicable maximum residue limits or maximum levels

1. Where the maximum residue limits for pharmacologically active substances authorised in veterinary medicinal products or as feed additives, set on the basis of Regulation (EC) No 470/2009 and Regulation (EC) No 1831/2003 have been exceeded or, where the maximum levels for residues of pharmacologically active substances resulting from the unavoidable carry-over of these substances in non-target feed, set on the basis of Regulation (EEC) No 315/93, have been exceeded, the competent authority shall:

— declare the carcases and products concerned by the non-compliance unfit for human consumption and order the operator to dispose of all products as category 2 material, as laid down in Regulation (EC) No 1069/2009;

— take any other measures necessary to safeguard public health, which may include prohibiting animals from leaving the farm concerned or products from leaving the farm or establishment concerned for a set period;

— order that the operator takes appropriate action to address the causes of the non-compliance;

— perform additional official controls to verify that action taken by the operator, to address the cause of non-compliance is effective. This may include taking as many follow-up samples as considered necessary in relation to animals or products from the same farm or establishment.

2. In the event of repeated non-compliance by the same operator, the competent authority shall perform regular additional official controls, including sampling and analysis, on the animals and products from the operator concerned for a period of at least six months from the date on which the second non-compliance was established. It shall also order the operator to ensure that the concerned animals and the carcases, meat, offal, by-products, milk, eggs and honey from these animals are kept separate from other animals, that they do not leave the farm or establishment of origin and are not handed over to any other person without prior authorisation of the competent authority.

3. If the operator fails to take all necessary measures to comply with the orders of the competent authority in accordance with this Article, the competent authority shall take measures having the same effect, at the expense of the operator.

Article 6

Follow-up of illegal treatments and the possession of prohibited or unauthorised substances or products

1. Where substances within the scope of Directive 96/22/EC, prohibited or unauthorised substances or products are discovered in the possession of non-authorised persons, thereby creating a suspicion of illegal treatment, those substances or products shall be placed under official detention until the measures provided for under paragraphs 2, 3 and 4 of this Article are taken by the competent authority, without prejudice to the subsequent destruction of the products and the possible imposition of penalties on the offender(s).

2. Where illegal treatment is established or where substances falling under the scope of Directive 96/22/EC, prohibited or unauthorised substances or products are discovered in the possession of non-authorised operators or persons, the competent authority shall:

— place or keep the livestock and the carcases, meat, offal and by-products of the animals concerned by the illegal treatment together with the milk, eggs and honey from those animals under official detention as provided for in Article 4(4)(b);

— take samples from all relevant batches of animals belonging to the farm.

— order the operator to kill the animal or animals for which illegal treatment has been established, and to dispose them as laid down in Regulation (EC) No 1069/2009;

— declare all carcases or products concerned by the illegal treatment unfit for human consumption and order the operator to dispose of them as laid down in Regulation (EC) No 1069/2009;

3. For the purposes of paragraph 2:

— all animals of the batch or batches from which one or more animals were confirmed to have been subject to an illegal treatment with prohibited or unauthorised substances shall be considered to have been also subject to an illegal treatment, unless the competent authority, at the request and at the expense of the operator, agrees to perform additional official controls on all animals of the relevant batch or batches to ascertain that no illegal treatment took place in relation to those animals.

— all animals of the batch or batches from which one or more animals were confirmed to have been subject to an illegal treatment due to the use in food producing animals of substances or veterinary medicinal products authorised under Union legislation for purposes or under conditions other than those laid down in that legislation or, where appropriate, in national legislation, shall be considered to have been also subject to an illegal treatment, unless the competent authority, at the request and at the expense of the operator, agrees to perform additional official controls on the animals of the relevant batch or batches, which are suspected to have been illegally treated, to ascertain that no illegal treatment took place in relation to those animals.

4. In the case of established illegal treatment in aquaculture, samples from all relevant ponds, pens and cages shall be taken. In case the illegal treatment in aquaculture is established, if the sample taken from a specific pond, pen or cage is non-compliant, all the animals in that pond, pen or cage shall be considered to have been subject to illegal treatment.

5. The competent authority shall perform regular additional official controls for a period of at least 12 months from the date upon which the non-compliance was ascertained on the farm or farms under the responsibility of the same operator and on the animals and goods belonging to the farm or farms in question.

6. The farms or establishments, supplying the holding concerned by the non-compliance, as well as all farms in the same supply chain of animals and animal feed as the farm of origin or departure may be subject to official controls to determine the origin of the substance in question:

— during the transport, distribution and sale or acquisition of pharmacologically active substances;

— at any point in the animal feed production and distribution chain;

— throughout the production chain of animals and products of animal origin

7. If the operator fails to take all necessary measures to comply with the orders of the competent authority in accordance with this Article, the competent authority shall take measures having the same effect, at the expense of the operator.

Article 7

Requirements for analytical methods and sampling

All samples referred to in this Regulation shall be taken and analysed in accordance with Regulation (EU) 2017/625, Commission Decision 1998/179/EC ([15]) and Commission Decision 2002/657/EC ([16]).

Article 8

Actions on registration, authorisation and official approval arrangements

Where the possession, use or manufacture of unauthorised substances or products is confirmed, all registration, authorisation or official approval arrangements enjoyed by the establishment or the operator concerned shall be suspended for a period established by the competent authority.

In case of a repeat offence, such arrangements shall be withdrawn by the competent authority. In case of withdrawal, the operator shall be required to re-apply for the concerned registration, authorization or official approval arrangements and demonstrate its compliance with relevant requirements in this regard.

([15]) Commission Decision 1998/179/EC of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products (OJ L 65, 5.3.1998, p. 31).

([16]) Commission Decision 2002/657/EC of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (OJ L 221, 17.8.2002, p. 8)

Article 9

Administrative assistance

Where the non-compliance referred to in Articles 5 and 6 is ascertained in relation to animals or products of animal origin originating from another Member State, the competent authority carrying out the investigation shall send a notification of the established non-compliance in accordance with Articles 105 and 106 of Regulation (EU) 2017/625 and, if required, it shall issue a request for administrative assistance from the competent authority of the Member State of origin in accordance with Article 104 of that Regulation. The competent authority of the Member State of origin shall apply Articles 5 and 6 of this Regulation to the farm or establishment of origin or departure.

Article 10

References

References to Article 13, Article 15(3), Article 16(2), Article 16(3), Article 17, Article 18, and Articles 22 to 25 of Directive 96/23/EC shall be construed as references to this Regulation and read in accordance with the correlation table in the Annex.

Article 11

Entry into force and application

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 14 December 2019 onwards.

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

Done at Brussels, 19 June 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

CORRELATION TABLE REFERRED TO IN ARTICLE 10

Directive 96/23/EC	This Regulation
Article 13	Article 4
Article 15(3)	Article 4, 5, 6 and 9
Article 16(2)	Article 4, 5 and 6
Article 17	Article 6
Article 18	Article 5
Article 22	Article 6(1)
Article 23(1)	Article 4(4)
Article 23(2), 23 (3), 23 (4) and 23 (5)	Article 6
Article 24	Article 3
Article 25	Article 8