Changes to legislation: *There are outstanding changes not yet made to Commission Delegated Regulation (EU) 2019/2090. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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)

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.

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(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.

(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

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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.

(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.

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(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.

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;

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(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.