EUROPEAN
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COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

amending Delegated Regulation (EU) 2019/2090 as regards the enforcement actions in case of non-compliance with the withdrawal period, maximum residue limits or maximum levels and in case of illegal treatment

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Commission Delegated Regulation (EU) 2019/2090 lays down specific rules as regards the requirements for the performance of official controls on the use or residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives and rules for the cases where competent authorities, in relation to non-compliance or suspicion thereof, are to take specific measures.

Based on the experience with the application of that Regulation, some additional provisions to the existing legal provisions as regards the specific actions to be taken in the event of non-compliance or suspected non-compliance should be set out to facilitate their enforcement in a uniform manner throughout the Union:

- at the slaughterhouse in case of non-compliance with the withdrawal period where concerned animals are already slaughtered;

- as regards the investigation and follow-up in case of non-compliance with the withdrawal period;

- in case of batches containing non-compliant and compliant products of animal origin.

For the sake of consistency, all references in Delegated Regulation (EU) 2019/2090 to repealed Directive 2001/82/EC of the European Parliament and of the Council are to be replaced by references by Regulation (EU) 2019/6 of the European Parliament and of the Council.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Member States' experts were consulted within the Commission Expert Group on Residues of Veterinary Medicines[1], which met to discuss the subject on 4 May 2026.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal basis for the Delegated Regulation is Article 19(2), points (a) and (b), of Regulation (EU) 2017/625.

[1] Reference E03595 in the Register of Commission Expert Groups and other similar entities.

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(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 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)[2], and in particular Article 19(2), points (a) and (b), thereof,

Whereas:

(1) Commission Delegated Regulation (EU) 2019/2090[3] lays down specific requirements for official controls and measures for cases of non-compliance with Union rules applicable to the use of pharmacologically active substances, among others for the cases where the competent authorities are to take specific measures in relation to non-compliance with the withdrawal period, exceedance of maximum residue limits or maximum levels or illegal treatment.

(2) Since Directive 2001/82/EC of the European Parliament and of the Council[4] was repealed by Regulation (EU) 2019/6 of the European Parliament and of the Council[5], it

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2 OJ L 95, 7.4.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/625/oj.

3 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 (OJ L 317, 9.12.2019, p. 28, ELI: http://data.europa.eu/eli/reg_del/2019/2090/oj).

4 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, ELI: http://data.europa.eu/eli/dir/2001/82/oj).

5 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, ELI: http://data.europa.eu/eli/reg/2019/6/oj).

is appropriate to replace the references to Directive 2001/82/EC in Delegated Regulation (EU) 2019/2090 accordingly.

(3) Concerning actions to be taken at the slaughterhouse, Delegated Regulation (EU) 2019/2090 sets out the rules for cases where an official veterinarian performing official controls has evidence that animals have been treated with an authorised veterinary medicinal product, but the withdrawal period as defined in Article 4(34) of Regulation (EU) 2019/6 has not been respected. Since that Regulation does not provide for actions to be taken in case where the animals concerned are already slaughtered, it is appropriate to set out the rules for such cases.

(4) Furthermore, carcases, meat and meat products and offal from the animals concerned that are still on the premises of the slaughterhouse could have been incorporated into batches containing compliant products. Therefore, it is appropriate to provide for enforcement actions to be taken by the competent authority in such cases.

(5) Concerning investigations, to clarify the origin and the extent of the non-compliance concerning the withdrawal period, it is appropriate to provide that an investigation should be performed in this respect, taking into account the nature of non-compliance.

(6) Concerning the follow-up of non-compliance, in order to ensure appropriate and harmonised enforcement to protect human health, rules should be adopted on the actions to be taken where, after investigation, non-compliance with the withdrawal period has been established.

(7) In addition, since the non-compliance as regards the withdrawal period, maximum residue limits or maximum levels and illegal treatment could concern a large variety of products originating from affected animals, and also products that have been incorporated into batches containing compliant products, the enforcement actions to be taken by the competent authority should cover such cases.

(8) Rules on administrative assistance laid down in Delegated Regulation (EU) 2019/2090 in case of non-compliance with maximum residue limits or maximum levels and in case of illegal treatment should be applied also in case of non-compliance with the withdrawal period.

(9) Delegated Regulation (EU) 2019/2090 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) 2019/2090 is amended as follows:

(1) in Article 2, the introductory sentence is replaced by the following:

‘For the purposes of this Regulation, the definitions in Regulation (EC) No 852/2004 of the European Parliament and of the Council*, Regulation (EC) No 853/2004 of the European Parliament and of the Council**, Regulations (EU) 2017/625, (EC) No 470/2009 and (EU) 2019/6 shall apply.

The following definitions shall also apply:

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* Regulation (EC) Nå o 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/852/oj).

** Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55, ELI: http://data.europa.eu/eli/reg/2004/853/oj).';

(2) Article 3 is amended as follows:

(a) paragraphs 3 and 4 are replaced by the following:

'3. If the official veterinarian performing official controls in a slaughterhouse or the official auxiliary performing 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 the withdrawal period has not been respected, the official veterinarian shall order that the concerned animals be 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 not be shorter than:

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

— the withdrawal period established under the relevant 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 with Articles 113 and 114 of Regulation (EU) 2019/6 or, if no withdrawal period is prescribed for such uses, the minimum withdrawal period laid down in Article 115 of that Regulation.

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

(b) in paragraph 5, the first sentence is replaced by the following:

'If the official veterinarian performing official controls in a slaughterhouse or the official auxiliary performing certain tasks in the framework of those controls has evidence that the animals present in the slaughterhouse have been treated with an authorised veterinary medicinal product, but that the withdrawal period has not been respected, the official veterinarian shall order that the animals concerned be separated from other batches of animals present or arriving at the slaughterhouse, under conditions to be established by the competent authority.';

(c) the following paragraph 5a is inserted:

'5a. If the official veterinarian performing official controls in a slaughterhouse or the official auxiliary performing certain tasks in the framework of these controls suspects or has evidence that the carcases, meat and meat products, offal and by-products originate from slaughtered

animals that have been treated with an authorised veterinary medicinal product, but that the withdrawal period has not been respected, the official veterinarian shall declare them unfit for human consumption and order the operator to dispose of them as category 2 material, as laid down in Regulation (EC) No 1069/2009.

The same shall apply where such carcases, meat and meat products, offal and by-products have been incorporated in batches containing products not concerned by the non-compliance from which they can be isolated.

Where they have been incorporated in batches containing products not concerned by the non-compliance from which they cannot be isolated, the official veterinarian shall assess all available information and take any measure appropriate to eliminate or reduce risks to human health, including the following:

(a) restrict or prohibit placing of the products concerned on the market;

(b) order the operator to increase the frequency of own controls;

(c) order increased official controls of the operator concerned;

(d) order the withdrawal, removal and destruction of the products concerned.';

(d) paragraph 6 is replaced by the following:

'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) to (5a), the official veterinarian or the competent authority shall take measures having the same effect, at the expense of the operator.';

(3) in Article 4, the following paragraph 1-a is inserted before paragraph 1:

'1-a. Where the withdrawal period has not been respected and the concerned animal is already slaughtered, the competent authority shall carry out any measure or investigation, which it deems appropriate in relation to that finding.';

(4) the following Article 4a is inserted:

'Article 4a

Follow-up of non-compliance with the withdrawal period referred to in Article 4(34) of Regulation (EU) 2019/6

Where the withdrawal period has not been respected, the competent authority shall declare the unprocessed and processed products of animal origin 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.

The same shall apply where such unprocessed and processed products of animal origin have been incorporated in batches containing products not concerned by the non-compliance from which they can be isolated.

Where they have been incorporated into batches containing products not concerned by the non-compliance from which they cannot be isolated, the competent authority shall assess all available information and take any measure appropriate to eliminate or reduce risks to human health, including the following:

(a) restrict or prohibit placing of the concerned products on the market;

(b) order to the operator to increase the frequency of own controls;

(c) order increased official controls of the operator concerned;

(d) order the recall, withdrawal, removal and destruction of the products concerned.';

(5) Article 5(1) is amended as follows:

(a) the first indent is replaced by the following:

'— declare the unprocessed and processed products of animal origin 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;';

(b) the following subparagraphs are added:

'The same shall apply where such unprocessed and processed products of animal origin have been incorporated in batches containing products not concerned by the non-compliance from which they can be isolated.

Where they have been incorporated into batches containing products not concerned by the non-compliance from which they cannot be isolated, the competent authority shall assess all available information and take any measure appropriate to eliminate or reduce risks to human health, including the following:

(a) restrict or prohibit placing of the concerned products on the market;

(b) order to the operator to increase the frequency of own controls;

(c) order increased official controls of the operator concerned;

(d) order the recall, withdrawal, removal and destruction of the concerned products.';

(6) Article 6(2) is amended as follows:

(a) the fourth indent is replaced by the following:

'— declare the unprocessed and processed products of animal origin concerned by the illegal treatment unfit for human consumption and order the operator to dispose of them as category 1 material as laid down in Regulation (EC) No 1069/2009.';

(b) the following subparagraphs are added:

'The same shall apply where such unprocessed and processed products of animal origin have been incorporated in batches containing products not concerned by the non-compliance from which they can be isolated.

Where they have been incorporated into batches containing products not concerned by the non-compliance from which they cannot be isolated, the competent authority shall assess all available information and take any measure appropriate to eliminate or reduce risks to human health, including the following:

(a) restrict or prohibit placing of the concerned products on the market;

(b) order to the operator to increase the frequency of own controls;

(c) order increased official controls of the operator concerned;

(d) order the recall, withdrawal, removal and destruction of the products concerned.';

(7) Article 9 is replaced by the following:

'Article 9

Administrative assistance

Where the non-compliance referred to in Articles 4a, 5 and 6 is established 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, 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 4a, 5 and 6 of this Regulation to the farm or establishment of origin or departure.'.

Article 2

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

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN