SANTE 11987-2017 Rev5.

COMMISSION IMPLEMENTING REGULATION (EU) …/…

of XXX

on rules applicable to national official control programmes and annual reports by Member States on residues of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and 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) 1107/2009, (EU) 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, 60/425/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(3) and 113(2) 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 for the verification of compliance with the Union legislation in the area of food and food safety. Article 9 lays down that competent authorities shall perform such official controls on a risk basis with an appropriate frequency. Article 109 lays down the obligation of

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

Member States to ensure that the controls within the scope of Regulation (EU) 2017/625 are performed by the competent authorities on the basis of a multi-annual national control plan. Article 110 of that Regulation specifies the general requirements for the content of multi-annual national control programmes and Article 113 specifies the general requirements for Member States for the annual report on their multi-annual national control programmes.

(2) Directive 96/22/EC[2] prohibits the use in stockfarming of certain substances having a hormonal or thyreostatic action and of beta-agonists, unless for the specified therapeutic or zootechnical uses.

(3) Commission Regulation (EU) No 37/2010[3] of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin lays down in table 1 of its Annex maximum residue limits for allowed pharmacologically active substances and in table 2 of its annex a list of prohibited substances.

(4) Certain pharmacologically active substances are authorised as feed additives according to Regulation (EU) No 1831/2003[4] and residues of these substances can occur in products of animal origin. Maximium residue limits for specific pharmacologically active substances, authorised as feed additives, are set under the Union legislation concerning their authorisation. For coccidiostats or histomonostats resulting from the unavoidable carry-over in non-target feed, maximum levels are set under Regulation (EC) No 124/2009[5].

(5) Directive 96/23/EC[6] of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and Commission Decision 97/747/EC[7] lay down provisions on monitoring programmes for the detection of

[2] 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).

[3] 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).

[4] Regulation (EC) No 1831/2013 of the European Parliament and of the Council of 22 September 2013 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

[5] 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).

[6] 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, 26.5.1996, p. 10).

[7] Commission Decision 97/747/EC of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products (OJ L 303, 611.1997, p. 12).

residues or substances. Directive 96/23/EC is repealed by Regulation (EU) 2017/625 by 14 December 2019. Article 150 of that Regulation sets out transitional measures related to the repeal of Directive 96/23/EC.

(6) Union legislation on controls of residues in animals and animal products is needed, to ensure harmonised controls in the different Member States. Also for combatting effectively the illegal use of growth and productivity promoters in stock farming in all Member States, controls should be organized at Union level. Therefore rules need to be established for the content and sampling frequency of Member States' national official control programmes on residues of pharmacologically active substances. In order to ensure a harmonised reporting on the Member States' residues controls, requirements should be set for the Member States reporting on their programmes and on the outcome of the controls carried out under these programmes.

(7) Risk-based controls should be carried out by and in the Member States on their domestic production in order to verify the absence of prohibited or unauthorised substances in live animals, their body parts and fluids, excrements, tissues, animal products, animal by-products, animal feed and water. For pharmacologically active substances authorised as veterinary medicinal products or as feed additives, in food of animal origin risk-based controls should be carried out to verify the compliance with the maximum residue limits and maximum levels. These controls should be continued to be carried out at least at the existing frequency. For this purpose sampling frequencies should be defined, which are based on the production volumes of the Member States'.

(8) Article 47 of Regulation (EU) 2017/625 lays down that animals, products of animal origin and animal by-products imported into the Union, shall be subject to official controls at border control posts. Article 49 of that Regulation lays down that these controls shall include identity and documentary and physical checks.

(9) According to Article 29 of Directive 96/23/EC (Future Delegated Regulation on the basis of Article 126 of Regulation (EU) 2017/625) the import of animals and animal products from third countries into the EU is subject to the submission of an approved residues control plan. In order to verify the effectiveness of third countries' residue controls and the compliance of imported animals and products of animal origin, as part of the physical checks also imported animals and products of animal origin should be included in the Member States' residues control programmes. In order to harmonise the controls among the Member States, minimum sampling frequencies should be defined for the Member States, through which the animals and products of animal origin enter into the EU. These frequencies should be based on the imported volumes of those animals and products of animal origin.

(10) As it needs to be investigated whether the scope of the risk based programme for domestic production is appropriate or whether it would need to be expanded with certain

substances. Member States should include in their national control programmes a dedicated surveillance programme, which includes a wide range of substances. In order to identify unauthorised pharmacologically active substances, which are relevant to be included in the risk-based programmes, Member States shall include in their surveillance programme controls on unauthorised substances, which are currently not included in the risk based national programmes, but which may be misused for the treatment of food producing animals. In addition to controls, using analytical reference standards, non-targeted library screening methods, are effective for identifying unexpected illegal uses for both authorised and unauthorised pharmacologically active substances. Furthermore as information is needed on the non-compliance rate regarding pharmacologically active substances in food of animal origin and on the consumer exposure to these substances, through a surveillance plan with random sampling these data can obtained. The data gathered under this programme, should be used as input for ensuring an appropriate design and the continuous updating of the Member States' risk based national control programmes.

(11) For the surveillance part of the programme, on the basis of a binomial probability distribution, it can be calculated that examination of 7683 samples allows estimating with a 95% confidence an expected prevalence of non-compliance of 0.2% with a precision of 0.1%, considering a random sampling scheme. Collection of these samples should be apportioned over the different Member States according to their citizens' population size and should be apportioned over the animal species and products proportionate to the national production.

(12) The procedures set up by the competent authorities of the Member States responsible for sampling and treatment of samples, until the samples reach the laboratory, have a direct influence on the presence of illegal substances in samples and the possibilities for detecting the residues of certain substances. Commission Decision 98/179/EC[8] lays down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products, which apply to the control programme laid down in Directive 96/23/EC. These provisions should equally apply to the control programmes provided for in this Regulation.

(13) It is necessary to ensure comparability of the analytical results gathered under the control programmes for pharmacologically active substances and of the interpretation of the results. Commission Decision 2002/657/EC[9] lays down rules for the performance of analytical methods and the interpretation of results.

(14) Commission Decision 97/747/EC should be repealed as its provisions are replaced by the provisions included in this Regulation.

[8] Commission Decision 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, 5.3.98, p. 31).

[9] Commission Decision 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).

(15) As the rules laid down in Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products are repealed by 14 December 2022, this Regulation should apply from that date onwards.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

CHAPTER I

Subject matter, scope and definitions

Article 1

Subject matter and scope

This Regulation lays down rules for the performance of official controls by the competent authorities of the Member States on residues of pharmacologically active substances, authorised as veterinary medicinal products or feed additives and of prohibited or unauthorised pharmacologically active substances, with a view of ensuring food safety. This Regulation lays down requirements for a minimum frequency of these official controls, for specific additional content of the Member States' national control programmes, in addition to those laid down in Art. 110 of Regulation (EU) 2017/625 and for the annual reports by Member States.

The production process of animals and primary products of animal origin shall be monitored in accordance with this Regulation for the purpose of detecting the presence of the residues and substances listed in Annex I in live animals, their body parts and fluids, excrements tissues, animal products, animal by-products, animal feed and water. Controls shall also be carried out on animals traded between EU and EFTA Member States and destined for slaughter in another EU or EFTA Member State than the EU or EFTA Member State of origin.

Article 2

Definitions

For the purposes of this Regulation, the definitions in Regulation (EC) No 178/2002, Regulation (EC) No 470/2009, Regulation (EU) 2017/625, Decision 2002/657/EC and SANTE 11990/2017 shall apply and in addition the following definitions shall apply. :

(a) 'Official sample' shall mean a sample taken by the competent authority, which bears, for the purposes of examination of the residues or substances listed in Annex I, a reference to the species, the type, the quantity concerned, the method of collection and particulars identifying the sex of the animal and the origin of the animal or of the animal product if applicable.

(b) 'Targeted sample' shall mean an official sample, which is taken with the aim of detecting an illegal treatment or a non-compliance with the maximum residue limits or maximum levels, established under Union legislation for pharmacologically active substances.

(c) 'Random sample' shall mean an official sample which is taken under statistical consideration to provide representative data.

(d) 'Suspect sample' shall mean an official sample, which is taken as the follow-up to an suspected or established non-compliance with the Union rules on pharmcacologically active substances, as laid down in SANTE 11990/2017.

(d) 'Matrix' shall mean the material from which a sample is taken: animal body parts, fluids, excrements, tissues, animal products, animal by-products, animal feed and water.

CHAPTER II

Control programmes

Article 3

Risk based control programme for EU-production

To verify compliance with the EU legislation on residues of pharmacologically active substances in animals and animal products produced in the EU, Member States shall establish a national risk-based control programme for the substance groups listed in Annex I. Member States shall control live animals, their body parts and fluids, excrements, tissues, animal products, animal by-products, animal feed and water, whichever is the most relevant.

Member States shall take into account the risk criteria, relevant species, products and matrices, listed in Annex II and shall ensure compliance with the sampling rules and minimum sampling frequencies, described in Annexes III and IV. Member States shall control a wide range of substances within the sub-groups of group A and group B substances listed in Annex I.

When there are indications or suspicions that illegal treatments may take place for residue or substance groups in species or products, not covered by the table included in Annex II, also these controls shall be included in the risk-based control progamme for EU production. In the case of the identification of illegal treatments in the course of the ongoing year, which are not

yet included in the risk-based programme for EU-production, the programme shall be amended to ensure controls on such uses.

Article 4

Risk-based control programme for third country imports

To verify compliance with the EU legislation on residues of pharmacologically active substances in animals and animal products, imported into the EU from third countries and in order to verify the effectiveness of the third countries' control system, Member States, via whose Border Control Posts or other points of entry animals and products of animal origin enter into the EU, shall establish a national risk-based control programme for those animals and products of animal origin. For this programme they shall take into account the substance groups listed in Annex I, the relevant species, products and risk criteria, listed in Annex II, supplemented by those listed in Annex V and they shall ensure compliance with the sampling rules laid down in Annex VI. The sampling frequencies of the controls carried out under this programme shall not be less than the sampling frequencies established for the risk-based programmes for EU production, laid down in Article 3. In order to ensure harmonised minimum sampling frequencies for residues analyses at the different Member States' Border Control Posts, the minimum frequencies of such controls are defined in Annex VII. Member States shall ensure that in addition to the established safeguard measures and the intensified official controls, laid down in Art. 65 of Regulation (EU) 2017/625, the minimum sampling frequencies of Annex VII are respected, which shall be calculated on the basis of the imported volumes.

Article 5

Surveillance programme for EU production

In order to verify the appropriateness of the scope of the risk based national control programmes and in order to gather information on the non-compliance rate regarding pharmacologically active substances in food of animal origin and on the consumer exposure to these substances, the Member States shall include in their national control programmes a surveillance programme.

In order to identify unauthorised pharmacologically active substances, which are relevant to be included in the risk-based programmes, Member States shall include in their surveillance programme controls on unauthorised substances, which are currently not included in their risk based national programme, but which may be misused for the treatment of food producing animals. In case of the identification of new illegal uses, the risk based programme for domestic production shall be updated accordingly in the course of the ongoing year, where appropriate.

For the substance groups of Group B listed in Annex I, Member States shall ensure analysis of the groups of substances according to the species and products, listed in Annex VIII, the sampling strategy listed in Annex IX and the sampling frequencies listed in Annex X.

The surveillance programme for authorised pharmacologically active substances shall be carried out for as many substances as possible, for which MRLs are set in Table 1 of the Annex to Regulation (EU) No 37/2010. All the samples allocated to a specific Member State in Annex X, shall be analysed as a minimum for all substance groups of Group B in the scope of the surveillance programme as listed in Annex VIII. Additional substance categories may be analysed on a voluntary basis.

In order to obtain useful information or the occurrence of residues of authorised pharmacologically active substances in products of animal origin, the analysis of these samples shall be carried out with quantitative methods. For the samples in which residues of authorised substances are identified, the concentration shall be reported, when above the 10% of the maximum residue limit or maximum level, provided that a CC beta value at or below 10% of the maximum residue limit or maximum level is analytically achievable. Where such low CC beta value is not analytically achievable, the CC beta value shall be as low as analytically achievable and all concentrations at or above the CC beta value of the method shall be reported.

CHAPTER III

Sampling procedures and official sample treatment

Article 6

For the control of certain substances and residues thereof in live animals and animal products, the sampling procedures and detailed rules for sample treatment shall be followed a set out in Decision 98/179/EC.[5]

CHAPTER IV

Risk-based control programme for EU production, risk-based control programme for third country imports and surveillance programme for EU production: content, submission and evaluation of the programme and submission of the report

Article 7

Content of the programmes

The programmes provided for in articles 3, 4 and 5 shall specify:

(a) The list of substances and their residues to be analysed for specific species and products in specific matrices accordance with Annex II for the risk-based programme for EU production, in accordance with Annex V for the risk-based programme for third country imports and in accordance with Annex VIII for the surveillance programme for EU production.

(b) The species and production types to be sampled and the measures for the detection of the presence of the substances referred to in (a) in the animals, animal body parts and fluids, excrements, animal tissues, animal products, animal by-products, in the water and feed of the animals and in all places where the animals are bred or kept.

(c) A justification for the selected substances, species, products and matrices included in the programmes under Articles 3 and 4 on the basis of the criteria listed in Annexes II and V, including a justification on how the criteria, listed in these Annexes, were taken into account, even if no changes were made compared to the programme of the previous year.

(d) The number of official samples to be taken in accordance with the sampling levels and frequencies laid down in Annexes IV, VII and X and where in Annexes IV and VII a sampling frequency is established on the basis of the number of slaughtered animals of the species concerned, the volume of harvested honey, milk, eggs or the volume of imported products in the preceding year, the relation between these numbers and the sampling frequency shall be explained.

(e) The legislation on the use of the substances listed in Annex I and, in particular, provisions on their prohibition or authorisation, distribution and placing on the market and the rules governing their administration, in so far as such legislation is not harmonised.

(f) The infrastructure of the relevant departments of the competent authority, providing details of the type and size of the organisations involved in implementing the programmes.

(g) The list of official laboratories.

(h) The methods of analysis and the analytical standards to be used for interpreting the findings.

(i) The type of measures, taken by the competent authorities, with regard to animals or products in which residues have been detected, including further follow-up by suspect sampling.

Article 8

Submission and evaluation of the programme

By 30 March of each year Member States, Norway and Iceland shall submit electronically a programme to the Commission for implementing Articles 3, 4 and 5 of this Regulation. The programme shall describe the national measures of the programme to be implemented in that year and shall be updated during the ongoing year, when new information becomes available, which impacts on the risk-based design of the programmes laid down in Articles 3 and 4.

The Commission shall evaluate the programmes of the Member States, Norway and Iceland and shall communicate its evaluation to each Member State, Norway and Iceland by 30 June of each year. In case of critical comments, which are essential for the well-functioning of the programme, the Member States, Norway and Iceland shall by 30 September of each year reply to the Commission on how its comments were taken into account for an update of the ongoing programme. The Member States, Norway and Iceland shall clearly describe in the next years' programme, how the Commissions' comment were taken into account.

Article 9

Submission of the report

By 30 June each year, Member States, Norway and Iceland shall submit to European Food Safety Authority (EFSA) the control data gathered under the programmes set out in Articles 3, 4 and 5, as well as the information on the follow-up actions taken for non-compliant samples. The information shall be submitted in the electronic reporting format as set out by EFSA, for compilation into one database.

CHAPTER V

General provisions

Article 10

Decision 97/747/EC shall be repealed.

Article 11

References to Articles 3, 4, 5, 6, 7 and 8 of Directive 96/23/EC, to Annexes I, II, III and IV of Directive 96/23/EC and to Decision 97/747/EC shall be construed as references to this Regulation.

Article 12

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 shall become applicable in all Member States on 14 December 2022.