SANTE 11988-2017 Rev1.

COMMISSION DELEGATED REGULATION (EU) …/…

of XXX

on conditions to be respected by animals and goods entering the Union from third countries, in order to ensure that the animals and goods provide equivalent guarantees regarding the Union restrictions on the use of pharmacologically active substances and regarding the Union requirements on contaminants and residues of pharmacologically active substances and pesticides in animals and products thereof.

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 Article 126.2 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 and Articles 125-129 lay down conditions for the entry of animals and goods into the Union. Article 125 specifies the general information to be submitted by the third countries as regards the general organisation and management of sanitary and

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

phytosanitary control systems in their territory and Article 126 foresees for the establishment of additional conditions for entry into the Union of animals and goods.

(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] 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) Regulation (EC) No 1831/2003[4] of the European Parliament and of the Council on additives for use in animal nutrition lays down rules for the authorisation of pharmacologically active substances as feed additives and for the establishment of maximum residues limits for such substances in animals and product of animal origin. These maximum residue limits are set under the Union legislation concerning the authorisation of the pharmacologically active substances as feed additives. For coccidiostats or histomonostats resulting from the unavoidable carry-over in non-target feed, maximum levels are set under Commission Regulation (EC) No 124/2009[5].

(5) Article 107 of Regulation (EU) 2018/XXXX of the European Parliament and the Council on veterinary medicinal products (the new VMP Regulation)[6] lays down that antimicrobial medicinal products shall not be applied routinely and that antimicrobial medicinal products shall not be used in animals for the purpose of promoting growth or increasing yield. According to Article 118 this equally applies to operators in third countries. Furthermore Article 107 lays down that designated antimicrobials, reserved for the treatment of infections in humans, shall not be used in animals. Operators in third countries should equally comply with this provision, insofar as relevant in

[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 1831/2003 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).

[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] Regulation (EU) 2018/… of the European Parliament and of the Council on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L …, p. …). 2014/0257(COD).

respect of animals or products of animal origin exported from such third countries to the Union and intended for human consumption.

(6) Commission Implementing Regulation (EU) No 2015/262 foresees that in the EU all *equidae* must be accompanied by a passport, when moving between holdings or to slaughter. The passport has a section, in which treatments with certain veterinary medicinal products must be recorded according to Articles 7 and 37 and Annex I, Part 1 of Regulation (EU) No 2015/262. According to Articles 108 and 109 of Regulation (EU) 2018/XXXX (the new VMP Regulation) all medicinal treatments must also be recorded in a medicines record kept on the farm. Horses for food production may only be treated with substances listed in Table 1 of the Annex to Regulation (EC) No 37/2010 and Regulation (EC) No 1950/2006[7]. When equidae are treated with substances other than those listed, they must be excluded from the food chain and signed out from the food chain in their passport. The third country should provide guarantees that horses (and products for human consumption derived therefrom) which have been treated with substances, which are prohibited or non-authorised in the EU, will not be imported into the EU as food-producing horses.

(7) Commission Implementing Regulation SANTE 11987-2017 lays down rules on the controls of residues of pharmacologically active substances in animals and products of animal origin, to ensure harmonised controls in the different Member States.

(8) By means of Regulation (EC) No 396/2005 of the European Parliament and of the Council maximum residue levels are set for pesticides in food. Compliance with these maximum residue levels is controlled through the EU coordinated multiannual control program and the Member States national control programmes laid down in respectively Articles 29 and 30 of that Regulation.

(9) By means of Commission Regulation (EC) No 1881/2006 maximum levels are set for contaminants in food. Compliance with these maximum levels is monitored through the Member States national control programmes laid down in SANTE 2019/XXXX.

(10) In order to ensure that the animals and goods from third countries, which are imported into the EU, provide equivalent guarantees regarding the Union restrictions on the use of pharmacologically active substances and regarding the Union requirements on contaminants and residues of pharmacologically active substances and pesticides in animals and products thereof, specific rules need to be set for the authorisation of import of these products.

[7] 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 (OJ L 367, 22.12.2006, p. 33).

(11) Currently the authorisation for importation of specific animal species or products of animal origin from specific third countries is subject to the submission of a residues control plan according Directive 96/23/EC.

(12) Directive 96/23/EC is repealed by Regulation (EU) 2017/625, which applies from 14 December 2019. Article 150 of that Regulation sets out transitional measures related to the repeal of Directive 96/23/EC.

(13) The authorisation for import of specific animals species or products of animal origin from specific third countries should be continued to be subject to the submission of a third country residues control plan, which is equivalent to the requirements of Member States' risk-based control plans for EU production, so that guarantees are made available of the third countries' commitment to ensure compliance with the EU legislation on the use and residues of pharmacologically active substances in food producing animals.

(14) In order to allow for an evaluation of the third country control plans by the Commission, they should to be submitted to the Commission. In case the plan provides sufficient guarantees, the third country should be authorised to export the concerned products of animal origin into the EU.

(15) Currently a list of third countries, authorised to export certain animal species or products of animal origin to the EU, is laid down in Commission Decision 2011/163/EU[8], in accordance with of Directive 96/23/EC. Following the repeal of Directive 96/23/EC Commission Decision 2011/163/EU should be replaced by an Implementing Regulation of the basis of Article 127 of Regulation No 2017/625.

HAS ADOPTED THIS REGULATION:

Scope

Article 1

This Regulation lays down the conditions to be fulfilled by animals and products of animal orgin entering into the Union from a third country, on the basis of a third country plan for controls on contaminants, pharmacologically active substances and pesticides. Such third country plan shall provide equivalent guarantees regarding the Union restrictions on the use of pharmacologically active substances and regarding the Union requirements on contaminants and residues of pharmacologically active substances and pesticides in animals and products thereof, intended for human consumption. The inclusion and retention of third countries on the list of third countries provided for in Union legislation, from which Member States are

[8] Commission Decision of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

authorised to import animals and products of animal origin, shall be subject to the submission to and approval of the third countries' plans by the Commission.

Third country plans: required guarantees on the use and residues of pharmacologically active substances

Article 2

The third countries' plans shall provide guarantees as regards the control of residues and substances referred to in Annex I to SANTE 2017/11987, which are at least equivalent to those provided for by the plans laid down in Articles 3 and 4 of SANTE 2017/11987.

In case pharmacologically active substances are used or authorised in the third country, whose use on food producing animals is not authorised under Union legislation, they shall be included in the third country's control plan and guarantees shall be provided that no residues of these substances, which can be reliably identified and confirmed, are present in the animals and products of animal origin, which are intended for export to the EU.

In addition the plan shall contain guarantees as regards the third countries' ability to comply with the Union restrictions on the use of prohibited substances and with the Union restrictions on the use of pharmacologically active substances on food-producing horses, in accordance Articles 3, 4 and 5 of this Regulation.

Article 3

Third countries shall provide guarantees that the prohibition laid down in Directive 96/22/EC, to use in stockfarming certain substances having a hormonal or thyreostatic action and of beta-agonists, as well as the prohibition to use in food-producing animals the substances included in Table 2 of the Annex to Commission Regulation (EU) No 37/2010, are complied with for animals and the products derived therefrom, which are intended for export into the EU.

Article 4

Third countries shall provide guarantees that the provisions of Article 107 of Regulation (EU) 2018/XXXX (the new VMP Regulation), as regards the prohibition to use antimicrobial agents in food-producing animals, for the purpose of promoting growth or increasing yield and the prohibition to use in animals substances, which are reserved for the treatment of certain infections in humans, are complied with for animals and the products derived therefrom, which are intended for export into the EU.

Article 5

Third countries shall provide guarantees that horses and products for human consumption derived therefrom, which have been treated with substances, which are prohibited or non-authorised in the EU, will not be imported into the EU as food-producing horses. Such guarantees shall be provided via a system for identification and traceability of *equidae*, for record keeping of sales and administration of veterinary medicinal products and for a horse passport, which indicates all treatments with pharmacologically active substances.

Third country plans: required guarantees on residues of pesticides

Article 6

The third countries' plans shall provide guarantees as regards controls on pesticides residues to ensure compliance of products of animal origin with the maximum residue levels referred to in the Annexes to Regulation (EC) No 396/2005. These guarantees shall be at least equivalent to those provided for by the plan laid down in Article 29 of Regulation (EC) No 396/2005.

Third country plans: required guarantees on contaminants

Article 7

The third countries' plans shall provide guarantees as regards controls on contaminants to ensure compliance of products of animal origin with the maximum levels of the contaminants referred to in the Annex of Regulation (EC) No 1881/2006. These guarantees shall be at least equivalent to those provided for by the plans laid down in SANTE 2019/XXXX.

Submission and format of the plans

Article 8

Third countries shall apply for listing in Implementing Regulation SANTE 2018-XXXX for a specific animal species or product of animal origin, by means of a written application to the Commission and an online submission of the plan in the electronic reporting format, as set out by the Commission. Once the plan is approved and the listing granted, the third country shall each year submit online an update of the plan in the electronic reporting format as set out by the Commission.

The provisions of Article 7 and 8 of Implementing Regulation SANTE 11987-2017 concerning the contents and the time limits for the submission and updating of the Member States programmes, shall equally apply to the plans to be submitted by third countries.

Evaluation of the plans, inclusion in the list of third countries authorised to import animals and products of animal origin into the EU and follow-up.

Article 9

If the third country's plan provides sufficient guarantees to ensure equivalence with the Union legislation on pharmacologically active substances, pesticides residues and contaminants, the Commission shall approve the plan and the third country shall for the concerned animal species or product of animal origin be included in the list, laid down in Implementing Regulation SANTE 2018-XXXX, following the procedure referred to Articles 126 and 127 of Regulation (EU) 2017/625.

When the requirements laid down in Articles 1-8 of this Regulation are not complied with, the listing of a third country on the list, included in Implementing Regulation SANTE 2018-XXXX, shall be revoked as laid down in Article 127 of Regulation (EU) 2017/625.

Article 10

The compliance with the requirements of and adherence to the guarantees offered by the plans, submitted by third countries, shall be verified by means of the controls referred to in Article 120 of Regulation (EU) 2017/625.

Article 11

Member States shall inform the Commission each year on the results of the residue controls, carried out on animals and animal products imported from third countries, in accordance with Articles 43-58 of Regulation EU 2017/625 and Article 9 of Implementing Regulation SANTE 11987-2017.

References

Article 12

References to Article 29 of Directive 96/23/EC shall be construed as references to this Regulation.

Application

Article 13

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 be applicable in all Member States from 14 December 2022 onwards, however Articles 4 and 5 shall be applicable from 1 January 2024.