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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to the traceability of certain kept terrestrial animals

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

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laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to the traceability of certain kept terrestrial animals

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')¹, and in particular Article 120(1) and Article 120(2)(c), (d) and (f) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down traceability requirements for kept terrestrial animals and germinal products and empowers the Commission to adopt implementing acts in that respect.
- (2) Commission Delegated Regulation (EU) 2019/2035² supplements Regulation (EU) 2016/429 by providing detailed rules concerning the traceability of kept terrestrial animals and hatching eggs.
- (3) To ensure the uniform application in the Union of the traceability rules laid down in Regulation (EU) 2016/429 and Delegated Regulation (EU) 2019/2035, certain rules should be adopted by means of this Regulation.
- (4) Articles 112, 113 and 115 of Regulation (EU) 2016/429 lay down obligations for operators keeping animals of bovine, ovine, caprine and porcine species to transmit information related to their animals into the computer databases set up in accordance with Article 109(1) of that Regulation. To ensure that all updates are transmitted to those databases regularly, it is necessary to specify in this Regulation the deadlines for transmitting that information.
- (5) Moreover, the information transmitted by the operators of kept bovine, ovine, caprine and porcine animals should be accessible to them in respect of their animals and their establishments after transmission. Rules for uniform access to data contained in the computer databases set up in accordance with Article 109(1) of Regulation (EU) 2016/429 should therefore be laid down in this Regulation.

¹ OJ L 84, 31.3.2016, p. 1.

² Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs (OJ L 314, 5.12.2019, p. 115).

- (6) In addition, certain other technical and operational details and formats of computer databases for kept bovine, ovine, caprine and porcine animals should also be laid down in this Regulation in order to ensure comparable quality of databases across the Union.
- (7) Under the conditions set out in Article 110(1)(b) and in point (b) of Article 112 of Regulation (EU) 2016/429, the exchange of electronic data between Member States may replace the issuing of identification documents for bovine animals when those animals are moved between Member States. The BOVEX protocol, established by the Commission, is designed for the exchange of electronic data between computer databases of Member States in respect of bovine animals. The Commission should recognise the full operability of those exchanges of electronic data between computer databases of Member States following this protocol.
- (8) Whilst the means of identification to be used for various species of terrestrial animals, in particular kept bovine, ovine, caprine, porcine, camelid and cervid animals and psittacidae, are determined by Delegated Regulation (EU) 2019/2035, the technical specifications for these means of identification should be set out in this Regulation.
- (9) Delegated Regulation (EU) 2019/2035 sets out requirements for electronic identification of kept bovine, ovine, caprine, porcine, camelid and cervid animals and psittacidae. Such electronic identifiers should be approved by the competent authority of the Member State where the animals are kept. In order to ensure the readability of those electronic identifiers when animals are moved between Member States, the rules and conditions under which the competent authority may approve such electronic identifiers should be laid down in this Regulation. Those approvals should also take account of relevant ISO/IEC standards.
- (10) To ensure uniform application of identification and traceability throughout the Union, the periods for the application of the means of identification to kept bovine, ovine, caprine, porcine, camelid and cervid animals and psittacidae should be set out in this Regulation.
- (11) Until the date of application of Regulation (EU) 2016/429, Union rules on traceability include various exemptions from the identification and registration system with respect to some categories of animals, such as animals kept under extensive conditions. It is appropriate to review those rules and apply a balanced and harmonised approach to the exemptions from the identification and registration system, taking into account the relevant risks on the one hand and the proportionality and efficiency of the measures on the other hand. New rules reflecting this approach should therefore be laid down in this Regulation.
- (12) It is essential to preserve full traceability of kept bovine, ovine, caprine, porcine, camelid and cervid animals and psittacidae at any moment and avoid any operations that may jeopardise traceability. Removals, modifications and replacements of the means of identification are operations that could jeopardise traceability. Therefore those operations are to be carried out only after the competent authority has granted operators permission to do so. Certain rules concerning removals, modifications and replacements are laid down in Delegated Regulation (EU) 2019/2035. Additional provisions for those operations are needed to address specific aspects, including the deadlines of those operations, and should be laid down in this Regulation.
- (13) In order to ensure a smooth transition to the new legal framework, operators in Member States should be in a position to continue to use the means of identification

approved before 21 April 2021 in accordance with Regulation (EC) No 1760/2000 of the European Parliament and of the Council³, Council Regulation (EC) No 21/2004⁴ and Council Directive 2008/71/EC⁵, as well as with the acts adopted on the basis of those Regulations and that Directive for a transitional period not exceeding 2 years from the date of application of this Regulation.

- (14) As Regulation (EU) 2016/429 applies with effect from 21 April 2021, this Regulation should also apply from that date.
- (15) 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 1

General provisions

Article 1

Subject matter and scope

This Regulation lays down rules concerning:

1. the deadlines for the transmission of information by operators for the registration of kept bovine, ovine, caprine and porcine animals in computer databases;
2. uniform access to data contained in computer databases of kept bovine, ovine, caprine and porcine animals and the technical specifications and operational rules of such databases;
3. the technical conditions and modalities for the exchange of electronic data in respect of kept bovine animals between Member States' computer databases and the recognition of full operability of a data exchange system;
4. the technical specifications, formats and design for means of identification of kept bovine, ovine, caprine, porcine, camelid and cervid animals;
5. the technical requirements for means of identification of kept psittacidae;
6. the time periods for the application of means of identification of kept bovine, ovine, caprine, porcine, camelid and cervid animals born in the Union or after the entry into the Union of those animals;
7. the configuration of the identification code of kept bovine, ovine, caprine, camelid and cervid animals;

³ Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 (OJ L 204, 11.8.2000, p. 1).

⁴ Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC (OJ L 5, 9.1.2004, p. 8).

⁵ Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (OJ L 213, 8.8.2008, p. 31).

8. the removal, modification and replacement of means of identification of kept bovine, ovine, caprine, porcine, camelid and cervid animals and the deadlines for such operations;
9. transitional measures regarding approval of means of identification.

Article 2
Definitions

For the purposes of this Regulation, the definitions laid down in Article 2 of Delegated Regulation (EU) 2019/2035 shall apply.

Chapter 2
Computer Databases

Article 3
Deadlines and procedures for the transmission of information by operators for the registration of kept bovine, ovine, caprine and porcine animals

1. Operators keeping bovine, ovine, caprine and porcine animals shall transmit the information on movements, births and deaths referred to in point (d) of Article 112 of Regulation (EU) 2016/429 and on movements referred to in Article 113(1)(c) of that Regulation and in point (b) of Article 56 of Regulation (EU) 2019/2035 for registration in the computer databases set up for those species within a time period for transmission to be determined by the Member States. The maximum time period to transmit the information shall not exceed 7 days following the movement, birth or death of the animals, as applicable.
2. In the case of births, when determining the maximum time period for transmitting the information, Member States may use the date when the means of identification is applied to the animal as the starting point of the time period concerned, provided that there is no risk of confusion between this date and the date of birth of the animal.
3. By way of derogation from paragraph 1, the competent authority may extend the maximum time period to transmit the information on movements referred to in paragraph 1 up to 14 days following movements of bovine animals within the same Member State from establishments of origin to registered pasture establishments located in mountain areas for grazing. The competent authority may decide to accept lists of the bovine animals subject to movements to registered pasture establishments from the operators of those establishments. Those lists shall contain:
 - (a) the unique registration number of the registered pasture establishment;
 - (b) the animals' identification code;
 - (c) the unique registration number of the establishment of origin;
 - (d) the animals' date of arrival at the registered pasture establishment;
 - (e) the animals' estimated date of departure from the registered pasture establishment.

Article 4

Uniform access to data contained in computer databases of kept bovine, ovine, caprine and porcine animals

Member States shall ensure that operators keeping bovine, ovine, caprine and porcine animals have, on their request and free of charge, at least read-only access to a minimum of information related to their establishments that is contained in the computer databases referred to in Article 109(1)(a) to (c) of Regulation (EU) 2016/429.

Article 5

Technical specifications for computer databases of kept bovine, ovine, caprine and porcine animals

Member States shall ensure that the computer databases of kept bovine, ovine, caprine and porcine animals referred to in Article 109(1)(a) to (c) of Regulation (EU) 2016/429 are set up in such a way that the information recorded in those databases can be exchanged between computer databases of Member States in the format set out in the third column of the table in Annex I to this Regulation.

Article 6

Operational rules of computer databases of kept bovine, ovine, caprine and porcine animals

Member States shall implement appropriate technical and organisational measures to ensure that the computer databases of kept bovine, ovine, caprine and porcine animals referred to in Article 109(1)(a) to (c) of Regulation (EU) 2016/429 continue operating in the face of potential disruptions. Those measures shall also guarantee the security, integrity and authenticity of the information recorded in such databases.

Article 7

Technical conditions and modalities for the electronic exchange of identification document data in respect of kept bovine animals between Member States' computer databases

1. When Member States exchange electronically with other Member States identification document data in respect of kept bovine animals that is referred to in points (a) to (c) of Article 44 of Delegated Regulation (EU) 2019/2035, that data shall be exchanged in the format of XML Schema Definition made available by the Commission to the competent authority.
2. The competent authority in the Member State of origin of the kept bovine animals intended to be moved shall ensure that the identification document data is transmitted electronically to the Member State of destination before the departure of the animals, and that a timestamp is provided with each transmission.

Article 8

Recognition of the full operability of a system for electronic exchange of identification document data in respect of kept bovine animals between Member States' computer databases

1. Member States exchanging electronically identification document data through a system established by the Commission and designed for the exchange of data in respect of kept bovine animals between Member States' computer databases shall be recognised as having a system of full operability.

2. The Commission shall establish and make public on its website the list of Member States exchanging identification document data through that system.

Chapter 3

Means of identification

Article 9

Technical specifications, formats and design for means of identification of kept bovine, ovine, caprine, porcine, camelid and cervid animals

1. The competent authority shall only approve the use of conventional ear tags or conventional pastern bands referred to in points (a) and (b) of Annex III to Delegated Regulation (EU) 2019/2035 as means of identification of kept bovine, ovine, caprine, porcine, camelid and cervid animals, if those means of identification fulfil the technical specification set out in Part 1 of Annex II to this Regulation.
2. The competent authority shall only approve the use of tattoos referred to in point (g) of Annex III to Delegated Regulation (EU) 2019/2035 as means of identification of kept ovine, caprine, porcine and cervid animals, as provided for in Article 46(2) and (3) and in Articles 52(1)(b), 73(2)(c) and 76(1)(c) of that Delegated Regulation, if those tattoos ensure indelible marking and proper reading.
3. The competent authority shall only approve the use of electronic identifiers referred to in points (c) to (f) of Annex III to Delegated Regulation (EU) 2019/2035 as means of identification of kept bovine, ovine, caprine, porcine, camelid and cervid animals, if those means of identification fulfil the technical specifications set out in Part 2 of Annex II to this Regulation. In addition, the electronic identifiers referred to in points (c) and (f) of Annex III to Delegated Regulation (EU) 2019/2035 shall fulfil the technical specification set out in Part 1 of Annex II to this Regulation.
4. By way of derogation from paragraph 3, the competent authority may approve the use of electronic ear tags as means of identification of kept porcine animals, if those means of identification fulfil the technical specifications laid down by the Member State where the porcine animals are kept, and display visibly, legibly and indelibly the unique registration number of:
 - (a) the establishment of birth of the animals; or
 - (b) the last establishment of the supply chain referred to in Article 53 of Delegated Regulation (EU) 2019/2035, when those animals are moved to an establishment outside that supply chain.

Article 10

Technical specifications, formats and design for means of identification of kept psittacidae

1. Operators keeping psittacidae shall ensure that:
 - (a) the leg ring referred to in Article 76(1)(a) of Delegated Regulation (EU) 2019/2035 fulfils the technical specifications set out in Part 1 of Annex II to this Regulation;
 - (b) the tattoo referred to in Article 76(1)(c) of Delegated Regulation (EU) 2019/2035 ensures indelible marking and proper reading.

2. The competent authority shall only approve the use of injectable transponders referred to in Article 76(1)(b) of Delegated Regulation (EU) 2019/2035 as means of identification of kept psittacidae, if those means of identification fulfil the technical specifications set out in point 2 of Part 2 of Annex II to this Regulation.

Article 11

Operational rules for the approval of electronic identifiers of kept bovine, ovine, caprine, porcine, camelid and cervid animals and psittacidae

1. When granting approval of the electronic identifiers referred to in points (c) to (f) of Annex III to Delegated Regulation (EU) 2019/2035 of kept bovine, ovine, caprine, porcine, camelid and cervid animals and psittacidae, the competent authority shall ensure that the manufacturers of the electronic identifiers have provided evidence that the conformance and performance tests referred to in point 4 of Part 2 of Annex II to this Regulation have been carried out in test centres accredited in accordance with ISO/IEC standard 17025 ‘General requirements for the competence of testing and calibration laboratories’.
2. When granting approval of the electronic identifiers referred to in paragraph 1, the competent authority may require that the manufacturers of the electronic identifiers apply additional tests for robustness and endurance to ensure their functionality under the specific geographic or climatic conditions of the Member State concerned in accordance with standards laid down by that Member State.

Article 12

Configuration of the identification code of kept bovine, ovine, caprine, camelid and cervid animals

The identification code of kept bovine, ovine, caprine, camelid and cervid animals shall be as follows:

- (a) the first element of the identification code shall be:
 - (i) the country code of the Member State where the means of identification was first applied to the animals, in the format of either the two-letter code in accordance with ISO standard 3166-1 alpha-2, except for Greece, for which the two-letter code ‘EL’ shall be used; or
 - (ii) the three-digit country code in accordance with ISO standard 3166-1 numeric;
- (b) the second element of the identification code shall be a unique code for each animal not exceeding 12 numeric characters.

Article 13

Time periods for the application of means of identification of kept bovine animals

1. Operators shall ensure that the means of identification referred to in point (a) of Article 112 of Regulation (EU) 2016/429 are applied to kept bovine animals before the expiry of a maximum time period after birth, to be determined by the Member State in which the animals were born. The maximum time period shall be calculated from the date of birth of the animals and shall not exceed 20 days.
2. By way of derogation from paragraph 1, Member States may authorise operators to extend the maximum time period for the application of a second means of identification to up to 60 days, following the date of birth of the animals, for reasons

related to the physiological development of the animals, if the second means of identification is a ruminal bolus.

3. By way of derogation from paragraph 1, Member States may authorise operators to extend the maximum time period referred to in paragraph 1 to up to 9 months, under the following conditions:
 - (a) the animals are:
 - (i) reared under extensive conditions, with calves staying with their mothers;
 - (ii) not accustomed to regular contact with humans;
 - (b) the area where the animals are kept, ensures a high degree of isolation of the animals;
 - (c) the extension does not compromise the traceability of the animals.

Member States may restrict the authorisation referred to in the first subparagraph to particular geographical regions or specific species or breeds of kept bovine animals.

4. Operators shall ensure that no kept bovine animals leave the establishment of birth unless the means of identification referred to in point (a) of Article 112 of Regulation (EU) 2016/429 have been applied to those animals.

Article 14

Time periods for the application of means of identification of kept ovine and caprine animals

1. Operators shall ensure that the means of identification referred to in Article 113(1)(a) of Regulation (EU) 2016/429 are applied to kept ovine and caprine animals before the expiry of a maximum time period after birth, to be determined by the Member State in which the animals were born. The maximum time period shall be calculated from the date of birth of the animals and shall not exceed 9 months.
2. Operators shall ensure that no kept ovine or caprine animals leave the establishment of birth unless the means of identification referred to in Article 113(1)(a) of Regulation (EU) 2016/429 have been applied to those animals.

Article 15

Time periods for the application of means of identification of kept porcine animals

1. Operators shall ensure that the means of identification referred to in point (a) of Article 115 of Regulation (EU) 2016/429 are applied to kept porcine animals before the expiry of a maximum time period after birth, to be determined by the Member State in which the animals were born. The maximum time period shall be calculated from the date of birth of the animals and shall not exceed 9 months.
2. Operators shall ensure that no kept porcine animals leave the establishment of birth or exit the supply chain unless the means of identification referred to in point (a) of Article 115 of Regulation (EU) 2016/429 have been applied to those animals.

Article 16

Time periods for the application of means of identification of kept camelid and cervid animals

1. Operators shall ensure that the means of identification referred to in Article 73(1) and (2) of Delegated Regulation (EU) 2019/2035 are applied to kept camelid and cervid animals before the expiry of a maximum time period after birth, to be determined by the Member State in which the animals were born. The maximum time period shall be calculated from the date of birth of the animals and shall not exceed 9 months.
2. Operators shall ensure that no kept camelid or cervid animals leave the establishment of birth or the establishment of first arrival if those animals were moved to that establishment from the habitat where they stayed as wild animals, unless the means of identification referred to in Article 73(1) and (2) of Delegated Regulation (EU) 2019/2035 have been applied to those animals.
3. The competent authority may exempt operators keeping reindeer from the requirements in paragraphs 1 and 2, provided that the exemption does not compromise the traceability of the animals.
4. By way of derogation from paragraph 1, Member States may exempt operators keeping cervid animals from the requirements in paragraph 1, under the following conditions:
 - (a) the animals are:
 - (i) reared under extensive conditions;
 - (ii) not accustomed to regular contact with humans;
 - (b) the area where the animals are kept, ensures a high degree of isolation of the animals;
 - (c) the exemption does not compromise the traceability of the animals.

Article 17

Time periods for the application of means of identification of kept bovine, ovine, caprine, porcine, camelid and cervid animals after their entry into the Union

1. After the entry into the Union of kept bovine, ovine, caprine, porcine, camelid and cervid animals and where those animals remain in the Union, operators shall ensure that the means of identification referred to in Article 81 of Delegated Regulation (EU) 2019/2035 are applied to those animals within 20 days following their arrival at the establishment of first arrival.
2. By way of derogation from paragraph 1, Member States of first arrival may authorise operators to extend the maximum time period for the application of a second means of identification to up to 60 days, following the date of birth of the animals, for reasons related to the physiological development of the animals, if the second means of identification is a ruminal bolus.
3. Operators shall ensure that no kept bovine, ovine, caprine, porcine, camelid or cervid animals leave the establishment of first arrival unless the means of identification referred to in Article 81 of Delegated Regulation (EU) 2019/2035 have been applied to those animals.

Article 18

Removal and modification of means of identification of kept bovine, ovine, caprine, porcine, camelid and cervid animals

The competent authority may only authorise operators to remove or modify the means of identification of kept bovine, ovine, caprine, porcine, camelid and cervid animals if the removal or modification does not compromise the traceability of the animals, including the traceability of the establishment in which they were born, and if individual identification of the animals, if applicable, remains possible.

Article 19

Replacement of means of identification of kept bovine, ovine, caprine, porcine, camelid and cervid animals and deadlines for such operations

1. The competent authority may only authorise operators to replace the means of identification of kept bovine, ovine, caprine, porcine, camelid and cervid animals if the replacement does not compromise the traceability of the animals, including the traceability of the establishment in which they were born, and if individual identification of the animals, if applicable, remains possible.
2. The replacement referred to in paragraph 1 may be authorised as follows:
 - (a) where animals have been identified by two means of identification and one of those means of identification has become illegible or has been lost, provided that the animals' identification code remains unchanged and continues to match the code on the remaining means of identification;
 - (b) where animals have been identified by one or two means of identification displaying the animals' identification code and those means of identification have become illegible or have been lost, provided that it remains possible to determine the animals' identification code with reasonable certainty and the animals' identification code remains unchanged;
 - (c) where kept ovine, caprine or porcine animals have been identified by a means of identification displaying the unique registration number of an establishment and that means of identification has become illegible or has been lost, provided that it remains possible to determine with reasonable certainty the establishment of birth of the animals or, if applicable, the last establishment of the supply chain, and that the replacement means of identification displays the unique registration number of that establishment or, if applicable, that last establishment.
 - (d) in case of kept ovine and caprine animals, the replacement of the means of identification referred to in points (a) and (b) with new means of identification displaying a new identification code may be authorised, provided that the traceability is not compromised.
3. The replacement of the means of identification referred to in paragraph 1 shall be carried out as soon as possible and before the expiry of a maximum time period, to be determined by the Member State whose competent authority authorised operators to replace the means of identification, and before the animals are moved to another establishment.
4. Where the identification code of kept bovine, ovine, caprine and porcine animals displayed on the means of identification referred to in points (a) and (b) of Annex III

to Delegated Regulation (EU) 2019/2035 cannot be reproduced on an electronic identifier due to technical limitations, the competent authority shall only allow the application to those animals of a new electronic identifier displaying a new identification code, if both identification codes are recorded in the computer databases referred to in Article 109(1) of Regulation (EU) 2016/429.

Chapter 4

Transitional and final provisions

Article 20

Transitional measures regarding approvals of means of identification

By way of derogation from Articles 9, 10 and 11 of this Regulation, for a transitional period ending on 20 April 2023, Member States may continue to use the means of identification approved before 21 April 2021 in accordance with Regulations (EC) No 1760/2000 and (EC) No 21/2004 and Directive 2008/71/EC, as well as with the acts adopted on the basis of those Regulations and that Directive.

Article 21

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 21 April 2021.

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