

**COMMISSION IMPLEMENTING REGULATION (EU) 2022/1345****of 1 August 2022****laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to registration and approval of establishments keeping terrestrial animals and collecting, producing, processing or storing germinal products****(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 of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') <sup>(1)</sup>, and in particular Article 86(1) and (2) and Article 96(3) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for animal diseases that are transmissible to animals or humans, including rules on the registration and approval by the competent authority of establishments keeping terrestrial animals and collecting, producing, processing or storing germinal products.
- (2) Commission Delegated Regulation (EU) 2019/2035 <sup>(2)</sup> supplements Regulation (EU) 2016/429 by laying down detailed rules concerning the registers to be kept by the competent authority of registered and approved establishments keeping terrestrial animals and collecting, producing, processing or storing germinal products registered with it or approved by it.
- (3) More particularly, Article 18, point (d), of Delegated Regulation (EU) 2019/2035 provides that the competent authority is to include in its register of establishments of kept terrestrial animals and of hatcheries registered with it the address and geographical coordinates (latitude and longitude) of the location of the establishment. Furthermore, Article 18, point (h), of Delegated Regulation (EU) 2019/2035 provides that the competent authority is to include in that register information about the period during which animals or hatching eggs are kept on the establishment if it is not continuously occupied, including seasonal occupation or occupation during particular events. While Article 84(1), point (b), of Regulation (EU) 2016/429 provides that operators of establishments keeping terrestrial animals or collecting, producing, processing or storing germinal products are to provide the competent authority with certain information in order for their establishments to be registered, that information does not include all the detailed information required under Article 18, points (d) and (h), of Delegated Regulation (EU) 2019/2035. It is therefore appropriate to lay down a requirement for the operators of establishments of kept terrestrial animals and of hatcheries to provide such detailed information to the competent authority for the purpose of registration.
- (4) Similarly, Article 21, points (d) and (h), of Delegated Regulation (EU) 2019/2035 also provide that the competent authority is to include in its register of establishments approved by it the same detailed information required by Article 18, points (d) and (h), of that Delegated Regulation. While Article 96(1) of Regulation (EU) 2016/429 requires operators to provide the competent authority with certain information for the purposes of their application for approval of their establishment, that information does not include all the detailed information required under Article 21, points (d) and (h), of Delegated Regulation (EU) 2019/2035. It is therefore appropriate to lay down a requirement for the operators of establishments of kept terrestrial animals and of hatcheries to provide such detailed information to the competent authority for the purpose of approval.

<sup>(1)</sup> OJ L 84, 31.3.2016, p. 1.

<sup>(2)</sup> 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).

- (5) In addition, Article 85 of Regulation (EU) 2016/429 provides that Member States may, by way of derogation from Article 84(1) of that Regulation, exempt from the registration requirement certain categories of establishments posing an insignificant risk to animal or public health. Such exemptions may only be granted if those categories of establishments are of a type falling under the rules laid down in an implementing act adopted in accordance with Article 86(2) of that Regulation. Rules concerning the types of establishments posing an insignificant risk that may be exempted by the Member States from the registration requirement in accordance with Article 85 should therefore be laid down.
- (6) Certain establishments, in particular those keeping ungulates cannot be considered as posing an insignificant risk, as referred to in Article 85 of Regulation (EU) 2016/429, due to a number of listed diseases that may be transmitted by ungulates and which may affect the animal health status of establishments or zones in that respect. Similarly, dogs, cats and ferrets kept on an establishment for breeding purposes cannot be considered as posing an insignificant risk, especially from a human health perspective.
- (7) The movement of animals, germinal products and products of animal origin constitutes an important risk factor for animal and human health. Establishments where movements take place, involving in particular movements to or from other Member States or third countries, should therefore not be considered as posing an insignificant risk. However, establishments where animals, germinal products or products of animal origin are kept with a certain continuity and the primary purpose is not the movement of those animals, germinal products or products of animal origin to or out of the establishment, can be considered as posing an insignificant risk, even if such movements could occur on an occasional basis.
- (8) Operators often keep terrestrial animals of several species on the same establishment. If a Member State exempts from the registration requirement certain categories of establishments posing an insignificant risk, as provided for in Article 85 of Regulation (EU) 2016/429, it is not proportionate to the risk involved to require operators to provide the information referred to in Article 84(1), point (b)(iii), regarding kept terrestrial animals for which the establishment could be exempted from the registration requirement in accordance with Article 3 of this Regulation as if those animals were the only animals kept on that establishment.
- (9) 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:

#### *Article 1*

#### **Subject matter and scope**

This Regulation lays down rules concerning:

- (a) the information to be provided by operators of establishments of kept terrestrial animals and of hatcheries for the purpose of the registration of their establishments, as provided for in Article 84(1) of Regulation (EU) 2016/429;
- (b) the types of establishments keeping terrestrial animals posing an insignificant risk that may be exempted by the Member States from the registration requirement in accordance with Article 85 of Regulation (EU) 2016/429;
- (c) the information to be provided by operators of establishments of kept terrestrial animals and of hatcheries in their application for approval of their establishment in accordance with Article 96(1) of Regulation (EU) 2016/429.

*Article 2***Information to be provided by operators for the purpose of the registration of their establishment**

1. Operators of establishments of kept terrestrial animals and of hatcheries referred to in Article 84(1) of Regulation (EU) 2016/429 shall, in addition to the information referred to in Article 84(1), point (b), of that Regulation, before they commence such activities, provide the competent authority with the following information:

- (a) the address and geographical coordinates (latitude and longitude) of the location of the establishment to be registered;
- (b) the period during which the kept terrestrial animals or hatching eggs are kept on the registered establishment if it is not continuously occupied, including seasonal occupation or occupation during particular events.

2. Operators of establishments of kept terrestrial animals referred to in Article 84(1) of Regulation (EU) 2016/429 shall not be obliged to provide the competent authority with the information referred to in Article 84(1), point (b)(iii), of that Regulation, regarding kept terrestrial animals falling within the derogation used by the Member State in accordance with Article 3 of this Regulation.

*Article 3***Types of establishments keeping terrestrial animals that may be exempted by the Member States from the registration requirement**

1. Member States may exempt from the registration requirement establishments keeping terrestrial animals posing an insignificant risk, as provided for in Article 85 of Regulation (EU) 2016/429, if the following criteria are fulfilled:

- (a) no ungulates are kept on the establishment;
- (b) no dogs, cats or ferrets are kept for breeding on the establishment;
- (c) the establishment is not involved in any movement of kept terrestrial animals, germinal products or products of animal origin to or from another Member State or third country;
- (d) the kept terrestrial animals, germinal products or products of animal origin on the establishment are not intended to be moved out of the establishment.

2. Member States that exempt establishments in accordance with paragraph 1 may lay down additional criteria regarding limitations on the number of kept terrestrial animals that may be kept on such establishments and restrict the geographical location of those establishments, in particular in relation to their proximity to establishments registered or approved by the competent authority.

*Article 4***Information to be provided by operators in their application for approval of their establishment**

Operators of establishments of kept terrestrial animals and of hatcheries shall, for the purposes of their application for approval of their establishment as provided for in Article 94(1) and Article 95, point (a), of Regulation (EU) 2016/429, in addition to the information referred to in Article 96(1) of that Regulation, provide the competent authority with the following information:

- (a) the address and geographical coordinates (latitude and longitude) of the location of the establishment to be approved;
- (b) the period during which animals or hatching eggs are kept on the approved establishment if it is not continuously occupied, including seasonal occupation or occupation during particular events.

*Article 5***Entry into force**

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, 1 August 2022.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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