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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Regulation (EU) 2016/429 on transmissible animal diseases ('Animal Health Law')

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1. INTRODUCTION

Regulation (EU) 2016/429 on transmissible animal diseases ('Animal Health Law')⁽¹⁾ was adopted in 2016. This Regulation entered into force on 21 April 2016, and it has been applicable since 21 April 2021.

The Regulation replaces the entire body of fully harmonised animal health legislation (39 Directives and Regulations) and provides for a simpler and more flexible regulatory framework while ensuring a more risk-based approach to set out animal health requirements, enhanced disease preparedness, prevention and control for listed transmissible diseases.

In addition, it clarifies the role of the different actors in animal health and opens possibilities to reduce administrative burden for farmers, other operators and competent authorities without compromising the animal health status in the Union. Furthermore, it provides more suitable tools to deal with crisis situations (e.g. emerging diseases) or to address specific risks (e.g. antimicrobial resistance) and contributes to fewer economic losses due to disease outbreaks.

According to its provisions, the Commission is empowered to adopt a large number of implementing and delegated acts. It also imposes on the Commission the obligation to report to the co-legislator on the exercise of the delegated powers it contains.

2. LEGAL BASIS

This report is required under Article 264(3) of Regulation (EU) 2016/429. Pursuant to this provision, the power to adopt delegated acts concerning the matters listed therein is conferred on the Commission for a period of five years from 20 April 2016 and the Commission is required to prepare a report in respect of the delegated power at the latest nine months before the end of the five-year period. The previous report was published on 12 February $2021(^2)$.

According to Article 264(3), the Commission is empowered to adopt delegated acts referred to in Articles 3(5), 5(2) 5(4), 14(3), 16(2), 18(3), 20(3), 29, 31(5), 32(2), 37(5), 39, 41(3), 42(6), 47(1), 48(3), 53(2), 54(3), 55(2), 58(2), 63, 64(4), 67, 68(2), 68(3), 70(3), 72(2), 73(3), 74(4), 76(5), 77(2), 87(3), 94(3), 97(2), 101(3), 106(1), 109(2), 118(1), 118(2), 119(1), 122(1), 122(2), 125(2), 131(1), 132(2), 135, 136(2), 137(2), 138(3), 139(4), 140, 144(1), 146(1), 147, 149(4), 151(3), 154(1), 156(1), 160(1), 160(2), 161(6), 162(3), 162(4), 163(5), 164(2), 165(3), 166(3), 167(5), 168(3), 169(5), 176(4), 181(2), 185(5), 189(1), 192(2), 197(3), 200(3), 201(3), 202(3), 203(2), 204(3), 205(2), 211(1), 213(1), 214,

⁽¹⁾ *OJ L 084 31.3.2016, p. 1*

^{(&}lt;sup>2</sup>) <u>COM/2021/57 final</u>

216(4), 218(3), 221(1), 222(3), 223(6), 224(3), 228(1), 230(3), 234(2), 237(4), 239(2), 240(2), 241(2), 242(2), 245(3), 246(3), 249(3), 252(1), 254, 263, 271(2), 272(2), 279(2), and 280(4) of Regulation (EU) 2016/429.

Article 264(3) of that Regulation lays down that the delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period, while Article 264(4) states that the delegation of power may be revoked at any time by the European Parliament or by the Council.

3. EXERCISE OF THE DELEGATION

The Commission exercised the delegation based on Regulation (EU) 2016/429 as from 2018 onwards and drew up a report on the exercised powers for the period from 2016 to 2021 in 2021 (³).

This is the second report on the exercised powers under the cited regulation and it covers a five-year period as from the last report, from 2021 onwards.

During the reporting period, the Commission exercised its delegated powers, by adopting the following delegated acts:

- Commission Delegated Regulation (EU) 2022/139 of 16 November 2021 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the management, storage and replacement of stocks of the Union antigen, vaccine and diagnostic reagent banks and the biosecurity, biosafety and bio-containment requirements for the operation of those banks (⁴);
- Commission Delegated Regulation (EU) 2023/361 of 28 November 2022 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards rules for the use of certain veterinary medicinal products for the purpose of prevention and control of certain listed diseases (⁵);
- Commission Delegated Regulation (EU) 2024/2623 of 30 July 2024 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for approval and recognition of disease-free status of compartments keeping terrestrial animals (⁶).

By now the Commission has used 85 of the 110 empowerments to adopt delegated acts as provided in Regulation (EU) 2016/429.

The below table shows the additional acts adopted since the previous report was published and the relevant empowerments in Regulation (EU) 2016/429.

^{(&}lt;sup>3</sup>) <u>COM/2021/57 final</u>

^{(&}lt;sup>4</sup>) *OJ L 23, 2.2.2022, p. 1–10*

^{(&}lt;sup>5</sup>) *OJ L 52*, 20.2.2023, *p. 1–42*

^{(&}lt;sup>6</sup>) OJ L, 2024/2623, 4.10.2024

Delegated Act	Empowerments in Regulation (EU) 2016/429
Commission Delegated Regulation (EU) 2022/139 of 16 November 2021 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the management, storage and replacement of stocks of the Union antigen, vaccine and diagnostic reagent banks and the biosecurity, biosafety and bio-containment requirements for the operation of those banks	Article 48(3)
Commission Delegated Regulation (EU) 2023/361 of 28 November 2022 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards rules for the use of certain veterinary medicinal products for the purpose of prevention and control of certain listed diseases	Article 47(1)
Commission Delegated Regulation (EU) 2024/2623 of 30 July 2024 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for approval and recognition of disease-free status of compartments keeping terrestrial animals	Article 37(5)

Moreover, several Delegated Regulations adopted before 2021 and included in the previous report, were amended as follows:

Delegated Regulation:	Amended by:	EmpowermentsinRegulation(EU)2016/429
CommissionDelegatedRegulation(EU)2019/2035 of 28June 2019supplementingRegulation(EU)2016/429of	Commission Delegated Regulation (EU) 2020/1625 of 25 August 2020 (⁸)	Articles 118(1), 118(2)
European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and	CommissionDelegatedRegulation (EU)2021/2168 of21 September 2021 (9)	Articles 94(3),97(2),118(1), 118(2), 122(2)

^{(&}lt;sup>8</sup>) OJ L 366, 4.11.2020, p. 1

^{(&}lt;sup>9</sup>) *OJ L 438, 8.12.2021, p. 38*

hatcheries, and the traceability of certain kept	CommissionDelegatedRegulation (EU)2023/590 of	Articles 3(5), 87(3), 94(3), 97(2), 101(3),
terrestrial animals and hatching eggs (⁷)	12 January 2023 (¹⁰)	106(1), 118(1), 118(2), 119(1), 122(2), 271(2), 279(2)
Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product	Commission Delegated Regulation (EU) 2021/880 of 5 March 2021 (¹²)	Articles 122(1), 122(2), 160(1), 160(2) 162(3), 162(4), 163(5), 164(2), 165(3), 279(2)
approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals (¹¹)	Commission Delegated Regulation (EU) 2023/647 of 13 January 2023 (¹³)	Articles 160(1), 160(2), 162(4) and 164(2)
CommissionDelegatedRegulation (EU)2020/687 of17December2019supplementingRegulation(EU)2016/429of	Commission Delegated Regulation (EU) 2021/1140 of 5 May 2021 (¹⁵)	The first paragraph of Articles 67, Article 272(2)
European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (¹⁴)	Commission Delegated Regulation (EU) 2023/751 of 30 January 2023 (¹⁶)	Article 67
CommissionDelegatedRegulation (EU)2020/688 of17DecembersupplementingRegulation	Commission Delegated Regulation (EU) 2021/1706 of 14 July 2021 (¹⁸)	Articles 131(1), 135, 136(2), 140, 144(1), 147, 156(1)

- (⁷) *OJ L 314, 5.12.2019, p. 115*
- (¹⁰) *OJ L* 79, 17.3.2023, *p.* 46
- (¹¹) *OJ L 174, 3.6.2020, p. 1*
- (¹²) *OJ L 194*, 2.6.2021, *p. 1*
- (¹³) *OJ L 81, 21.3.2023, p. 1*
- (¹⁴) OJ L 174, 3.6.2020, p. 64
- (¹⁵) *OJ L 247, 13.7.2021, p. 50*
- (¹⁶) *OJ L 100, 13.4.2023, p. 7*
- (¹⁸) OJ L 339, 24.9.2021, p. 56

(EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (¹⁷)	CommissionDelegatedRegulation (EU)2023/118 of23 September 2022 (19)CommissionDelegatedRegulation (EU)2023/2515 of2.5 September 2022 (20)	Articles 140(b), 149(4) Articles 131(1), points (c) and (d), 132(2), 140(1) 144(1)
	8 September 2023 (²⁰)	140(b), 144(1), points (a) and (b), Article 146(1), Article 149(4)
	Commission Delegated Regulation (EU) 2024/3160 of 9 October 2024 (²¹)	Article 131(1), points (c) and (d),
Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease- free status for certain listed and emerging diseases (²²)	Commission Delegated Regulation (EU) 2021/881 of 23 March 2021 (²³)	the introductory phrase and points (a) and (d) of Article 29, the introductory phrase and points (a) and (b) of Article 31(5), the introductory phrase and point (c) of Article 32(2), the introductory phrase and points (a) and (b) of Article 41(3), Article 42(6)
	CommissionDelegatedRegulation (EU)2023/1570 of23 May 2023 (24)	Article 42(6)
	Commission Delegated Regulation (EU) 2023/1798 of 10 July 2023 (²⁵)	Articles 29, points (a) and (d), 37(5), 39, 41(3)

- (¹⁷) *OJ L 174, 3.6.2020, p. 140*
- (¹⁹) *OJ L 16*, *18.1.2023*, *p. 1*
- (²⁰) *OJ L 2023/2515, 14.11.2023*
- (²¹) *OJ L 2024/3160, 20.12.2024*
- (²²) OJ L 174, 3.6.2020, p. 211
- (²³) *OJ L 194*, 2.6.2021, p. 10
- (²⁴) *OJ L 192, 31.7.2023, p. 9*
- (²⁵) *OJ L 233, 21.9.2023, p. 24*

Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (²⁶)	CommissionDelegatedRegulation (EU)2021/1703 of13 July2021 (27)	Articles 234(2), 237(4), 239(2)
	CommissionDelegatedRegulation (EU)2021/1705 of14 July2021 (28)	Articles 234(2), 237(4), 239(2), 279(2)
	CommissionDelegatedRegulation (EU)2022/54 of21 October 2021 (29)	Article 239(2)
	CommissionDelegatedRegulation (EU)2023/119 of9 November 2022 (30)	Articles 3(5), 234(2), 237(4), 239(2)

Certain empowerments of Regulation (EU) 2016/429 have not been used to date, for the reasons explained below.

- The empowerments of Article 14(3) on tasks that competent authorities can delegate to veterinarians other than official veterinarians and of Article 16(2) on safety measures in laboratories were not used so far. The Commission is continuing to assess the need to prepare specific acts relating to both these empowerments.
- The empowerments of Articles 18(3) and 20(3) related to disease notification and reporting were not used so far. The Commission will assess the need to act in this respect in the light of experience on the practical application of the new rules. The same is true for empowerments Article 151(3) on self-declaration documents for terrestrial animals and Article 167(5) with regard to derogations from the certification obligation for the movements of products of animal origin.
- The empowerment of Article 109(2) concerning the recording of information in computer database of kept terrestrial animals of animal species other than those set out in the basic regulation was not used so far. Nevertheless, it has to be extended to enable the Commission to lay down requirements for the computer database for those animal species if, or when, such need arises in the future. In accordance with this provision, the Commission continuously assesses the need to proceed with the preparation of a delegated act to lay down such requirements.
- The empowerments of Article 138(3) and 139(4) as regards the rules for the granting of derogations by competent authorities for certain movements of terrestrial animals were not used so far. Similar conditions apply for the empowerments of Articles 200 and Article 204 on certain types of movements of aquatic animals and Article 214 as

- (²⁹) *OJ L 10, 17.1.2022, p. 1*
- (³⁰) *OJ L 16*, *18.1.2023*, *p. 5*

^{(&}lt;sup>26</sup>) *OJ L 174, 3.6.2020, p. 379*

^{(&}lt;sup>27</sup>) *OJ L 339*, 24.9.2021, *p*. 29

^{(&}lt;sup>28</sup>) *OJ L 339*, 24.9.2021, *p.* 40

regards rules for animal health certification for specific types of movements of aquatic animals. The Commission will continuously assess the need to act in this respect in the light of experience on the practical application of the new rules.

- The empowerment of Article 228 enabling the Commission to lay down animal health requirements for "other animals", i.e. animals that are neither terrestrial nor aquatic animals, was not used so far. The Commission has not acted to date, but it should be in a position to lay down animal health rules for such animals (e.g. reptiles, amphibians) when the health risk involved requires more detailed or specific traceability, disease prevention or control rules for such species.
- The empowerment of Article 230(3) as regards limiting the possibility for Member States to draw lists of third countries from which they can allow entry of certain commodities in the Union in the absence of the lists to be drawn up in Union legislation was not used so far. The lists of third countries for all commodities are not drawn up in Union legislation. The Commission follows closely the evolvement of the lists and assesses the need for the rules to be adopted based on this empowerment. The Commission therefore considers it prudent to keep this empowerment for the future.
- The empowerments of Articles 240 to 242 give powers to the Commission to lay down at Union level specific protective and preventive measures, including biosecurity, related to entry into the Union of certain products and means of transport. These empowerments are important as they provide for a possibility for such rules to be developed in the future in order to prevent the spread of animal diseases into the EU and contribute to reinforce biosecurity at the EU external borders.
- A delegated act on non-commercial movements of pet animals using the empowerments of Part VI (Articles 245 to 254) of Regulation (EU) 2016/429 is in development and its adoption is planned in 2025.
- The empowerment of Article 263 to amend Annex III to Regulation (EU) 2016/429 was not used during the reporting period, as there were no taxonomical changes giving the reason for such amendment. Such taxonomical changes may happen at any time and the Commission may need to react accordingly and introduce necessary amendments.

4. CONCLUSION

Given the fact that Regulation (EU) 2016/429 has been in force since 21 April 2021 and that the empowerments have been used so far extensively and for the benefit of Member States and the agriculture and aquaculture sectors in the Union, the Commission sees the need to extend all empowerments to adopt delegated acts as provided for in that Regulation beyond the current five-year period. The possibility to develop rules based on the empowerments remains of importance in order to provide the necessary flexibility in the implementation of the rules, their simplification and clarification, to adjust them regularly to the latest scientific standards and to give possibility to the Commission to act in the areas where it did not to this moment, but it may need to do so in the future.