EUROPEAN
COMMISSION

Brussels, 12.2.2021
COM(2021) 57 final

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 shall apply from 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.

According the 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, 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.

[1] *OJ L 084 31.3.2016, p. 1*

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

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

- Commission Delegated Regulation (EU) 2018/1629 of 25 July 2018 amending the list of diseases set out in Annex II 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')[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[3]

- 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 establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals[4]

- Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (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[5]

- 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[6]

- Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases[7]

- Commission Delegated Regulation (EU) 2020/691 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for aquaculture establishments and transporters of aquatic animals[8],

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2 *OJ L 272, 31.10.2018, p. 11*
3 *OJ L 314, 5.12.2019, p. 115*
4 *OJ L 174, 3.6.2020, p. 1*
5 *OJ L 174, 3.6.2020, p. 140*
6 *OJ L 174, 3.6.2020, p. 211*
7 OJ L 174, 3.6.2020, p. 64
8 *OJ L 174, 3.6.2020, p. 345*

- 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[9]

- Commission Delegated Regulation (EU) 2020/990 of 28 April 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health and certification requirements for movements within the Union of aquatic animals and products of animal origin from aquatic animals[10]

- Commission Delegated Regulation (EU) 2020/2154 of 14 October 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards animal health, certification and notification requirements for movements within the Union of products of animal origin from terrestrial animals[11].

By now the Commission has used 83 of the 110 empowerments to adopt delegated acts as provided in Regulation (EU) 2016/429. Some of these delegated powers were bundled in a single delegated act where the rules are substantively linked. The bundling in a single act rather than a number of cross-referenced separate acts was considered necessary in the interest of simplicity, transparency, to facilitate the effective application of the rules and to avoid duplication.

The below table shows which acts contain the specific measures adopted under the relevant empowerments in Regulation (EU) 2016/429.

Delegated Act	Empowerments in Regulation (EU) 2016/429
Commission Delegated Regulation (EU) 2018/1629 of 25 July 2018 amending the list of diseases set out in Annex II 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')	Article 5(2) and (4)
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	Articles 3(5), 87(3), 94(3), 97(2), 101(3), 106(1), 118(1) and (2), 119(1) and 122(2), Articles 271(2) and 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 establishments and the traceability and animal health requirements	Articles 94(3), Article 97(2), Article 101(3), Article 106(1), Article 122(1) and (2), Article 131(1), Article 160(1) and (2), Article 161(6), Article 162(3) and (4), Article 163(5), Article 164(2), Article 165(3) and Article 279(2)

9 *OJ L 174, 3.6.2020, p. 379*
10 *OJ L 221, 10.7.2020, p. 42*
11 *OJ L 431, 21.12.2020, p. 5*

for movements within the Union of germinal products of certain kept terrestrial animals	
Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (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	Article 3(5), Article 125(2), Article 131(1), Article 132(2), Article 135, Article 136(2), Article 137(2), Article 140, Article 144(1), Article 146(1), Article 147, Article 149(4), Article 154(1), Article 156(1), Article 160, Article 162(3) and (4), Article 163(5)(b) and (c) and Article 164(2)
Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases	Articles47(1), Article 53(2), Article 54(3), Article 55(2), Article 58(2), the first paragraph of Article 63, Article 64(4), the first paragraph of Article 67, Article 68(3), Article 70(3), Article 72(2), Article 73(3), Article 74(4), Article 76(5), Article 77(2) and Article 272(2)
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	Article 29, Article 31(5), 32(2), 37(5), Article 39, Article 41(3), Article 42(6) and Article 280(4)
Commission Delegated Regulation (EU) 2020/691 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for aquaculture establishments and transporters of aquatic animals	Articles 176(4), 181(2), 185(5), 189(1) and 279(2)
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	Articles 234(2), 237(4) and 239(2)
Commission Delegated Regulation (EU) 2020/990 of 28 April 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health and certification requirements for movements within the Union of aquatic animals and products of animal origin from aquatic animals	Articles 192(2), 197(3), 201(3), 202(3), 205(2), 211(1), 213(1), 216(4), 218(3), 221(1), 222(3), 223(6), and 224(3)
Commission Delegated Regulation (EU) 2020/2154 of 14 October 2020 supplementing	Articles 166(3), 168(3) and 169(5)

Regulation (EU) 2016/429 of the European Parliament and of the Council as regards animal health, certification and notification requirements for movements within the Union of products of animal origin from terrestrial animals	

Certain empowerments of Regulation (EU) 2016/429 have not been used during the reporting period 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. However, the Commission is assessing the need to proceed with the preparation of specific acts to cover those aspects, especially in light of experience on the practical application of the new rules.

- The empowerments in Articles 18(3) and 20(3) related to disease notification and reporting were not used so far. Once Regulation (EU) 2016/429 becomes applicable, rules on their basis might be needed to address any implementation problem that may arise in Member States, or for the Commission. 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 of Article 68(3) concerning the restoration of disease free status for certain animal diseases, 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.

- A delegated act on Union antigen, vaccine and diagnostic reagent banks using the empowerment of Article 48(3) is in development and its adoption is planned in 2021.

- 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. 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 on specific types of movements of terrestrial animals laid down in Articles 138 and 139 were not used. Nevertheless, such rules providing further details may be needed after the date of application of Regulation (EU) 2016/429 in case difficulties arise in the implementation of those provisions. Similar conditions apply for the empowerments of Articles 200 and Article 204 on certain types of movements of aquatic animals and Article 214 as 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 so far, 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 need to gather more experience on the practical application of the new rules before deciding to develop such acts.

- 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.

- The empowerments of Part VI (Articles 245 to 254) of Regulation (EU) 2016/429 on non-commercial movements of pet animals were not used. In accordance with Article 277 the rules laid down in Part VI will only apply after 21 April 2026. The Commission will use those powers once Part VI starts applying.

- 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 is not yet applicable, 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 need to develop rules based on the empowerments will remain in the future. This will be particularly important to provide the necessary flexibility in the implementation of the new rules, 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.