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') (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) 2018/1629

of 25 July 2018

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(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')[(1)], and in particular Article 5(2) and (4) thereof,

Whereas:

(1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases which are transmissible to animals or to humans, including rules for the prioritisation and categorisation of diseases of Union concern. Article 5 of Regulation (EU) 2016/429 provides that disease-specific rules for the prevention and control of diseases apply to the diseases listed in that Article and in Annex II to that Regulation. In addition, Article 5(3) of that Regulation lays down certain criteria to be taken into account in amending the list in that Annex, while the assessment parameters to be used in order to determine whether a disease meets the conditions requiring it to be listed in accordance with that Article are laid down in Article 7 of that Regulation.

(2) In addition, Article 275 of Regulation (EU) 2016/429 provides that the Commission is to review the list of diseases set out in Annex II to that Regulation by 20 April 2019 at the latest.

(3) The Commission systematically assessed the animal diseases which require Union intervention with the assistance of the European Food Safety Authority (EFSA), drawing on the scientific expertise provided by the EU Animal Health Reference Laboratories and the international standards of the World Organisation for Animal Health (OIE). For the purposes of that assessment, it used the criteria laid down in Article 5(3) of Regulation (EU) 2016/429 and the assessment parameters laid down in Article 7 of that Regulation.

(4) The assessed diseases consist of 39 diseases that are currently listed in Annex II to Regulation (EU) 2016/429, as well as another 19 diseases of special relevance for disease prevention, control or trade measures, such as enzootic bovine leukosis, infectious bovine rhinotracheitis or infection with Aujeszky's disease virus, and certain other diseases which have been listed by the OIE, such as surra (*Trypanosoma evansi*) or contagious caprine pleuropneumonia.

(5) For the purposes of the assessments, 29 scientific opinions were requested from EFSA on different animal diseases. In providing them, EFSA followed the method set out in its Scientific Opinion adopted on 5 April 2017 on ad hoc method for the assessment on listing and categorisation of animal diseases within the framework of the Animal Health Law[(2)]. For the remaining diseases, the assessments were based on recent EFSA opinions or on information provided by the EU Animal Health Reference Laboratories. As regards all assessed diseases, the relevant OIE standards were considered.

(6) The results of the scientific assessments by EFSA were inconclusive for certain diseases such as surra (Trypanosoma evansi)[(3)], enzootic bovine leukosis[(4)], Venezuelan equine encephalomyelitis[(5)], infestation with *Varroa spp.* (Varroosis)[(6)] and Koi herpes virus disease[(7)]. Taking into account the discussions held at the meetings of the expert group on animal health[(8)], those five diseases fulfil the requirements laid down in Article 5(3) of Regulation (EU) 2016/429. Therefore those diseases should be included in the list set out in Annex II to that Regulation.

(7) The results of the scientific assessments carried out showed that swine vesicular disease[(9)], vesicular stomatitis[(9)], epizootic ulcerative syndrome[(10)] and Teschen disease do not fulfil the requirements laid down in Article 5(3) of Regulation (EU) 2016/429. Therefore, those diseases should be removed from the list set out in Annex II to that Regulation.

(8) At the same time, surra (Trypanosoma evansi)[(3)], Ebola virus disease[(11)], paratuberculosis[(12)], Japanese encephalitis[(13)], West Nile fever[(14)], Q fever[(15)], infectious bovine rhinotracheitis/infectious pustular vulvovaginitis[(16)], bovine viral diarrhoea[(17)], bovine genital campylobacteriosis[(18)], trichomonosis[(19)], enzootic bovine leukosis[(4)], contagious caprine pleuropneumonia[(20)], ovine epididymitis (*Brucella ovis*)[(21)], infection with *Burkholderia mallei* (Glanders), infection with equine arteritis virus, equine infectious anaemia, dourine, contagious equine metritis, equine encephalomyelitis (Eastern and Western)[(22)], infection with Aujeszky's disease virus[(23)], infection with porcine reproductive and respiratory syndrome virus[(24)], avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*)[(25)], infection with low pathogenic avian influenza viruses[(26)], avian chlamydiosis[(27)], infestation with *Varroa spp.* (Varroosis)[(6)], infestation with *Aethina tumida* (Small hive beetle)[(28)], American foulbrood, infestation with *Tropilaelaps spp*[(28)] and infection with *Batrachochytrium salamandrivorans*[(29)] do fulfil the requirements laid down in Article 5(3) of Regulation (EU) 2016/429. Therefore those diseases should be included in the list set out in Annex II to that Regulation.

(9) In addition, Article 2(2) of Regulation (EU) 2016/429 provides that that Regulation is to apply to transmissible diseases, including zoonosis, without prejudice to rules laid down in Decision No 1082/2013/EU of the European Parliament and of the Council[(30)], Regulation (EC) No 999/2001 of the European Parliament and of the Council[(31)], Directive 2003/99/EC of the European Parliament and of the Council[(32)] and Regulation (EC) No 2160/2003 of the European Parliament and of the Council[(33)]. As the diseases covered by the rules laid down in those acts, namely listeriosis, salmonellosis (zoonotic salmonella), trichinellosis, verotoxigenic E. coli and transmissible spongiform encephalopathies (TSE) are already covered by sector-specify rules, they should therefore be removed from the list set out in Annex II to Regulation (EU) 2016/429.

(10) The list of diseases in Annex II to Regulation (EU) 2016/429 should therefore be amended accordingly.

(11) Regulation (EU) 2016/429 should therefore be amended.

(12) As Regulation (EU) 2016/429 applies with effect from 21 April 2021, the amendments made to it by this Regulation should also apply from that date,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EU) 2016/429 is replaced by the text set out in the Annex to this Regulation.

Article 2

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, 25 July 2018.

For the Commission

The President

Jean-Claude JUNCKER