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From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 25.7.2018 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')

Delegations will find attached document C(2018) 4785 final.

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Brussels, 25.7.2018
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COMMISSION DELEGATED REGULATION (EU) .../...

of 25.7.2018

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

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 (hereinafter the 'AHL') establishes a list of transmissible animal diseases (listed diseases). That list is set out in Article 5 and Annex II to that Regulation, and it comprises diseases which pose a risk to animal or public health in the Union and which can have an impact on animal or public health, the economy or the environment.

The list of diseases in Annex II to Regulation (EU) 2016/429 is not comprehensive and up-to-date. Pursuant to Article 275 of that Regulation, the Commission is required to review that list by 20 April 2019 at the latest. Should it be apparent from that review that an application of the rules set out in Regulation (EU) 2016/429 requires Annex II to be amended, the Commission is required to amend that Annex.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE DELEGATED ACT

Rules on animal diseases are currently laid down in various Union acts, mainly Directives and some Regulations according to subject matter such as disease notification (e.g. Council Directive 82/894/EEC on the notification of animal diseases within the Community²), disease control (e.g. Council Directive 2003/85/EC on Community measures for the control of foot-and-mouth disease³, Council Directive 2001/89/EC on Community measures for the control of classical swine fever⁴) or cross-border trade in animals (e.g. Council Directive 92/65/EEC laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC⁵).

Pursuant to Article 5 of the AHL, a disease fulfils the criteria to be listed if it complies with all of the following requirements: it is transmissible and the susceptible species, reservoir or vectors are present in the EU and it has negative effects on animal health or poses a risk to public health and there are diagnostic tools available and the risk mitigating measures or surveillance is effective and proportionate in the Union. In addition, in order for a disease to fulfil the criteria to be listed, it needs to fulfil at least one of the following requirements: it causes significant negative effects on animal health or public health or the economy or the environment or biodiversity or has the potential to generate a crisis or to be used in bioterrorism actions or has developed resistance to treatments.

¹ OJ L 84, 31.3.2016, p. 1.

² OJ L 378, 31.12.1982, p. 58.

³ OJ L 306, 22.11.2003, p. 1.

⁴ OJ L 316, 1.12.2001, p. 5.

⁵ OJ L 268, 14.9.1992, p. 54.

Following the analysis of the criteria laid down in Article 5 of the AHL, a comprehensive evaluation of the diseases that could be relevant for Union intervention has been carried out together with the European Food Safety Authority (EFSA), the EU Animal Health Reference Laboratories (EURLs) and available information from the World Organisation for Animal Health (OIE), the international standard setting body for animal health.

The review of the list of diseases has taken into account both the diseases listed in Annex II of the AHL, and additional diseases currently listed for disease prevention, control or trade measures such as enzootic bovine leukosis, infectious bovine rhinotracheitis⁶ or Ebola virus disease⁷. In addition, other diseases of special relevance, such as contagious caprine pleuropneumonia or surra (*Trypanosoma evansi*), which are currently not covered by Union acts, were also assessed due to the importance that the OIE attaches to them.

All these diseases have been scrutinised against the set of criteria laid down in Article 5 of the AHL for the protection of animal health, public health and the environment in the Union.

To avoid duplication, this evaluation did not take into consideration zoonotic diseases and transmissible spongiform encephalopathies (TSE) which are already covered by specific EU legislation.⁸

For some diseases (infection with Rift Valley fever virus⁹, infection with rabies virus¹⁰, infestation with *Echinococcus multilocularis*¹¹, infection with epizootic haemorrhagic disease virus¹², Q fever¹³, infection with lumpy skin disease virus¹⁴, sheep pox and goat pox¹⁵, infection with peste des petits ruminants virus¹⁶, swine vesicular disease¹⁷, vesicular stomatitis¹⁸, infection with Newcastle disease virus¹⁹, avian chlamydiosis²⁰, infestation with *Aethina tumida* (Small hive beetle)²¹, infestation with *Tropilaelaps spp*²² and epizootic ulcerative syndrome²³, infection with highly polymorphic region (HPR) deleted infectious salmon anaemia virus²⁴) the EFSA delivered opinions which were adopted shortly before this review and independently of it. In the cases where these opinions gave sufficient information on

⁶ OJ 121, 29.7.1964, p. 1977.

⁷ OJ L 268, 14.9.1992, p. 54.

⁸ OJ L 293, 5.11.2013, p. 1; OJ L 147, 31.5.2001, p. 1; OJ L 325, 12.12.2003, p. 31; OJ L 325, 12.12.2003, p. 1.

⁹ EFSA Journal 2013;11(4):3180. [48 pp.]

¹⁰ EFSA Journal 2015;13(7):4164, 70 pp.

¹¹ EFSA Journal 2015;13(12):4373, 129 pp.

¹² EFSA Journal 2009; 7(12): 1418 pp. [67 pp.]

¹³ EFSA Journal 2010; 8(5):1595. [114 pp.]

¹⁴ EFSA Journal 2015;13(1):3986, 73 pp.

¹⁵ EFSA Journal 2014;12(11):3885, 122 pp.

¹⁶ EFSA Journal 2015; 13 (1):3985.

¹⁷ EFSA Journal 2012;10(4):2631. [97 pp.]

¹⁸ EFSA Journal 2012;10(4):2631. [97 pp.]

¹⁹ EFSA Journal (2007), 477,1-25.

²⁰ https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scah_out73_en.pdf

²¹ EFSA Journal 2013;11(3):3128. [127 pp.] doi:10.2903/j.efsa.2013.3128

²² EFSA Journal 2013;11(3):3128. [127 pp.] doi:10.2903/j.efsa.2013.3128

²³ EFSA Journal 2011;9(10):2387. [58 pp.]

²⁴ EFSA Journal 2012;10(11):2971.[22 pp.]

the criteria for the listing of diseases, the conclusions of the opinions were used to complete the assessment of those diseases.

In addition, for some diseases the evaluation drew on the EURLs' scientific expertise and the international standards of the OIE (infection with rinderpest virus, infection with *Burkholderia mallei* (Glanders), infection with equine arteritis virus, equine infectious anaemia, dourine, contagious equine metritis, Teschen disease, American foulbrood, epizootic haematopoietic necrosis, viral haemorrhagic septicaemia, infectious haematopoietic necrosis, infection with *Mikrocytos mackini*, infection with *Perkinsus marinus*, infection with *Bonamia ostreae*, infection with *Bonamia exitiosa*, infection with *Marteilia refringens*, infection with Taura syndrome virus, infection with yellow head virus and infection with white spot syndrome virus).

Furthermore, for those diseases for which either no recent scientific information was available, or due to their particularities and likely implications for farmers and Member States, the EFSA adopted new scientific opinions within the framework of Regulation (EU) 2016/429 (infection with *Brucella abortus*, *B. melitensis* and *B. suis*²⁵, infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*)²⁶, infection with bluetongue virus (serotypes 1-24)²⁷, anthrax²⁸, surra (*Trypanosoma evansi*)²⁹, Ebola virus disease³⁰, Borna disease³¹, paratuberculosis³², Japanese encephalitis³³, West Nile fever³⁴, infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia)³⁵, infectious bovine rhinotracheitis/infectious pustular vulvovaginitis³⁶, bovine viral diarrhoea³⁷, bovine genital campylobacteriosis³⁸, trichomonosis³⁹, enzootic bovine leukosis⁴⁰, contagious caprine pleuropneumonia⁴¹, ovine epididymitis (*Brucella ovis*)⁴², Border disease⁴³, Venezuelan equine encephalomyelitis⁴⁴, equine encephalomyelitis (Eastern and Western)⁴⁵, infection with Aujeszky's disease virus⁴⁶, infection with porcine reproductive and respiratory syndrome virus⁴⁷, avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*)⁴⁸, infection with

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- 25 EFSA Journal 2017;15(7):4889, 46 pp
26 EFSA Journal 2017;15(8):4959, 42 pp
27 EFSA Journal 2017;15(8):4957, 74 pp
28 EFSA Journal 2017;15(7):4958, 32 pp
29 EFSA Journal 2017;15(7):4892, 34 pp
30 EFSA Journal 2017;15(7):4890, 37 pp
31 EFSA Journal 2017;15(7):4951,33 pp
32 EFSA Journal 2017;15(7):4960, 47 pp
33 EFSA Journal 2017;15(7):4948, 23 pp
34 EFSA Journal 2017;15(8):4955, 51 pp
35 EFSA Journal 2017;15(10):4995, 30 pp
36 EFSA Journal 2017;15(7):4947, 25 pp
37 EFSA Journal 2017;15(8):4952, 45 pp
38 EFSA Journal 2017;15(10):4990, 30 pp
39 EFSA Journal 2017;15(10):4992, 37 pp
40 EFSA Journal 2017;15(8):4956, 28 pp
41 EFSA Journal 2017;15(10):4996, 27 pp
42 EFSA Journal 2017;15(10):4994, 30 pp
43 EFSA Journal 2017;15(10):4993, 30 pp
44 EFSA Journal 2017;15(8):4950, 23 pp
45 EFSA Journal 2017;15(7):4946, 26 pp
46 EFSA Journal 2017;15(7):4888, 25 pp
47 EFSA Journal 2017;15(7):4949, 34 pp
48 EFSA Journal 2017;15(8):4953, 40 pp

Salmonella Pullorum, *S. Gallinarum* and *S. arizonae*⁴⁹, infection with low pathogenic avian influenza viruses⁵⁰, infestation with *Varroa spp.* (Varroosis)⁵¹, infection with *Batrachochytrium salamandrivorans*⁵² and Koi herpes virus disease⁵³).

In addition to this science-based preparatory work, extensive consultations with experts from Member States and interested stakeholders have been held which contributed to the review of the list of diseases set out in Annex II to Regulation (EU) 2016/429⁵⁴.

The draft delegated regulation was available to public for feedback through the Commission's 'Better regulation portal' during the period between 2 May and 30 May 2018. 21 feedbacks were received in total, including opinion of 13 stakeholders (Copa-Cogeca, FESASS, Dogs Trust, British and Irish association of Zoos and aquariums, European Association of Zoo and Wildlife Veterinarians, Ornamental Fish International (OFI) and European Pet organization, (EPO), Comité Interprofessionnel des Produits de l'aquaculture, Federation of Veterinarians of Europe, World Horse Welfare, European association of Zoos and Aquaria (EAZA), Swedish Association for the Protection of animals, Federation of Swedish Farmers) and 8 citizens opinions. The following comments were made: inclusion of some new diseases into the list and exemptions for certain categories of animals (e.g. captive birds, zoo animals) from the general requirements for some diseases.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Article 5(2) and (4) of Regulation (EU) 2016/429 provide for the adoption of delegated acts concerning amendments to the list of diseases set out in Annex II thereto.

⁴⁹ EFSA Journal 2017;15(8):4954, 50 pp

⁵⁰ EFSA Journal 2017;15(7):4891, 34 pp

⁵¹ EFSA Journal 2017;15(10):4997, 25 pp

⁵² EFSA Journal 2017;15(11):5071, 34 pp

⁵³ EFSA Journal 2017;15(7):4907, 35 pp

⁵⁴ https://ec.europa.eu/food/animals/health/expert_group_en,
https://ec.europa.eu/food/animals/health/advisory_committees_en

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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

¹ OJ L84, 31.3.2016, p. 1.

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 Law². 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 leukosis⁴, Venezuelan equine encephalomyelitis⁵, infestation with *Varroa spp.* (Varroosis)⁶ and Koi herpes virus disease⁷. Taking into account the discussions held at the meetings of the expert group on animal health⁸, 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 disease⁹, vesicular stomatitis¹⁰, epizootic ulcerative syndrome¹¹ 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*)¹², Ebola virus disease¹³, paratuberculosis¹⁴, Japanese encephalitis¹⁵, West Nile fever¹⁶, Q fever¹⁷, infectious bovine rhinotracheitis/infectious pustular vulvovaginitis¹⁸, bovine viral diarrhoea¹⁹, bovine genital campylobacteriosis²⁰, trichomonosis²¹, enzootic bovine leukosis²²,

² EFSA Journal 2017;15(7):4783.

³ EFSA Journal 2017;15(7):4892.

⁴ EFSA Journal 2017;15(8):4956.

⁵ EFSA Journal 2017;15(8):4950.

⁶ EFSA Journal 2017;15(10):4997.

⁷ EFSA Journal 2017;15(7):4907.

⁸ https://ec.europa.eu/food/animals/health/expert_group_en

⁹ EFSA Journal 2012;10(4):2631.

¹⁰ EFSA Journal 2012;10(4):2631.

¹¹ EFSA Journal 2011;9(10):2387.

¹² EFSA Journal 2017;15(7):4892.

¹³ EFSA Journal 2017;15(7):4890.

¹⁴ EFSA Journal 2017;15(7):4960.

¹⁵ EFSA Journal 2017;15(7):4948.

¹⁶ EFSA Journal 2017;15(8):4955.

¹⁷ EFSA Journal 2010; 8(5):1595.

¹⁸ EFSA Journal 2017;15(7):4947.

¹⁹ EFSA Journal 2017;15(8):4952.

²⁰ EFSA Journal 2017;15(10):4990.

²¹ EFSA Journal 2017;15(10):4992.

²² EFSA Journal 2017;15(8):4956.

contagious caprine pleuropneumonia²³, ovine epididymitis (*Brucella ovis*)²⁴, infection with *Burkholderia mallei* (Glanders), infection with equine arteritis virus, equine infectious anaemia, dourine, contagious equine metritis, equine encephalomyelitis (Eastern and Western)²⁵, infection with Aujeszky's disease virus²⁶, infection with porcine reproductive and respiratory syndrome virus²⁷, avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*)²⁸, infection with low pathogenic avian influenza viruses²⁹, avian chlamydiosis³⁰, infestation with *Varroa spp.* (Varroosis)³¹, infestation with *Aethina tumida* (Small hive beetle)³², American foulbrood, infestation with *Tropilaelaps spp*³³ and infection with *Batrachochytrium salamandrivorans*³⁴ 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 Council³⁵, Regulation (EC) No 999/2001 of the European Parliament and of the Council³⁶, Directive 2003/99/EC of the European Parliament and of the Council³⁷ and Regulation (EC) No 2160/2003 of the European Parliament and of the Council³⁸. 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.

²³ EFSA Journal 2017;15(10):4996.

²⁴ EFSA Journal 2017;15(10):4994.

²⁵ EFSA Journal 2017;15(7):4946.

²⁶ EFSA Journal 2017;15(7):4888.

²⁷ EFSA Journal 2017;15(7):4949.

²⁸ EFSA Journal 2017;15(8):4953.

²⁹ EFSA Journal 2017;15(7):4891.

³⁰ Report of the Scientific Committee on Animal Health and Animal Welfare adopted on 16 April 2002, https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scah_out73_en.pdf

³¹ EFSA Journal 2017;15(10):4997.

³² EFSA Journal 2013;11(3):3128.

³³ EFSA Journal 2013;11(3):3128.

³⁴ EFSA Journal 2017;15(11):5071.

³⁵ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

³⁶ Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

³⁷ Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31).

³⁸ Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents (OJ L 325, 12.12.2003, p. 1).

(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, 25.7.2018

*For the Commission
The President
Jean-Claude JUNCKER*