EFTA SURVEILLANCE AUTHORITY DELEGATED DECISION

of 22 April 2021

approving the disease-free status of rabies virus (RABV) of Norway and amending Decision No 032/21/COL [2021/1333]

THE EFTA SURVEILLANCE AUTHORITY,

Having regard to the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, in particular Articles 1(2) and 3 of Protocol 1 thereof,

Having regard to the Act referred to at Point 13. of Part 1.1 of Chapter I of Annex I to the Agreement on the European Economic Area ('EEA Agreement'), 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 ([1]) ('Regulation (EU) 2016/429'), as amended and as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to that Agreement, and in particular Articles 36(3) and 266 (2) thereof,

Having regard to the Act referred to at Point 13h. of Part 1.1 of Chapter I of Annex I to the EEA Agreement, 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 ([2]) ('Delegated Regulation (EU) 2020/689'), as adapted by the specific and the sectoral adaptations referred to in Annex I to that Agreement, and in particular Article 70(3) thereof,

as adapted to the EEA Agreement by point 4(d) of the Protocol 1 to the EEA Agreement,

Whereas:

Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/689 were incorporated into the Annexes to the EEA Agreement with effect from 17 April 2021. In accordance with the application date stated in each of Regulation (EU) 2016/429, Commission Delegated Regulation (EU) 2020/687 ([3]) and Delegated Regulation (EU) 2020/689, those Regulations apply from 21 April 2021.

Regulation (EU) 2016/429 establishes a new legislative framework for the prevention and control of diseases transmissible to animals or humans. In particular, it provides for approval of the disease-free status of States of the European Economic Area ('EEA States') or zones thereof with regard to certain diseases listed in Article 5(1) of that Regulation for one or more relevant animal species ('statuses').

Decision No 032/21/COL lists the disease-free and non-vaccination statuses and eradication programmes of Norway and Iceland and zones or compartments thereof approved in accordance with Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/689.

([1]) OJ L 84, 31.3.2016, p. 1.
([2]) OJ L 174, 3.6.2020, p. 211.
([3]) 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 (OJ L 174, 3.6.2020, p. 64).

For certain listed diseases, including infection with rabies virus (RABV), Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/689 establish for the first time rules for the approval of the disease-free status for Member States or zones or compartments thereof.

Article 36(3) of Regulation (EU) 2016/429 provides that applications for disease-free status of EEA States or zones thereof for certain listed diseases shall be approved where freedom from the disease in question has been demonstrated by historical and surveillance data.

Pursuant to Article 39(a)(iii) of Regulation (EU) 2016/429, Article 70 of Delegated Regulation (EU) 2020/689 establishes the criteria for recognition of the disease-free status of an EEA State or zone thereof based on historical or surveillance data, including in relation to infection with rabies virus (RABV).

Article 70(3) of Delegated Regulation (EU) 2020/689 provides that the Authority *"may, for a period of two years following the entry of application of this Regulation, grant disease-free status to [Norway] or zones as regards:*

(a) infection with RABV, if it was notifiable in accordance with Article 8 of Directive 64/432/EEC and, when necessary monitoring was implemented in accordance with Article 4 of Directive 2003/99/EC of the European Parliament and of the Council ([4]), and no case was reported in listed animals species for the past two years;".

By letter dated 25 November 2020 (Doc No 1166401), the Norwegian Food Safety Authority submitted to the Authority an application for approval of disease-free status for the whole territory of Norway concerning infection with rabies virus (RABV). This application was accompanied by a report of the Norwegian Veterinary Institute provided for the purpose of demonstrating the historical freedom of Norway from infection from rabies virus (RABV) (Doc No 1166395).

The Authority, in close cooperation with the European Commission, has examined the report and, in light of that information, considers that the conditions laid down in Article 36(3) of Regulation (EU) 2016/429 and Article 70(3)(a) of Delegated Regulation (EU) 2020/689 are fulfilled by Norway (Doc No 1190351). The status of Norway as free from infection with rabies virus (RABV) is therefore approved by the Authority by this Decision and the Annex to Decision No 032/21/COL is amended accordingly.

The Authority, by its Delegated Decision No 030/21/COL (Document No 1194415), duly submitted the draft Decision to the Committee in accordance with Articles 36(4) and 266(2) of Regulation (EU) 2016/429. The Committee approved the draft Decision. Accordingly, the draft Decision is in accordance with the opinion of the Committee.

Consequently Decision No 032/21/COL is to be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The status of free from infection with rabies virus (RABV) for the whole territory of Norway is hereby approved.

The Annex of Decision No 032/21/COL is hereby replaced by the Annex to this Decision.

([4]) The Act referred to at Point 8a. of Part 7.1. of Chapter I of Annex I to the EEA Agreement, 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, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to the EEA Agreement.

Article 2

This Decision shall enter into force on the day of its signature.

Article 3

This Decision is addressed to Norway.

Article 4

This Decision shall be authentic in the English language.

Done at Brussels, 22 April 2021.

For the EFTA Surveillance Authority, acting under Delegation Decision No 130/20/COL,

Högni S. KRISTJÁNSSON	Carsten ZATSCHLER
Responsible College Member	*Countersigning as Director, Legal and Executive Affairs*

ANNEX

Disease-free and non-vaccination statuses and eradication programmes of Norway and Iceland or zones or compartments thereof approved in accordance with Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/689

In Norway:

Disease-free or non- vaccination status	Area: Whole territory or zone	Legal Basis	No of previous or new EFTA Surveillance Authority Decision
infection with *Brucella abortus, B. melitensis and B. suis* in bovine animal populations	Whole territory	Article 84(1)(a)(i) of Delegated Regulation (EU) 2020/689	28/07/COL of 19 February 2007 (previous Decision repealed)
infection with *Brucella melitensis* in ovine and caprine animal populations	Whole territory	Article 84(1)(a)(ii) of Delegated Regulation (EU) 2020/689	029/21/COL of 13 April 2021 (previous Decision repealed)
infection with *Mycobacterium tuberculosis* complex (*M. bovis, M.caprae and M. tuberculosis*) ('MTBC')	Whole territory	Article 84(1)(b) of Delegated Regulation (EU) 2020/689	28/07/COL of 19 February 2007 (previous Decision repealed)
Enzootic bovine leucosis ('EBL')	Whole territory	Article 84(1)(c) of Delegated Regulation (EU) 2020/689	28/07/COL of 19 February 2007 (previous Decision repealed)
Infectious bovine rhinotracheitis ('IBR')/infectious pustular vulvovaginitis ('IPV')	Whole territory	Article 84(1)(d) of Delegated Regulation (EU) 2020/689	159/10/COL of 21 April 2010 (previous Decision repealed)
infection with Aujeszky's disease virus ('ADV')	Whole territory	Article 84(1)(e) of Delegated Regulation (EU) 2020/689	160/10/COL of 21 April 2010 (previous Decision repealed)
infection with Newcastle disease virus without vaccination	Whole territory	Article 84(1)(g) of Delegated Regulation (EU) 2020/689	221/96/COL of 4 December 1996 (previous Decision repealed)
Rabies virus ('RABV')	Whole territory	Article 36(4) of Regulation (EU) 2016/429 and Article 70(3)(a) of Delegated Regulation (EU) 2020/689	033/21/COL of 22 April 2021
infection with *Marteilia refringens*	Zone: the entire coastline of Norway, with the exception of the containment area in the municipality of Bømlo in the County of Hordaland in southern Norway, specifically described in § 2 of the Norwegian Regulations on the control area to fight the disease Marteiliose in molluscs, Bømlo municipality, Hordaland (FOR-2017-09-08- 1377)	Article 84(1)(l) of Delegated Regulation (EU) 2020/689	18/18/COL of 9 February 2018 (previous Decision repealed)

infection with *Bonamia ostreae*	Zone: The entire coastline of Norway, with the exception of the county of Aust-Agder in southern Norway	Article 84(1)(k) of Delegated Regulation (EU) 2020/689	18/18/COL of 9 February 2018 (previous Decision repealed)
Infectious haematopoietic necrosis ('IHN')	Whole territory, with the exception of the Norwegian part of the catchment areas of Grense Jacobselv and Pasvik river and the rivers in between and the associated coastal region (Zone)	Article 84(1)(i) of Delegated Regulation (EU) 2020/689	264/12/COL of 5 July 2012 (previous Decision repealed)
Viral haemorrhagic septicaemia ('VHS')	Whole territory, with the exception of the Norwegian part of the catchment areas of Grense Jacobselv and Pasvik river and the rivers in between and the associated coastal region (Zone)	Article 84(1)(h) of Delegated Regulation (EU) 2020/689	264/12/COL of 5 July 2012 (previous Decision repealed)

Eradication programme	Area: Whole territory, zone or compartment	Legal Basis	No of EFTA Surveillance Authority Decision
Currently no entries			

In Iceland:

Disease-free or non- vaccination status	Area: Whole territory or zone	Legal Basis	No of previous or new EFTA Surveillance Authority Decision
Infectious haematopoietic necrosis ('IHN')	Whole territory	Article 84(1)(i) of Delegated Regulation (EU) 2020/689	227/04/COL of 9 September 2004 and No 36/16/COL of 9 February 2016 (previous Decision repealed)

Eradication programme	Area: Whole territory, zone or compartment	Legal Basis	No of EFTA Surveillance Authority Decision
Currently no entries			