# EFTA SURVEILLANCE AUTHORITY DECISION

## of 21 April 2021

## regarding approval of disease-free and non-vaccination statuses and eradication programmes of Norway and Iceland or certain zones or compartments thereof as regards certain listed diseases in accordance with Regulation (EU) 2016/429 of the European Parliament and of the Council and Commission Delegated Regulation (EU) 2020/689 [2021/1332]

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 point 4(d) of Protocol 1 thereof and the specific and the sectoral adaptations referred to in Annex I to that Agreement, and in particular Articles 31(3), 36(4) and 280 thereof,

Having regard to the Act referred to at Point 13e. of Part 1.1 of Chapter I of Annex I to the EEA Agreement, Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council [2], as regards rules for the prevention and control of certain listed diseases ('Delegated Regulation (EU) 2020/687'), as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement, and in particular Article 112 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 [3] ('Delegated Regulation (EU) 2020/689'), as adapted by point 4(d) of Protocol 1 thereof and the sectoral adaptations referred to in Annex I to that Agreement, and in particular Article 84 thereof.

Whereas:

Regulation (EU) 2016/429 Delegated Regulation (EU) 2020/687 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, Delegated Regulation (EU) 2020/687 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 or non-vaccination status and eradication programmes of States of the European Economic Area ('EEA States') or zones or compartments thereof with regard to certain diseases listed in Article 5(1) of that Regulation for one or more relevant animal species.

[1] OJ L 84, 31.3.2016, p. 1. Incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 179/2020 of 11 December 2020.

[2] OJ L 174, 3.6.2020, p. 67. Incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 3/2021 of 5 February 2021.

[3] OJ L 174, 3.6.2020, p. 211. Incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 4/2021 of 5 February 2021.

Article 280(1) of Regulation (EU) 2016/429 lays down transitional measures for disease-free or non-vaccination statuses ('statuses') approved prior to application of that Regulation in accordance with, as relevant, Council Directives 64/432/EEC ([4]), 91/68/EEC ([5]) and 2006/88/EC ([6]) or Council Directive 2009/158/EC ([7]) ('the relevant previous Directive'). These are referred to herein as 'existing statuses'.

Article 84(1) of Delegated Regulation (EU) 2020/689 supplements Article 280(1) of Regulation (EU) No 2016/429 by providing that existing statuses shall be deemed approved in accordance with Delegated Regulation (EU) 2020/689 where the relevant existing status was approved before the date of application of that Regulation.

The EFTA Surveillance Authority ('the Authority') adopted a number of Decisions approving statuses of Norway and Iceland, or certain zones thereof, in accordance with the relevant previous Directive prior to the implementation of Delegated Regulation (EU) 2020/689 ('the former status Decisions').

The former status Decisions include decisions adopted by the Authority under EEA legislation preceding the relevant previous Directive, where the approval criteria under that legislation was equivalent to the approval criteria under the relevant previous Directive. These existing statuses concern the following listed diseases:

— infection with *Brucella abortus*, *B. melitensis*, *B. suis* in bovine, ovine and caprine animal populations;

— infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae*, *M. Tuberculosis*) ('MTBC');

— enzootic bovine leucosis ('EBL');

— infectious bovine rinotracheitis/infectious pustular vulvovaginitis ('IBR/IPV');

— infection with Aujeszky's disease virus ('ADV');

— infection with Newcastle disease virus without vaccination;

— viral haemorrhagic septicaemia ('VHS');

— infectious haematopoietic necrosis ('IHN');

— infection with *Marteilia refringens*, and

— infection with *Bonamia ostreae*.

Pursuant to Article 280(1) of Regulation (EU) 2016/429 and Articles 84(1) of Delegated Regulation (EU) 2020/689, such existing statuses are deemed approved in accordance with those Regulations. For the purpose of clarity, this Decision repeals the former status Decisions and lists in its Annex those statuses deemed approved.

Norway and Iceland may apply to the Authority for approval of disease-free or non-vaccination status and eradication programmes for one or more of the listed diseases in accordance with Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/689 for one or more of the relevant animal species, for its entire territory or for one or more zones or compartments thereof, provided that the conditions set out in Regulation (EU) 2016/429 are fulfilled. The Authority may approve, subject to amendments where necessary, applications by EEA EFTA States for disease-free status or non-vaccination status or eradication programmes when the relevant conditions are fulfilled.

([4]) The Act previously referred to at Point 1. of Part 4.1. of Chapter I of Annex I to the EEA Agreement, Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ 121, 29.7.1964, p. 1977), as amended and as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to the EEA Agreement.

([5]) The Act previously referred to at Point 2. of Part 4.1. of Chapter I of Annex I to the EEA Agreement, Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19), as amended and as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to the EEA Agreement.

([6]) The Act previously referred to at Point 8a. of Part 3.1.and at Point 4a. of Part 8.1. of Chapter I of Annex I to the EEA Agreement, Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof (OJ L 328, 24.11.2006, p. 14), and on the prevention and control of certain diseases of aquatic animals, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to the EEA Agreement.

([7]) The Act previously referred to at Point 4a. of Part 4.1. of Chapter I of Annex I to the EEA Agreement, Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs, (OJ L 343, 22.12.2009, p. 74), as amended and as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to the EEA Agreement.

The Authority is required, in accordance with Articles 31(3), 36(4) and 266(2) of Regulation (EU) 2016/429, to submit any draft Decision regarding approval of disease-free and non-vaccination statuses, or approval of eradication programmes of Norway and Iceland or certain zones or compartments thereof, as regards certain listed diseases ('draft Approval Decision') to the EFTA Veterinary and Phytosanitary Committee ('the Committee'). The Committee is the relevant Committee designated to assist the Authority in carrying out this function under the Decision of the Standing Committee of the EFTA States No 4/2012/SC of 26 October 2012.

The Committee is required to deliver its opinion on any draft Approval Decision submitted, in accordance with the examination procedure established pursuant to Article 3 of the Decision of the Standing Committee of the EFTA States No 3/2012/SC of 26 October 2012. If the draft Approval Decision is approved by the Committee, the respective Annex to this Decision shall be amended to include the approved new disease-free and non-vaccination statuses or eradication programmes.

The Authority previously adopted Decisions No 67/95/COL, No 300/08/COL and No 265/12/COL approving the contingency plans submitted by Norway for the control of, respectively, foot-and-mouth disease, avian influenza and listed exotic diseases in aquatic animals. The Acts requiring approval of the respective contingency plans and on which those Decisions were based, respectively Council Directives 90/423/EEC ([8]), 2005/94/EC ([9]) and 2006/88/EC ([10]), were repealed by Regulation (EU) 2016/429 and, in the case of Directive 2005/94/EC only, by Delegated Regulation (EU) 2020/687. Articles 43 and 44 of Regulation (EU) 2016/429 concerning contingency plans neither require EEA States to submit contingency plans for approval, nor to provide transitional measures permitting recognition of contingency plans approved prior to application of that Regulation. Therefore, for the sake of clarity, this Decision repeals Decisions No 67/95/COL, No 300/08/COL and No 265/12/COL,

HAS ADOPTED THIS DECISION:

*Article 1*

The disease-free and non-vaccination statuses and eradication programmes of Norway and Iceland and zones or compartments thereof approved in accordance with Regulations (EU) 2016/429 and Delegated Regulation (EU) 2020/689 are listed in the Annex to this Decision.

*Article 2*

The previous decisions of the Authority in this field, as indicated in the fourth and final column of the tables in the Annex to this Decision, are hereby repealed.

*Article 3*

Decisions No 67/95/COL, No 300/08/COL and No 265/12/COL are hereby repealed.

*Article 4*

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

([8]) The Act previously referred to at Point 2. of Part 3.1. of Chapter I of Annex I to the EEA Agreement, Council Directive 90/423/EEC of 26 June 1990 amending Directive 85/511/EEC introducing Community measures for the control of foot-and-mouth disease, Directive 64/432/EEC on animal health problems affecting intra-Community trade in bovine animals and swine and Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat or meat products from third countries (OJ L 224, 18.8.1990, p. 13), as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to the EEA Agreement.

([9]) The Act previously referred to at Point 5a. of Part 3.1. of Chapter I of Annex I to the EEA Agreement, Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC (OJ L 10, 14.1.2006, p. 16), as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to the EEA Agreement.

([10]) More specifically, Article 5(4) of Directive 90/423/EEC, Article 62(4) of Directive 2005/94/EC and Article 47(4) of Directive 2006/88/EC.

*Article 5*

This Decision is addressed to Norway and Iceland.

*Article 6*

This Decision shall be authentic in the English language.

Done at Brussels, 21 April 2021.

*For the EFTA Surveillance Authority,*

Bente ANGELL-HANSEN
*President*

Högni KRISTJÁNSSON
*Responsible College Member*

Frank J. BÜCHEL
*College Member*

Carsten ZATSCHLER
*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) |
| 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) |

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|---|---|---|---|
| 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* | | | |