

**EFTA SURVEILLANCE AUTHORITY
DELEGATED DECISION**

of 16 July 2021

regarding the approval of national measures of Norway and Iceland designed to limit the impact of certain diseases of aquatic animals in accordance with Article 226(3) of Regulation (EU) 2016/429 and repealing Decision No 58/16/COL-D

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* ('Regulation (EU) 2016/429'),¹

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 226, 266(2) and 270(2) thereof,

Having regard to the Act referred to at Point 13j of Part 1.1 of Chapter I of Annex I to the EEA Agreement,

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* ('Delegated Regulation (EU) 2020/990'),²

as adapted to the EEA Agreement, by the sectoral adaptations referred to in Annex I to that Agreement, and in particular Article 13(2)(c) thereof,

Having regard to the Act referred to at Point 13k of Part 1.1 of Chapter I of Annex I to the EEA Agreement,

Commission Implementing Regulation (EU) 2020/2002 of 7 December 2020 *laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to Union notification and Union reporting of listed diseases, to formats and procedures for submission and reporting of Union surveillance programmes and of eradication programmes and*

¹ Incorporated into the EEA Agreement by a Joint Committee Decision No 179/2020 dated 17 December 2020.

² Incorporated into the EEA Agreement by a Joint Committee Decision No 4/2021 dated 4 February 2021.

for application for recognition of disease-free status, and to the computerised information system ('Implementing Regulation (EU) 2020/2002'),³

as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to that Agreement, and in particular Annex III and Section 4 of Annex V thereof,

Having regard to the Act referred to at Point 13m of Part 1.1. of Chapter I of Annex I to the EEA Agreement,

Commission Implementing Regulation (EU) 2020/2236 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates for the entry into the Union and movements within the Union of consignments of aquatic animals and of certain products of animal origin from aquatic animals, official certification regarding such certificates and repealing Regulation (EC) No 1251/2008 ('Implementing Regulation (EU) 2020/2236'),⁴

as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to the EEA Agreement, and in particular Article 6 and Chapters 1, 2, 3 or 5 of Annex I thereof,

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

Whereas:

- (1) Regulation (EU) 2016/429, Delegated Regulation (EU) 2020/990, Implementing Regulation (EU) 2020/2002 and Implementing Regulation (EU) 2020/2236 began to apply in the States of the European Economic Area ('EEA States') from 21 April 2021.
- (2) Regulation (EU) 2016/429 establishes a new legislative framework for the prevention and control of diseases transmissible to animals or humans. Article 226(1) provides that Norway and Iceland may adopt national measures to prevent the introduction, or control the spread, of a disease other than a listed disease referred to in Article 9(1)(d) of that Regulation where that disease constitutes a significant risk for the health of aquatic animals in that EEA State. Diseases other than a listed disease referred to in Article 9(1)(d) of Regulation (EU) 2016/429 include aquatic animal diseases not included in any of the categories of listed diseases under Article 9(1) ('non-listed diseases') and the listed disease Koi herpes virus disease for which there is a need for surveillance within the EEA pursuant to Article 9(1)(e) of Regulation (EU) 2016/429.
- (3) Such national measures must not exceed the limits of what is appropriate and necessary in order to prevent the introduction, or control the spread, of the disease in question within Norway or Iceland as relevant.
- (4) Article 226(2), (3) and (4) of the same Regulation requires Norway and Iceland to notify the EFTA Surveillance Authority ('the Authority') in advance of any proposed national measures and provides that the Authority shall approve such national measures where the establishment of movement restrictions between Norway or Iceland and other EEA States is necessary in order to prevent the introduction, or control the spread, of the relevant disease, taking into account the overall impact on the EEA of the disease in question and of the measures taken.

³ Incorporated into the EEA Agreement by a Joint Committee Decision No 4/2021 dated 4 February 2021.

⁴ Incorporated into the EEA Agreement by a Joint Committee Decision No 93/2021 dated 19 March 2021.

- (5) In order to protect the health status of Norway and Iceland insofar as either country has national measures approved for a particular disease pursuant to Article 226(3) of Regulation (EU) 2016/429, consignments of species of aquatic animals which are susceptible to the disease in question and which are moved to, and within, Norway or Iceland ('relevant consignments') are required to originate from an EEA State, or part thereof, which is free from that disease. Such consignments are to be accompanied by an official certificate attesting to this disease-free status.
- (6) Pursuant to Article 13(2)(c) of Delegated Regulation (EU) 2020/990, operators shall ensure that animal health certificates for relevant consignments state that aquatic animals of the relevant species comply with the health guarantees necessary to comply with those national measures.
- (7) Animal health certificates attesting as to the place of origin of relevant consignments are included in the relevant model official certificates for the movement of aquatic animals between EEA States set out in Implementing Regulation (EU) 2020/2236 and are to be used in the case of relevant consignments.
- (8) Norwegian or Icelandic national measures approved pursuant to Article 226(3) of Regulation (EU) 2016/429 should apply only for as long as they continue to be appropriate and necessary in order to prevent the introduction, or control the spread, of the relevant disease in the relevant country. To allow the Authority to make a regular assessment of the appropriateness and necessity of any such measures, and to provide an opportunity to amend them if necessary, Norway and Iceland should send an annual report to the Authority detailing the functioning of the measures in the previous year. Any such annual reports and other relevant reporting should include certain information set out in Implementing Regulation (EU) 2020/2002.
- (9) Eradication programmes approved in accordance with Article 226(3) of Regulation (EU) 2016/429 should lead to an improvement in the disease situation within a reasonable period of time. In the interest of coherence, this period of time should not be longer than the period within which an eradication programme for a disease referred to in Article 9(1)(c) of Regulation (EU) 2016/429 is to be completed. The period of application of an eradication programme approved in accordance with Article 226(3) of Regulation (EU) 2016/429 should, therefore, not exceed six years from the date of its initial approval by the Authority. In duly justified cases, and at the request of Norway or Iceland as relevant, the Authority should have the possibility of extending the period of application of the eradication programme for an additional six-year period. This maximum period of application is laid down in order to give an adequate period of time within which an eradication programme may be completed, whilst at the same time preventing the disproportionate and long-lasting disruption of movements of aquatic animals within the EEA.
- (10) By Decision No 58/16/COL-D of 3 March 2016 ('Decision No 58/16/COL-D'), the Authority approved national measures by Norway designed to limit the impact of infection with *Gyrodactylus salaris* in areas of Norway considered free from that disease, pursuant to Article 43 of Directive 2006/88/EC.⁵ Regulation (EU) 2016/429 repeals Directive 2006/88/EC, being the legal basis for both Decision No

⁵ The Act previously referred to at Point 8a. of Part 3.1. 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, 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.

58/16/COL-D and certain Acts (Regulation (EC) No 1251/2008⁶ and Commission Decision No 2010/221/EC⁷) to which that Decision refers. For the purpose of clarity, Decision No 58/16/COL-D is therefore repealed by this Decision.

- (11) The Authority has, in close cooperation with the European Commission, assessed the national measures designed to limit the impact of infection with *Gyrodactylus salaris* (a non-listed disease) notified by Norway pursuant to Article 226(2) of Regulation (EU) 2016/429 (Doc No 1207866), taking into account the standards of the World Organisation for Animal Health (OIE)⁸ and the overall impact on the EEA of the disease in question and of the notified measures.
- (12) The Authority is satisfied that Norway has designed an effective eradication programme for those areas of Norway which remain infected with *Gyrodactylus salaris*. The Authority is further satisfied that Norway has maintained the disease-free status of those areas of Norway considered free from *Gyrodactylus salaris* under Decision No 58/16/COL-D and demonstrated disease-free status in all other areas of Norway not covered by the eradication programme. Finally, the Authority is satisfied that Norway has demonstrated the appropriateness and necessity of the national measures establishing movement restrictions in order to prevent the introduction, or to control the spread, of the disease. The national measures are therefore approved by the Authority by this Decision in accordance with Article 226(3) and (4) of Regulation (EU) 2016/429.
- (13) The Authority, by its Delegated Decision No 201/21/COL (Document No 1212279), duly submitted the draft Decision to the Committee in accordance with Articles 226(3) 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.

HAS ADOPTED THIS DECISION:

Article 1

The areas of Norway and Iceland listed in the fourth column of the table in Annex I to this Decision are considered free from the diseases listed in the relevant rows of the first column of that table and the relevant country is granted approval to adopt national measures in accordance with Article 226(3) of Regulation (EU) 2016/429.

Article 2

The eradication programmes adopted by Norway and Iceland for the diseases which are subject to national measures and which are listed in the first column of the table in Annex

⁶ The Act previously referred to at Point 86 of Part 4.2. of Chapter I of Annex I to the EEA Agreement, Commission Regulation (EC) No 1251/2008 of 12 December 2008 implementing Council Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of aquaculture animals and products thereof and laying down a list of vector species, 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 referred to at Point 94 of Part 4.2. of Chapter I of Annex I to the EEA Agreement, Commission Decision 2010/221/EU of 15 April 2010 approving national measures for limiting the impact of certain diseases in aquaculture animals and wild aquatic animals in accordance with Article 43 of Council Directive 2006/88/EC, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to the EEA Agreement.

⁸ The OIE Aquatic Animal Health Code and the OIE Manual of Diagnostic Tests for Aquatic Animals.

II to this Decision, in respect of the areas listed in the relevant rows of the fourth column thereof, are approved.

The period of application of an eradication programme shall not exceed six years from the date of its initial approval by the Authority. In duly justified cases, the Authority may, at the request of Norway or Iceland as relevant, extend the period of application of the eradication programme for an additional six year period.

Article 3

Species of aquatic animals susceptible to the diseases set out in the second column of Annex III to this Decision shall, insofar as the relevant disease is the subject of national measures in Norway or Iceland, only be moved to relevant areas of Norway and Iceland listed in the fourth column of the tables in Annexes I and II to this Decision if they:

- (a) originate from a EEA State or part thereof which is approved as free from the disease in question; and
- (b) are accompanied by an official certificate issued by the competent authority of the EEA State of origin, drawn up in accordance with an appropriate model animal health certificate set out in Chapters 1, 2, 3 or 5 of Annex I to Implementing Regulation (EU) 2020/2236, specifying, in accordance with Article 13(2)(c) of Delegated Regulation (EU) 2020/990, that the health guarantees necessary to comply with the relevant Norwegian or Icelandic national measures are complied with.

Article 4

By 30 April each year at the latest, Norway and Iceland shall submit to the Authority a report on their national measures approved in accordance with Article 226(3) of Regulation (EU) 2016/429.

The report shall:

- (a) include information on measures taken in the previous calendar year to maintain any relevant disease-free status, including at least the information set out in Annex III to Implementing Regulation (EU) 2020/2002;
- (b) include information on the evolution of any relevant eradication programme, including details of the testing which has been carried out in the previous calendar year and at least the information set out in Section 4 of Annex V to Implementing Regulation (EU) 2020/2002; and
- (c) outline the reasons why the relevant disease-free status or eradication programme should continue to apply for a further calendar year. Particular reference shall be made to the availability of treatments, vaccines, disease resistant stocks, or other relevant developments should one or more of these have become a viable option for the prevention and control of infection with *Gyrodactylus salaris* since the submission of the previous report.

Article 5

National measures of Norway or Iceland approved by the Authority in accordance with Article 226(3) of Regulation (EU) 2016/429 may be amended by the Authority should the information referred to in Article 4(c) of this Decision, or other such information relating to

developments in animal health, indicate that the establishment of movement restrictions between EEA States is no longer necessary or justified in order to prevent the introduction, or to control the spread, of the relevant disease.

Article 6

Decision No 58/16/COL-D is hereby repealed.

Article 7

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

Article 8

This Decision is addressed to Norway and Iceland.

Done at Brussels,

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

Högni S. Kristjánsson
Responsible College Member

For Melpo-Menie Joséphidès
Countersigning as Director,
Legal and Executive Affairs

This document has been electronically authenticated by Högni S. Kristjánsson, Catherine Howdle.

ANNEX I

Areas of Norway and Iceland regarded as being free from certain diseases affecting aquatic animals and for which national measures are approved in accordance with Article 226(3) of Regulation (EU) 2016/429

| Disease | EFTA EEA State | Code | Geographical demarcation of the area for which the national measures are approved | No of EFTA Surveillance Authority Decision approving national measure |
|---|-----------------------|-------------|--|--|
| Infection with <i>Gyrodactylus salaris</i> (GS) | Norway | NO | Whole territory, with the exception of the water catchment areas subject to an approved eradication programme for GS, as listed in Annex II to this document | 203/21/COL |

ANNEX II
Areas of Norway and Iceland with eradication programmes for certain diseases affecting aquatic animals and for which national measures are approved in accordance with Article 226(3) of Regulation (EU) 2016/429

| Disease | EFTA EEA State | Code | Geographical demarcation of the area for which the national measures are approved | No of EFTA Surveillance Authority Decision approving national measure |
|---|----------------------|------|---|---|
| Infection with <i>Gyrodactylus salaris</i> (GS) | Norway | NO | The water catchment areas of the Skibotnelva, Signaldalselva and Kitdalselva (Troms), Leirelva, Ranelva, Drevja, Fusta, Vefsna, Hundåla, Halsanelva, Hestdalselva, Dagsvikelva and Nylandselva (Nordland), Batnfjordselva, Driva, Litledalselva, Usma (Øksendalselva) (Møre and Romsdal), Drammenselva and Lierelva (Buskerud), Vesleelva (Sandeelva) and Selvikvassdraget (Vestfold) | 203/21/COL |

ANNEX III
Species of aquatic animals susceptible to diseases subject to national measures under Article 226(1) of Regulation (EU) 2016/429

| Disease | Susceptible species |
|---|--|
| Koi herpes virus disease (KHV) | As set out in column 3 of the table in the Annex to Implementing Regulation (EU) 2018/1882 |
| Spring viraemia of carp (SVC) | Bighead carp (<i>Aristichthys nobilis</i>), goldfish (<i>Carassius auratus</i>), crucian carp (<i>Carassius carassius</i>), grass carp (<i>Ctenopharyngodon idellus</i>), common carp and koi carp (<i>Cyprinus carpio</i>), silver carp (<i>Hypophthalmichthys molitrix</i>), sheatfish (<i>Silurus glanis</i>), tench (<i>Tinca tinca</i>), orfe (<i>Leuciscus idus</i>) |
| Bacterial kidney disease (BKD) | All species of <i>Salmonidae</i> |
| Infectious pancreatic necrosis (IPN) | Brook trout (<i>Salvelinus fontinalis</i>), brown trout (<i>Salmo trutta</i>), Atlantic salmon (<i>Salmo salar</i>), (<i>Oncorhynchus spp.</i>) whitefish (<i>Coregonus lavaretus</i>) |
| Infection with <i>Gyrodactylus salaris</i> (GS) | Atlantic salmon (<i>Salmo salar</i>), rainbow trout (<i>Oncorhynchus mykiss</i>), Arctic char (<i>Salvelinus alpinus</i>), North American brook trout (<i>Salvelinus fontinalis</i>), grayling (<i>Thymallus thymallus</i>), North American lake trout (<i>Salvelinus namaycush</i>), brown trout (<i>Salmo trutta</i>) and any species which has been in contact with these species |
| Ostreid herpes virus 1 μ var (OsHV-1 μ var) | Pacific oyster (<i>Crassostrea gigas</i>) |
| Infection with salmonid alphavirus (SAV) | Atlantic salmon (<i>Salmo salar</i>), rainbow trout (<i>Oncorhynchus mykiss</i>), brown trout (<i>Salmo trutta</i>) |