REPORT FOR THE HEARING

in Case E-8/24

REQUEST to the Court under Article 34 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice by the Supreme Court of Norway (*Norges Høyesterett*), in the case between

Nordsjø Fjordbruk AS

and

The Norwegian State, represented by the Ministry of Trade, Industry and Fisheries (*Nærings- og fiskeridepartementet*),

concerning the interpretation of 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').

I INTRODUCTION

1. By a letter received and registered at the Court on 29 April 2024, the Norwegian Supreme Court (*Norges Høyesterett*) requested an advisory opinion in the case pending before it between Nordsjø Fjordbruk AS ("Nordsjø") and the Norwegian State, represented by the Ministry of Trade, Industry and Fisheries.

2. The case before the referring court concerns the validity of the Norwegian Food Safety Authority's decision of 29 April 2022, by which Nordsjø's application for approval of its operating plan for 2022 was refused.

3. According to the referring court, the case concerns the interpretation of 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') and its underlying acts.

4. The referring court requests an advisory opinion from the Court on whether the Animal Health Law, in particular Articles 9, 10, 176, 181, 183-184, 191-192, 226 and 269 thereof, must be interpreted as meaning that EEA States' central veterinary authorities are precluded from prohibiting the movement of farmed fish from one aquaculture establishment to another within national boarders, or are precluded from refusing to approve an operating plan for an aquaculture establishment, subject to certain conditions.

II LEGAL BACKGROUND

EEA law

5. 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') (OJ 2016 L 84, p. 1, and Norwegian EEA Supplement 2023 No 2, p. 21) ("the Animal Health Law") was incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 179/2020 of 11 December 2020 (OJ 2023 L 240, p. 5, and Norwegian EEA Supplement 2023 No 70, p. 5) and is referred to at point 13 of Part 1.1. of Annex I (Veterinary and phytosanitary matters) to the EEA Agreement. Constitutional requirements indicated by Iceland, Liechtenstein and Norway were fulfilled on 16 April 2021, and the decision entered into force on 17 April 2021.

6. Article 9 of the Animal Health Law, headed "Disease prevention and control rules to be applied to different categories of listed diseases", reads:

> *1. Disease prevention and control rules shall apply to listed diseases as follows:*
>
> *(a) As regards listed diseases that do not normally occur in the Union and for which immediate eradication measures must be taken as soon as they are detected, the following rules shall apply, as relevant:*
>
> > *(i) the rules for disease awareness and preparedness provided for in Title I of Part III (Articles 43 to 52);*
> >
> > *(ii) the disease control measures provided for in Chapter 1 of Title II of Part III (Articles 53 to 71); and*
> >
> > *(iii) the rules for compartmentalisation provided for in Article 37(1).*
> >
> > *For those listed diseases, the measures referred to in point (b), as appropriate, as well as points (d) and (e), shall also apply, as relevant.*
>
> *(b) As regards listed diseases which must be controlled in all Member States with the goal of eradicating them throughout the Union, the following rules shall apply, as relevant:*

(i) the rules for compulsory eradication programmes provided for in Article 31(1);

(ii) the rules for disease–free Member States and zones provided for in Article 36;

(iii) the rules for compartmentalisation provided for in Article 37(2); and

(iv) the disease control measures provided for in Articles 72 to 75, Articles 77 to 79 and Articles 81 and 83.

For those listed diseases, the measures referred to in points (d) and (e) shall also apply, as relevant.

(c) As regards listed diseases which are of relevance to some Member States and for which measures are needed to prevent them from spreading to parts of the Union that are officially disease-free or that have eradication programmes for the listed disease concerned, the following rules shall apply, as relevant:

(i) the rules for optional eradication provided for in Article 31(2);

(ii) the rules for disease–free Member States and zones provided for in Article 36;

(iii) the rules for compartmentalisation provided for in Article 37(2); and

(iv) the rules for disease control measures provided for in Articles 76, 77, 78, 80, 82 and 83.

For those listed diseases, the measures referred to in points (d) and (e) shall also apply, as relevant.

(d) As regards listed diseases for which measures are needed to prevent them from spreading on account of their entry into the Union or movements between Member States, the following rules shall apply, as relevant:

(i) the rules for movement within the Union provided for in Chapters 3 to 6 of Title I (Articles 124 to 169), Chapters 2 and 3 of Title II of Part IV (Articles 191 to 225) and Chapters 2 and 3 of Part VI (Articles 247 to 251); and

(ii) the rules for entry into the Union and export from the Union provided for in Part V (Articles 229 to 243).

The listed diseases referred to in points (a), (b) and (c) shall also be considered as listed diseases under this point, as well as those referred to in point (e), where the risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products.

(e) As regards listed diseases for which there is a need for surveillance within the Union, the following rules shall apply, as relevant:

(i) the rules for notification and reporting provided for in Chapter 1 of Part II (Articles 18 to 23); and

(ii) the rules for surveillance provided for in Chapter 2 of Part II (Articles 24 to 30).

The listed diseases referred to in points (a), (b) and (c) shall also be considered as listed diseases under this point.

2. The Commission shall, by means of implementing acts, determine the application of the disease prevention and control rules referred to in paragraph 1 to the respective listed diseases on the basis of the criteria set out in Annex IV, also in the light of newly available significant scientific data.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

3. The Commission shall, by means of implementing acts, modify the application of the disease prevention and control rules referred to in paragraph 2 to the respective listed diseases when the disease in question no longer fulfils the criteria laid down in the relevant Section of Annex IV, also in the light of newly available significant scientific data.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4. On duly justified imperative grounds of urgency relating to a listed disease representing an emerging risk having a highly significant impact, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

7. Article 10 of the Animal Health Law, headed "Responsibilities for animal health and biosecurity measures", reads:

1. Operators shall:

(a) as regards kept animals and products under their responsibility, be responsible for:

(i) the health of kept animals;

(ii) prudent and responsible use of veterinary medicines, without prejudice to the role and responsibility of veterinarians,

(iii) minimising the risk of the spread of diseases;

(iv) good animal husbandry;

(b) where appropriate, take such biosecurity measures regarding kept animals, and products under their responsibility, as are appropriate for:

(i) the species and categories of kept animals and products;

(ii) the type of production; and

(iii) the risks involved, taking into account:

— geographical location and climatic conditions; and

— local circumstances and practices;

(c) where appropriate, take biosecurity measures regarding wild animals.

2. Animal professionals shall take action to minimise the risk of the spread of diseases in the context of their occupational relationship with animals and products.

3. Point (a) of paragraph 1 shall also apply to pet keepers.

4. The biosecurity measures referred to in point (b) of paragraph 1 shall be implemented, as appropriate, through:

(a) physical protection measures, which may include:

(i) enclosing, fencing, roofing, netting, as appropriate;

(ii) cleaning, disinfection and control of insects and rodents;

(iii) in the case of aquatic animals, where appropriate:

— measures concerning the water supply and discharge;

— natural or artificial barriers to surrounding water courses that prevent aquatic animals from entering or leaving the establishment concerned, including measures against flooding or infiltration of water from surrounding water courses;

(b) management measures, which may include:

(i) procedures for entering and exiting the establishment for animals, products, vehicles and persons;

(ii) procedures for using equipment;

(iii) conditions for movement based on the risks involved;

(iv) conditions for introducing animals or products into the establishment;

(v) quarantine, isolation or separation of newly introduced or sick animals;

(vi) a system for safe disposal of dead animals and other animal by–products.

5. Operators, animal professionals and pet keepers shall cooperate with the competent authority and veterinarians in the application of the disease prevention and control measures provided for in this Regulation.

6. The Commission may, by means of implementing acts, lay down minimum requirements necessary for the uniform application of this Article.

Such implementing acts shall reflect the matters referred to in point (b) of paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

8. Article 176 of the Animal Health Law, headed "Approval of certain aquaculture establishments and delegated acts", reads:

1. Operators of the following types of aquaculture establishments shall apply to the competent authority for approval in accordance with Article 180(1):

(a) aquaculture establishments where aquaculture animals are kept with a view to their being moved therefrom, either alive or as products of aquaculture animal origin;

(b) other aquaculture establishments which pose a significant risk due to:

(i) the species, categories and number of aquaculture animals kept there;

(ii) the type of aquaculture establishment concerned;

(iii) movements of aquaculture animals into and out of the aquaculture establishment concerned.

2. By way of derogation from paragraph 1, Member States may exempt from the obligation to apply for approval operators of the following types of establishment:

(a) aquaculture establishments producing a small quantity of aquaculture animals for supply for human consumption either:

(i) to the final consumer directly; or

(ii) to local retail establishments directly supplying the final consumer;

(b) ponds and other installations where the population of aquatic animals is maintained only for recreational fishing purposes, by restocking with aquaculture animals which are confined and unable to escape;

(c) aquaculture establishments keeping aquaculture animals for ornamental purposes in closed facilities,

provided that the establishment in question does not pose a significant risk.

3. Unless a derogation has been granted under paragraph 4 of this Article, operators shall not commence activity at an aquaculture establishment as referred to in paragraph 1 of this Article until that establishment has been approved in accordance with Article 181(1), and shall cease such activity at an aquaculture establishment referred to in paragraph 1 of this Article where:

(a) the competent authority withdraws or suspends its approval in accordance with Article 184(2); or

(b) in the event of conditional approval, granted in accordance with Article 183(3), the aquaculture establishment concerned fails to comply with the outstanding requirements referred to in Article 183(4) and does not obtain a final approval in accordance with Article 183(3).

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) derogations from the requirement for operators to apply to the competent authority for approval of the types of aquaculture establishments referred to in point (a) of paragraph 1, concerning types of establishments other than those specified in points (a)(i) and (ii) of paragraph 2, where those establishments do not pose a significant risk;

(b) the types of aquaculture establishments which must be approved in accordance with point (b) of paragraph 1.

5. When adopting delegated acts as provided for in paragraph 4, the Commission shall base those acts on the following criteria:

(a) the species and categories of aquaculture animals kept in an aquaculture establishment;

(b) the type of aquaculture establishment and the type of production; and

(c) typical movement patterns of the type of aquaculture establishment concerned and of the species or category of aquaculture animals concerned.

6. An operator may apply for approval of a group of aquaculture establishments, provided that the requirements provided for in points (a) and (b) of the first paragraph of Article 177 are complied with.

9. Article 181 of the Animal Health Law, headed "Granting of, and conditions for, approval and delegated acts", reads:

1. The competent authority shall only grant approvals of aquaculture establishments as referred to in Article 176(1) and point (a) of Article 178, groups of aquaculture establishments as referred to in Article 177 and disease control aquatic food establishments as referred to in Article 179, where such establishments:

(a) comply with the following requirements, where appropriate, in relation to:

(i) quarantine, isolation and other biosecurity measures taking into account the requirements provided for in point (b) of Article 10(1)) and any rules adopted pursuant to Article 10(6);

(ii) surveillance requirements as provided for in Article 24, where relevant for the type of establishment concerned and the risk involved, in Article 25;

(iii) record-keeping as provided for in Articles 186 to 188 and any rules adopted pursuant to Articles 189 and 190;

(b) have facilities and equipment that are:

(i) adequate to reduce the risk of the introduction and spread of diseases to an acceptable level, taking into account the type of establishment concerned;

(ii) of a capacity adequate for the species, categories and quantity (numbers, volume or weight) of aquatic animals concerned;

(c) do not pose an unacceptable risk as regards the spread of diseases, taking into account the risk-mitigation measures in place;

(d) have in place a system which enables the operator concerned to demonstrate to the competent authority that the requirements laid down in points (a), (b) and (c) are fulfilled.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) quarantine, isolation and other biosecurity measures as referred to in point (a)(i) of paragraph 1;

(b) surveillance as referred to in point (a)(ii) of paragraph 1;

(c) facilities and equipment as referred to in point (b) of paragraph 1.

3. When establishing the rules to be laid down in the delegated acts to be adopted pursuant to paragraph 2, the Commission shall base those rules on the following matters:

(a) the risks posed by each type of establishment;

(b) the species and categories of aquaculture or aquatic animals relevant for the approval;

(c) the type of production concerned;

(d) typical movement patterns of the type of aquaculture establishment and species and categories of animals kept in those establishments.

10. Article 183 of the Animal Health Law, headed “Procedures for the granting of approval by the competent authority”, reads:

1. The competent authority shall establish procedures for operators to follow when applying for approval of their establishments in accordance with Article 176(1) and Articles 178 and 179.

2. Upon receipt of an application for approval from an operator in accordance with Article 176(1), Article 178 or Article 179, the competent authority shall make an on–site visit.

3. Provided that the requirements referred to in Article 181 are fulfilled, the competent authority shall grant the approval.

4. Where an establishment does not fulfil all requirements for approval as referred to in Article 181, the competent authority may grant conditional approval of an establishment if it appears, on the basis of the application by the operator concerned and the subsequent on-site visit provided for in paragraph 2 of this Article, that the establishment meets all the main requirements that provide sufficient guarantees that the establishment does not pose a significant risk.

5. Where conditional approval has been granted by the competent authority in accordance with paragraph 4 of this Article, it shall grant full approval only where it appears from another on–site visit to the establishment, carried out within three months from the date of the grant of conditional approval, or from documentation provided by the operator within three months from that date, that the establishment meets all the requirements for approval provided for in Article 181(1) and the rules adopted pursuant to Article 181(2).

Where the on–site visit or the documentation referred to in the first subparagraph shows that clear progress has been made but that the establishment still does not meet all of those requirements, the competent authority may prolong the conditional approval. However, conditional approval shall not be granted for a period exceeding, in total, six months.

11. Article 184 of the Animal Health Law, headed "Review, suspension and withdrawal of approvals by the competent authority", reads:

1. The competent authority shall keep approvals of establishments granted in accordance with Article 181(1) under review, at appropriate intervals based on the risk involved.

2. Where a competent authority identifies serious deficiencies in an establishment as regards compliance with the requirements laid down in Article 181(1) and the rules adopted pursuant to Article 181(2), and the operator of that establishment is not able to provide adequate guarantees that those deficiencies will be eliminated, the competent authority shall initiate procedures to withdraw the approval of the establishment.

However, the competent authority may merely suspend, rather than withdraw, approval of an establishment where the operator can guarantee that it will eliminate those deficiencies within a reasonable period of time.

3. Approval shall only be granted after withdrawal or restored after suspension in accordance with paragraph 2 when the competent authority is satisfied that the establishment fully complies with all the requirements of this Regulation appropriate for that type of establishment.

12. Article 191 of the Animal Health Law, headed "General requirements for movements of aquatic animals", reads:

1. Operators shall take appropriate measures to ensure that the movement of aquatic animals does not jeopardise the health status at the place of destination with regard to:

(a) the listed diseases referred to in point (d) of Article 9(1);

(b) emerging diseases.

2. Operators shall only move aquatic animals into an aquaculture establishment or for human consumption purposes, or release them into the wild, if the animals in question fulfil the following conditions:

(a) they come, except in the case of wild aquatic animals, from establishments that have been:

(i) registered by the competent authority in accordance with Article 173,

(ii) approved by that competent authority in accordance with Articles 181 and 182, when required by Article 176(1), Article 177 or Article 178, or

(iii) granted a derogation from the registration requirement laid down in Article 173.

(b) they are not subject to:

(i) movement restrictions affecting the species and categories concerned in accordance with the rules laid down in Article 55(1), Article 56, Article 61(1), Articles 62, 64 and 65, point (b) of Article 70(1), Article 74(1), Article 79 and Article 81 and the rules adopted pursuant to Article 55(2), Articles 63 and 67 and Articles 70(3), 71(3), 74(4) and 83(2); or

(ii) the emergency measures laid down in Articles 257 and 258 and the rules adopted pursuant to Article 259.

However, operators may move those aquatic animals where derogations from the movement restrictions for such movements or release are provided for in

Title II of Part III (Articles 53–83) or derogations from emergency measures are provided for in rules adopted pursuant to Article 259.

3. Operators shall take all necessary measures to ensure that aquatic animals, after leaving their place of origin, are consigned directly to the final place of destination.

13. Article 192 of the Animal Health Law, headed "Disease prevention measures in relation to transport", reads:

1. Operators shall take the appropriate and necessary disease prevention measures to ensure that:

(a) the health status of aquatic animals is not jeopardised during transport;

(b) transport operations of aquatic animals do not cause the potential spread of listed diseases as referred to in point (d) of Article 9(1) to humans or animals en route, and at places of destination;

(c) cleaning and disinfection of equipment and means of transport and other adequate biosecurity measures are taken, as appropriate to the risks involved with the transport operations concerned;

(d) any exchanges of water and discharges of water during the transport of aquatic animals intended for aquaculture or release into the wild are carried out at places and under conditions which do not jeopardise the health status with regard to the listed diseases referred to in point (d) of Article 9(1) of:

(i) the aquatic animals being transported;

(ii) any aquatic animals en route to the place of destination;

(iii) aquatic animals at the place of destination.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) the conditions and requirements for cleaning and disinfection of equipment and means of transport in accordance with point (c) of paragraph 1 of this Article and the use of biocidal products for such purposes;

(b) other appropriate biosecurity measures during transport as provided for in point (c) of paragraph 1 of this Article;

(c) water exchanges and discharges of water during transport as provided for in point (d) of paragraph 1 of this Article.

14. Article 226 of the Animal Health Law, headed "National measures designed to limit the impact of diseases other than listed disease", reads:

1. Where a disease other than a listed disease as referred to in point (d) of Article 9(1) constitutes a significant risk for the health of aquatic animals in a

Member State, the Member State concerned may take national measures to prevent the introduction, or to control the spread, of that disease.

Member States shall ensure that those national measures do not exceed the limits of what is appropriate and necessary in order to prevent the introduction, or to control the spread, of the disease in question within the Member State concerned.

2. Member States shall notify the Commission in advance of any proposed national measures as referred to in paragraph 1 that may affect movements of aquatic animals and products of animal origin from aquatic animals between Member States.

3. The Commission shall approve and, if necessary, amend the national measures referred to in paragraph 2 of this Article by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4. The approval referred to in paragraph 3 shall only be granted where the establishment of movement restrictions between Member States is necessary in order to prevent the introduction, or to control the spread, of the disease referred to in paragraph 1, taking into account the overall impact on the Union of the disease in question and of the measures taken.

15. Article 269 of the Animal Health Law, headed "Additional or more stringent measures by Member States", reads:

1. In addition to what follows from other provisions in this Regulation, allowing the Member States to adopt national measures, Member States may apply within their territories measures that are additional to, or more stringent than, those laid down in this Regulation, concerning:

(a) responsibilities for animal health as provided for in Chapter 3 of Part I (Articles 10 to 17);

(b) notification within Member States as provided for in Article 18;

(c) surveillance as provided for in Chapter 2 of Part II (Articles 24 to 30);

(d) registration, approval, record-keeping and registers as provided for in Chapter 1 of Title I (Articles 84 to 107), and Chapter 1 of Title II, of Part IV (Articles 172 to 190);

(e) traceability requirements for kept terrestrial animals and germinal products as provided for in Chapter 2 of Title I of Part IV (Articles 108 to 123).

2. The national measures referred to in paragraph 1 shall respect the rules laid down in this Regulation and shall not:

(a) hinder the movement of animals and products between Member States;

(b) be inconsistent with the rules referred to in paragraph 1.

National law

16. The Animal Health Law is implemented in Norwegian law through Regulation No 631 of 6 April 2022 on animal health (*forskrift om dyrehelse (dyrehelseforskriften) av 6. april 2022 nr. 631*), while its underlying acts are implemented through a number of different regulations. Those regulations have been issued on the basis of Act No 124 of 19 December 2003 relating to food production and food safety, etc. (*lov om matproduksjon og mattrygghet mv. (matloven) av 19. desember 2003 nr. 124*) ("the Food Act") and Act No 75 of 15 June 2001 relating to veterinarians and other animal health personnel (*lov om veterinærer og annet dyrehelsepersonell (dyrehelsepersonelloven) av 15. juni 2001 nr. 75*).

17. The first and sixth paragraphs of Section 40 of Regulation No 822 of 17 June 2008 on the operation of aquaculture establishments (*forskrift om drift av akvakulturanlegg (akvakulturdriftsforskriften) av 17. juni 2008 nr. 822*) read as follows:

> *An operating plan for aquaculture establishments in seawater shall be in place at all times. In the event of joint operations, a joint operating plan shall be in place.*
>
> *...*
>
> *The Norwegian Directorate of Fisheries (Fiskeridirektoratet) shall, in consultation with the Norwegian Food Safety Authority, adopt decisions on approval of that part of the plan which concerns the first year. The Norwegian Food Safety Authority may, by decision, refuse approval if considerations of fish health (fiskehelse) at the individual site or in an area so warrant.*

18. Under Section 69 of that regulation, violation can give rise to penalties and other sanctions, including closure and quarantine of the operation pursuant to Section 25 of the Food Act.

19. Section 19 of the Food Act reads:

> *Everyone shall show due diligence, so that a risk of development or spread of transmissible animal diseases does not occur.*
>
> *Live animals shall not be placed on the market, kept, moved or released when there are grounds for suspecting the presence of transmissible animal disease which may entail significant societal consequences.*
>
> *The King may issue specific regulations for the prevention, surveillance and control of animal diseases and infectious agents, including concerning:*
>
> *a. classification and grouping of diseases and infectious agents;*

b. creation of zones with different health and disease status and epidemiologically separate regions;

c. approval and use of vaccines and other medicinal treatment of animals;

d. movement, transport, placing on the market and use of live and dead animals, animal by-products, objects, etc.;

e. control of breeding animals, withdrawal of germinal products and reproduction of animals; and

f. restrictions on permission for persons who may carry infection to buildings used for animals, animal feed or equipment, and concerning obligations to allow his or her person and accompanying objects to be disinfected.

III FACTS AND PROCEDURE

20. Nordsjø is a subsidiary of Alsaker Fjordbruk AS and engages in food fish production of salmon in Norway at a number of different sites in the counties of Vestland and Rogaland.

21. In order to operate an aquaculture establishment at sea, the aquaculture establishment must be approved. Additionally, there must at all times be an approved operating plan in place for the establishment.

22. In the autumn of 2021, Nordsjø applied for approval of the operating plan for the Nappeholmane site.

23. On 10 November 2021, the Norwegian Food Safety Authority (*Mattilsynet*) adopted a decision by which approval of the operating plan for Nappeholmane was refused. Nordsjø appealed against that decision on 30 November 2021. The Norwegian Food Safety Authority's appeals body upheld the refusal by decision of 29 April 2022.

24. The reason given for the refusal was that the risk of the spread of disease associated with the planned movement of fish was considered to be too high and that the operating plan entailed an unacceptable risk of spread of disease and infection.

25. It was further stated, with reference to the preparatory works to the Food Act, that the Norwegian Food Safety Authority must show "due diligence" in its treatment of operating plan applications, and that precautionary considerations are to be a guiding principle in the assessments and findings forming the basis of the decision. In the specific assessment, reference was made to the fact that the Nappeholmane site is

an open marine facility which is not situated so as to be protected against infection from fish farming facilities in the immediate area, and that the establishment is situated approximately nine kilometres from two different surveillance zones for the fish disease *infectious salmon anemia* (ISA). It was also stated that the site has had previous detected incidences of the fish disease *pancreas disease* (PD) and that, as a result, there was a risk that the fish would be exposed to infection prior to movement. By reference to the precautionary principle, it was stated that it was not decisive that there was no detected disease or actual suspected presence of disease at the site, since the fish could still be a carrier of latent diseases. It was further stated that there was a high risk of spread of disease to other fish farming facilities during transport of the fish involving the use of well boats.

26. The Norwegian Food Safety Authority found that the overall risk of the spread of infection exceeded what was an acceptable risk, and that "considerations of fish health" warranted non-approval of the operating plan.

27. On 19 August 2022, Nordsjø lodged proceedings against the Norwegian State, represented by the Ministry of Trade, Industry and Fisheries, seeking to have the Norwegian Food Safety Authority's decision of 29 April 2022 annulled.

28. On 1 March 2023, Haugaland and Sunnhordland District Court (*Haugaland og Sunnhordaland tingrett*) delivered judgment in favour of the Norwegian State, represented by the Ministry of Trade, Industry and Fisheries. The District Court found that the Norwegian Food Safety Authority's decision was not contrary to the Animal Health Law and is therefore valid. Nordsjø appealed against that judgment.

29. By judgment of 31 October 2023, Gulating Court of Appeal (*Gulating lagmannsrett*) dismissed the appeal. The Court of Appeal also held that the decision is not contrary to the Animal Health Law. Both the District Court and the Court of Appeal referred in particular to Article 269(1)(a) and its reference to Article 10 of the Animal Health Law as grounds for finding that the decision is in accordance with the Animal Health Law.

30. Nordsjø's appeal to the Norwegian Supreme Court is directed at the Court of Appeal's application of the law in relation to the rules in the Animal Health Law and its underlying acts. By decision of 4 February 2024 of the Appeals Selection Committee of the Supreme Court (*Høyesteretts ankeutvalg*), leave to appeal was granted.

31. Against this background, the Norwegian Supreme Court decided to refer the following question to the Court:

> **Must Regulation (EU) 2016/429, in particular Articles 9, 10, 176, 181, 183–184, 191–192, 226 and 269 thereof, be interpreted as meaning that the Member States' central veterinary authorities are precluded from prohibiting the movement of farmed fish from one aquaculture establishment to another one within national borders, or are**

precluded from refusing to approve an operating plan for an aquaculture establishment, in a situation where:

- **there is no detected disease or concrete suspicion of disease in the fish,**

- **but the veterinary authority, following a specific assessment, has found that considerations of fish health at the individual site or in an area warrant such a prohibition or refusal?**

IV WRITTEN OBSERVATIONS

32. Pursuant to Article 20 of the Statute of the Court and Article 90(1) of the Rules of Procedure, written observations have been received from:

- Nordsjø Fjordbruk AS, represented by Jan Magne Langseth, advocate;

- the Norwegian Government, represented by Helge Røstum, acting as Agent;

- the Icelandic Government, represented by Hendrik Daði Jónsson and Hjalti Jón Guðmundsson, acting as Agents, and Jóhannes Karl Sveinsson, attorney;

- the EFTA Surveillance Authority ("ESA"), represented by Kyrre Isaksen, Sigrún Ingibjörg Gísladóttir and Melpo-Menie Josephides, acting as Agents; and

- the European Commission ("the Commission"), represented by Flor Castilla Contreras, Bruno Rechena and Miriam Zerwes, acting as Agents.

V PROPOSED ANSWERS SUBMITTED

Nordsjø Fjordbruk AS

33. Nordsjø submits that the question referred should be answered as follows:

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" or "AHL") in particular Article 9, 10, 176, 181, 183–184, 191–192, and 269 thereof, read in conjunction with 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, shall be interpreted as meaning that:

- *The EEA States' central veterinary authorities are precluded from prohibiting the movement of clinically healthy farmed fish from one*

approved aquaculture establishment to another in a situation where there is no detected disease or concrete suspicion of disease in the fish, unless they are subject to the movement restrictions vested in Article 191(2)(b) i) in accordance with the rules laid down in Article 55(1), Article 56, Article 61(1), Articles 62, 64 and 65, point (b) of Article 70(1), Article 74(1), Article 79 and Article 81 and the rules adopted pursuant to Article 55(2), Articles 63 and 67 and Articles 70(3), 71(3), 74(4) and 83(2); or (ii) the emergency measures laid down in Articles 257 and 258 and the rules adopted pursuant to Article 259. EEA States cannot adopt more stringent restrictions on the movement of fish based on Article 269.

- *Movement of fish adhering to the movement provisions in the AHL and the Commission's delegated acts does not constitute grounds for refusing or withdrawing the approval of an operating licence for an establishment with reference to Article 184 AHL.*

Norwegian Government

34. The Norwegian Government submits that the question referred should be answered as follows:

> *Regulation (EU) 2016/429 does not preclude a national rule such as that at issue in the present case, which allow the Member States' veterinary authorities to refuse approval of an operating plan for an aquaculture establishment involving movement of fish, in a situation where there is no detected disease or concrete suspicion of disease in the fish, but the veterinary authority, following a specific risk assessment, has found that considerations of fish health and the risk of spread of disease at the individual site or in an area warrant such a refusal.*

Icelandic Government

35. The Icelandic Government submits that the question referred should be answered as follows:

> *Pursuant to Article 269 of the Animal Health Law, the Contracting Parties may adopt additional or more stringent measures than those laid down in the Regulation concerning, inter alia, the responsibilities for animal health as provided for in Chapter 3 of Part I therein and the approval of establishments as provided for in Chapter 1 of Title II of Part IV. Such measures may include the setting of a biosecurity management measure, in the context of Article 10(4)(b) of the Animal Health Law, which prohibits the movement of farmed fish between aquaculture establishments altogether, where such measures are justified based on a specific assessment of the risk involved in such movement. The Regulation must therefore not be interpreted as precluding competent authorities from adopting such measures.*

ESA

36. ESA submits that the question referred should be answered as follows:

> *The Regulation is to be interpreted as allowing the Central Competent Authorities in the EEA States to prohibit the movement of farmed fish from one aquaculture establishment to another one within national borders, or to refuse to approve an operating plan for an aquaculture establishment, in a situation:*
>
> - *where there is no detected disease or concrete of suspicion of the disease in the fish,*
>
> - *but the competent authority, following an individual assessment backed up with evidence, has found that considerations of fish health at the individual site or in an area warrant such prohibition or refusal.*

European Commission

37. The Commission submits that the question referred should be answered as follows:

> *Regulation (EU) 2016/429 is to be interpreted as not precluding EEA States' national authorities from refusing the approval of an operating plan which foresees movements of farmed fish from one aquaculture establishment to another in a situation where there is no detected disease or concrete suspicion of disease in the fish, but the national authority, following a specific and objective risk assessment in compliance with the AHL – which is for the national court to determine – has found that the operating plan entails an unacceptable risk of spread of diseases which warrants such a refusal, provided that this measure only concerns domestic establishments and does not hinder movements between EEA States.*

Páll Hreinsson

Judge-Rapporteur