



## JUDGMENT OF THE COURT

12 December 2024\*

*(Animal health law – Regulation (EU) 2016/429 – Article 10 – Article 181 – Article 269 – Right of national competent authorities to prohibit movement of farmed fish between aquaculture establishments)*

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'),

THE COURT,

composed of: Páll Hreinsson, President (Judge-Rapporteur), Bernd Hammermann and Michael Reiertsen, Judges,

Registrar: Ólafur Jóhannes Einarsson,

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\* Language of the request: Norwegian. Translations of national provisions are unofficial and based on those contained in the documents of the case.

having considered the written observations submitted on behalf of:

- Nordsjø Fjordbruk AS (“Nordsjø Fjordbruk”), represented by Jan Magne Langseth, attorney;
- 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 Joséphidès, acting as Agents; and
- the European Commission (“the Commission”), represented by Flor Castilla Contreras, Bruno Rechen and Miriam Zerwes, acting as Agents,

having regard to the Report for the Hearing,

having heard oral arguments of Nordsjø Fjordbruk, represented by Jan Magne Langseth; the Norwegian Government, represented by Marte Brathovde, acting as Agent; the Icelandic Government, represented by Jóhannes Karl Sveinsson; ESA, represented by Kyrre Isaksen; and the Commission, represented by Miriam Zerwes, at the hearing on 18 September 2024,

gives the following

## **JUDGMENT**

### **I LEGAL BACKGROUND**

#### **EEA law**

- 1 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 Regulation”) 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 Norway were fulfilled on 16 April 2021, and the decision entered into force on 17 April 2021.
- 2 Recitals 4, 8, 14, 15 (in extract), 20 (in extract), 28, 43, 146, 149, 165 and 174 of the Regulation read as follows:

(4) *In order to ensure high standards of animal and public health in the Union and the rational development of the agriculture and aquaculture sectors, and to increase productivity, animal health rules should be laid down at Union level. Those rules are necessary in order, inter alia, to contribute to the completion of the internal market and to avoid the spread of infectious diseases. Those rules should also ensure, as far as possible, that the existing animal health status in the Union is maintained and that consequent improvement of that status is supported.*

(8) *The Commission's communication of 19 September 2007 on a new Animal Health Strategy for the European Union (2007-2013) where 'Prevention is better than cure' aims to promote animal health by placing greater emphasis on preventive measures, disease surveillance, disease control and research, in order to reduce the incidence of animal diseases and minimise the impact of outbreaks when they do occur. It proposes the adoption of a single and simplified regulatory framework for animal health seeking convergence with international standards while ensuring a firm commitment to high standards of animal health.*

(14) *In specific circumstances where a significant animal or public health risk exists but scientific uncertainty persists, Article 5(7) of the SPS Agreement, which has been interpreted for the Union in the Commission communication of 2 February 2000 on the precautionary principle, allows members of that Agreement to adopt provisional measures on the basis of available pertinent information. In such circumstances, the member concerned is required to obtain the additional information necessary for a more objective assessment of risk and to review the measure accordingly within a reasonable period of time.*

(15) *The risk assessment on the basis of which the measures under this Regulation are taken should be based on the available scientific evidence and undertaken in an independent, objective and transparent manner. ...*

(20) *Animal diseases are not only transmitted through direct contact between animals or between animals and humans. They are also carried further afield through water and air systems, vectors such as insects, or the semen, oocytes and embryos used in artificial insemination, oocyte donation or embryo transfer.*

(28) *For transmissible animal diseases, a disease condition is usually associated with clinical or pathological manifestation of the infection. However, for the purpose of this Regulation, which aims to control the spread of, and eradicate, certain transmissible animal diseases, the disease definition should be wider in order to include other carriers of the disease agent.*

(43) *Biosecurity is one of the key prevention tools at the disposal of operators and others working with animals to prevent the introduction, development and spread of transmissible animal diseases to, from and within an animal population. The role of biosecurity is also recognised in the impact assessment for the adoption of this Regulation, in which possible impacts are specifically*

*assessed. The biosecurity measures adopted should be sufficiently flexible, suit the type of production and the species or categories of animals involved and take account of the local circumstances and technical developments. Implementing powers should be conferred on the Commission to lay down minimum requirements necessary for the uniform application of biosecurity measures in the Member States. Nevertheless, it should always remain within the power of operators, Member States or the Commission to promote prevention of transmissible diseases through higher biosecurity standards by developing their own guides to good practice. While biosecurity may require some upfront investment, the resulting reduction in animal disease should be a positive incentive for operators.*

*(146) To encourage Member States to enhance the health status of their aquatic populations, certain adjustments and added flexibility should be introduced in this Regulation.*

*(149) Union aquaculture production is extremely diverse as regards species and production systems, and this diversification is rapidly increasing. This may require the adoption at Member State level of national measures concerning diseases other than those regarded as listed diseases in accordance with this Regulation. However, such national measures should be justified, necessary and proportionate to the goals to be achieved. Furthermore, they should not affect movements between Member States unless they are necessary in order to prevent the introduction, or to control the spread, of disease. National measures affecting trade between Member States should be approved and regularly reviewed at Union level.*

*(165) This Regulation lays down general and specific rules for the prevention and control of transmissible animal diseases and ensures a harmonised approach to animal health across the Union. In some areas, such as general responsibilities for animal health, notification, surveillance, registration and approval or traceability, the Member States should be allowed or encouraged to apply additional or more stringent national measures. However, such national measures should be permitted only if they do not compromise the animal health objectives set out in this Regulation and are not inconsistent with the rules laid down herein, and provided that they do not hinder movements of animals and products between Member States, unless this is necessary in order to prevent the introduction, or to control the spread, of disease.*

*(174) In line with the preventive approach to animal health that is promoted by this Regulation, the special measures concerning salmonella that applied to live animals dispatched to Finland and Sweden prior to 20 April 2016 should continue to apply and Regulation (EC) No 2160/2003 should be amended accordingly.*

3 Article 1 of the Regulation, headed “Subject matter and aim”, reads:

1. *This Regulation lays down rules for the prevention and control of animal diseases which are transmissible to animals or to humans.*

*Those rules provide for:*

- (a) the prioritisation and categorisation of diseases of Union concern and for the establishment of responsibilities for animal health (Part I: Articles 1 to 17);*
- (b) the early detection, notification and reporting of diseases, surveillance, eradication programmes and disease-free status (Part II: Articles 18 to 42);*
- (c) disease awareness, preparedness and control (Part III: Articles 43 to 83);*
- (d) the registration and approval of establishments and transporters, movements and traceability of animals, germinal products and products of animal origin within the Union (Part IV: Articles 84 to 228; and Part VI: Articles 244 to 248 and 252 to 256);*
- (e) the entry of animals, germinal products, and products of animal origin into the Union and the export of such consignments from the Union (Part V: Articles 229 to 243; and Part VI: Articles 244 to 246 and 252 to 256);*
- (f) non-commercial movements of pet animals into a Member State from another Member State or from a third country or territory, (Part VI: Articles 244 to 256);*
- (g) the emergency measures to be taken in the event of a disease emergency situation (Part VII: Articles 257 to 262).*

2. *The rules referred to in paragraph 1:*

*(a) aim to ensure:*

- (i) improved animal health to support sustainable agricultural and aquaculture production in the Union;*
- (ii) the effective functioning of the internal market;*
- (iii) a reduction in the adverse effects on animal health, public health and the environment of:*
  - certain diseases;*
  - the measures taken to prevent and control diseases;*

*(b) take into account:*

- (i) the relationship between animal health and:*
  - public health;*
  - the environment, including biodiversity and valuable genetic resources, as well as the impact of climate change;*
  - food and feed safety;*
  - animal welfare, including the sparing of any avoidable pain, distress or suffering;*
  - antimicrobial resistance;*

— *food security;*

*(ii) the economic, social, cultural and environmental consequences arising from the application of disease control and prevention measures;*

*(iii) relevant international standards.*

4 Article 4(16) and (23) of the Regulation, headed “Definitions”, reads, in extract:

*(16) ‘disease’ means the occurrence of infections and infestations in animals, with or without clinical or pathological manifestations, caused by one or more disease agents;*

*(23) ‘biosecurity’ means the sum of management and physical measures designed to reduce the risk of the introduction, development and spread of diseases...*

5 Article 9 of the Regulation, headed “Disease prevention and control rules to be applied to different categories of listed diseases”, reads, in extract:

*1. Disease prevention and control rules shall apply to listed diseases as follows:*

...

*(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.*

...

6 Article 10 of the Regulation, 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).*

7 Article 176 of the Regulation, headed “Approval of certain aquaculture establishments and delegated acts”, reads, in extract:

*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.*

...



8 Article 181 of the Regulation, headed “Granting of, and conditions for, approval and delegated acts”, reads, in extract:

*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.*

...

9 Article 183 of the Regulation, 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.*

10 Article 191 of the Regulation, headed “General requirements for movements of aquatic animals”, reads, in extract:

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.*

...

11 Article 192 of the Regulation, headed “Disease prevention measures in relation to transport”, reads, in extract:

*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.*

...

- 12 Article 226 of the Regulation, 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.*

- 13 Article 269 of the Regulation, 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**

- 14 According to the request, the Regulation is implemented in Norwegian law through Regulation No 631 of 6 April 2022 on animal health (*forskrift 6. april 2022 nr. 631 om dyrehelse (dyrehelseforskriften)*), 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 19. desember 2003 nr. 124 om matproduksjon og mattrygghet mv. (matloven)*) (“the Food Act”) and Act No 75 of 15 June 2001 relating to veterinarians and other animal health personnel (*lov 15. juni 2001 nr. 75 om veterinærer og annet dyrehelsepersonell (dyrehelsepersonelloven)*).
- 15 The first and sixth paragraphs of Section 40 of Regulation No 822 of 17 June 2008 on the operation of aquaculture establishments (*forskrift 17. juni 2008 nr. 822 om drift av akvakulturanlegg (akvakulturdriftsforskriften)*) 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 Regional Office (Fiskeridirektoratets regionkontor) 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.*

## **II FACTS AND PROCEDURE**

- 16 Nordsjø Fjordbruk 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.

- 17 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.
- 18 In the autumn of 2021, Nordsjø Fjordbruk applied for approval of the operating plan for the Nappelholmane site.
- 19 On 10 November 2021, the Norwegian Food Safety Authority (*Mattilsynet*) adopted a decision by which approval of the operating plan for Nappelholmane was refused. Nordsjø Fjordbruk 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.
- 20 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.
- 21 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 Nappelholmane 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 infectious salmon anaemia. It was also stated that the site has had previous detected incidences of fish pancreas disease 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.
- 22 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.
- 23 On 19 August 2022, Nordsjø Fjordbruk 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.
- 24 On 1 March 2023, Haugaland and Sunnhordland District Court (*Haugaland og Sunnhordland 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 Regulation and therefore valid. Nordsjø Fjordbruk appealed against that judgment.

- 25 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 Regulation. Both the District Court and the Court of Appeal referred in particular to Article 269(1)(a) of the Regulation and its reference to Article 10 thereof as grounds for finding that the decision was in accordance with the Regulation.
- 26 Nordsjø Fjordbruk'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 Regulation 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.
- 27 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?*

- 28 Reference is made to the Report for the Hearing for a fuller account of the legal framework, the facts, the procedure and the proposed answers submitted to the Court. Arguments of the parties are mentioned or discussed hereinafter only insofar as is necessary for the reasoning of the Court.

### **III ANSWER OF THE COURT**

- 29 The referring court asks, in essence, whether the Regulation, and in particular Articles 9, 10, 176, 181, 183–184, 191–192, 226 and 269 thereof, must be interpreted as entailing that EEA 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 where 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.
- 30 As a preliminary point, the Court notes that Article 17 EEA provides that Annex I thereto contains specific provisions and arrangements concerning veterinary and

phytosanitary matters. It follows from that Article and Article 7 EEA that acts incorporated into Annex I which concern agriculture and fishery products are binding upon the Contracting Parties (see the judgment of 1 February 2016 in *Ferskar kjötvörur*, E-17/15, paragraphs 44 and 47).

- 31 The acts incorporated into Chapter I of Annex I contain provisions on veterinary issues, which set out requirements pertaining, inter alia, to animal diseases, animal welfare and the hygiene of products of animal origin. These acts regulate the conditions for live animals and the production of products of animal origin, allowing them to be marketed on the internal market. This contributes to a common and high standard of food safety in the EEA and facilitates the circulation of food products of animal origin within it.
- 32 The Court observes that Article 1(2) of the Regulation provides that the purpose of the legal framework set out therein is to ensure improved animal health, the effective functioning of the internal market and a reduction of the adverse effects on animal health, public health and the environment of certain diseases and the measures taken to prevent and control diseases. Recital 4 thereto clarifies that the Regulation aims to ensure high standards of animal and public health, in order to avoid the spread of disease.
- 33 In addition, the Court notes that it follows from recitals 8 and 174 that the Regulation is based on a preventive strategy, and aims to promote animal health by placing greater emphasis on preventive measures. Indeed, as noted by ESA and the Commission, recital 8 makes explicit reference to the European Commission’s communication of 19 September 2007 on a new Animal Health Strategy for the European Union (2007-2013) where “prevention is better than cure”.
- 34 As observed by the Commission, the Regulation’s provisions, and particularly recitals 20 and 28 and Article 4(16) thereof, entail a broad understanding of the concept of disease, which comprises the occurrence of infection in animals, with or without clinical or pathological manifestation, and that of the spread of disease, which includes the mere risk of spreading infection by any means, not only through animal-to-animal contact but also by other possible means, including contact with particles, premises or means of transport.
- 35 The Court notes that the Regulation generally follows a risk-based approach and is based on the precautionary principle, which is reflected in recital 8 thereof. Preventive measures adopted on the basis of the Regulation, however, cannot be based on a purely hypothetical approach to the risk but on a scientific risk assessment. This is a scientific process consisting, in so far as possible, in the identification and characterisation of a hazard, the assessment of exposure to the hazard and the characterisation of the risk (compare the judgment of 17 March 2021, *FMC v Commission*, T-719/17, EU:T:2021:143, paragraph 66 and the case law cited). Moreover, recital 15 makes it clear that any risk assessment undertaken on the basis of which the measures under the Regulation are taken should be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.



- 36 In this context, recital 14 of the Regulation states that, in specific circumstances where a significant animal or public health risk exists but scientific uncertainty persists, the precautionary principle allows competent authorities to adopt provisional risk management measures on the basis of the available information without having to wait until the reality or extent of the risk becomes apparent (see also the judgment of 12 September 2011 in *Philip Morris*, E-16/10, paragraphs 82 and 83 and the case law cited, and compare, the judgment of 29 July 2024 in *ASCEL*, C-436/22, EU:C:2024:656, paragraph 73 and the case law cited).
- 37 As observed by the Commission and the Icelandic Government, the Regulation replaced 39 previous pieces of legislation. Thus, the Regulation introduces a single, comprehensive and flexible regulatory framework for animal health policy and its scope encompasses terrestrial and aquatic animals and their products. Recital 43 of the Regulation states that biosecurity is one of the key tools to prevent the introduction, development and spread of transmissible animal diseases to, from and within an animal population and that the biosecurity measures adopted should be sufficiently flexible, suit the type of production and the species or categories of animals involved and take account of the local circumstances and technical developments. Biosecurity is defined in Article 4(23) as the sum of management and physical measures designed to reduce the risk of the introduction, development and spread of diseases to, from and within an animal population, or an establishment, zone, compartment, means of transport or any other facilities, premises or location.
- 38 The Court observes, in the context of the case in the main proceedings, that the question referred entails the movement of farmed fish. As such, the specific rules laid down by the Regulation pertaining to aquaculture are applicable.
- 39 In relation to aquatic animals, recital 146 of the Regulation states that, in order to encourage EEA States to enhance the health status of their aquatic populations, certain adjustments and added flexibility should be introduced. Recital 149 further notes that, as between EEA States, aquaculture production is extremely diverse as regards species and production systems, and this may require the adoption at EEA State level of national measures beyond those specifically foreseen in the Regulation. However, such national measures should be justified, necessary and proportionate to the goals to be achieved.
- 40 As observed by the Icelandic Government, the Regulation applies to the aquaculture sector as a framework establishing procedural requirements to be supplemented by national provisions as necessary to meet the legislation’s objective. As such, “aquaculture establishments where aquaculture animals are kept with a view to their being moved therefrom, either alive or as products of aquaculture animal origin” must apply to the competent authority for approval pursuant to Article 176 of the Regulation.
- 41 Article 181 of the Regulation sets forth the conditions which must be fulfilled for the competent authority to grant approval of aquaculture establishments. Under point (a) of Article 181(1), establishments must comply, where appropriate, with the requirements in relation to quarantine, isolation and other biosecurity measures taking into account the requirements provided for in point (b) of Article 10(1). That provision requires

operators of aquaculture establishments, inter alia, to take such biosecurity measures regarding kept animals, and products under their responsibility, as are appropriate for the species and categories of kept animals and products, the type of production, and the risks involved, taking into account geographical location and climatic conditions, and local circumstances and practices. Article 10(4)(b) specifies that such biosecurity measures shall be implemented, inter alia, through management measures, which may include conditions for movement based on the risks involved. Moreover, point (c) of Article 181(1) further provides that such establishments must “not pose an unacceptable risk as regards the spread of diseases, taking into account the risk-mitigation measures in place”.

- 42 The Court notes that these conditions are not precisely defined in terms of what they entail and, as such, can only be fulfilled on the basis of the competent authority’s risk assessment on the basis of a case-by-case assessment. In the light of recital 15 of the Regulation, this assessment should be based on available scientific evidence and undertaken in an independent, objective and transparent manner.
- 43 The Icelandic Government has explained that so-called “dormant diseases”, or diseases where fish may be asymptomatic, are prevalent in the aquaculture sector. As such, and contrary to the submissions of Nordsjø Fjordbruk, it is clear that the assessment under Article 181 of the Regulation, in taking into account the inherent scientific uncertainty involved in transporting fish that may or may not be carriers of disease, the grant of and conditions for approval of aquaculture establishments cannot be contingent upon a confirmed outbreak or concrete suspicion of disease. Rather, a case-by-case assessment must take place, taking account of all relevant risk factors, including – but not limited to – geographical and climatic elements, which may significantly influence the level of risk from one EEA State to another, or from one geographic region to another.
- 44 Moreover, with respect to the facts at issue in the main proceedings, the Court observes that it is specifically foreseen in Article 269(1)(a) and (d) of the Regulation that EEA States may apply within their territories measures that are additional to, or more stringent than, those laid down in the Regulation, concerning both the approval of aquatic establishments provided for in Article 181 and the biosecurity measures imposed on operators pursuant to Article 10, the compliance with which is in and of itself a condition for approval under Article 181. As noted in recital 146, this reflects the additional flexibility the Regulation grants to EEA States in relation to aquatic animals.
- 45 EEA States enjoy flexibility to adopt national measures they deem necessary, provided, pursuant to Article 269(2) of the Regulation, that they do not hinder the movement of animals and products between EEA States and are not themselves inconsistent with the rules of the Regulation that they supplement. In this context, it should be noted that there is no suggestion that the case at issue involves movement between EEA States. Rather, the request refers only to movement taking place between different aquaculture establishments, in this instance, some 39 kilometres apart, within a single EEA State, in the present case, Norway. With respect to the second criterion, namely that national measures should not be inconsistent with the rules of the Regulation, the Court observes

that the Regulation specifically foresees that movement restrictions could be imposed at national level in the aquaculture sector due to the risk of the spread of disease associated with movements between those establishments.

- 46 As noted by the Icelandic Government, limitations on the movement of fish between aquaculture establishments are biosecurity measures that are widely adopted to prevent the outbreak and transmission of animal diseases. Such biosecurity measures may represent the only effective way to address the types of transmissible diseases prevalent in aquaculture fish, many of which are without symptoms for extended periods of time, and some of which may develop incurable diseases.
- 47 As is apparent from Article 10(4)(b)(iii) of the Regulation, movements of animals are considered one of the main risk factors for the spread of transmissible animal diseases, and minimising risk and taking biosecurity measures as regards the movement of aquatic animals are therefore responsibilities of operators. Further, as noted in the request, the purpose of the approval requirement for the operating plan is for the competent authority to be able to take decisions regarding the management of the risks created by the implementation of the operating plan in a specific aquaculture establishment and to assess the appropriateness of the biosecurity measures put in place by the operator to prevent the risk of spread of fish diseases. This will entail, amongst other things, an assessment as to whether any proposed movements of fish under the operating plan will be compatible with Article 10(4)(b).
- 48 As the referring court pointed out, Section 40 of the Norwegian Regulation on aquaculture operations requires an operator of an aquaculture establishment to have an operating plan in place at all times and to have that plan approved by the competent authority at regular intervals based on certain criteria. Such a requirement may be held to constitute an additional and more stringent measure within the meaning of Article 269(1)(a) of the Regulation, even if such a provision were to go beyond what is foreseen by Article 181.
- 49 As noted by the Commission, the mere fact that the approval of an operating plan also relates to movements of fish to or from a particular site does not affect the conclusion that such a measure may fall under Article 269 of the Regulation. Rather, it is clear from Article 10 thereof that movements of animals constitute a practice that may have consequences with respect to biosecurity, during which operators are also obliged to minimise the risk of spread of diseases. Moreover, it follows from Article 269(2)(a) that national measures taken on the basis of the first paragraph of that provision can potentially have a restrictive effect on the movement of animals.
- 50 To sum up, a systematic interpretation of Article 269(1)(a) and (d) of the Regulation, in conjunction with Articles 10 and 181, and considering the broader context and purpose of the Regulation, suggests that EEA States may impose stricter rules on animal health concerning biosecurity measures to prevent disease outbreaks, as well as conditions for approval of establishments, which may involve movement restrictions. Hence, a measure that essentially prohibits the movement of farmed fish between aquaculture establishments may be consistent with the Regulation, provided that the central

veterinary authority, following a specific and scientific risk assessment in accordance with the interpretation of the precautionary principle provided for above, determines that considerations of fish health at the individual site or in an area warrant such a measure.

- 51 Moreover, contrary to the submissions of Nordsjø Fjordbruk, movements may be restricted for reasons of preventing the spread of diseases, even if there is no suspected or confirmed disease outbreak. This follows from the fact that the rules on movement of aquatic animals are laid down in a different part of the Regulation to the movement restrictions as part of disease control measures. They do not require a suspicion of disease and even less an outbreak of a disease, but are based on the assessment of the general risk of the spread of certain diseases involved with the specific movement of aquatic animals for the health status, in particular, at the place of destination. This conclusion is further borne out by the definition of “disease” in Article 4(16) of the Regulation, which involves the occurrence of infections and infestations in animals, with or without clinical or pathological manifestations.
- 52 Articles 191 and 192 of the Regulation, to which the plaintiff refers, lay down general requirements concerning movements of aquatic animals. However, these provisions do not exhaustively lay down the conditions under which movements are allowed to take place. They lay down obligations with which operators are obliged to comply and do not confer any rights concerning movement of aquatic animals on these operators.
- 53 As noted by the Commission, a prohibition on fish movement can also follow from the application of other provisions if the risk associated with that movement is considered too high. The obligation to take appropriate biosecurity measures in the context of movements can also amount to not moving the animals at all, for example on the basis of Article 10(4)(b)(iii) of the Regulation. As such, it is clear that further restrictions on movement can also follow from rules that were applied in accordance with Article 269(1).
- 54 The Court observes that the various issues taken into account by the competent authority when making the specific assessment as to whether considerations of fish health warrant the refusal of the approval of the operating plan are also relevant within the context of the requirements for movements as laid down in Articles 191 and 192 of the Regulation, as they also require an assessment of the risk associated with a particular movement taking into account potential risk mitigating measures.
- 55 The fact that the national authority looks at future planned movements when assessing the operating plan does not entail that the risk being considered is purely hypothetical. As noted by the Commission, the process of risk assessment is inherently prospective, as the concept of “risk” relates to the probability of possible adverse effects that have not occurred at the time of the assessment but might occur in the future. This does not mean that the risk is hypothetical. A hypothetical approach to the risk is an approach that is founded on a mere conjecture which has not been scientifically verified (compare the judgment of 17 May 2018, *Bayer CropScience and Others v Commission*, T-429/13 and T-451/13, EU:T:2018:280, paragraph 116).

- 56 The Court adds that recital 165 of the Regulation, which concerns Article 269 thereof, states that national measures should be permitted only if they do not compromise the animal health objectives pursued by the Regulation. Thus, it is clear that a national measure such as that at issue in the main proceedings, which provides for an approved operating plan in order to ensure a high biosecurity standard as regards the operation of aquaculture establishments, is in line with this spirit and the general objective of the Regulation.
- 57 On the basis of the foregoing, the reply to the referring court must be that the Regulation, and in particular Article 269(1) thereof, must be interpreted as permitting the competent authorities to adopt a measure such as that at issue in the main proceedings, namely refusing to approve an operating plan of an aquaculture establishment at sea because the implementation of the operating plan would entail an unacceptable risk of the spread of disease. However, such a measure must comply with the requirements of the Regulation as regards risk assessment and management, and therefore in particular result from a specific risk assessment that is objective, independent and transparent and must not be based on a mere hypothetical risk.

#### IV COSTS

- 58 Since these proceedings are a step in the proceedings pending before the Norwegian Supreme Court, any decision on costs for the parties to those proceedings is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds,

#### THE COURT

in answer to the question referred to it by the Norwegian Supreme Court hereby gives the following Advisory Opinion:

**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 in particular Article 269(1) thereof, permits the competent authorities to adopt a measure such as that at issue in the main proceedings, namely refusing to approve an operating plan of an aquaculture establishment at sea because the implementation of the operating plan would entail an unacceptable risk of the spread of disease. However, such a measure must comply with the requirements of the Regulation as regards risk assessment and management, and therefore in particular result from a specific risk assessment that is objective, independent and transparent and must not be based on a mere hypothetical risk.**

Páll Hreinsson

Bernd Hammermann

Michael Reiertsen

Delivered in open court in Luxembourg on 12 December 2024.

Ólafur Jóhannes Einarsson  
Registrar

Páll Hreinsson  
President