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TO THE PRESIDENT AND MEMBERS OF THE EFTA COURT

WRITTEN OBSERVATIONS

submitted pursuant to Article 20 of the Statute of the EFTA Court and Article 90(1) of the Rules of procedure of the EFTA Court by the

EUROPEAN COMMISSION

represented by: Flor CASTILLA CONTRERAS, Bruno RECHENA and Miriam ZERWES, Members of the Legal Service acting as agents, with an address for service at: *Service Juridique, Greffe contentieux, BERL 01/093, 1049 Bruxelles,*

in Case E-8/24

concerning a request for an advisory opinion submitted by the Supreme Court of Norway (*Norges Høyesterett*) pursuant to Article 34 of the Agreement between the EFTA States on the establishment of a Surveillance Authority and a Court of Justice in the case:

Nordsjø Fjordbruk AS

Appellant

against

The Norwegian State

Respondent

regarding 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”) which was incorporated into point 13 of Part 1.1 of Chapter I of Annex I to the EEA Agreement by EEA Joint Committee Decision No 179/2020 of 11 December 2020.

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1. INTRODUCTION

1. The *Norges Høyesterett* requests an advisory opinion on the interpretation of certain rules of Regulation (EU) 2016/429 ⁽¹⁾ (hereinafter “Animal Health Law” – “AHL”) applicable to aquaculture animals. In the request, the *Norges Høyesterett* enquires about the compatibility with that Regulation of a measure, such as the one at hand in the main proceedings, namely the rejection by the Norwegian Food Safety Authority of an application for approval of an operating plan for an aquaculture site, which proposed to move fish from the site concerned by the operating plan to two other sites. The reason given for the refusal to approve the operating plan was that, after carrying out a specific assessment, the Norwegian Food Safety Authority concluded that, overall, the risk of the spread of infection/disease associated with the planned movement of fish was too high, even though there was no detected disease in the fish or concrete suspicion thereof. Therefore, in the view of the Norwegian Food Safety Authority, “considerations of fish health” at the individual site or in an area warranted the measure. Since the operating plan provided for the movement of fish from one site to two other sites, the *Norges Høyesterett* also enquires about the possibility under the AHL for a national authority to prohibit the movement of farmed fish from one aquaculture establishment to another one within national borders. After outlining the applicable legal framework and the relevant factual background, as it arises from the request for advisory opinion in Sections 2 and 3, the European Commission (hereinafter: “the Commission”) describes in Section 4 the objectives and general features of the AHL and provides its views on the correct interpretation of that Regulation.

2. APPLICABLE LEGAL FRAMEWORK

2.1. EEA law

2. The AHL became applicable from 21 April 2021 between Member States of the European Union and by incorporation into point 13 of Part 1.1 of Chapter I of

⁽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 L 84, 31.3.2016, p. 1, ELI: <http://data.europa.eu/eli/reg/2016/429/oj>.

Annex I to the EEA Agreement by EEA Joint Committee Decision No 179/2020 of 11 December 2020 amending Annex I (Veterinary and phytosanitary matters) to the EEA Agreement [2023/1981] ⁽²⁾, with certain adaptations, to Norway.

3. The following recitals of the AHL are relevant in particular:

*“(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.

*(9) The aim of this Regulation is to implement the commitments and visions provided for in that Animal Health Strategy, including the ‘One health’ principle, and to consolidate the legal framework for a common Union animal health policy through a single, simplified and flexible regulatory framework for 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

⁽²⁾ OJ L 240, 28.9.2023, p. 5, ELI: <http://data.europa.eu/eli/dec/2023/1981/oj>.

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 [...].

(22) Union legislation adopted prior to this Regulation lays down separate animal health rules for terrestrial and aquatic animals. Council Directive 2006/88/EC lays down specific rules for aquatic animals. Yet in most cases, the main principles for good animal health governance and good animal husbandry are applicable to both groups of animal species. Accordingly, this Regulation should cover both terrestrial and aquatic animals and should align those animal health rules where applicable. However, for certain aspects, in particular the registration and approval of establishments and the traceability and movements of animals within the Union, this Regulation adheres to the approach adopted in the past, which was to lay down different sets of animal health rules for terrestrial and aquatic animals due to their different environments and accordingly different requirements to safeguard health. [...]

(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. [...]

(42) Operators working with animals are in the best position to observe and ensure the health of the animals and to monitor products under their responsibility. They should therefore bear primary responsibility for carrying out

measures for the prevention and control of the spread of diseases among animals and the monitoring of products under their responsibility.

(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. [...]

(48) Member States, and in particular their competent authorities responsible for animal health, are amongst the key actors in the prevention and control of transmissible animal diseases. [...]

(136) The registration and approval of aquaculture establishments is necessary in order to allow the competent authority to perform adequate surveillance and to prevent, control and eradicate transmissible animal diseases. Directive 2006/88/EC requires all establishments which move aquatic animals to be authorised. That system of authorisation should be maintained under this Regulation [...]

(141) As in the case of terrestrial animals, it is necessary to lay down harmonised rules on the movement of aquatic animals, including rules on animal health certification and movement notification.

(142) Directive 2006/88/EC lays down rules for movements of aquatic animals which apply equally to movements within and between Member States. The key determining factor in relation to rules on the movement of aquatic animals is the

health status, as regards listed diseases, of the Member State, zones and compartments of destination. [...]

(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. [...]

(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.”

4. Article 4(16) of the AHL defines “disease” as “*the occurrence of infections and infestations in animals, with or without clinical or pathological manifestations, caused by one or more disease agents*”. “Establishment” is defined in Article 4(27) of the AHL as “*any premises, structure, or, in the case of open-air farming, any environment or place, where animals or germinal products are kept, on a temporary or permanent basis [...]*”.
5. In its Chapter 3 of Part I the AHL sets out general rules on responsibilities for animal health. As regards responsibilities of operators, Article 10 of the AHL provides:

“Article 10

Responsibilities for animal health and biosecurity measures

1. *Operators shall:*

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

(i) the health of kept animals; [...]

(iii) minimising the risk of the spread of diseases; [...]

(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; [...]

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. [...]

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

(a) physical protection measures, [...]

(b) management measures, which may include:

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

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

(iv) conditions for introducing animals or products into the establishment; [...]"

6. Articles 172 et seq. of the AHL lay down rules as regards the registration and approval of aquaculture establishments. In that context, Articles 176, 180 and 181 of the AHL provide:

“Article 176

Approval of certain aquaculture establishments and delegated acts

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:

[...]

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

Article 180

Obligation of operators to provide information with a view to obtaining approval

1. Operators shall, for the purposes of their application for approval of their establishment as provided for in Article 176(1), Article 177, point (a) of Article 178 and Article 179, provide the competent authority with the following information: [...]

(f) other aspects of the mode of operation of the aquaculture establishment in question which are relevant for determining the risk, posed by it; [...]

(h) the establishment's biosecurity measures.[...]

Article 181

Granting of, and conditions for, approval and delegated acts

1. The competent authority shall only grant approvals of aquaculture establishments as referred to in Article 176(1) [...], 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); [...]

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

7. Part IV, Title II, Chapter 2 of the AHL contains rules on movements of aquatic animals. In this context, Articles 191 and 192 of the AHL, located in Section 1 on general requirements for movements, read as follows:

“Article 191

General requirements for movements of aquatic animals

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. [...]*

Article 192

Disease prevention measures in relation to transport

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; [...]*
- (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. [...]*”.

8. Under Title III “Member States’ Measures” of Part VIII, headed “Common provisions”, Article 269 of the AHL provides:

“Article 269

Additional or more stringent measures by Member States

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); [...]*

(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); [...]*

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.”*

9. Commission Delegated Regulation (EU) 2020/691 ⁽³⁾ supplements the AHL as regards rules for aquaculture establishments and transporters of aquatic animals. Its Article 5 reads:

“Article 5

Requirement for approved aquaculture establishments and groups thereof to have a biosecurity plan

The competent authority shall only approve aquaculture establishments referred to in Article 7 and Articles 9 to 19, or groups of aquaculture establishments referred to in Article 8, if their operators have developed and documented a biosecurity plan, which complies with the following requirements:

- (a) it identifies the routes whereby a disease agent can enter the aquaculture establishment or group of aquaculture establishments, spread within it and transfer from it to the environment or to other aquaculture establishments;*
- (b) it takes account of the specificities of the individual aquaculture establishment or group of aquaculture establishments and identifies risk-mitigation measures for each biosecurity risk which has been identified; [...]*”

10. Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (hereinafter “General Food Law” – “GFL”) ⁽⁴⁾ provides in its Articles 6 and 7 as follows:

⁽³⁾ Commission Delegated Regulation (EU) 2020/691 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for aquaculture establishments and transporters of aquatic animals, OJ L 174, 3.6.2020, p. 345, ELI: http://data.europa.eu/eli/reg_del/2020/691/oj, incorporated into point 13i of Part 1.1 of Chapter I of Annex I to the EEA Agreement by EEA Joint Committee Decision No 4/2021 of 5 February 2021 amending Annex I (Veterinary and phytosanitary matters) to the EEA Agreement [2024/23], OJ L, 2024/23, 11.1.2024, ELI: <http://data.europa.eu/eli/dec/2024/23/oj>.

⁽⁴⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety

“Article 6

Risk analysis

1. *In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.*
2. *Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.*
3. *Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5. [...]*

Article 7

Precautionary principle

1. *In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.*
2. *Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under*

Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>, incorporated into point 13 of Part 7.1 of Chapter I of Annex I to the EEA Agreement by EEA Joint Committee Decision No 134/2007 of 26 October 2007 amending Annex I (Veterinary and phytosanitary matters) and Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement, OJ L 100, 10.4.2008, p. 33, ELI: [http://data.europa.eu/eli/dec/2007/134\(2\)/oj](http://data.europa.eu/eli/dec/2007/134(2)/oj).

consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.”.

2.2. Norwegian law

11. The *Norges Høyesterett* explains that the AHL is implemented in Norwegian Law through Regulation No 631 of 6 April 2022 an animal health. Regulations based on the AHL have been implemented in Norwegian law through a number of different regulations, in turn based on the Act No 124 of 19 December 2003 relating to food production and food safety, etc. (the “Norwegian Food Act”). Section 19 of the Norwegian Food Act provides as follows:

“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 [...].”

12. The *Norges Høyesterett* further explains that based on Article 19 of the Norwegian Food Act, Norway adopted Regulation No 822 of 17 June 2008 on the operation on aquaculture establishments (“Regulation on aquaculture operations”). Its section 40, titled “Operating plan and fallowing” ⁽⁵⁾, reads as follows in its first and sixth paragraphs:

“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. [...]

⁽⁵⁾ Free Translation.

The Norwegian Directorate of Fisheries 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 at the individual site or in an area so warrant.”.

13. According to the *Norges Høyesterett*, in Norway, operators of an aquaculture establishment at sea need to be granted approval of the operating plan of the establishment *in addition* to the approval of the establishment itself.
14. The Commission further understands that, under section 40 of the Norwegian Regulation on aquaculture operations the operating plan should cover the following two calendar years of operation of the establishment and must indicate, among other things, at which sites fish will be placed, the number of fish placed and the timing of the placement. It must also include the following periods and whether the fish will be moved during the following period to other sites. According to the *Norges Høyesterett* “fallowing” entails that all establishments within the zone in question are emptied of fish for a period of time ⁽⁶⁾, that nets are taken up from the sea and that all equipment is cleaned and disinfected. It is a measure to reduce the risk of spread of transmissible fish diseases.

3. FACTS AND THE QUESTION ASKED

15. The appellant in the main proceedings is a company that engages in food fish production of salmon at different sites in Norway. In autumn 2021, the appellant applied for the approval of the operating plan for its Nappelholmane site, an aquaculture establishment at sea. The operating plan provided for the movement of fish from that site to the Ulvøyo and Flathomen sites, which are approximately 39 km away and are located in a different fallowing zone to the Nappelholmane site. On 10 November 2021, the Norwegian Food Safety Authority adopted a decision by which it denied approval of the operating plan for the Nappelholmane site based

⁽⁶⁾ The Commission understands that the Norwegian rules in principle provide for a fallowing period of 2 months after each production cycle for food fish.

on section 40 of the Norwegian Regulation on aquaculture operations as it considered that the risk of spread of disease associated with the planned movement was too high. Following an appeal of the appellant, the refusal was upheld by the Norwegian Food Safety Authority's appeals body by decision of 29 April 2022.

16. That decision was mainly based on the finding that for refusing the approval of an operating plan pursuant to the second sentence of the sixth paragraph of section 40 of the Regulation on aquaculture operations, it is sufficient that, based on a specific assessment, there is objective support for the position that the implementation of the operating plan will entail an unacceptable risk of spread of disease and infection. In assessing the application, the Norwegian Food Safety Authority took into account a number of objective factors: (i) the distance between the Nappholmane and the Ulvøyo and Flatholmen sites and their different following zones; (ii) that the Nappholmane site is an open marine facility, not protected against infection from fish farming facilities in its vicinity; (iii) that the Nappholmane site is located ca. 9 km from two surveillance zones for the fish disease *Infectious salmon anemia* (ISA); (iv) that previously there had been instances of *pancreas disease* (PD) at the Nappholmane site and that, as a result there was a risk that the fish would have been exposed to infection prior to the planned movement; and (v) that there was a high risk of spread of disease to other fish farming facilities during transport involving the use of well boats. Thus, the Norwegian Food Safety Authority concluded that the overall risk of spread of infection exceeded what was an acceptable risk and rejected the application. The decision was informed by the precautionary principle. Thus, the national authority did not consider it necessary for there to be a suspected or confirmed presence of disease at the site, as the fish could still be carriers of latent diseases.
17. On 19 August 2022, the appellant 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 declared invalid.
18. The decision was upheld by the Haugaland and Sunnhordland District Court by judgment of 1 March 2023 and, upon appeal by the appellant, by the Gulating Court of Appeal by judgment of 31 October 2023. Both courts found that the Norwegian Food Safety Authority's decision was not contrary to the AHL. Both

courts referred in particular to Articles 10 and 269(1), point (a) of the AHL as grounds for finding that the Norwegian Food Safety Authority's decision was consistent with the AHL.

19. The appellant appealed to the *Norges Høyesterett*, which granted leave to appeal by decision of 4 February 2024.
20. According to the *Norges Høyesterett*, the appeal is directed against the Court of Appeal's application of the law in relation to the rules in the AHL. The appellant does not claim that the Norwegian Food Safety Authority's decision is contrary to section 40 of the Regulation on aquaculture operations or section 19 of the Norwegian Food Act. The parties to the main proceedings mainly disagree on the interpretation of certain provisions of the AHL and whether the aforementioned Norwegian rules are contrary to the AHL, including the Regulations based on it. In essence, the parties disagree as to whether certain provisions of the AHL apply and if they preclude Member States from adopting national rules allowing national competent authorities to adopt decisions such as the decision at issue in the main proceedings, which may have the effect of prohibiting movements of fish in individual cases, within national borders, based on considerations such as those supporting that decision.
21. According to the *Norges Høyesterett*, the case raises, more specifically, the following questions of interpretation of the AHL. First, whether Article 269(1), point (a) AHL applies and how it should be construed, in particular the significance of its reference to Article 10 AHL, since according to the respondent the decision at issue in the proceedings concerns responsibilities for animal health and both lower courts relied on Article 269(1), point (a) AHL. Second, whether the decision at issue in the main proceedings could be examined under Article 269(1), point (d) AHL and the AHL rules on approval of aquaculture establishments, since the refusal to approve the operating plan may in practice have the same implications on movements of fish as a refusal or withdrawal of the approval of an aquaculture establishment. Third, even if the decision at issue can be based on Article 269(1), points (a) or (d) of the AHL, whether the conditions of Article 296(2) AHL are met, as the appellant relies on Articles 191 and 192 of the AHL which concern movements of aquatic animals and argues that Member States

cannot apply more stringent rules under Article 269(1), points (a) or (d) of the AHL than what follows from these provisions. Furthermore, the appellant puts forward that the assessment of whether or not a movement is to be permitted is to be undertaken proximately to the time of movement. Hence, the respondent was not allowed to refuse approval of an operating plan foreseeing future movements on the basis of a future, hypothetical risk of spread of infection at the planned time of movement on the basis of the precautionary principle in section 19 of the Norwegian Food Act. Finally, although the parties have not relied on Articles 9 and 226 AHL, they have discussed these provisions for the sake of completeness and the *Norges Høyesterett* signals their potential relevance.

22. Therefore, the *Norges Høyesterett* has referred the following question to the EFTA Court for an advisory opinion:

“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?”.*

4. ANALYSIS

4.1. Preliminary observations

23. The AHL replaces 39 EU directives and regulations on different aspects of animal health and introduces a single, comprehensive and flexible regulatory framework for animal health policy as envisaged in 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”⁽⁷⁾. That strategy aims to promote animal health by placing greater emphasis, among others, on preventive measures, disease surveillance, and disease control, in order to reduce the incidence of animal diseases and minimise the impact of outbreaks when they do occur ⁽⁸⁾. Therefore, the AHL aims to achieve a high level of animal and public health protection ⁽⁹⁾, by following a preventive approach to animal health (cfr. recital 174 of the AHL).

24. As is apparent from Article 1(2) of that Regulation and its recital 4, and consistently with the Treaty rules that form its legal bases, the AHL aims to ensure improved animal health to support sustainable agricultural and aquaculture production in the Union, the effective functioning of the internal market, as well as a reduction in the adverse effects on animal health, public health and the environment of certain diseases and the measures taken to prevent and control diseases. It provides, in particular, for harmonised rules on the prevention and control of animal diseases transmissible to animals and to humans, in animals kept by humans, wild animals and certain animal products. The AHL’s rules comprise requirements for disease prevention, awareness, surveillance, control and eradication, biosecurity, traceability of animals and animal products, movements within the EU and entry into the Union of animals and animal products, as well as emergency measures.

25. Rules in the AHL are two-fold. On the one hand, there are general rules that apply to terrestrial and aquatic animals regardless of the diseases affecting them. Such rules include rules on the general responsibilities for animal health, including biosecurity, on registration and approval of establishments and on traceability. On the other hand, there are disease-specific rules, such as surveillance, disease

⁽⁷⁾ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a new Animal Health Strategy for the European Union (2007-2013) where “Prevention is better than cure”, COM(2007)0539 final, [EUR-Lex - 52007DC0539 - EN - EUR-Lex \(europa.eu\)](#).

⁽⁸⁾ Recital 8 of the AHL.

⁽⁹⁾ Recital 4 of the AHL.

control measures, movement requirements and rules on the entry into the Union, that address certain diseases listed in the Regulation, as well as emerging diseases.

26. The AHL's objective of a high level of animal health protection and its emphasis on prevention means that its rules are underpinned by a broad understanding of the concepts of "disease" and "spread of disease" (cfr. recitals 20, 28 and Article 4(16) of the AHL). This 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 and the possibility to adopt preventive measures also if animals show no clinical signs of disease.
27. Moreover, the AHL follows a risk-based approach and is also based on the precautionary principle. Measures taken under the AHL are to be based on a scientific risk assessment. This is a scientific process consisting in the identification and characterisation of a hazard, the assessment of exposure to the hazard and the characterisation of the risk ⁽¹⁰⁾. The risk assessment on the basis of which the measures under the AHL are taken should be based on the available scientific evidence and undertaken in an independent, objective and transparent manner (recital 15 of the AHL). Thereafter, the competent authority is to take a risk management decision. This is a process distinct from risk assessment in which the competent authority, taking into account the results of the risk assessment, other legitimate factors and the precautionary principle decides on the appropriate measures to manage the risks ⁽¹¹⁾. In this context, it should be borne in mind that as recital 14 of the AHL explains, where the possibility of harmful effects is identified 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

⁽¹⁰⁾ See, Judgment of 11 September 2002, T-13/99, *Pfizer Animal Health v Council*, EU:T:2002:209, para.156 and Articles 3(11) and 6 of the GFL. The GFL applies, alongside the AHL, to aquaculture establishments that handle fish intended to be used as food.

⁽¹¹⁾ See, Article 6(3) of the GFL.

risk becomes apparent ⁽¹²⁾. In this respect, such measures cannot be based on a purely hypothetical approach to risk, which is founded on mere conjecture and has not been scientifically verified ⁽¹³⁾. In addition, such measures should be proportionate and not more restrictive of trade than it is necessary to achieve the high level of protection of health chosen by the EU legislator ⁽¹⁴⁾. The Commission suggests that the same approach should be taken under the EEA agreement ⁽¹⁵⁾.

28. As regards the disease invoked by the decision of the Norwegian Food Safety Authority, it is to be noted that ISA is currently listed in Annex II to the AHL and categorised by Commission Implementing Regulation (EU) 2018/1882 ⁽¹⁶⁾ as a C, D, and E disease only in the form of *Infection with highly polymorphic region (HPR) deleted infectious salmon anaemia virus*. In these observations, the Commission assumes that it is the latter disease that is referred to in the national authority's decision. PD is not a listed disease under the AHL.

4.2. On the Question

29. The request from the *Norges Høyesterett* contains two parts. First, the court is asking whether the AHL, and in particular Articles 9, 10, 176, 181, 183-184, 191-

⁽¹²⁾ See, Judgment of 5 May 1998, C-180/96, *United Kingdom of Great Britain and Northern Ireland v Commission*, EU:C:1998:192, para. 99-100, judgment of 11 September 2002, T-13/99, *Pfizer Animal Health v Council*, EU:T:2002:209, para 139.

⁽¹³⁾ See, Judgment of 11 September 2002, T-13/99, *Pfizer Animal Health v Council*, EU:T:2002:209, para. 143.

⁽¹⁴⁾ See, Article 7 of the GFL.

⁽¹⁵⁾ See, for public health already judgment of 5 April 2001, E-3/00, *EFTA Surveillance Authority v The Kingdom of Norway*, para. 27; judgment of 21 March 2023, E-5/23, *LDL*, para. 81, 84, 92.

⁽¹⁶⁾ Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases, OJ L 308, 4.12.2018, p. 21, ELI: http://data.europa.eu/eli/reg_impl/2018/1882/oj, incorporated into point 13a of Part 1.1. of Chapter I of Annex I to the EEA Agreement by EEA Joint Committee Decision 179/2020 of 11 December 2020 (see paragraph 2 above).

192, 226 and 269 thereof, must be interpreted as meaning that EEA States' central veterinary authorities 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 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.

30. Second, the court asks if the authority is precluded from prohibiting movements of farmed fish from one aquaculture establishment to another within national borders in the situation described above.

31. The Commission assumes that the referring court is enquiring about the prohibition of movement because the appellant, as it seems, has brought forward in essence that the refusal of the operating plan in the case at hand in the main proceedings would lead to a movement prohibition of the movements described in that plan which is not in line with the AHL rules on movements of aquatic animals.

32. Therefore, the Commission will first and foremost analyse the question of the refusal of the approval of an operating plan which gave rise to the issue in the main proceedings. In that context, it will address the relevant rules on (the prohibition of) movements of aquatic animals contained in the AHL.

33. In its assessment, the Commission assumes that with its question, the referring court is, in substance, asking about the compatibility of a law such as the one in place in Norway, which allows a competent national authority to adopt a decision such as the refusal of the approval of an operating plan of an aquaculture establishment at sea as described above.

4.2.1. Article 269 of the AHL

4.2.1.1. Article 269(1), point (a) of the AHL

34. Article 269 of the AHL allows for EEA States to apply within their territories measures that are additional to or more stringent than those laid down in the areas listed in paragraph 1 of that provision. Article 269(1), point (a) of the AHL refers

to responsibilities for animal health as provided for in Chapter 3 of Part I of the AHL, namely Articles 10-17 of the AHL.

35. Under Article 10 of the AHL operators are *inter alia* responsible for minimising the risk of the spread of diseases (Article 10(1), point (a) (iii) of the AHL) and for taking biosecurity measures regarding kept animals as appropriate (Article 10(1), point (b) of the AHL). Biosecurity is defined in Article 4(23) of the AHL 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*”⁽¹⁷⁾. According to Article 10(4), point (b) (iii) of the AHL biosecurity measures by operators are to be implemented, as appropriate, through, amongst others, management measures, which may include conditions for movement based on the risks involved.
36. The Commission takes the view that a requirement, such as the one laid down in section 40 of the Norwegian Regulation on aquaculture operations, for operators of an aquaculture establishments 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, may be held to constitute an additional and more stringent measure within the meaning of Article 269(1), point (a) AHL for the following reasons.
37. First, based on the request for advisory opinion and section 40 of the Norwegian Regulation on aquaculture operations, the operating plan provides a detailed description of the operation of the aquaculture establishment, as regards the placing of a certain quantity of aquatic animals at a certain point in time, and of the concrete movements of fish that are envisaged by the operator from a certain site. As is apparent from Article 10 of the AHL (see paragraph 35 above), movements of animals are considered one of the main risk factors for the spread of transmissible animal diseases, and minimising risk and taking biosecurity

⁽¹⁷⁾ Recital 43 of the AHL describes biosecurity as the “key prevention tools” at the disposal of operators.

measures as regards the movement of aquatic animals are therefore responsibilities of operators. ⁽¹⁸⁾

38. Second, the operating plan must also describe the fallowing periods at the site. Fallowing entails that all establishments within a zone are emptied of fish for a period of time and that nets and equipment are taken up from the sea and cleaned and disinfected, which are also responsibilities of operators.
39. Third, it can be inferred from the request for advisory opinion and section 40 of the Norwegian Regulation on aquaculture operations that fallowing is an important measure to reduce the risk of spread of transmissible fish disease ⁽¹⁹⁾ and may be considered a biosecurity measure within the meaning of the AHL as it is “*designed to reduce the risk of the introduction, development and spread of diseases to, from and within an animal population, or an establishment*”, which is an operator’s responsibility.
40. Fourth, the Commission understands from the request for advisory opinion and section 40 of the Norwegian Regulation on aquaculture operations that 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. From the request for advisory opinion, it appears that the competent authority carries out an overall assessment of the elements outlined in the operating plan, including, if the case is, of the risk posed by planned movements of fish between sites. The Commission understands that the approval of the operating plan is required independently of any plan to move fish as it also concerns aspects such as the length of fallowing periods which is a crucial biosecurity measure. Hence, the elements outlined in an operating plan

⁽¹⁸⁾ See also recital 42 of the AHL according to which operators should bear the primary responsibility for carrying out measures for the prevention and control of the spread of diseases among animals.

⁽¹⁹⁾ Section 40 of the Norwegian Aquaculture Regulations is titled ‘Operating plan and fallowing’ therefore underscoring the relevance of fallowing for the operating plan of aquaculture establishments.

as approved by the competent authority appear to concern core areas of responsibility of the operator of an aquaculture establishment.

41. Fifth, the requirement to have an operating plan approved by the competent authority is an additional and more stringent measure than what is laid down in in the AHL as the latter does not require operators to have such an operating plan, and therefore does not require approval of such a plan by the competent authority either.
42. Therefore, in the Commission's view, the requirement to have in place an approved operating plan may be considered as a measure to prevent infection from the operation of an aquaculture establishment at sea and to concern responsibilities of animal health within the meaning of Article 269(1), point (a) of the AHL.
43. The fact that the approval of an operating plan also relates to movements of fish to/from the concerned site does not affect this conclusion. It is obvious from Article 10 AHL that movements of animals constitute a crucial area where operators are also obliged to minimise the risk of spread of diseases (cfr. Article 10(2) and (4), point (b) (iii) of the AHL). Furthermore, it is already implied by the existence of Article 269(2), point (a) of the AHL that national measures taken in the areas listed in the first paragraph of that provision can potentially have a (restrictive) effect on the movements of animals.

4.2.1.2. Article 269(1), point (d) of the AHL

44. As suggested by the *Norges Høyesterett*, the requirement to have an approved operating plan for an aquaculture establishment at sea could also constitute an additional or more stringent measure concerning the registration and approval (of establishments) as provided for in Articles 172 et seq. of the AHL within the meaning of Article 269(1), point (d) of the AHL.
45. It should be noted that the AHL distinguishes between aquaculture establishments that are only subject to registration and aquaculture establishments subject to approval depending on the degree of risk of spread of disease involved and a corresponding more intense level of official surveillance and control. In line with the increased risk of spread of diseases that is involved with the movement of

aquatic animals, operators of aquaculture establishments where aquaculture animals are kept with a view to their being moved therefrom or of other aquaculture establishments which pose a significant risk due to movements of aquaculture animals into and out of the aquaculture establishment concerned need to apply for approval (cfr. Article 176(1), points (a) and (b) (iii) of the AHL). It would seem that the establishment at hand in the main proceedings would constitute an establishment subject to approval in accordance with Articles 176 et seq. of the AHL.

46. According to the *Norges Høyesterett*, under national law, the approval of an operating plan is additional to the approval of an aquaculture establishment. It would therefore seem that the approval of an aquaculture establishment is granted or refused irrespective of the approval of an operating plan, since the operating plan must be re-approved at regular intervals and that therefore the two approvals are separate decisions. Furthermore, the subject of the approval of an establishment is the “establishment” as defined by Article 4(27) of the AHL: “*any premises, structure, or, in the case of open-air farming, any environment or place, where animals or germinal products are kept, on a temporary or permanent basis*”.
47. However, although formally a distinct measure from the approval of the establishment, the approval of the operating plan may be considered as a measure that “concerns”, in a broader sense, the “approval” of an establishment within the meaning of Article 269(1), point (d) of the AHL. The content of the operating plan, in particular which movements take place and how they are implemented, and the test applied by the authority when assessing if approval can be granted, namely whether “considerations of fish health at the individual site or in an area warrant” refusal of the operating plan - which implies the identification of risks created by the implementation of the operating plan in a specific aquaculture establishment and the assessment of the appropriateness of the biosecurity measures -, are considerations that also need to be made by the competent authority when assessing if approval of the establishment can be granted.
48. This can for example be inferred from Article 180(1), points (f) and (h) of the AHL according to which operators, for the purposes of their application for

approval of their establishment, must provide information regarding other aspects of the “mode of operation” of the establishment which are relevant for determining the risk posed by it as well as regarding the establishment’s biosecurity measures. Furthermore, Article 181(1), point (c) of the AHL provides that one condition for approval is that the establishment does not pose an unacceptable risk as regards the spread of diseases, taking into account the risk-mitigation measures in place. In accordance with point (a) (i) of that provision, approval can only be granted if the requirements for “*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)*” are complied with. In fact, it seems that it would be difficult to assess the risk emanating from an establishment without looking into how that establishment will be operated and that therefore both elements are inextricably linked.

49. This finding is also supported by Articles 5 and 7 of Commission Delegated Regulation (EU) 2020/691 according to which aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom can only be approved if their operators have developed and documented a biosecurity plan, which *inter alia* identifies the routes whereby a disease agent can enter the aquaculture establishment, spread within it and transfer from it to the environment or to other aquaculture establishments and takes account of the specificities of the individual aquaculture establishment and identifies risk-mitigation measures for each biosecurity risk which has been identified.
50. In addition, if, under national law, the test to be applied for the approval of an operating plan had been designed as an additional requirement for the approval of the aquaculture establishment (the denial of which consequently would have led to the refusal of the approval of the establishment), it would undoubtedly have qualified as an additional or more stringent measure within the meaning of Article 269 of the AHL. In the Commission’s view, the assessment under Article 269(1), point (d) of the AHL should depend, essentially, on the substantive content of the measure in question rather than the formal regulatory design of the relevant provisions.

51. Furthermore, if Article 269(1), point (d) of the AHL was only to be understood as referring to the *requirements* for approval, “more stringent” and “additional” would have the same meaning. That interpretation would therefore deprive one element of its scope of application.
52. As the AHL does not formally foresee the approval of an operating plan as such, the requirement to have a (separately) approved operating plan is an additional measure within the meaning of Article 269(1) of the AHL.
53. It can be inferred from the request for an advisory opinion that the requirement to have an approved operating plan only applies to establishments “*within the territory*” of the EEA State and is thus also in line with that condition from the introductory sentence of Article 269(1) of the AHL. It would therefore be indispensable that the requirement to have an operating plan which is approved by the competent authority would only apply to aquaculture establishments within the territory of the EEA State and would not be a requirement that would be requested for fish originating from establishments located in other EEA States.

4.2.1.3. Article 269(2) of the AHL

54. In addition to concerning one of the areas listed in Article 269(1) of the AHL, the requirement to have an operating plan which is approved by the competent authority needs to comply with the conditions as laid down in Article 269(2) of the AHL. Consequently, it needs to respect the rules laid down in the AHL and must not
- hinder the movement of animals and products between EEA States (Article 269(2), point (a) of the AHL); and
 - be inconsistent with the rules referred to in paragraph 1 (Article 269(2), point (b) of the AHL).
55. As regards the case at hand in the main proceedings, the denial of the approval of the operating plan only concerned movements foreseen by that plan within the territory of Norway and therefore did not hinder the movement of animals between EEA States.

56. Furthermore, the requirement to have an approved operating plan is not inconsistent with the rules referred to in paragraph 1 of Article 269 of the AHL. In this regard, as far as Article 269(1), point (a) of the AHL is concerned, it needs to be noted that the Commission has until now not acted under the empowerment provided for in Article 10(6) of the AHL to lay down minimum requirements necessary for the uniform application of that Article by means of implementing acts. Insofar as the measure can be based on Article 269(1), point (d) of the AHL, it is to be noted that even though the AHL does not require a specific approval of operating procedures, it does not prevent it either. The requirement to have an approved operating plan is, in particular, consistent with the rules on the approval of establishments as it is intended to ensure that the risks associated with (the operation of) an aquaculture establishment, including foreseeable movements from and to there, are assessed, and that there are appropriate biosecurity measures in place before operation is taken up (cfr. also Article 176(3) of the AHL).
57. Finally, the Commission considers that a measure such as the one at issue in the main proceedings does respect, in particular, the rules on the movements of aquatic animals as laid down in Articles 191 et seq. of the AHL, contrary to what the appellant seems to contend in the main proceedings. This is based on the following considerations.
58. First, it should be noted that the fact that the approval of an operating plan would be refused despite there not being a suspected or confirmed disease outbreak does not mean that movements cannot be restricted for reasons of preventing the spread of diseases. This already follows from the fact that the rules on movement of aquatic animals are laid down in a different part of the AHL than the movement restrictions as part of disease control measures. Therefore, 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 spread of certain diseases involved with the concrete movement for the health status, in particular, of the place of destination (cfr. recital 142 of the AHL). Consequently, in line with the preventive approach of the AHL, the mere existence of Articles 191 et seq. of the AHL shows that that Regulation acknowledges that there can be a risk of spread of diseases despite there being no concrete factors giving rise to the suspicion of the presence of a

disease. Further, this finding is supported by the definition of “disease” in Article 4(16) of the AHL which comprises the occurrence of infection in animals, with or without clinical or pathological manifestation ⁽²⁰⁾.

59. In that context, the Commission would like to point out that, contrary to what the parties in the main proceedings contend (paragraph 30 of the request for an advisory opinion) and in line with what has just been said, Article 9 of the AHL can also be relevant in cases where there is no suspicion or confirmation of a disease as it also concerns measures of disease prevention regarding listed diseases (see e.g. Article 9(1), point (d) of the AHL).
60. Third, Articles 191 and 192 of the AHL, to which the appellant refers, are general requirements for movements of aquatic animals (cfr. the heading of Section 1 of Chapter 2 of Title II of Part IV of the AHL). They are addressed to operators (“*operators shall (only move... if)*”) who want to move aquatic animals and therefore constitute *obligations* of those operators. This is in line with the idea expressed in recital 42 of the AHL that operators should bear primary responsibility for carrying out measures for the prevention and control of the spread of diseases. Hence, Articles 191 et seq. of the AHL do not exhaustively lay down the conditions under which a movement is allowed to take place. They lay down obligations with which operators need to comply and do not confer any rights on these operators.
61. In fact, the obligation not to move (which equals a prohibition to move), 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, cfr. e.g. Article 10(4), point (b) (iii) of the AHL (“*conditions for movement based on the risks involved*”). Therefore, further restrictions to exercise a movement can e.g. also follow from rules that were adopted in accordance with Article 269(1) of the AHL.

⁽²⁰⁾ Cfr. also recital 28 of the AHL.

62. Fourth, the considerations made by the competent authority when making the specific assessment if 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 et seq. the AHL, as they also require an assessment of the risk associated with a particular movement taking into account potential risk mitigating measures. In that vein, it could be considered that the same elements which lead the authority to conclude that the risk involved with the movements foreseen by the operating plan is too high would lead e.g. to the conclusion that that the operator would not comply with its obligation that the movement does not jeopardise the health status of the place of destination with regard to a listed disease referred to in point (d) of Article 9(1) AHL (Article 191(1) of the AHL) or that the transport operation does not cause the potential spread of listed diseases (Article 192(1), point (b) of the AHL).
63. In this context, it should be noted that the fact that the national authority looks at future planned movements when assessing the operating plan does not mean, contrary to what the appellant in the main proceedings seems to argue, that the risk being considered is purely hypothetical. 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 ⁽²¹⁾. This does not mean that the risk is hypothetical. As aforementioned (paragraph 27) a hypothetical approach to the risk is an approach that is founded on a mere conjecture which has not been scientifically verified. ⁽²²⁾.
64. Fifth, as explained above, the AHL provides for general measures on approvals of establishments and responsibilities of operators, in particular biosecurity measures. These are complementary to the rules on movements of aquaculture animals. Thus, under Article 191(2) AHL one of the main requirements for movements to be able to take place is that the fish come from an approved (or registered) establishment.

⁽²¹⁾ See, definition of “risk” in Article 3(9) of the GFL.

⁽²²⁾ See, Judgment of 11 September 2002, T-13/99, *Pfizer Animal Health v Council*, EU:T:2002:209, para. 143.

This is because, among other reasons, the AHL presupposes that in order to be approved, or to continue to be approved, an establishment must have in place adequate biosecurity measures to prevent the risk of introduction, development and spread of infection. Therefore, if, as the appellant appears to argue, a competent authority could not refuse approval of an operating plan for an establishment because it entails movements of fish even if the implementation of the operating plan at the site poses an unacceptable risk of spread of infection, Article 191(2) AHL could not fulfil its purpose, and the AHL could not attain the high level of health protection sought since it could not ensure that movements of fish do not risk carrying diseases to the recipient site. It is precisely the preventive measures taken at the establishment where the fish are moved from, which are assessed and approved by the competent authority, that ensure that the movement will not risk carrying diseases to the establishment where the fish are moved to.

65. Sixth, it is apparent from the AHL that the predominant objective of the legislature was to improve the animal health status of aquatic populations. To this effect, recital 165, which concerns Article 269 of the AHL, states that the national measures should be permitted only if they do not *compromise* the animal health objectives set out in this regulation. A national measure, such as the one at hand 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 AHL (cfr. also recital 43).
66. Seventh, recital 146 shows that, also in the context of movements of aquatic animals, the AHL aims at an added flexibility for EEA States rather than a restriction of their freedom to regulate in certain areas in order to encourage them to enhance the health status of their aquatic population.
67. Therefore, Article 269 AHL allows competent authorities to adopt a measure such as the one in the main proceedings 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 spread of infection. However, such a measure must comply with the requirements of the AHL as regards risk assessment and management (see, paragraph 27, above), 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. This is for the national court to determine.

4.2.2. *Other provisions*

68. For the sake of completeness, the Commission points out that as regards diseases other than a listed disease referred to in Article 9(1), point (d) of the AHL, the measures described by the referring court could potentially also be based on Article 226(1) of the AHL where that disease constitutes a significant risk for the health of aquatic animals and the measure does not affect movements between EEA States. There is however no indication in the request for an advisory opinion that in the case at hand the approval of an operating plan was required specifically in view of such a disease.
69. Finally, the Commission would like to point out that certain movement restrictions could also follow from the disease-free status of or an approved eradication programme for the place of destination (see Article 197 of the AHL), however there is no indication of that in the request for an advisory opinion either.

5. CONCLUSION

70. In the light of the foregoing, the Commission considers that the question referred to the EFTA Court for an advisory opinion by the *Norges Høyesterett* 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.

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