



ATTORNEY GENERAL FOR CIVIL AFFAIRS

To the EFTA Court

OSLO, 5.7.2024

Written observations by the Norwegian Government

represented by Helge Røstum, advocate at the Office of the Attorney General for Civil Affairs, submitted pursuant to Article 20 of the Statute of the EFTA Court

Case E-8/24 Nordsjø Fjordbruk AS – v. The Norwegian Government

in which the Supreme Court of Norway has requested the EFTA Court to give an advisory opinion pursuant to Article 34 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice (SCA).

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1 INTRODUCTION

- (1) The request for an advisory opinion from the Supreme Court of Norway raises questions 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 (“the Animal Health Law”, or “AHL”).
- (2) The case before the Supreme Court concerns the validity of the Norwegian Food Safety Authority’s (“NFSA”) decision of 29 April 2022, where Nordsjø Fjordbruk AS’s (“Nordsjø”) application for approval of its operating plan for 2022 was refused.
- (3) The Supreme Court seeks guidance on the interpretation of the AHL, and has posed the following question to the EFTA Court:

Must Regulation (EU) 2016/429, in particular Article 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 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?*

2 THE BACKGROUND OF THE CASE

2.1 National law – approval of operating plans

- (4) As described by the referring court in section 4.1 of the referral, the national system for aquaculture establishments distinguishes between the general approval of the establishment and approval of the establishments' operating plans. The latter is regulated in Forskrift om drift av akvakulturanlegg av 17. juni 2008 nr. 822 («Regulation on aquaculture operations”).
- (5) Section 40 (1) of the Regulation on aquaculture operations require that an operating plan for aquaculture establishments in seawater is in place. An application for approval must include information for a period of two years, while an approval is granted for one year at a time.
- (6) Further, section 40 set out several requirements for what an operating plan must contain. It must, inter alia, describe the facilities intended for use. Furthermore, it must describe any plan that involves movement of the fish, as well as plans concerning fallowing of facilities. Fallowing involves emptying a facility of fish and cleaning the facility (possibly disinfecting it). Such measures aim to reduce the risk for spread of diseases, such as ISA (Infectious Salmon Anaemia). Section 40 grants the NFSA authority to require coordinated fallowing. This is done by dividing the areas into zones. Potential effects from such measures are reduced if an operator is allowed to move fish between different fallowing zones.
- (7) Based on the information provided in the application, the NFSA will, in cooperation with the Directorate of Fisheries, decide whether an operating plan shall be approved. According to section 40 (6), fish health is a consideration that can necessitate a refusal from the authorities, as considerations of fish health is closely linked to the risk for spread of diseases. The purpose of this rule is to provide the veterinary authorities an opportunity to consider whether there are circumstances related to the operation of the establishment that represents an unacceptable risk for spread of diseases before a plan is approved.

2.2 NFSA's assessment of the operating plan

- (8) As explained in section 3 of the referral, NFSA's refusal to approve the operating plan in the present case was based on a specific assessment of the risk for spread of disease caused by the planned movement of fish from the facility in Nappholmane to the facility in Ulvøyo and

Flatholmen, see paragraphs 3 and 10 of the referral. Those facilities are located in different following zones with previous incidences of outbreak of disease.

- (9) It should be emphasised that even though there were no detected or suspected incidence of disease at the time of NFSA's decision, the fish could still carry latent disease. It is not unusual that fish are infected but demonstrates no symptoms. If there is an outbreak of disease, it may have a detrimental effect, not only for the fish itself, but also for the economy of the operators in question and other operators in the same area. The negative consequences of an outbreak may be particularly devastating in situations where the fish have been moved over large distances, especially between different following zones.
- (10) In the present case, the NFSA found that the risk for spread of disease was unacceptable. As a result, the operating plan was not approved. The authorities focused on previous disease history, the design of the facilities, the distance between the facilities, the fact that the facilities were in different following zones and the conditions during transport. Further, the NFSA took the precautionary principle into consideration in its assessment.

2.3 EEA Law

- (11) With regard to the relevant EEA law, the referring court has given an extensive description of the AHL and the relevant provisions of the regulatory framework in the referral. Where necessary for the observations below, reference will be made to the relevant paragraphs of the request.

3 QUESTION OF THE CASE

3.1 Preliminary observations

- (12) The referring court has referred to a number of provisions in the AHL. As the Government sees it, the case primarily revolves around the interpretation of Articles 269, 10 and 191-192 of the AHL.
- (13) The essential question is whether the AHL preclude a national rule as the one at issue in the present case. As explained, this measure grants the veterinary authorities' competence to refuse approval of an operating plan involving movement of fish within national borders from one facility to another, in circumstances where there is no detected or suspected disease, but where the veterinary authorities find that the movement entails an unacceptable risk for spread of disease. Such decisions are based on specific assessments.
- (14) The Government submits that the question should be answered in the negative. Such a rule is not precluded by the regulatory framework of the AHL.
- (15) The main purpose of the AHL is to prevent the spread of disease and ensure better animal health within the internal market. It is submitted that Member States may, for this purpose, adopt national measures that supplement or are more stringent than those that are expressly provided for by the AHL in certain areas. This includes measures concerning

responsibilities for animal health (see Chapter 3 of Part 1 of the AHL), as well as measures that aim to prevent the spread of disease, also in connection with movement of aquatic animals between facilities, cf. Articles 269 (1) and 10.

3.2 Legal analysis of the question from the referring court

- (16) The Government notes that the AHL does not contain a rule or measure similar to the national rule at issue in the present case. There are also no provisions in the AHL that explicitly precludes such a measure.
- (17) The AHL have rules on approval of aquaculture establishments. In order to be approved, Article 181 requires that the competent authority find that the establishment does not pose an unacceptable risk as regards the spread of disease. That does not mean that the AHL preclude a national rule that allows for the same assessment in connection with approval of operating plans. Nowhere in the AHL is it stated or implied that it regulates the area of risk-mitigation measures for aquaculture establishments exhaustively and precludes a more extensive regulation in the Member States in certain situations. The Government refers to the impact assessment for the adoption of the AHL¹, where it is stated that the preferred regulatory option of the AHL

would be flexible to allow MS to set their own specific rules in certain cases to achieve these outcomes. It envisages that these specific rules would be based on veterinary risk assessment and cost benefit analysis to best suit particular situations in MS.

- (18) That flexibility has a legal basis in Article 269 of the AHL. Article 269 (1) explicitly grants the Member States competence to adopt national measures within their territories that are additional to, or more stringent than, the rules that are laid down in the AHL. One of the areas where the Member States are granted competence to adopt additional or more stringent national rules or measures, are rules concerning “(a) responsibilities for animal health, as provided for in Chapter 3 of Part I (Articles 10 to 17)”.
- (19) Article 10 in Chapter 3, Part I, to which Article 269 (1) a) refers, concern responsibilities for animal health and biosecurity measures. It imposes several measures and obligations with regard to animal health and biosecurity on operators of, inter alia, aquaculture establishments, cf. paragraph 23 and 24 of the referral.
- (20) The Government emphasises that biosecurity measures are one of the key tools used by operators and others working to prevent the spread of transmissible animal diseases. Biosecurity measures are 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:

a) an animal population, or

¹ Page 37 of the Commission staff working document, 6.5.203, SWD (2013)

b) an establishment zone, compartment, means of transport or any other facilities, premises or locations

- (21) With regard to the responsibilities concerning animal health and biosecurity measures, Article 10 (1) (a) (iii) states that operators shall be responsible for "*minimising the risk of spread of diseases*". Article 10 also states that operators shall be responsible for taking appropriate biosecurity measures, cf. Article 10 (1) (b) (iii). Those biosecurity measures cover management measures, which also may include "*conditions for movement based on the risks involved*" and "*conditions for introducing animals or products into the establishment*", cf. Article 10 (4) b (iii) and (iv).
- (22) The Government submits that the national measure at issue in the present case has a legal basis in these provisions. That is supported by the wording of Article 269 (1) a) and Article 10. The fact that the risk for spread of disease is linked to a plan to move fish between facilities, does not bring the measure outside the scope of Articles 269 (1) (a) and 10, considering that the biosecurity measures under Article 10 also covers "*conditions for movement based on the risks involved*".
- (23) The position of the Government is supported by the context of Articles 269 (1) (a) and 10.
- (24) Section 165 of the recital state that in some areas, such as responsibilities for animal health, the Member States should be allowed, or even encouraged, to apply additional or more stringent national measures if it is considered necessary to prevent the spread of disease. While this competence is not absolute, paragraph 165 indicates that the competence of the Member States to adopt national measures in the areas covered by Article 269 (1), should not be construed narrowly.
- (25) Furthermore, with regard to the competence of national authorities to adopt national measures on biosecurity, the Government refer to paragraph 43 of the recital. It is stated 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. 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

- (26) The recital clearly indicates that the regulation of biosecurity measures in the AHL is meant to be a flexible tool, and that Member States should have power to promote prevention of transmissible diseases through the development of higher biosecurity standards at a national level. The aim of the national rule or measure at issue in the present case, is exactly to "*promote prevention of transmissible diseases through higher biosecurity standards [...]*"

- (27) Also, the purpose and aim of the AHL, and of Articles 269 (1) and 10, support the position that the AHL does not preclude a rule such as the one at issue in the present case.
- (28) As explained, the national rule is based on preventive considerations. It aims to provide the veterinary authorities with an opportunity to assess whether there are circumstances related to the specific operation that represents an unacceptable risk for spread of disease. When the assessments are executed in advance, the risk for spread of diseases is reduced.
- (29) That purpose aligns well with the purpose of the AHL.
- (30) According to Article 2 of the AHL, the purpose of that legal framework 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. According to paragraph 4 of the recital, the AHL aims to ensure higher standards of animal and public health, in order to avoid the spread of disease. Also, it follows from paragraph 8 of the recital that the AHL is based on the strategy that "*Prevention is better than cure*" and aims to promote animal health by placing greater emphasis on preventive measures.
- (31) It would contradict that purpose if the AHL is interpreted in a way that precludes a national rule that grants the veterinary authorities' competence to refuse approval of an operating plan involving movement of aquatic animals, where the refusal is warranted by a specific assessment of the risk for spread of disease.
- (32) Further, as mentioned in section 2.1, it is not unusual that fish are infected, but have no symptoms of disease. Therefore, it cannot be decisive that there is no detected disease or concrete suspicion of disease in the fish at the time of decision. In order to achieve its purpose, the rule must be based on a specific risk-assessment where the available scientific evidence and the objective circumstances of the case at issue is taken into account.
- (33) The Government acknowledges that the competence granted to Member States under Article 269 (1) is not unfettered. According to Article 269 (2), the competence to adopt 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.*
- (34) The requirement set out in Article 269 (2) (a) is not relevant in the present case as it does not involve movement of animals between Member States.
- (35) As for Article 269 (2) (b), the Government cannot see that the national rule in the present case is inconsistent with any of the rules referred to in paragraph 1. The Government specifically refers to the arguments presented in paragraphs 16-19, and 26-27.

- (36) Nordsjø has argued that the national rule at issue does not respect the rules on movement of aquatic animals laid down in Articles 191 and 192. Nordsjø argues that there is no room for a national rule that allows for the refusal of an operating plan based on the risk for spread of disease triggered by the movement of fish, unless the refusal has a legal basis in the non-fulfilment of the rules on movement of aquatic animals in Article 191 and 192 itself.
- (37) The Government submits that the national rule at issue in the present case respect the rules on movement and transport in Articles 191 and 192.
- (38) Article 191 regulates "*General requirements for movements of aquatic animals*". Article 191 (1) (a) and (b) states that the operator 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 listed diseases and emerging diseases. Article 191 (2) set out certain minimum conditions that must be fulfilled in order to move aquatic animals.
- (39) Article 192 regulates "*Disease prevention measures in relation to transport*". Article 192 (1) (a)-(c) obliges the operators to take the appropriate and necessary disease prevention measures to ensure, inter alia, that the health status of aquatic animals is not jeopardised during transport, that transport operations do not cause the potential spread of listed disease, and that adequate biosecurity measures are taken as appropriate to the risks involved with the transport operations.
- (40) While these provisions impose a number of obligations on the operators which must be fulfilled in order for the operator to be allowed to move the aquatic animals, it is not stated that if the requirements are fulfilled, the operator has a *right* to move the animals to, or between facilities. If the provision were to be understood this way, as Nordsjø argues, one would expect the wording to be framed differently, for instance by stating that "The operator has, under these conditions, the right to move," or "is entitled to move in the following cases, etc.".
- (41) Such an understanding would also contradict the aim of strengthening preventive efforts to avoid spread of disease, particularly in a situation where the veterinary authorities have assessed that the movement connected with an operating plan entails an unacceptable risk of spread of disease.
- (42) Article 191 (1) merely states that the operator shall take "*appropriate measures*" to ensure that the movement of aquatic animals does not jeopardise the health status at the place of destination. The Government fails to see how the national rule at issue in the present case, is inconsistent with or contradict this provision. In any case, the correct view must be that if the veterinary authority has assessed that an operating plan involving movement of aquatic animals entails an unacceptable risk for spread of disease, the movement of the animals would not be an appropriate measure within the meaning of that provision.
- (43) For those reasons, the Government concludes that the national rule at issue in the present case is not inconsistent with any of the rules referred to in Article 269 (1) but has a legal basis in Article 269 (1) (a) and Article 10.

4 ANSWER TO THE QUESTION

Based on the foregoing, the Government respectfully submits that the question from the Supreme Court should be answered as follows:

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

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