Reykjavík, 8 July 2024

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 of the Rules of Procedure of the EFTA Court by

the Government of Iceland

represented by
Mr. Hendrik Daði Jónsson, Legal Adviser, Ministry for Foreign Affairs, and
Mr. Hjalti Jón Guðmundsson, Legal Adviser, Ministry of Food, Agriculture and Fisheries,
acting as Agents, and Mr. Jóhannes Karl Sveinsson, Attorney to the Supreme Court of
Iceland, acting as Counsel in

Case E-8/24
Nordsjø Fjordbruk AS
v
The Norwegian State,
represented by the Ministry of Trade, Industry and Fisheries

in which the Supreme Court of Norway (Norges Høyesterett) 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 on whether Regulation (EU) 2016/429 of the European Parliament and of the Council, in particular Articles 9, 10, 176, 181, 183–184, 191–192, 226 and 269 thereof, must 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, subject to certain conditions.

The Government of Iceland has the honour of lodging the following written observations.

I. Introduction

1. With a request dated 17 April 2024, the Supreme Court of Norway ("the Referring Court") requested an Advisory Opinion from the EFTA Court, pursuant to Article 34 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, on the interpretation of certain provisions 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 "the Regulation") in relation to the operation of aquaculture establishments.

2. The national case in which the Referring Court's question has arisen concerns the refusal of the Norwegian Food Safety Authority to approve an operating plan for an aquaculture establishment operated by Nordsjø Fjordbruk AS ("the Plaintiff"). The operating plan included plans to move fish between the site where the establishment was located to other establishments. The establishments, between which the movement of fish was foreseen, are located in different fallowing zones. The reason for the refusal was the assessment of the Norwegian Food Safety Authority that the planned movement of fish entailed a risk of the spread of disease which was assessed to be too high. The Plaintiff and the Norwegian State disagree as to whether the refusal is compatible with the obligations of the Animal Health Law, which was incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 179/2020 of 11 December 2020. The adopted Joint Committee Decision entered into force on 17 April 2021 and, as a result, the Animal Health Law became simultaneously applicable in the EU and the EEA on 21 April 2021.

3. For further details on the factual background of the case, the Government of Iceland refers to the request for an Advisory Opinion.

4. The Government of Iceland submits that the question of the Referring Court should be answered in the negative for the reasons outlined in the following observations.

II. Aquaculture and the Importance of Disease Prevention

5. With the world population projected to surpass 10 billion by 2060, the global demand for food is set to soar. This presents a challenge to securing food production without the unsustainable exploitation of natural resources and ecosystems, which will further deteriorate the earth's biosystems and biodiversity. As a result, there is great demand for the development and implementation of sustainable food production methods. Fish and other aquatic foods are key to meeting global demand for sustainable food as they have certain advantages in terms of sustainability and nutritional content relative to other protein sources. As the global output of wild capture fisheries has not risen since its peak in the 1990s and such fisheries are inherently limited by the status of wild fish stocks, aquaculture can play a vital role in meeting the expected growth in fish demand.

6. However, aquaculture is not free of challenges any more than other animal protein production. One of the greatest risks involved in aquaculture is the spread of transmissible diseases between fish. Farmed fish in open sea net cages are exposed to environmental pathogens, a threat that is very limited in land-based aquaculture. These pathogens can spread from wild fish to farmed fish and between sea sites via, for example infected fish, currents, well-boats, work boats and staff. As a result, strict biosecurity measures need to be put in place to minimise the risk of the spread of disease. Such measures can reduce the risk of transmission, but they can never eliminate that risk completely due to the nature of open sea pens. A crucial challenge specific to this form of aquaculture is the fact that clinical signs can be hidden over long periods of time. In these instances, disease prevention is the only measure that can be taken to avoid the spread of disease.

7. Diseases in salmon farming were first detected in the early 1960s and have followed salmon farming ever since. Diseases and mortality due to them are a significant threat to animal health and to the local economies dependent on aquaculture as an industry. At times, the outbreak of disease has posed a significant threat to the industry in several countries, with many farmers nearing or reaching insolvency due to operational losses. An example of this is the outbreak of the infectious salmon anaemia virus (“ISA”) in Iceland, which was detected for the first time in November 2021 at a single establishment located on the East Coast of Iceland in the fjord Reyðarfjörður. Within 6 months, all active sea sites in the fjord tested positive for ISA. By the end of May 2022, the two active sea sites in the fjord Berufjörður, also on the East Coast but around 40 km distance from Reyðarfjörður, tested positive for ISA. A total of 5.4 million fish in 48 cages were removed and the areas were fallowed for 90 days, in accordance with the applicable national regulations. The outbreak of the disease was catastrophic for the operator and the communities involved.

8. After sequencing the genetic material of the ISA virus on the East Coast of Iceland, it was apparent that the initial outbreak in Reyðarfjörður originated from a mutation of the non-pathogenic variant of the ISA virus, which is commonly present in the sea

environment. Sequencing of the virus in the latter outbreak in Berufjörður revealed that the viruses in the two outbreaks were closely related; that is, there had been a transmission of the virus between the two fjords. After an epidemiological study, it was believed, although not proven, that transmission of the virus occurred via a well-boat alternating between transport of slaughter fish from Reyðarfjörður and smolts to Berufjörður in the months before clinical signs became apparent in the first outbreak.

9. A disease called BKD (Bacterial kidney disease), caused by Renibacterium salmonarium, is endemic in the wild salmonid population in Iceland and can easily be transmitted from wild fish to farmed salmon in sea cages. Wild salmonids are predominantly asymptomatic carriers. In farmed salmonids, the bacteria can either cause subclinical disease with no clinical symptoms or disease with clinical symptoms. The disease is notifiable in Iceland and can cause high mortalities, especially in farmed salmon. BKD has a long prepatent period, where no clinical signs are apparent for up to 2 years after infection. This makes the disease exceptionally hard to contain, and prevention by biosecurity measures is key.

10. There is no effective treatment for the ISA virus or for BKD, and prevention is the most effective approach to control of the diseases. The chance of a primary disease outbreak from a wild salmonid population of both the non-pathogenic ISA virus and Renibacterium salmonarium is always present in Icelandic open sea cages. A major risk factor contributing to the transfer of the pathogens is poor biosecurity measures on and between farms. Infection can be carried over long distances with the transport of infected but asymptomatic live fish.

11. The aquaculture industry and responsible competent authorities are increasingly focusing on preventive efforts to reduce the number of disease outbreaks through better biosecurity measures.

12. The Animal Health Law applies to aquaculture production in the European Economic Area. The general principles of the Animal Health Law apply to such production, but the Regulation also sets out more stringent obligations specific to the sector that take into account the fact that it entails greater risks than traditional land-based animal husbandry.

III. General Observations

13. At the outset, the Government of Iceland submits that the question referred to the EFTA Court pertains to the most basic task of any society: to secure to its population the supply of safe and nourishing food. At any scale, food production presents risks to human and animal health, especially when it involves live animals. The outbreak of transmissible animal diseases can endanger the lives of both human and animal populations, compromise the safety of food and have devastating impacts on communities and livelihoods. Parties involved in food production apply measures to curb these risks and States have established food, veterinary and health authorities in which they have vested competence to protect the safety of the food chain. With the referred question, the EFTA Court is asked to consider the degree to which the authorities closest to food production may act to prevent risks they assess to be unacceptable to human and animal health.

14. The Government of Iceland submits that that the referred question must be answered in light of the object and purpose of the Animal Health Law as a framework regulation intended to secure a high standard of animal health in the European Economic Area, specifically through the prevention of the outbreak of disease, *inter alia* through biosecurity measures.

3.1. Rules on Animal Health under the EEA Agreement

15. Through the EEA Agreement, the Contracting Parties have created a dynamic and homogeneous European Economic Area which entails the harmonisation of rules applicable to many fields relevant to economic activity between them, including the food sector as the largest single economic sector in the EEA. Pursuant to Article 17 of the Agreement, European Union acts concerning veterinary and phytosanitary matters are incorporated into Annex I thereto. 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.

16. The Government of Iceland observes that the present request for an Advisory Opinion is the first case in which a European court is tasked with interpreting the substantive provisions of the Animal Health Law. With reference to that, and to the importance of the Regulation's effective implementation in the aquaculture sector in particular, the Government of Iceland considers it appropriate to submit observations on the background of the instrument and the purpose it has been intended to serve.

i. The background of the Animal Health Law

17. The Animal Health Law was adopted in 2016 after a review process carried out by the European Commission from 2004 to evaluate the performance of the then Community Animal Health Policy.

18. Its adoption marked a legislative milestone as it consolidated the legal framework for a common Union animal health policy through a single, simplified and flexible

regulatory framework for animal health. The Regulation served to implement the vision of the Animal Health Strategy for the European Union (2007-2013) which was centred on the principle that *"Prevention is better than the cure"*, i.e. preventative animal health measures are more effective than responsive ones. This vision was aligned with the *"One World – One Health"* approach developed by the World Health Organization, the World Organisation for Animal Health ("the OIE") and the Food and Agricultural Organization of the United Nations. The Regulation provided a modernised, principles and risk-based approach to the protection of animal, human and ecosystem health with an emphasis on disease prevention through biosecurity, surveillance and traceability measures.

19. In implementation of the One Health approach, the European Union has replaced many detailed acts which previously governed individual sectors with larger umbrella acts addressing the food chain at large. The Animal Health Law is one of these umbrella acts and individually replaced 38 older pieces of legislation. As such, its provisions address all animal diseases that can be transmitted to other animals or to humans and they establish principles and rules for the prevention and control of such diseases in animals and animal products. Like with the Animal Health Strategy, the central thesis of the Animal Health Law is that *"prevention is better than the cure"*.

20. While longer than an average EU act, the Regulation is remarkable for its brevity given its extensive scope of application which includes kept and wild animals, germinal products, products of animal origin, animal by-products and derived products, as well as facilities, means of transport, equipment and all other paths of infection and material involved or potentially involved in the spread of transmissible animal diseases.

21. This brevity is achieved using generally worded provisions seeking to regulate outcomes, process and responsibilities which can be applied to various situations and supplemented, where relevant, by further secondary legislation or national measures. While some provisions are intended only to regulate certain sectors, such as those specifically applicable to aquaculture, most of the articles apply on a cross-sectoral basis, underscoring their general adaptability to vastly different fields of food production in service of the overarching objective of disease prevention.

ii. The Animal Health Law establishes a general framework

22. The Animal Health Law was designed to be a streamlined and flexible regulatory framework whose objectives are reached through implementation tailored to on-the-ground realities in each Member State or, in an EEA context, each Contracting Party. This is clear from both the text of the Regulation and its associated preparatory documents.

23. It is stated in recital (43) 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.

24. It is further stated that the implementing powers conferred on the Commission should be used 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.

25. This acknowledged need for flexibility and the express intention for the Regulation to lay down the minimum requirements to be, as necessary, supplemented by Member States and local authorities is reflected in several other recitals. In recital (165), which elaborates on Article 269 of the Regulation, it is stated that in some areas, *"the Member States should be allowed or encouraged to apply additional or more stringent national measures"*. It follows that the Regulation is intended to be tailored to different situations across its area of application, rather than made to apply stricto sensu. In fact, the strict application of its black-letter provisions as such without due regard to the specific assessments of the national competent authorities would, in certain circumstances, yield results which directly contradict the Regulation's clear objectives.

26. The same flexible approach is described in The Explanatory Note accompanying the Proposal for the Regulation, where it is explained that:

"The Animal Health Law establishes a general framework for the prevention, control and eradication of animal diseases. This framework is built on outcome-based rules, avoiding over-prescriptiveness, and leaving room for MS to regulate or set more detailed legislation when necessary, so providing for the flexibility to adapt the rules to national, regional or local circumstances."

27. The Regulation's Impact Assessment from 2013 further elaborates on what was intended by a flexible approach:

"Under this option, a new legal framework would set out the principles and objectives for animal health policy required to achieve desired outcomes. The outcomes, such as certain animal health and linked public health standards, would be agreed at EU level. However, the framework 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."

28. The same can be seen from the European Commission's website, where a summary of the Animal Health Law is set forth. There it is stated that the Regulation's key priorities in tackling disease include inter alia *"**more flexibility** to adjust rules to local circumstances and emerging issues such as climate and social change"*.

29. Nowhere in the Regulation is it stated or implied that its provisions regulate the area exhaustively and thereby preclude national legislation in the Member States to exceed the terms of the Regulation. On the contrary, the flexibility is reflected in numerous provisions throughout the Regulation foreseeing that Member States may adopt more lenient or stringent measures for certain sectors or scenarios.

30. In light of the above, the Government of Iceland submits that the flexibility in national application of the Animal Health Law is an integral part of the legislation and that the framework established by it presupposes that its provisions will be supplemented as appropriate and necessary by the measures of competent authorities.

IV. Application to the Question Referred

31. The question posed to the EFTA Court reads as follows:

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?*

32. The Government of Iceland submits that the Animal Health Law applies to the aquaculture sector in the EEA in the same way as it does to other sectors: 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. Article 181 of the Regulation sets forth the conditions which must be fulfilled for the competent authority to grant approval, including on *"quarantine, isolation and biosecurity measures taking into account the requirements*" and that they "*do not pose an unacceptable risk as regards the spread of diseases, taking into account the risk-mitigation measures in place"*. As with other provisions of the Animal Health Law, these conditions are non-specific in what they entail and can only be fulfilled on the basis of the competent authority's risk assessment in every instance.

33. Furthermore, it is specifically foreseen in Paragraph 1 of Article 269 of the Regulation that Member 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.

34. The Member States have flexibility to adopt the national measures they deem necessary pursuant to Article 269 provided that they do not *"hinder the movement of animals and products between Member States"* and are not themselves inconsistent with the rules of the Regulation which they supplement. Importantly, the obligation not to hinder movement applies only to movement between Member States and not within them. As to the second criteria, that national measures should not be inconsistent with the rules of the Regulation, the Government of Iceland submits that the Regulation specifically foresees that movement restrictions could be imposed at national level in the aquaculture sector due to the great risk of the spread of disease associated with movements between those establishments. This is the reason why all establishments whose operations entail any movement of fish are subject to approval by the competent authority rather than to registration. The Government refers to recital (149) for further elaboration of this division of tasks foreseen between the Regulation and the Member States.

35. Limitations on the movement of fish between aquaculture establishments, such as those described in the request for an Advisory Opinion, are common and effective biosecurity measures which are widely adopted to prevent the outbreak and transmission of animal diseases. As the Government of Iceland has outlined in Chapter II above, the availability of this biosecurity measure is the only effective way to address the types of transmissible diseases prevalent in aquaculture fish, many of which are asymptomatic for extended periods of time. The practice of fallowing and other associated biosecurity measures are internationally recognised, including in the OIE Codes which the Animal Health Law is aligned with.

36. The Government of Iceland submits that it follows from the above that the Animal Health Law must not be interpreted in a way that precludes a national veterinary authority from adopting a biosecurity measure which limits the movement of fish between different aquaculture establishments within national borders, even though such measures are not individually listed as minimum requirements for approval in Article 181 of the Regulation.

37. The fact that Articles 191 and 192 of the Regulation lay down *"general requirements"* for the movement of aquatic animals and disease prevention measures for transport cannot mean that such movement may not be restricted by specific requirements that follow from the national measures of Member States, such as those adopted in relation to Articles 10, 176 or 181. Such a reading would be irreconcilable with the rationale of the Animal Health Law as a framework regulation and it would severely inhibit the attainment of its disease prevention objective by restricting the capacity of competent authorities to intervene in the aspects of aquaculture which present the greatest risk to the spread of disease. In this regard it must be underlined that the Animal Health Law does not provide for specific rules regarding limitations on the movement of fish between different aquaculture establishments within national

borders based on the assessment of the national veterinary authority that the consideration of fish health in the area warrants such limitations, even though no disease has been detected or any suspicion of disease has arisen.

38. Therefore, the Government of Iceland submits that the Regulation should not be interpreted so that it prevents national authorities from limiting the movement of fish between different aquaculture establishments to cases where disease has been detected or any suspicion of disease has arisen. Such limitations on the regulatory capacity of competent authorities would directly undermine the effectiveness of the Animal Health Law to prevent the outbreak of transmissible animal diseases in the European Economic Area.

V. ANSWER TO THE QUESTION REFERRED

39. The Government of Iceland respectfully submits that the EFTA Court answer the question from the referring court as follows:

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

For the Government of Iceland,

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