

EFTA Court Registry 1, Rue du Fort Thüngen L-1499 Luxembourg

Oslo, 5 July 2024

WRITTEN OBSERVATIONS

ТО

THE EFTA COURT

submitted pursuant to Article 90 (1) of the Rules of Procedure of the EFTA Court

represented by

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IN CASE E-8/24

NORDSJØ FJORDBRUK AS

v.

THE NORWEGIAN STATE, REPRESENTED BY THE NORWEGIAN MINISTRY OF TRADE, INDUSTRY AND FISHERIES ("NÆRINGS- OG FISKERIDEPARTEMENTET")

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1 INTRODUCTION

- (1) On 17 April 2024, The Norwegian Supreme Court (hereinafter "the referring court" or "the Supreme Court") requested an Advisory Opinion from the EFTA Court (hereinafter also referred to as "the Court"). The parties in the main proceedings, Nordsjø Fjordbruk AS (hereinafter "the Plaintiff") and the Norwegian Government, represented by the Norwegian Ministry of Trade, Industry and Fisheries (hereinafter the "the Government"), as well as other relevant parties were requested by the Court to submit their written observations by 8 July 2024.
- (2) As stated in the request for an advisory opinion, the case concerns the interpretation of several provisions in 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") (hereinafter also referred to as "the Regulation" or "AHL"). The Regulation establishes and harmonises the legislative framework for preventing and controlling diseases transmissible to animals across the EEA.
- (3) As explained below, the Regulation entails, with a few limited exemptions, a complete harmonisation of the rules applicable to aquatic animals across the EEA The exhaustive harmonisation in the Regulation includes, *inter alia*, the rules on the movement of aquatic animals in Articles 191 221 AHL and the even more detailed rules in the Commission's delegated acts. Thus, national restrictions on fish movement not vested in the Regulation are incompatible with EEA law. Therefore, EEA States are precluded from introducing national movement restrictions deviating from the AHL, such as the movement restriction within the contested decision adopted by the Government.
- (4) The AHL and the Commission's delegated acts provide fully harmonised rules to ensure that operators, including transporters, take all the appropriate and necessary preventive measures to ensure that the health status of kept aquatic animals is not jeopardised during transport and that the movement does not jeopardise the health status at the place of destination.¹ Where all appropriate and necessary measures set out in the Regulation and the delegated acts have been complied with, there is no scope left for the EEA States to (further) restrict the movement of clinically healthy fish. In essence, the system in the Regulation is that the EU legislature has

¹ See, *inter alia*, AHL Article 192.

adopted common rules for the EEA to ensure harmonised and stringent animal health standards and contribute to the completion of the internal market as follows from, *inter alia*, recital 4.² Therefore, the movement rules in the Regulation are highly detailed to ensure that all relevant risks are considered.

(5) The case pending before the Supreme Court concerns the validity of the Norwegian Food Safety Authority's decision of 29 April 2022 rejecting Nordsjø Fjordbruk AS' application for an operating plan³ for 2022 and 2023. The plan was rejected due to the Plaintiff's intended movement of fish from the locality *Nappeholmane* to the localities *Ulvøyo* and *Flatholmen*. In a more recent decision by the Food Safety Authority of 16 May 2024, the operating plan for 2024 was rejected for essentially the same reason. Therefore, the pending case is also relevant to this recent decision. The core of the matter is summarised by the Supreme Court in the request in the following manner:

"The overall question, however, is at any rate whether the Member States [EEA States] may adopt national rules allowing the central veterinary authority to prohibit movement of farmed fish from one aquaculture establishment to another within national borders or refuse approval of an operating plan for an aquaculture establishment if considerations of fish health so warrant."⁴

- (6) This is the first time the EFTA Court has been requested to interpret the Regulation.⁵ The Court must interpret the Regulation in line with the principles of interpretation as developed in its own case law and the case law of the ECJ. That is to say, an interpretation that ensures the *effectiveness* of the harmonised rules on fish movement, and not one that would make these rules on fish movement redundant, devoid of meaning and easy to circumvent, e.g. by "camouflaging" movement restrictions under national approval procedures for establishments, or the sites, where fish is held by the operators.
- (7) It is not disputed that the Food Safety Authority may deny the movement of fish. As already indicated, the core of the dispute is whether the Authority must do so by applying and adhering to the (movement) rules in the AHL (or the delegated acts).

² "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."

³ No.: "Driftsplan."

⁴ Cf. the referral at para. 40.

⁵ To the Plaintiff's best knowledge, there is no case law from the Court nor CJEU on interpreting the Regulation.

- (8) The parties in the main proceedings do not dispute that Article 269 of the Regulation permits the EEA States to establish additional or more stringent measures for certain specific areas covered by the AHL, as exhaustively listed in Article 269(1) (a) (e). However, Article 269(1) does <u>not</u> apply to the fully harmonised areas as this would be "inconsistent" with the AHL, cf. Article 269(2)(b). Therefore, the rules on movement of fish in Article 191 et seq. are not covered in Article 269(1) (a) (e).
- (9) Below, the Plaintiff will describe the relevant background of the dispute (pt. 2) and present the question referred (pt. 3). In pt. 4, the relevant national legislation and the contested decision will be described. In pt. 5, the Plaintiff will give an overview of the relevant EEA law and conduct the legal analysis for each different issue of interpretation in detail as posed by the referring court before the Plaintiff will render a proposed answer to the question referred (pt. 6).

2 THE BACKGROUND TO THE DISPUTE IN THE MAIN PROCEEDINGS

2.1 Background and the Norwegian decisional practice

- (10) It is not disputed that the sites where the fish was intended to be moved from and those to which it was to be transferred had the necessary licences and approvals. Still, approval of the operational plan was denied.
- (11) Generally, it is most common for the farmed fish to remain at the location where it is released until it is ready for slaughter. The operators usually avoid moving the fish. However, from a fish health perspective, moving fish during the production cycle can sometimes (in rare circumstances) be beneficial. Different local conditions can affect the fish differently at various growth stages. Therefore, on isolated occasions, fish farmers aim to relocate fish to more favourable areas once they have grown larger.
- (12) In recent years, the Norwegian Food Safety Authority ("Mattilsynet") has established a decision-making practice that completely prohibits fish movement between different fallowing⁶ zones. This is why Plaintiff has contested the decision in the case before the

⁶ No.: "Brakkleggingssoner". In aquaculture, "fallowing" refers to leaving a fish farm or other aquatic system empty of fish or other aquatic organisms for a period of time. Fallowing thus means, for disease management purposes, "an operation where a farm is emptied of aquaculture animals susceptible to the disease of concern or known to be capable of transferring the disease agent, and, where feasible, of the carrying water." See Annex I to the (now) repealed Fish Health Directive (Directive 2006/88).

referring court. This decisional practice is vested in Section 19 of the Norwegian Food Act and Section 40 of the Norwegian Aquaculture Operations Regulation.⁷ The Food Safety Authority rejected the Plaintiff's operational plan on the grounds of the precautionary principle in the Food Act Section 19.

(13) In the contested decision, the Food Safety Authority stated that moving fish between locations presents a considerable risk of infection and that the consequences for the destination area could be significant.⁸ According to the Food Safety Authority's guidelines for moving salmonoids⁹ between fish farms (sites), the Authority will:

"... as a rule, refuse approval of operating plans that involve moving fish from open net cage systems to other facilities and fallowing groups with a low degree of contact with infection via the seawater with the sending facility."¹⁰

(14) The Norwegian Food Safety Authority has thus advised the industry that relocation of fish between different fallowing zones will not be permitted and that operations and planning of operations must, therefore, be organised so that relocation of fish is not an option. As an example, reference is made to the Norwegian Food Safety Authority's decision in case 2018/049006, where the following was pronounced:

"The Norwegian Food Safety Authority, therefore, believes that it is important to limit how far the fish can be moved and, at the same time, limit the geographical area over which the fish are spread. In 2017, the industry was informed that the Norwegian Food Safety Authority wanted a tightening so that operations are planned in such a way that the movement of fish is no longer applicable. Permission **will not be granted** for such relocation between food fish facilities in different fallowing zones." ¹¹ (Our emphasis added.)

(15) The Norwegian Food Safety Authority's consistent refusal practice applies regardless of whether there is suspicion of disease at the sender or recipient location. The Plaintiff is unaware of any cases where the Food Safety Authority has approved the relocation of fish to another fallowing zone after 2019. In its most recent decisional practice, the Food Safety Authority's

⁷ "Forskrift om drift av akvakulturanlegg (akvakulturdriftsforskriften)" - Forskrift om drift av akvakulturanlegg (akvakulturdriftsforskriften).

⁸ The contested decision will be cited in more detail under pt. 4 below.

⁹ Salmonoids refer, in simple terms, to species (salmon, trout and rainbow trout) within the "salmon family."

¹⁰ "Mattilsynet vil som regel nekte godkjenning av driftsplaner som innebærer flytting av fisk fra åpne merdanlegg til andre anlegg og brakkleggingsgrupper med liten grad av smittekontakt via sjøvannet med avsenderanlegget."

¹¹ "Mattilsynet mener derfor at det er viktig å begrense hvor langt fisken kan flyttes, og samtidig begrense det geografiske området fisken spres over. I 2017 ble næringa informert om at Mattilsynet ønsker en innstramming, slik at drifta planlegges på en slik måte at flytting av sjøsatt fisk ikke lenger er aktuelt. Det blir ikke gitt tillatelse til slik flytting mellom matfiskanlegg i ulike brakkleggingsområder."

denial of the Plaintiff's operational plans has been based on Articles 269 and 184 AHL, as well as relevant national regulations (which will described further below) with the following reasoning:

"In practice, the approval scheme for operational plans entails an annual assessment of whether the facility meets any of the fundamental prerequisites for the facility to pose an acceptable risk of spreading of disease. If the Norwegian Food Safety Authority detects <u>serious deficiencies in</u> <u>biosecurity</u> that render the facility not posing an acceptable risk, "... and the operator of that establishment is not able to <u>provide adequate guarantees</u> that those deficiencies will be <u>eliminated</u>, the competent authority shall initiate procedures to withdraw the approval of the establishment," see Article 184 of the Animal Health Regulation. (...)

Articles 191, 192, and 196 AHL impose independent requirements for the movement of fish from approved aquaculture facilities. These are requirements that must be met at the time of movement for fish to be moved from facilities that have adequate biosecurity and have implemented biosecurity measures to be approved for the movement of fish (see article 181). Article 191(2)(a)(ii) entails that the operator may only move fish into an aquaculture facility if the fish come from a facility approved by the competent authority in accordance with Articles 181 and 182 if required under Article 176(1), Article 177, or Article 178. If the **basic prerequisites** for approval are not present in a facility, the facility will also not be able to meet the requirements of Article 191."¹² (Our emphasis added.)

(16) This means that the Food Safety Authority (now) also applies Article 184 AHL to withdraw approvals and deny applications for operational plans even where movements are planned to occur per the Regulation's harmonised provisions on movement. This creates legal paradoxes due to the contradictory obligations or even "regulatory impasses." To allow for deviating movement restrictions under the pretext of a national review of approval procedure as set out in Article 184, cf. Article 181 AHL would imply that the harmonised movement rules in the AHL would become redundant and devoid of meaning. It would also imply that EEA States could easily circumvent the harmonised movement rules by "camouflaging" movement restrictions under the approval procedure. In this context, it shall also be mentioned that fish

¹² "I praksis innebærer godkjenningsordningen av driftsplaner en årlig vurdering av om anlegget oppfyller noen av de grunnleggende forutsetningen for at anlegget skal utgjøre en akseptabel risiko for spredning av sykdom. Dersom Mattilsynet oppdager alvorlige mangler i biosikkerheten som gjør at anlegget ikke utgjør en akseptabel risiko, "... og den driftsansvarlige for anlegget ikke kan legge fram tilstrekkelige garantier for at manglene vil bli utbedret, skal vedkommende myndighet sette i gang prosessen med å tilbakekalle godkjenningen av anlegget", se dyrehelseforordningens artikkel 184. (...) Dyrehelseforordningen artikkel 191, 192 og 196 stiller selvstendige krav til forflytninger av fisk fra godkjente akvakulturanlegg. Dette er krav som må være oppfylt på flyttetidspunktet for at fisk kan flyttes fra anlegg som har god nok biosikkerhet og som har iverksatt biosikkerhetstiltak til å være godkjent for forflytning av fisk (se art 181). Artikkel 191 nr. 2 a) ii) innebærer at driftsansvarlig bare kan flytte fisk inn i et akvakulturanlegg dersom fisken kommer fra et anlegg som er godkjent av vedkommende myndighet i samsvar med artikkel 181 og 182, dersom dette kreves i henhold til artikkel 176 nr. 1, artikkel 177 eller 178." The citation is from the Food Safety Authority's decision dated 15 May 2024. (Ref.: 2023/22050.)

Dersom de grunnleggende forutsetningene for godkjenning ikke er til stede i et anlegg, vil anlegget heller ikke kunne oppfylle kravene i artikkel 191.

health is not static but dynamic and that assessing health risks in connection with movements must be carried out within a short time frame of the planned movement as stipulated in the AHL and the delegated acts, cf. further on this under pt. 5.3 below.

(17) As can be seen from the statements cited above, the Food Safety Authority has denied the Plaintiff's latest operational plans due to alleged "serious deficiencies in biosecurity" caused by the planned movement of fish between different locations. For the sake of good order, it is underscored that the contested decision in the pending matter before the referring court did <u>not</u> refer to Article 184 as the legal basis for the denial of movement in compliance with Articles 191 and 192 AHL. This legal basis (Article 184 AHL) was invoked by the Food Safety Authority only after the contested decision was disputed. Since the referring court also refers to Articles 176–184 AHL, the Plaintiff will revert to the interpretation of these provisions in the AHL below.

2.2 The Government's previous interpretation of the (repealed) Fish Health Directive

(18) Before addressing the interpretation of the Regulation in more detail, the Plaintiff finds reason to point out that the Government (the Ministry) previously fully shared the Plaintiff's understanding of the rules on the movement of fish at several crossroads. The AHL essentially continues the rules for movement (of fish) in the now-repealed Fish Health Directive.¹³ As follows from recital 142 of the AHL, these movement rules for fish, as previously laid down in the Fish Health Directive, and continued under the current AHL, apply equally to movements <u>within</u> and between the EEA States. In the "EEA memorandum"¹⁴ before its adoption, the Ministry of Fisheries and Coastal Affairs stated:

"The legislative act [Fish Health Directive] gives freedom to draw up supplementary national rules, within certain limits. However, this freedom <u>does not apply</u> to the rules on movement **unless** it is specifically stated [in the Directive]."¹⁵ (Our emphasis added.)

(19) Illustrative of Plaintiff's view is also the Government's statements in a public consultation letter
 dated 19 December 2008 relating to "regulations concerning special requirements for

¹³ Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals.

¹⁴ No.: "EØS-notat."

¹⁵ "Rettsakten gir frihet til innen visse rammer å lage utfyllende nasjonale regler. Denne friheten gjelder imidlertid ikke for reglene om omsetning dersom det ikke er angitt spesifikt."

aquaculture related activities in or near national salmon rivers and national salmon fjords," where the Ministry of Fisheries and Coastal Affairs at that time considered whether it was permissible to impose a general prohibition on the movement of fish from sites in national salmon rivers and national salmon fjords. On that occasion, it was discussed (on page 5 of the consultation letter) whether such a prohibition would conflict with the general right to move clinically healthy fish under the Fish Health Directive:

"Such a general ban on moving healthy fish would normally be contrary to the provisions of the EEA Agreement. The EU Fish Health Directive (Council Directive 2006/88) states that it shall be permissible to move fish <u>as long as the fish are clinically healthy</u> and the disease status in the area from which the fish is to be moved is equal to or better than the disease status of the area to which the fish are moved."¹⁶ (Our emphasis added.)

(20) The Ministry has also subsequently made similar statements to this effect. For instance, in the consultation document "Report to the Storting [Parliament] on growth in Norwegian salmon and trout farming" from 2014, the Ministry stated under pt. 6.2:

"There is a framework for what the authorities can and should impose on an industry. An example of this is the EEA Agreement's restrictions on rules on the movement of live fish. <u>The general rule is that live fish without **clinical signs of disease** should be able to be transported and traded freely, provided that their known health status does not pose a threat to health status at the recipient site."¹⁷ (Our emphasis added.)</u>

(21) As explained in detail below, the Government's previous interpretation is also accurate regarding the current Regulation's <u>continued</u> harmonised rules governing fish movement between different locations.

3 THE QUESTIONS REFERRED

(22) The Norwegian Supreme Court has referred the following question to the EFTA Court:

Must Regulation (EU) 2016/429, in particular Articles 9, 10, 176, 181, 183–184, 191–192, 226 and 269 thereof, be interpreted as meaning that the Member States' [EEA States] central veterinary authorities are precluded from prohibiting the movement of farmed fish from one

¹⁶ "Et slikt generelt flytteforbud av frisk fisk vil normal være i strid med EØS-avtalens bestemmelser. EUs fiskehelsedirektiv (Rådsdirektiv 2006/88) sier at det skal være tillatt å flytte fisk såfremt fisken er klinisk frisk, og sykdomsstatusen i området fisken skal flyttes fra, er lik eller bedre enn sykdomsstatusen til området fisken flyttes til. Direktivet inneholder imidlertid en unntaksbestemmelse i Artikkel 2.3 som gjør det mulig å innføre et slikt flytteforbud av reelle artsbevaringshensyn."

¹⁷ "Det finnes rammer for hva myndighetene kan og skal pålegge en næring. Et eksempel på dette er EØS-avtalens begrensinger for regler om flytting av levende fisk. Hovedregelen er at levende fisk uten kliniske tegn til sykdom skal kunne transporteres og omsettes fritt, gitt at deres kjente helsestatus ikke utgjør en trussel for helsestatus på mottakerstedet." Source: "Høring – melding til Stortinget om vekst i norsk lakse- og ørretoppdrett" dated 24 November 2014 Chapter 6.

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 NATIONAL LAW AND THE CONTESTED DECISION

4.1 Introduction

- (23) Fish farming companies in Norway are subject to numerous national regulations. The Aquaculture Act¹⁸ and the Food Safety Act¹⁹ are the two most important laws, and the various regulations passed under these national acts contain detailed provisions. In Norway, salmon farming licences are required for farming in seawater. More detailed rules on the Norwegian system for licences pertaining to salmonoids are governed by the Norwegian regulation on aquaculture licenses for salmon, trout, and rainbow trout.²⁰ The Plaintiff holds all necessary licences as required under Norwegian law.
- (24) Like other concession-regulated industries, aquaculture companies need permission to engage in it. In other words, the "default" is that the activity is prohibited and can <u>only</u> be conducted within the framework of allocated permits (approval) according to the Aquaculture Act. The purpose of the Aquaculture Act is, *inter alia*, to ensure that all aquaculture operations have permission under the law and have thus been assessed according to the applicable allocation rules, particularly as stipulated in Sections 6 and 7 of the Act.²¹ There is a requirement for two separate permits to farm salmonid fish in Norway: (i) a company permit (occasionally referred to as a "farming permit" or "production permit"), which is tied to a specific production area, and (ii) a site permit, which is linked to the company permit. The company permit is an authorisation to have a specified number of fish in the sea, and the site permit is an authorisation to place a certain number of fish at a <u>specific</u> site.

¹⁸ Lov om akvakultur (akvakulturloven) – LOV-2005-06-17-79.

¹⁹ Lov om matproduksjon og mattygghet mv. (matloven) – LOV-2003-12-19-124

²⁰ Forskrift om tillatelse til akvakultur for laks, ørret og regnbueørret – FOR-2022-11-07-1929.

²¹ The rules governing the general conditions for the allocation of aquaculture licenses and aquaculture licenses for salmon, trout and rainbow trout in particular.

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(25) While the detailed rules are unnecessary to describe, the approval procedure under the provisions referred to by the referring court is outlined below for the sake of completeness.

4.2 The system pertaining to clearing and approving aquaculture establishments

- (26) Due to the implementation of the Regulation, a new approval system was implemented to adapt the approval process to the AHL.²² Stage one is the so-called "site clearance" (site permit). The county municipalities²³ coordinate the application for site clearance. The Food Safety Authority assesses the location and suitability of the site concerning the overall risk of infection, current conditions, biosecurity plans, the internal control system, contingency plans, etc. Two decisions are rendered by the Food Safety Authority in stage one:
 - A decision on approval or rejection under the animal welfare regulations, and
 - A decision on clearance or rejection under the animal *health* regulations (AHL).
- (27) The application must include information about the distance to other aquaculture facilities, activities, water exchange, how to address animal welfare considerations, internal control, and contingency plans. The Norwegian Aqua Biosafety Regulation²⁴ has additional documentation requirements parallel to the AHL's. Operators of aquaculture facilities (sites) that move animals for release or slaughter must, therefore, document, *inter alia*, a biosecurity plan that the premises and equipment adequately limit the risk of introducing or spreading disease to an acceptable level and that they have sufficient capacity required.
- (28) In the second stage of the approval process, the Food Safety Authority inspects cleared sites after the facility is completed. After inspection, the Authority decides whether to reject or approve the facility under the Norwegian animal health regulations. The Food Safety Authority can also initiate a withdrawal process under national animal health regulations if serious deficiencies regarding compliance with the requirements in the facility's biosecurity plan, record-keeping, or health monitoring are discovered before final approval is granted. According to the Food Safety Authority, the national procedure described above fully adheres

²² <u>https://www.mattilsynet.no/fisk-og-akvakultur/oppdrettsanlegg/godkjenning-av-akvakulturanlegg-i-to-trinn-og-nye-krav-til-soknaden</u>

²³ NO.: "Fylkeskommunene."

²⁴ Forskrift som utfyller dyrehelseforskriften med bestemmelser om krav til biosikkerhet ved godkjenning av akvakulturanlegg og forflytninger av akvatiske dyr mv. (akvabiosikkerhetsforskriften). FOR-2022-04-05-624

to the requirements for approving aquaculture establishments of Articles 176, 180, 181, 182, 183, and 184 AHL in addition to Articles 5 and 7 of Regulation 2020/691.²⁵

4.3 The Norwegian Food Act

(29) The relevant parts of the Food Act^{26} Section 19 reads:

"Everyone shall show due diligence so that a risk of developing or spreading 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 <u>issue specific regulations</u> for the prevention, surveillance and control of animal diseases and infectious agents, including concerning:

(...)

d. <u>movement</u>, transport, placing on the market and use of live and dead animals, animal by-products, objects, etc."²⁷

(30) The Food Act Section 19(d) is thus the (national) legal basis for adopting rules on, amongst other things, the movement and transport of live animals, hereunder aquatic animals. All areas covered by Section 19 are now harmonised and implemented through the national regulations incorporating the secondary EEA law in the AHL and the delegated acts.

4.4 The Norwegian Aquaculture Operations Regulation

(31) In Plaintiff's view, the most relevant national regulation in the present context (the disputed decision) is the regulation of June 17, 2008, no. 822 on the operation of aquaculture facilities (the "Aquaculture Operations Regulation" or "AOR").²⁸ The AOR is vested in the Food Act Section 19, which means that the Act's overarching principles and rules are relevant for

²⁵ 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.

²⁶ NO.: "Matloven" - Act of 19 December 2003, no. 124, on food production and food safety (the Food Act).

²⁷ "Enhver skal utvise nødvendig aktsomhet, slik at det ikke oppstår fare for utvikling eller spredning av smittsom dyresykdom. Levende dyr skal ikke omsettes, tas inn i dyrehold, flyttes eller settes ut når det er grunn til mistanke om smittsom dyresykdom som kan gi vesentlige samfunnsmessige konsekvenser."

²⁸ Forskrift 17. juni 2008 nr. 822 om drift av akvakulturanlegg (akvakulturdriftsforskriften).

interpreting the provisions and rendering decisions in accordance with the (national) regulations. Section 1 (1) and (2) AOR reads:

"The regulation aims to promote the profitability and competitiveness of the aquaculture industry within the framework of sustainable development and contribute to value creation along the coast.

The regulation aims to promote good health among aquaculture animals, macroalgae, and aquatic plants and to ensure the well-being of fish."²⁹

- (32) The AOR covers the operation of all aquaculture facilities, such as those in the dispute pending before the referring court. The implementation of the AHL in Norway took place with the adoption of the Norwegian Animal Health Regulation ("AHR"),³⁰ which entered into force on 28 April 2022. Thus, the AHR implements the AHL and the other Commission's delegated acts in Norway.
- (33) The AOR is still in force and essentially remains unchanged even after the adaptation of the AHR and AHL. It remains clear that there is a substantial <u>overlap</u> between the "old" AOR and the new implementing regulation (AHR), which may not always be easy to reconcile.³¹ This creates a "grey area" with overlapping provisions in the "old" national regulations and the AHL. Section 40 AOR contains provisions regarding operating plans and fallowing, and reads in extract:

"An operating plan for aquaculture establishments in seawater shall always be in place. A joint operating plan shall be in place in the event of joint operations.

The operating plan for the next two calendar years must at least indicate:

a. The sites where fish are planned to be released, the timing of the release, and the number of fish. For sites with multiple aquaculture licenses, it must specify which licenses the releases pertain to.

b. The period for fallowing, any storage of cleaner fish, and any relocation of fish to other sites.

c. Any sites that are not planned to be used.

²⁹ No.: "Forskriften skal fremme akvakulturnæringens lønnsomhet og konkurransekraft innenfor rammene av en bærekraftig utvikling, og bidra til verdiskaping på kysten. Forskriften skal fremme god helse hos akvakulturdyr, makroalger og vannlevende planter og ivareta god velferd hos fisk."

³⁰ Forskrift om dyrehelse (dyrehelseforskriften). FOR-2022-04-06-631, jf. EØS-avtalen vedlegg I kap. I del 1.1 nr. 13 (forordning (EU) 2016/429 som endret ved forordning (EU) 2017/625 og forordning (EU) 2018/1629) og nr. 13a (forordning (EU) 2018/1882 som endret ved forordning (EU) 2022/925.

³¹ For instance, the AOR regulates "General Requirements for Proper Operations," "Competence, Training, etc.," "Emergency Plans," Reception of Aquaculture Animals," "Record-Keeping," "Infection Hygiene and Infection Prevention," "Risk-Based Health Monitoring," and "Duty to Notify" "Internal Movement" – only to name a few.

(...)

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. By decision, the Norwegian Food Safety Authority may refuse approval if considerations of fish health at the individual site or in an area so warrant.

If significant changes are needed to the approved part of the plan, an application for approval of the changes must be submitted to the Directorate of Fisheries as soon as possible." (Our emphasis added.)

- (34) The Plaintiff's application for an operational plan for 2022 and 2023 was refused by reference to Section 40 AOR, sixth paragraph, second sentence (underlined in the citation above), cf. the Food Act Section 19. The wording of that provision allows for various circumstances to suggest that an operational plan application can be denied approval if it pertains to fish health "at the individual site or in an area."
- (35) The Plaintiff contends that the alignment between the "old" national regulations and the "new" AHL has not been adequately undertaken, creating a "legal landscape" where the Food Safety Authority, at the time the decision was rendered, applied the "old" rules despite the implementation of the AHL and its delegated acts. On this premise, it seems <u>evident</u> that the Food Safety Authority had not considered Protocol 35 EEA³² when applying the "old" conflicting national provisions.
- (36) The Government interprets the wording of Section 40 AOR to the effect that the assessment of an operating plan should relate to the risk of spreading infection or disease among farmed fish at the site or in a defined area. At the same time, the Government contends that the AOR does not require any form of suspicion or detection of disease *in concreto* to refuse approval of an operational plan where the operator plans to move fish according to the rules in the AHL. Additionally, the Government has argued that the wording of the national provision indicates that the power to refuse approval is <u>entirely</u> discretionary, under reference to the term "may" in Section 40 AOR. And it is precisely for that reason that the Food Safety Authority, also in its most recent decision against the Plaintiff, has rejected to approve an operating plan application because one planned movement of fish from one site in full compliance with the AHL's movement rules. Thus, the Authority, *de facto*, prohibits all movements of fish under reference to the precautionary principle in the Food Act Section 19. The term "may" in Section

³² Implemented by the EEA Act ("EØS-loven") Section 2.

40 AOR is interpreted by the Government as a *carte blanche* to reject fish movement outright, regardless of compliance with the movement provisions in the AHL.

4.5 The wrongful interpretation of the AHL by the Food Safety Authority in the contested decision

(37) The Food Safety Authority discussed the relationship between the Norwegian regulations and the AHL in the contested decision. According to the contested decision:

"(...) operational plan applications cannot be refused without a <u>specific case assessment</u>. There must be a specific discretionary comprehensive assessment of the risk of infection spread in each individual case as a basis for refusal. However, <u>we do not believe that the regulations [AHL] should</u> be understood to mean that the Food Safety Authority's ability to reject operational plans must be linked to suspicion or detection of specific fish diseases."³³

(38) And further:

"The regulation has now been implemented by the new (national) Animal Health Regulation of April 28, 2022. The regulation largely continues the previous legal state.

You argue that the Food Safety Authority disregards the Marketing and Disease Regulation for Aquatic Animals Section 11, first paragraph, [³⁴] by denying approval of an operational plan under the Aquaculture Operations Regulation Section 40, sixth paragraph, second sentence. We disagree with this. As noted above, the Marketing and Disease Regulation for aquatic animals has now been repealed and replaced by the Animal Health Regulation. The requirement for clinically healthy fish when moving fish has, however, been retained in the Animal Health Regulation Article 196, where it is required that the fish must not show symptoms of disease. We do not find support for your interpretation based on the rules in effect at the time of the complaint, nor in how the regulations must be interpreted today. As we understand, the provision specifies the conditions that apply to aquaculture animals when they are to be moved. <u>Still, it does not grant an unconditional right to move clinically healthy fish.</u> Whether an approval can be denied depends on a specific, <u>discretionary comprehensive assessment of</u> 'concerns for fish health,' as established by the Aquaculture Operations Regulation Section 40, sixth paragraph." ³⁵ (Our emphasis added.)

³³ "[Vi er] enige i at driftsplansøknader ikke kan nektes godkjent uten at det er foretatt en konkret vurdering av saken. Til grunn for nektelse må det foreligge en konkret skjønnsmessig helhetsvurdering av risikoen for smittespredning for det enkelte tilfelle. Vi mener imidlertid ikke at regelverket skal forstås slik at Mattilsynets adgang til å avslå driftsplaner må knyttes til mistanke om eller påvisning av konkrete fiskesykdommer." (The contested decision on page 4.)

³⁴ This regulation ("forskrift") was part of the implementation of the (now repealed) "*Council Directive* 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals." Section 11 of the regulation provided that aquaculture animals must be clinically healthy to be moved, which was also in line with the Directive's provisions regarding fish movement.

³⁵ "Forordningen er nå gjennomført ved ny dyrehelseforskrift av 28. april 2022. Forordningen er i stor grad en videreføring av den tidligere rettstilstanden. Dere mener at Mattilsynet tilsidesetter omsetnings- og sykdomsforskriften for akvatiske dyr § 11 første ledd ved å nekte godkjenning av driftsplan etter akvakulturdriftsforskriften § 40 sjette ledd andre punktum. Dette er vi ikke enig i. Som poengtert ovenfor er omsetnings- og sykdomsforskriften for akvatiske dyr nå opphevet og erstattet av dyrehelseforskriften. Kravet om

(39) In the contested decision, the Food Safety Authority also held that:

"<u>In light of the precautionary principle</u> in the Food Act, cf. Section 19, an assessment of the consequences of transferring fish between different fallowing zones must be made. Experience shows that transferring fish from one site to another poses a high risk of infection, with potentially severe consequences for the destination area.

The risk of spreading infection when moving fish from facilities that use untreated seawater but are otherwise well-shielded from infection could be significantly lower than from open net pens. Whether a facility is well-shielded from infection depends on several factors that must be assessed on a case-by-case basis. (...)

In this case, we consider the risk associated with the planned operation plan for 10303 Nappeholmane to be too high. We believe that the potential harm to the areas where the fish is planned to be moved outweighs the benefits for the applicant in carrying out the transfer. Following a comprehensive assessment of the above factors, we conclude that fish health considerations suggest that the operation plan for site 10303 Nappeholmane cannot be approved, cf. AOR Section $40."^{36}$

(40) The Food Safety Authority did not conduct a proper – if any – assessment of the AHL's rules on the movement of fish in its decision and whether the *de facto* movement restriction is compatible with the AHL. It talked about a "specific case assessment." Still, in the Plaintiff's view, it failed to recognise that such an assessment must be made solely based on the harmonised rules on the movement of fish and by assessing the specific situations in which the AHL allow restrictions (exemptions) on fish movement.

klinisk frisk fisk ved flytting av fisk er imidlertid videreført i dyrehelseforordningen artikkel 196, hvor det er et krav om at fisken ikke kan vise symptomer på sykdom. Vi finner ikke støtte for deres tolking slik regelverket gjaldt på klagetidspunktet, og heller ikke slik regelverket må tolkes i dag. Slik vi forstår bestemmelsen angir den hvilke vilkår som gjelder for akvakulturdyr når de skal flyttes, men den gir ingen ubetinget rett til flytting av klinisk frisk fisk. Hvorvidt en godkjenning kan nektes beror på en konkret, skjønnsmessig helhetsvurdering av "hensynet til fiskehelsen" slik akvakulturdriftsforskriften § 40 sjette ledd legger til grunn." ³⁶ "I lys av matlovens føre-var-prinsipp, jf. § 19 må det gjøres en vurdering av konsekvenser av flytting mellom ulike brakkleggingsområder. Erfaring viser at flytting av sjøsatt fisk mellom lokaliteter utgjør en stor smitterisiko, og konsekvensene for området det flyttes til kan bli svært store.

³⁶ "I lys av matlovens føre-var-prinsipp, jf. § 19 må det gjøres en vurdering av konsekvenser av flytting mellom ulike brakkleggingsområder. Erfaring viser at flytting av sjøsatt fisk mellom lokaliteter utgjør en stor smitterisiko, og konsekvensene for området det flyttes til kan bli svært store.

Risiko for spredning av smitte ved flytting av fisk fra anlegg som bruker ubehandlet sjøvann men likevel har god skjerming mot smitte, kan være betydelig lavere enn fra åpne merdanlegg. Hvorvidt et anlegg er godt skjermet mot smitte, er avhengig av mange faktorer som må vurderes i hvert enkelt tilfelle. (...)

I denne saken mener vi at risikoen knyttet til planlagt driftsplan for 10303 Nappeholmane er for stor. Vi vurderer at de potensielle skadevirkningene for området der fisken er planlagt flyttet til veier tyngre enn de fordeler det vil ha for søker å få gjennomført flyttingen. Etter en helhetsvurdering av momentene over, mener vi at hensynet til fiskehelse tilsier at driftsplanen for lokaliteten 10303 Nappeholmane ikke kan godkjennes, jf. akvakulturdriftsforskriften § 40."

4.6 Summary of the core of the dispute before the referring court

- (41) The core of the dispute before the referring court is whether the AHL precludes a national restriction or prohibition for the <u>movement</u> of *clinically healthy* fish between aquaculture establishments that are licensed (approved) and meet all requirements for such approvals under the AHL or whether the Food Safety Authority, under all circumstances, can carry out a fully discretionary assessment as required by the rule for operational plan approvals (under the "old" national AOR and after the implementation of the AHL) without adhering to the harmonised rules in the Regulation regarding the movement of aquatic animals. The question is also whether this decisional practice can be vested in Article 184 AHL.
- (42) For the sake of good order, the Plaintiff again underscores that it is <u>not</u> disputed that the movement of fish, under a vast number of circumstances governed by the AHL, can be denied. However, the Plaintiff contends that such denials must be vested in the AHL (and/or) the delegated acts and that the discretion exercised must be in line with the detailed rules of the Regulation and not based on deviating national rules with reference to the general precautionary principle in the Food Act Section 19. Within the field of harmonisation at the EEA level, "appropriate risk mitigation measures" are set out in detail in the AHL and its delegated acts, cf. the description under pt. 5 below. The point of comprehensive and highly detailed rules under fully harmonised secondary EEA law, such as the AHL and the delegated acts, is that the situations justifying restrictions on movement, including proportionality and "balancing of interests," have already been undertaken by the EU legislature, and is thus fully "consumed" by the harmonised rules. In that case, there is no national "room for manoeuvre" for the EEA States to deviate. This differs from assessments under primary EEA law, where restrictions based on a general precautionary principle may be accepted in individual cases.

4.7 Short on the legislative amendments and the Government's official position

(43) The EU's 2016 AHL and the delegated acts are implemented by 12 different Norwegian animal health regulations.³⁷ The new EEA legislation, which places an even greater emphasis on preventing the spread of infection than before, is aimed at several groups, including the Food Safety Authority as the responsible authority in the animal health area. In connection with the

³⁷ <u>https://lovdata.no/register/lovtidend?kunngjortDato=28.04.2022%20kl.%2016.00#28.04.202216.00</u>

implementation of the "AHL-package", the Government's position was that the AHL entails a <u>complete harmonisation</u> regarding aquatic animals:

"Regulations must be incorporated verbatim in a reference regulation (the Animal Health Regulation). On the fish side, the regulation entails <u>a complete harmonisation</u> of the health legislation."³⁸ (Our emphasis added.)

(44) The Government also made similar statements in the public consultation round:

"With the new [national] Animal Health Regulation and supplementary regulations, existing health provisions for aquatic animals will be repealed and replaced with new health provisions. The regulation [AHL] has a broader scope than the Fish Health Directive and represents a <u>complete</u> <u>harmonisation</u> of [the fish] health legislation." ³⁹ (Our emphasis added.)

(45) Further, the "EEA-memorandum" from the Ministry of Trade, Industry and Fisheries states:

"The Animal Health Regulation is a regulation that includes requirements for animal health personnel and health requirements for aquatic and terrestrial animals. The regulation will, therefore, must be authorised by both the Food Act and the Animal Health Personnel Act. Regulations must be included verbatim in a referral regulation (the Animal Health Regulations). For fish, the regulation entails a full harmonisation of health regulations."⁴⁰ (Our emphasis added.)

(46) The Food Safety Authority itself made similar statements in the (public) consultation paper before the national implementation of the AHL package:

"With the new animal health regulations and supplementary regulations, the current health provisions for aquatic animals will be repealed and replaced with new health regulations. The regulation has a wider scope than the Fish Health Directive and <u>fully harmonises</u> the health legislation. Despite this, the changes relating to fish are mainly technical."⁴¹ (Our emphasis added.)

(47) Although not relevant to the interpretation of the AHL, it is interesting to note that the Government contends the *contrary* view in the present matter compared to its own previous,

³⁸ "Forordninger må inntas ordrett i en henvisningsforskrift (dyrehelseforskriften). På fiskesiden innebærer forordningen en fullharmonisering av helseregelverket." <u>https://europalov.no/rettsakt/dyrehelseforordningen-2016/id-6131</u>

³⁹ Se også høringsbrevet "Med den nye dyrehelseforskriften og utfyllende forskrifter vil gjeldende helsebestemmelser for akvatiske dyr bli opphevet og erstattet med nye helsebestemmelser. Forordningen har et videre omfang enn fiskehelsedirektivet og er en fullharmonisering av helseregelverket." Source: Høring - forslag til ny dyrehelseforskrift – Mattilsynet" (19 December 2019.)

⁴⁰ "Dyrehelseforordningen er en forordning som omfatter krav til dyrehelsepersonell og krav til helse for akvatiske dyr og landdyr. Forordningen vil derfor måtte hjemles i både matloven og dyrehelsepersonelloven. Forordninger må inntas ordrett i en henvisningsforskrift (dyrehelseforskriften). På fiskesiden innebærer forordningen en fullharmonisering av helseregelverket." The EEA-memo dated 31 March 2021 under part IX and the heading "Rettslige konsekvenser" ("Legal consequences").

⁴¹ "Med den nye dyrehelseforskriften og utfyllende forskrifter vil gjeldende helsebestemmelser for akvatiske dyr bli opphevet og erstattet med nye helsebestemmelser. Forordningen har et videre omfang enn fiskehelsedirektivet og er en fullharmonisering av helseregelverket. Tross dette er endringene på fiskesiden i hovedsak regeltekniske."

clear public statements before and in connection with the implementation of the AHL on several occasions.

5 LEGAL ANALYSIS

5.1 Introduction – comments on the question referred

- (48) In essence, the referring court's question concerns whether the Regulation entails a complete harmonisation of the criteria that need to be fulfilled to move fish and the restrictions the EEA States might impose on such movement or whether the Government can deviate from the AHL and apply national discretionary rules to restrict, or even generally prohibit, movements, regardless of the Regulation's detailed provisions governing such movements in Articles 191 to 221 (in addition to the Commission's delegated acts).
- (49) The question referred can be divided into three different issues of interpretation:
- (50) Whether the rules on the movement of fish are fully harmonised and exhaustively regulated in the AHL Part IV, Title II, Chapter 2, specifically Article 191 et seq. and delegated acts thereof, to the effect that the Government are precluded from introducing national measures not vested in the permitted restrictions in the allowed restrictions therein, or if the rules on fish movement only are harmonised to a minimum degree, to the effect that the Government may adopt more stringent restriction than found in Article 191 et seq. based on Article 269 AHL?
 - 1. Is Article 184 AHL applicable to situations such as in the main proceedings, and subsequently, can the planned movement of fish in full compliance with the AHL be deemed "*serious deficiencies*" within the meaning of Article 184 AHL, thus justifying a rejection of an approval, such as the contested decision in the main proceedings?
 - 2. Can Article 226 justify the rejection of an approval in a situation such as in the main proceedings, where the contested decision is based on a hypothetical suspicion of a listed disease?
- (51) In the absence of case law regarding the issues raised in the main proceedings, these questions must be solved solely based on an independent interpretation of the Regulation. Before moving on to the detailed legal analysis of the specific issues, the Plaintiff will provide some comments on the general principles of interpretation in EU/EEA law for the sake of context.

5.2 The interpretation and application of harmonised secondary EEA law

5.2.1 Interpretation of EEA law

- (52) The starting point of an interpretation of EEA law is the usual meaning in the everyday language of the wording, while also considering the context in which they occur and the purposes of the rules they are part of.⁴² As such, the recital, other provisions and the systematics of the secondary law as a whole are essential factors when interpreting EEA law. Moreover, some general *principles* of interpretation flow from settled case law from the Court and the ECJ.
- (53) First, it is settled case law that a provision of EEA law must be interpreted as far as possible so as not to detract from its validity.⁴³ In the same vein, the ECJ has repeatedly held that if the wording of secondary law is open to more than one interpretation, preference should be given to the interpretation which renders the rules consistent with the Treaty rather than to one which would lead to incompatibility with the Treaty.⁴⁴
- (54) Second, it is settled case law that where a provision of EEA law is open to several interpretations, preference must be given to the interpretation, which ensures that the rules retain their <u>effectiveness</u>.⁴⁵ This is the principle of *effet utile*, a cornerstone in the method of interpretation followed by the ECJ and the EFTA Court. While the exact scope of that principle may be complex to determine in the abstract, as it may vary from case to case, it requires, at the very least, that no provision of EEA law can ever be interpreted in a manner that would lead other provisions of EEA law to become *redundant* or *devoid of meaning*.⁴⁶

⁴² See Case C-507/18 Associazione Avvocatura per i diritti LGBTI [2020], para. 32 and the cited case law.

⁴³ See, for instance, Case C-403/99 *Italy v Commission* [2001], para. 37; Case C-361/06 *Feinchemie Schwebda* [2008] ECR, para. 49; Case C-149/10 *Chatzi* [2010], para. 43, and Case C-12/11 *McDonagh* [2013], para. 44.

⁴⁴ Case C-547/14 Philip Morris v Secretary of State for Health [2016], paras. 71-72.

⁴⁵ See, for instance, Case 187/87 *Land de Sarre and Others* [1988], para. 19; Case C-434/97, *Commission v France* [2000], para. 21; and Joined Cases C-402/07 and C-432/07 *Sturgeon and Others* [2009].

⁴⁶ See, for instance, Case T-72/20 Satabank v ECB [2023], para. 65; Case T-250/08 Batchelor v Commission [2011], para. 75; Case C-654/18 Interseroh [2020], para. 50; Case C-136/02 P Mag Instrument [2004], para. 50; Case E-10/20 ADCADA Immobilien v Finanzmarktaufsicht [2021], para. 34; Case C-833/21 Endesa Generación [2023], para. 39; Case C-82/12 Jordi Besora [2014], paras 23 and 27; and Case C-715/20 KL. v X [2024], para. 64.

(55) Hence, in Case C-465/07 *Elgafaji*, for instance, a case concerning subsidiary protection for non-refugees, the ECJ (Grand Chamber) took this into account when it interpreted Directive 2004/83:

"... to ensure that Article 15(c) of the Directive has its own field of application." ⁴⁷

(56) The EFTA Court, like the ECJ, is also a proponent of the *effet utile* when interpreting secondary EEA law. When it interpreted Directive $89/662^{48}$ in Joined Cases E-2/17 and E-3/17 *ESA v Iceland*, the EFTA Court considered not only the wording but also the effectiveness of the rules:

"The objective of the Directive could not be realised, nor <u>its effectiveness achieved</u>, if the EEA States were free to go beyond its requirements. <u>Maintaining or adopting national measures other</u> than those **expressly provided for** in the Directive must therefore be regarded as **incompatible with the wording and purpose of the Directive** (see *Ferskar kjötvörur*, cited above, paragraph 66 and case law cited). Consequently, the Directive must be read as exhaustively harmonising the veterinary checks that may take place in the State of destination."⁴⁹ (Our emphasis added.)

(57) Second, and related to the above, provisions of secondary EEA law cannot be interpreted in a way which would make it easy to *circumvent* the rules and undermine the effectiveness of provisions by circumvention. In Case C-128/11 UsedSoft, the ECJ (Grand Chamber) held:

"As the Advocate General observes in point 59 of his Opinion, if the term 'sale' within the meaning of Article 4(2) of Directive 2009/24 were not given a broad interpretation as encompassing all forms of product marketing characterised by the grant of a right to use a copy of a computer program, for an unlimited period, in return for payment of a fee designed to enable the copyright holder to obtain a remuneration corresponding to the economic value of the copy of the work of which he is the proprietor, the effectiveness of that provision would be undermined, since suppliers would merely have to call the contract a 'licence' rather than a 'sale' in order to circumvent the rule of exhaustion and divest it of all scope."⁵⁰ (Our emphasis added.)

(58) Third, it is also settled case law that when a provision constitutes a derogation or exception from a general rule, the exception must be interpreted strictly for EEA law to be effective.⁵¹

⁴⁷ Case C-465/07 *Elgafaji* [2009], para. 36.

⁴⁸ Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market.

⁴⁹ Joined Cases E-2/17 and E-3/17 *ESA v Iceland* [2017], para. 66.

⁵⁰ Case C-128/11 UsedSoft [2012], para. 49.

⁵¹ See, for instance, Case C-346/08 Commission v United Kingdom [2010], para. 39.

5.2.2 Application of primary law in cases of harmonised secondary EEA law

- (59) It is settled case law that when the secondary law entails harmonisation of the internal market, the EEA States are precluded from adopting deviating national measures not vested in the secondary law under reference to the grounds of justification laid down in the primary EEA law.⁵² This is expressively stated by the Court in Case E-17/15 *Ferskar kjötvörur ehf. v Iceland*, and similarly by the ECJ in C-389/05 *Commission v France*.⁵³
- (60) Furthermore, a fundamental point in the pretext of the present case is that primary EEA law only allows for the EEA States to invoke the precautionary principle to restrict movement if there is *an absence of harmonisation* (and it passes the proportionality test under primary EEA law).⁵⁴ The Plaintiff refers to Joined Cases E-2/17 and E-3/17 *ESA v Iceland*, where the Court rejected the Icelandic Government's argument that one could rely on a general precautionary principle to restrict movement under Directive 89/662/EEC, and reasoned:

"In response to Iceland's arguments concerning Article 13 EEA, the Court notes that the aim to protect human and animal health in EEA trade mentioned in Article 13 EEA cannot be invoked to justify measures banning or restricting imports when a directive provides for the <u>harmonisation</u> of the measures necessary to guarantee the protection of animal and human health (see Ferskar kjötvörur, cited above, paragraph 76 and case law cited). For the same reason, Iceland's argument concerning the precautionary principle must also be rejected (see ESA v Norway, cited above, paragraph 25). Furthermore, the reference in Article 18 EEA to Article 13 EEA does not alter these conclusions since that reference does not make the latter provision applicable to instances where EEA legislation provides for <u>exhaustive harmonisation</u>."⁵⁵ (Our emphasis added.)</sup>

5.3 Overview of the AHL and the relevant delegated acts, and the rules on movement of fish

(61) The Regulation was incorporated into the Agreement on the European Economic Area ("the EEA Agreement") by Decision 179/2020 of the EEA Joint Committee of 11 December 2020 at Point 13 in Part 1.1 of Chapter I of Annex I to the EEA Agreement as adapted by Protocol 1.⁵⁶ As previously stated, the Regulation was part of a package of measures proposed by the Commission in May 2013 to strengthen the enforcement of health and safety standards for the

⁵² See, for instance, Case E-8/16 Netfonds [2017], para. 123.

⁵³ Case E-17/15 Ferskar kjötvörur ehf. v Iceland [2016] para. 65, and Case C-389/05 Commission v France [2008], paras 73-76.

⁵⁴ Case E-3/00 *ESA v Norway* [2001], para. 25.

⁵⁵ *Ibid*. at para. 67.

⁵⁶ In the EU, the European Parliament and the Council adopted the Regulation in March 2016. It has been applicable since 21 April 2021. The Constitutional requirements under Article 103 EEA were fulfilled by Norway on 16 April 2021.

whole agri-food chain. According to the Commission, the AHL is a vital output of the Animal Health Strategy 2007-2013, which states: "prevention is better than cure."⁵⁷ The AHL and its derived legislation (the Commission's delegated acts) aim to improve animal and fish health by laying down detailed rules for preventing and controlling animal diseases that can be transmitted to animals or humans.⁵⁸

- (62) Title II of Part IV of the AHL (Articles 172 to 226) applies to aquatic animals. The general regulation of the <u>movement</u> of aquatic animals can be found in Chapter 2 therein, set out in Articles 191 to 221 AHL.⁵⁹ Chapter 2 is further divided into Sections 1 to 6. The Regulation is structured to contain the general requirements for movement in Section 1 (Articles 191 to 195). Aquatic animals intended for aquaculture facilities or release into the wild are regulated in Section 2 (Articles 196 to 200), and aquatic animals intended for consumption in Section 3 (Articles 201 and 202). Section 4 (Articles 203 to 207) includes exemptions from Sections 1 3 and supplementary risk-reducing measures. Section 5 (Articles 208 to 218) concerns issuing health certificates, and Section 6 (Articles 219 to 225) concerns notifications on the movement of aquatic animals to other EEA States.
- (63) For the movement of fish between sites to be allowed under the AHL, the main rule is that the fish farming sites, or "establishments" where fish is to be moved to and from, must have been approved by the competent (national) authority. An "establishment,"⁶⁰ which includes an aquaculture establishment, is defined in Article 4(27) 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."

- (64) The relevant fish farming sites of the Plaintiff are all "establishments" within the meaning of this definition and are thus covered by it. All aquaculture establishments must be either:
 - registered by the competent authority in accordance with Article 173;
 - <u>approved</u> by the competent authority in accordance with Article 181(1); or

⁵⁷ <u>https://food.ec.europa.eu/animals/animal-health/eu-animal-health-strategy-2007-2013_en</u>

⁵⁸ Article 1 of the AHL.

⁵⁹ Article 3 (2) of the Regulation specifies its scope for aquatic animals.

⁶⁰ <u>https://food.ec.europa.eu/animals/aquatic-animals_en</u>

- exempted from the requirement to be registered by the competent authority in accordance with Article 174 of that Regulation and in accordance with the rules set out in Commission Implementing Regulation 2021/2037.⁶¹
- (65) Commission Delegated Regulation 2020/691⁶² supplements the rules set out in Chapter I in Title II of Part IV of the AHL regarding aquaculture establishments, particularly the rules concerning risk-based surveillance, biosecurity measures, and facilities and equipment that apply to certain aquaculture establishments. Further details concerning risk-based surveillance in approved aquaculture establishments are set out in Part I of Annex VI to Commission Delegated Regulation 2020/689.⁶³ In addition, and most notably in the present case, the Commission Delegated Regulation (EU) 2020/990⁶⁴ supplements the Regulation concerning animal health requirements, including certification requirements, for the movement within the EEA of aquatic animals (fish) and products of aquatic animals.
- (66) An overview of the <u>most</u> important rules⁶⁵ concerning the movements of aquatic animals in the EEA, which are intended for aquaculture, such as Plaintiff's salmonoids, are as follows:
 - The *general rules* concerning all movements of aquatic animals within the EEA are set out in Articles 191 to 196 AHL and cover the general requirements for movements of aquatic animals; disease prevention measures that apply during transport; rules concerning change of intended use; obligations of operators at the place of destination and general requirements for movements of aquaculture animals.
 - Specific rules concerning movements of aquatic animals intended for aquaculture establishments or release to the wild are set out in Articles 197, 198 and 200 AHL and

⁶¹ Commission Implementing Regulation (EU) 2021/2037 of 22 November 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to exemptions from the obligations for the registration of aquaculture establishments and record-keeping of operators.

⁶² 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.

⁶³ Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases.

⁶⁴ Commission Delegated Regulation (EU) 2020/990 of 28 April 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health and certification requirements for movements within the Union of aquatic animals and products of animal origin from aquatic animals.

⁶⁵ https://food.ec.europa.eu/animals/aquatic-animals/faqs_en

in Section 1, Chapter 2, Part II of Delegated Regulation 2020/990 concerning movements of listed species of aquatic animals to EEA States, zones, or compartments.

• *Additional rules* setting out even further details concerning the movement of aquatic animals intended for human consumption are set out in Articles 201 and 202 AHL and in Section 2, Chapter 2, Part II of Delegated Regulation 2020/990.

5.4 Are the rules on fish movement fully harmonised in the AHL and exhaustively regulated in Part IV, Title II, Chapter 2 AHL and the delegated acts thereof?

5.4.1 Introductory comments

- (67) The starting point of the analysis should, in the Plaintiff's view, be that the AHL (and the Commission's delegated acts as adopted under the AHL) entails harmonisation of the rules on animal health in the internal market and is not limited to mere coordination between EEA States. This is apparent from, inter alia, recital 4, as the Plaintiff has cited in pt. 1. The wording "*should be laid down at Union level*" in recital 4 implies that the EU legislature has adopted a standardising set of rules applicable across the whole EEA. As such, the wording undoubtedly points to a harmonising instrument.
- (68) The fact that the AHL and the delegated acts entail harmonisation does not imply that all areas under the scope of the AHL are harmonised to a full extent. The extent of harmonisation depends on an interpretation of the specific rules in the Regulation. As such, the Plaintiff does not dispute that *some* of the rules in the Regulation only entail minimum harmonisation, as is apparent from recital 146 of the AHL:

"To encourage EEA States to enhance the health status of their aquatic populations, <u>certain</u> <u>adjustments</u> and added flexibility should be introduced in this Regulation." (Our emphasis added.)

(69) The central question raised by the Supreme Court is whether the Regulation's rules on the <u>movement</u> of fish as laid down in Part IV, Title II, Chapter 2 AHL, including allowed restrictions on such movements, have been fully harmonized, or only made subject to minimum harmonisation, to the effect that the EEA State may impose national measures derogating from the Regulation, cf. Article 269 AHL. The answer depends on an interpretation of Article 191 et seq. and 269 AHL.

5.4.2 *Interpretation of Article 191 AHL et seq.*

5.4.2.1 The wording of the Article 191 AHL et seq.

- (70) As the Plaintiff will demonstrate below, the wording of Article 191 AHL et seq. implies that the rules on movement of fish are fully harmonised in the AHL and the delegated acts thereof, and that the allowed restrictions thereof are exhaustively listed therein.
- (71) Article 191(1) AHL sets out the general requirements for the movement of aquatic animals, and reads in extract:

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

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

- (b) emerging diseases."
- (...)

(72) The conditions for movement into *an aquaculture establishment* are set out in Article 191(2):

"2. Operators shall only move aquatic animals into an aquaculture establishment or for human consumption, 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

- registered by the competent authority in accordance with Article 173;

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

- granted a derogation from the registration requirement laid down in Article 173.

b) they are not subject to:

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

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

However, operators may move those aquatic animals where derogations from the movement restrictions for such movements or release are provided for in Title II of Part III (Articles 53–83) or derogations from emergency measures are provided for in rules adopted pursuant to Article 259."

(73) As previously stated, all the establishments in the matter pending before the referring court were all registered and approved. Finally, Article 191(3) provides that:

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

(74) As stated in Article 191(2) point (b)(i), there are <u>numerous</u> movement restrictions governed by

the Regulation itself in several circumstances allowing EEA States to restrict movement:

- Articles 55 and 56: Preliminary disease control measures in case of suspected diseases.
- *Article 61*: Measures on disease-affected establishments to be implemented at affected establishments in the event of an outbreak of a listed disease as referred to in point (a) of Article 9(1).
- Article 62: Extension of measures provided for in Article 61 on the spread of infection epidemiologically linked establishments and locations.
- *Article 64*: Establishment of restricted zones around affected establishments by the competent authority.
- Article 65: Disease control measures in restricted zones.
- *Article* 70(1)(b): Measures for preventing and controlling disease among wild animals.
- Article 74(1): Implementation of preliminary disease control measures for kept animals.
- Article 79: Disease control measures with respect to listed diseases and implementation of eradication programmes.
- Article 81: Disease control measures in wild animals.
- Other exceptions apply to rules issued by the European Commission pursuant to the Regulation itself, i.e. Articles 55(2) (detailed disease control measures), 63 (delegation of powers, etc.), 67 (delegation of powers, etc.), 70(3) (delegated act), 71(3) (specific disease control measures taken by the European Commission), 74(4) (legal authority for the Commission to adopt delegated acts), 83(2) (special rules for disease control measures for a limited period of time).
- *Article 257*: Emergency measures to be taken by the competent authority of the EEA State in the territory of which an outbreak of listed disease or emerging disease, or a hazard has occurred.
- (75) In short, the Regulation's disease prevention provisions grant the competent authority broad powers to impose restrictions on the movements of persons, animals, products, vehicles or any other material or substance that may be contaminated and contribute to the spread of disease in numerous types of situations. The Regulation imposes a strict duty upon the competent authority to take disease control measures immediately. <u>None</u> of the extensive exemptions from permitting movement included in Article 191(2)(a) and (b) apply in the present case.
- (76) Concerning aquatic animals intended for movement *between* aquaculture establishments, Article 196(1), entitled "Abnormal mortalities or other serious disease symptoms", provides supplementary rules allowing EEA States to restrict movement and reads:

"Operators shall only move aquatic animals from an aquaculture establishment or from the wild to another aquaculture establishment, or release them into the wild, if the animals in question:

(a) show no disease symptoms; and

(b) originate from an aquaculture establishment or environment where there are no abnormal mortalities with an undetermined cause."

(77) Again, <u>none</u> of these exemptions from permitting movement included in Article 196(1) apply in the present matter.

- (78) In addition, Article 197 contains rules on restricting movement regarding "Movements of aquaculture animals intended for EEA States, zones or compartments which have been declared disease-free or which are subject to an eradication programme, and delegated acts" and Article 198 regulates "Derogations by EEA States concerning the obligation of operators for movement of aquaculture animals between EEA States, zones or compartments which are subject to an eradication programme", including also restrictions. None of these exemptions from permitting movement included in Articles 197 and 198 apply in the present matter.
- (79) Article 192 also contains more detailed rules on "disease prevention measures in connection with transport" and authorises the Commission to adopt supplementary rules, which have also been done. Operators shall, pursuant to Article 192(1)(b), ensure that:

"... 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."

(80) Article 192(2)(b) further provides that:

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

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

- (81) The wording of the different Articles in Sections 1 to 3 cited above implies that Part IV, Title II, Chapter 2 exhaustively sets out the general rule for movement and the allowed restrictions EEA States might impose thereof. As is apparent from the wording of Article 191(2) letter (b), the provision lists in an exhaustive manner all the allowed restrictions for the movement of fish that are laid out elsewhere in the AHL outside Part IV, Title II, Chapter 2. Hence, the wording of said provisions strongly supports the Plaintiff's interpretation that the rules on fish movement are fully harmonised in Article 191 AHL et seq., and as such, precluding EEA States from adopting stricter national restrictions thereof not vested in these rules.
- (82) For this reason, it can also be deducted from the wording of said provisions, hereunder Article 192, that it is for the Commission, not the EEA States themselves, to issue additional rules on fish movements, hereunder introducing new allowed restrictions under the AHL.

5.4.2.2 The aim of rules on the movement of fish in the AHL

(83) Article 191 et seq. must be interpreted considering the AHL's aim. Recitals 147-148 state:

"147. In order to ensure control of the movement of aquatic animals, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the disease prevention measures applicable to transport, <u>specific rules applicable to movements of certain categories of aquatic animals</u> for different purposes, specific requirements or derogations in respect of certain types of movements, such as movements for scientific purposes, and additional requirements for movements of wild aquatic animals.

148. In order to ensure the possibility of <u>temporary derogations and specific requirements for</u> movements of aquatic animals, where the movement rules laid down in this Regulation are not sufficient or appropriate to limit the spread of a particular listed disease, implementing powers **should be conferred on the Commission** to lay down special movement rules or derogations for a limited period of time." (Our emphasis added.)

(84) In Plaintiff's view, the recitals further support that the movement rules have been fully harmonised. Hence, is clear from the recitals cited directly above that the EU legislature has been aware of a need and possibility to derogate (exempt) from the right to move fish between establishments in cases where the Regulation's rules may be insufficient to limit the spread of diseases. To account for such needs, the system adopted under the Regulation is one where (further) derogations from the right to move fish, supplementing those in the AHL, are "conferred on the Commission" through delegated acts and not on the EEA States themselves to adopt national restrictions.

5.4.2.3 The systematics in the AHL

- (85) As previously explained in pt. 5.3, Chapter 2 of Title II, Part IV is entitled "Movement within the Union of aquatic animals" and consists of Sections 1 to 6. Section 1 is entitled "General requirements for movements", whilst Sections 2 and 3 lay down specific rules for aquatic animals intended for aquaculture establishments and those aquatic animals intended to be released into the wild or for human consumption. Section 4 is entitled "Derogations from Sections 1 to 3 (Articles 191 to 202) and additional risk-mitigation measures" and provides exceptions from the rules in the said Sections.
- (86) Thus, the <u>systematics</u> of Part IV, Title II, Chapter 2 itself implies that the allowed restrictions on the movement of fish are exhaustively laid out and referenced therein. The systematics of AHL clearly indicate that the allowed restrictions on movement are fully harmonised in Article 191 AHL et seq., to the effect that there is no room for the EEA States to adopt national restrictions not grounded in the harmonised exceptions in the Regulation.

5.4.2.4 The Commission's delegated acts

(87) Moreover, Article 191 et seq. AHL must be interpreted considering the multiple delegated acts adopted by the Commission (its context). As the Plaintiff will demonstrate below, the delegated acts provide extensive and detailed additional rules complementing the rules on movement in Article 191 et seq., further supporting the Plaintiffs contention that the rules on movement of fish and restrictions thereof are fully harmonised.

- (88) Based on Article 192(2) AHL, the Commission has adopted Regulation 2020/990. Article 3 thereof, entitled "General obligations on operators as regards biosecurity requirements for the transport of aquatic animals", lays down, *inter alia*, requirements for loading and transport, water quality, cleaning, disinfection, etc. Article 4 contains "General obligations on operators as regards requirements for water exchanges and discharges during the transport of aquatic animals," and Article 5 sets out "Obligations on operators as regards specific transport and labelling requirements concerning means of transport and containers in which aquatic animals are transported."
- (89) Chapter 2 of Regulation 2020/990 contains "Supplementary animal health requirements for movements of aquatic animals." Chapter 3 provides rules on "Animal health certificates, selfdeclarations and movement notification." It shall also be mentioned that Section 3 of Chapter 3 contains rules on the responsibility of the competent authority for animal health certification.
- (90) It is illustrative for the focus on health and disease prevention that Article 15(1) provides that before signing an animal health certificate, the official veterinarian shall conduct detailed checks and examinations in the aquaculture establishment before any movement may take place:

"Before signing an animal health certificate as provided for in Article 216(2)(a) of Regulation (EU) 2016/429, the official veterinarian shall carry out the following checks and examinations in the aquaculture establishment:

- (a) a documentary check of the mortality records, movement records and health and production records kept at the aquaculture establishment; and
- (b) a clinical inspection and where relevant, a clinical examination of:

(i) the aquaculture animals to be moved.

(ii) any moribund aquaculture animals which are observed in production units other than those in which the aquaculture animals referred to in point (i) are kept;

(iii) aquaculture animals from any production unit in the aquaculture establishment where the documentary check has raised any suspicion of the presence of a listed disease or an emerging disease."

(91) Further, Article 15(3) and (4) of Regulation 2020/990 provide that the veterinarian shall, after completing the checks, inspections, and examinations provided for, issue an animal health

certificate for the consignment of aquaculture animals within a period of 72 hours before the time of departure of the shipment from the establishment of origin. The health certificate shall be valid for a period of only ten days from the date on which it is issued. This underscores Plaintiff's point that fish health is not static but dynamic and that assessing health risks in connection with movements must be conducted within a specific time frame of the planned movement. Assessing this risk at the time of issuing an operational plan is thus entirely hypothetical and, therefore, also not suitable nor functional to achieve any meaningful purpose because the health status of a fish population can potentially change, even <u>many</u> times, over a period of two years (which corresponds to the period the operating license is valid).

- (92) Regulation (EU) 2020/2236⁶⁶ provides supplementary provisions on the movement of aquatic animals <u>within</u> and between EEA States and further demonstrates that the rules on the movement of fish are exhaustively regulated, detailed and fully harmonised.
- (93) Moreover, specific biosecurity measures that the operator must adhere to also follow from Commission Delegated Regulation (EU) 2020/687⁶⁷ regarding rules for the prevention and control of certain listed diseases. Recital 5 of Regulation 2020/687 states that the regulations will provide "clear, <u>harmonised</u> and detailed rules for the control of animal diseases throughout the European Economic Area." This is similar to statements with the same effect in the recital 147 – 148 AHL, as previously cited.
- (94) It is important to note that Part III of Regulation 2020/687 covers aquatic animals and contains several provisions on establishing restricted zones, measures to control disease, etc. This delegated act also governs in which cases specific biosecurity measures can and shall be introduced, including prohibiting the movement of aquaculture animals to and from

⁶⁶ Commission Implementing Regulation (EU) 2020/2236 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates for the entry into the Union and movements within the Union of consignments of aquatic animals and of certain products of animal origin from aquatic animals, official certification regarding such certificates and repealing Regulation (EC) No 1251/2008. The regulation is implemented in Norway by FOR-2023-03-13-333 - Forskrift om helsesertifikater – akvatiske dyr og visse animalske produkter derav – forordning (EU) 2020/2236 (akvakulturhelsesertifikatforskriften).

⁶⁷ Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases.

aquaculture facilities.⁶⁸ <u>None</u> of these exemptions are relevant to the present matter in that they do not apply to the planned movement by the Plaintiff, which has been rejected.

(95) Chapter V of Regulation 2020/687 provides rules for "Disease control measures for category B and C diseases of aquatic animals," both concerning preliminary disease control measures (Article 110) and measures when category B or C disease is confirmed (Article 111). It refers to Commission Delegated Regulation 2020/689,⁶⁹ which governs various disease control measures. Article 55 of Regulation 2020/689 provides:

"1. The competent authority shall, when it suspects a case of the relevant disease in an establishment, conduct the necessary investigation.

2. Pending the outcome of the investigation referred to in paragraph 1, the competent authority shall:

(a) **prohibit** the introduction of animals or products of animal origin into the establishment;

(...)

(c) **prohibit** the movement of animals and products of animal origin out of the establishment unless authorised by the competent authority for the purpose of immediate slaughter or processing in a disease control aquatic food establishment, or for direct human consumption in the case of molluscs or crustacea which are sold live for that purpose;"

- (96) Articles 58-65 of Regulation 2020/689 also contain various provisions restricting movements when specific diseases are confirmed, hereunder restrictions on the movement of well-boats through restricted zones,⁷⁰ prohibitions on movements out of infected establishments and equipment,⁷¹ etc. Furthermore, derogations from the restriction of movement of animals and products of animal origin from infected establishments are only allowed if the cumulative criteria in Article 61 are fulfilled. <u>None</u> of these rules were relevant in relation to Plaintiff's planned movements.
- (97) As evident from the cited delegated act, these additional harmonising measures laid down by the Commission are extensive in nature and supplement the movement rules in Article 191

⁶⁸ In case of suspected outbreaks of Category A disease (see for example, Articles 70, 72, 75) and the prohibition of movement from or to protected zones (for instance Article 89).

⁶⁹ Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases.

⁷⁰ Article 58(4)(a).

⁷¹ Article 60(1)(b) and (d).

AHL et seq., further indicating that the movement rules and allowed restrictions are fully harmonised.

5.4.2.5 Conclusion

- (98) As is evident from the wording, aim, and context of Article 191 et seq., AHL and its adopted delegated act provide comprehensive, strict, and detailed rules to account for and prevent all the relevant risks. Thus, Article 191 et seq. interpreted in light of its wording, context and aim strongly indicates that the rules on the movement of fish are fully harmonised within Chapter 2 of Title II, Part IV and the delegated acts thereof, to the effect that EEA States are precluded from adopting national movement restrictions deviating from the fully harmonised rules.
 - 5.4.3 Does the exception in Article 269 apply to the movement of fish and justify a national restriction derogation from the rules laid down in Title II, Chapter 2, AHL?
 - 5.4.3.1 Interpretation of Article 269(1)(a)
- (99) The Plaintiff considers the interpretation of Article 269 AHL the decisive issue in the present matter since the rules on the movement of fish cannot be deemed fully harmonised if the EEA States can adopt stricter national restrictions for fish movement based on Article 269 AHL.
- (100) In the Plaintiff's view, Article 269(1) does not allow the EEA States to adopt stricter national rules for the movement of aquatic animals beyond those stipulated in Article 191 et seq.
- (101) Article 269(1) AHL is entitled "Additional or more stringent measures by EEA States" and permits the EEA States to adopt national measures derogation from specifically listed provision of the Regulation, and reads as follows:

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

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

- (b) notification within Member States as provided for in Article 18;
- (c) surveillance as provided for in Chapter 2 of Part II (Articles 24 to 30);

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

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

Since the provisions listed in letters (a) to (e) of Article 269(1) represent a derogation from the general objective and main rule of the Regulation, which is full harmonisation to complete the internal market, any derogations in the Regulation must be construed <u>narrowly</u>.

- (102) In simple terms, this implies that if the Regulation's rules concerning the <u>movement</u> of fish are not listed in (a) to (e), then there is no "room for manoeuvre" for the Government to restrict or even prohibit fish movement unless that restriction is vested in any of the exemptions provided in the Regulation itself (and delegated acts). As Plaintiff will get back to, the harmonised rules concerning the movement of fish, set out in Articles 191-221 AHL, are <u>not</u> among those rules listed in Article 269(1).
- (103) The wording of Article 269(1) implies that the provision entails "a carve-out" from the general rule of full harmonisation within the AHL. Hence, it can be derived from the wording of Article 269 that the provisions which are listed in Article 269(1) (a) to (e) only entail minimum harmonisation. As such, and more importantly in the pretext of the present case, the wording of Article 269 itself, which only permits for derogation from the listed provisions of the AHL, indicates that rules <u>not</u> listed in Article 269 are fully harmonised by the AHL and delegated acts and not subject for stricter national rules.
- (104) Furthermore, letters (a) to (e) provide for an <u>exhaustive</u> listing. As such, the wording does not allow EEA States to derogate from other areas of the AHL which are not explicitly listed in Article 269(1).
- (105) Specifically, letters (b) (e) open for derogations from other specific parts of the AHL regarding notifications, surveillance, registration, etc. The movement rules, including Articles 191 and 192, are not mentioned in the text of Article 269(1). Therefore, a derogation from the movement rules cannot be vested in the wording of Article 269. To interpret Article 269(1) as if it mentioned the movement rules when it does not would amount to a *contra legem* reading.
- (106) Further, it would be contrary to the aim and objective of the Regulation of laying down harmonised rules to complete the internal market, as apparent from the recitals 141 and 142, if Article 269 were interpreted to encompass the rules on the movement of fish.
- (107) As explained above, the Plaintiff contends that Article 269(1) does not allow the EEA States to adopt stricter national rules for the movement of aquatic animals beyond those stipulated in Article 191 et seq. in connection with the approval of an operating plan. It is illustrative that,

in the public consultation paper, the Norwegian Food Safety Authority acknowledged that the exemption in Article 269 AHL has a limited scope:

"Article 269 provides for national measures within the Member State, which either come in addition to or are stricter than the provisions of the Regulation. However, this <u>only</u> applies to the rules about **responsibility** between authorities and industry actors, national requirements for notification of diseases, national surveillance programs, national supplementary requirements for registration, approval, record keeping, and traceability rules for land animals and breeding material (breeding products). In these areas, the regulation is to be regarded as a minimum regulation. The national requirements must not prevent the movement of animals or products between Member States and/or be incompatible with those rules of the AHL."⁷² (Our emphasis added.)

- (108) The Plaintiff fully subscribes to the views the Food Safety Authority communicated in the public consultation paper.
- (109) As is evident from the wording, Article 269(1) does not list the rules on fish movement in Articles 191 221 AHL. Therefore, Government has relied the exemption for <u>"responsibilities for animal health as provided for in Chapter 3 of Part I (Articles 10 to 17)</u>" in Article 269(1)(a) before the national courts in all three instances, and has argued that Article 269(1) read in conjunction with Article 10, allows more stringent restrictions on fish movement. The question is, therefore, whether a decision refusing to move fish pursuant to Section 19 of the Food Act and Section 40 of the Aquaculture Operations Regulations falls within the scope of the exemption in Article 269(1)(a).

5.4.3.2 The relationship between Article 10 and 269

(110) As outlined above, Article 269(1)(a) provides for the adoption of supplementary or stricter rules than those set out in Articles 10 to 17. This is not in dispute. In this context, Article 10 – read in conjunction with Article 269(1)(a) – is, according to the Government, the (allegedly) relevant provision justifying the Food Safety Authority's restriction and a general prohibition against the Plaintiff's planned movement of clinically healthy fish between locations. More precisely, and again according to the Government, the movement restrictions are alleged to fall within Article 10's "minimum harmonisation;" cf. Article 269(1)(a), and thus that a general

⁷² No.: "I artikkel 269 er det hjemmel for nasjonale tiltak internt i medlemsstaten, som enten kommer I tillegg til eller som er strengere enn forordningens regler. Dette gjelder likevel bare for reglene om ansvar mellom myndigheter og næringsaktører, nasjonale krav til melding om sykdommer, nasjonale overvåkingsprogrammer, nasjonale tilleggskrav til registrering, godkjenning, journalføring og sporbarhetsregler for landdyr og formeringsmateriale (avlsprodukter). På disse områdene er forordningen å anse som en minimumsforordning. De nasjonale kravene må ikke hindre forflytning av dyr eller produkter mellom medlemsstatene og/eller være uforenelig med nevnte reglene i AHL." Consultation – Proposal for new animal health regulations (Mattilsynet: Høring - forslag til ny dyrehelseforskrift.) Dated 19 December 2019.

precautionary principle not vested in the Regulation itself may be used as a basis for prohibiting movement. In the Plaintiff's view, the Government's position is based on an erroneous interpretation of these provisions of the AHL.

- (111) The Plaintiff argues that Article 10 does not concern the movement of fish, and thus, Article 269(1)(a) cannot be relied on as a legal basis for national restrictions on fish movement not grounded in Article 191 AHL et seq.
- (112) Article 10 is entitled "Responsibilities for animal health and biosecurity measures" and reads in extract:
 - "1. Operators shall:
 - (a) as regards kept animals and products under their responsibility, be responsible for:
 - (i) the health of kept animals.

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

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

(iv) good animal husbandry;

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

- (i) the species and categories of kept animals and products;
- (ii) the type of production; and
- (iii) the risks involved, taking into account:
- geographical location and climatic conditions; and
- local circumstances and practices;

(...)

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

- (a) physical protection measures, which may include:
- (i) enclosing, fencing, roofing, netting, as appropriate;
- (ii) cleaning, disinfection and control of insects and rodents;
- (iii) in the case of aquatic animals, where appropriate:
- measures concerning the water supply and discharge

- natural or artificial barriers to surrounding water courses that prevent aquatic animals from entering or leaving the establishment concerned, including measures against flooding or infiltration of water from surrounding water courses (...)"
- (113) According to the wording of Article 10(1)(a), the "<u>operators shall</u>" regarding kept animals "<u>be</u> responsible for" the listed obligations in point (i) to (iv). In everyday language, the wording "operators shall" clearly indicates that Article 10 concerns <u>obligations</u> for the <u>operator</u>. Based on the wording, it is clear that the *ratione personae* is limited to the operator and does not concern the EEA States or their national competent authorities. Furthermore, the wording implies that the material scope of Article 10(1) is limited to <u>obligations</u> on animal health and does not concern in any way restrictions for the movement of fish.
- (114) Based on the wording, Article 10 imposes several <u>responsibilities</u> in paragraphs (a) and (b), which shall be carried out <u>by the operator</u>. Due to the "minimum harmonisation" nature of Article 10, cf. Article 269(1)(a), EEA States, such as Norway, could impose stricter compliance requirements upon the operator or expand the scope of operators responsibility by encompassing additional areas, thus place a more stringent responsibility upon the operator, on the assumption that this complies with Article 269(2).
- (115) However, regulating "responsibilities" has nothing to do with rules on the movement of fish, and there is nothing in the wording of Article 10 to suggest that it governs the conditions for or restrictions on movement, which is regulated elsewhere in the Regulation (Article 191 et seq.).
- (116) The fact that Article 10 refers to, *e.g.* "minimising the risk of the spread of diseases" and "biosecurity measures," two concepts which are also relevant to the AHL's movement rules, does not alter this. Indeed, the need for biosecurity measures to avoid spreading diseases flows through the entire Regulation. It would then <u>wholly undermine the effectiveness</u> of the full harmonisation of the AHL, including its comprehensive and detailed movement rules, if anything with a "link" to biosecurity could be "stretched" to fall within Article 10 and thus be covered by the more stringent national restrictions. The operator should indeed take relevant biosecurity measures. This falls under the operator's <u>responsibility</u>, which is what Article 10 deals with not the movement itself.

- (117) As such, the wording of Article 10 underpinned that Article 269(1)(a), read in conjunction with Article 10 AHL, does serve as a valid legal basis for the EEA State to prohibit the movement of fish on a discretionary basis.
- (118) The Plaintiff's interpretation is further supported by the aim of Article 10 and its context. Recital 42 of the Regulation reads:

"... should ... 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." (Our emphasis added.)

- (119) It is apparent from recital 42 that the point of Article 10 is not to regulate the movement of fish but to underline that the operator is responsible for carrying out disease prevention and control measures.
- (120) Moreover, Article 10 falls under Part I, Chapter 3, entitled "Responsibilities for animal health," and Section 1, which deals with "Operators, animal professionals and pet keepers." The Regulation's systematics further indicate that Article 10 is limited to the operator's responsibility for the kept animals and does not concern restrictions on fish movement.
- (121) For comparison and illustration, Article 12 provides "Responsibilities of <u>veterinarians</u> and aquatic animal <u>health professionals</u>" and Article 13 "<u>EEA States</u>' responsibilities." These provisions are thus <u>personal competence rules</u> that govern the <u>responsibilities</u> to be carried out by the operators and other players. They are <u>not</u> substantive rules affecting <u>procedures</u> for fish movement and do not in any way regulate the requirements that must be complied with to move fish or the derogations (exemptions) from the right to move fish, which has been fully harmonised in Article 191 et seq. and the delegated acts.
- (122) The Plaintiff's interpretation is also supported by Article 1(1) AHL, from which it is clear that the "establishment of responsibilities", as mentioned in letter (a), is systematically something different from the "movement" rules for animals, such as fish, as mentioned in letter (d).
- (123) Furthermore, Article 10(4) provides that biosecurity measures referred to in paragraph 1(b) shall be implemented through various forms of operational measures, which may also include:
 "(iii) conditions of movement based on associated risks" cf. Article 10(4)(b). Furthermore, it follows from Article 10(5) that:

"Operators, animal professionals and pet keepers shall cooperate with the competent authority and veterinarians in the application of the disease prevention and control measures **provided for in this Regulation**." (Our emphasis added.)

- (124) As already explained, the Commission is responsible for laying down delegated acts reflecting the matters referred to in Article 10(4)(b) (operational measures), in the same manner as for the movements of fish in Article 191 AHL et seq.
- (125) Article 10, conversely, does <u>not</u> grant the competent national authorities the right to adopt measures that deviate from the substantive movement rules of the Regulation or delegated acts. The AHL is structured so that the Commission is responsible for laying down rules for biosecurity measures, including measures pertaining to the movement of fish.⁷³
- (126) Lastly, the Plaintiff contends that the harmonised provisions of the AHL and the delegated acts governing the movement of fish would have <u>no real independent meaning</u> if the view of the Government prevails. The comprehensive and highly detailed rules concerning the movement of fish and permitted restrictions on such movement would then have been redundant to include in the harmonised AHL as the Government would have been able to circumvent all of it by simply pointing at Article 10, read in conjunction with Article 269(1)(a).
- (127) In Plaintiff's view, it is clear that Article 10 of the AHL cannot be interpreted as opening up for refusing, restricting or prohibiting the movement of fish or deviating from the general rules of the Regulation (and the delegated acts) on the right for movement of aquatic animals, unless a restriction (exemption) from the movement right can be vested in the AHL or the delegated acts.
- (128) To conclude, the Plaintiff contends that Article 10 does not concern the movement of fish, and thus, Article 269(1)(a) cannot be relied on as a legal basis for national restrictions on fish movement not grounded in Article 191 AHL et seq.
 - 5.4.4 Conclusion: The rules on movement of fish are fully harmonised and exhaustively regulated in Part IV, Title II, Chapter 2 AHL and the delegated acts thereof
- (129) Based on the wording of Article 191 et seq. and Article 269, read in conjunction with the aim, objective and systematics of the AHL, the Plaintiff contends that Article 269 does not provide a legal basis for national restrictions on fish movement deviating from the allowed restrictions

⁷³ Examples concerning aquatic animals can be found in Article 181(2) and Article 192(2) of the Regulation.

on movement of fish as laid down in Article 191 AHL et seq., and therefore, entailing that the rules on the movement of fish are <u>fully harmonised</u> in the rules set out in Part IV, Title II, Chapter 2 AHL. Thus, EEA States are precluded from adopting more stringent restrictions on fish movement than those stipulated in Article 191 et seq., such as the restriction adopted by the contested decision in the main proceeding.

5.4.5 In the alternative: Article 269(2) and primary EEA law still apply

- (130) If the Court considers that the EEA States can impose stricter national measures for the movement of fish based on Article 269(1)(a) AHL, the Plaintiff will address some key issues regarding such an interpretation.
- (131) It is important to note that even if the national measure at issue would fall under Article 269(1)(a), creating a "leeway" to adopt more stringent national movement restrictions, the "flexibility" afforded by the Regulation to the EEA States in this regard is not <u>unlimited</u>, in particular for the two reasons addressed below.
- (132) First, even if the movement rules are only subject to "minimum harmonisation," the EEA State's flexibility to adopt more stringent national rules deviating from secondary law must be compatible with the rules laid down in the main part of the EEA Agreement, as these rules apply in the absence of complete harmonisation.
- (133) Second, and more importantly, in the pretext of the present case, Article 269(2) sets out further requirements for the deviating national measure to be allowed under the AHL and reads:

"The national measures referred to in paragraph 1 <u>shall respect the rules⁷⁴ laid down in this</u> <u>Regulation</u> and <u>shall not</u>:

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

- (b) be **inconsistent** with the rules referred to in paragraph 1." (Our emphasis added.)
- (134) Accordingly, the wording of Article 269(2) states that the national measure <u>"shall respect the rules"</u> in the Regulation and <u>"shall not be inconsistent"</u> with the rules listed in Article 269(1), which they deviate from.

⁷⁴ Da.: "overholde reglerne." Fr.: "respectent les dispositions." De.: "stehen im Einklang mit."

As a starting point, the wording "shall" implies an absolute requirement, and as such, the national measure <u>must</u> comply with the requirements of Article 269(2).

- (135) Further, the wording of letter (b) references explicitly "the rules referred to in paragraph 1" and, as such, references the listing in Article 269(1)(a) (e), where the movement rules are not mentioned. As previously explained, the "entry requirement" for stricter/deviating national rules to be allowed under Article 269 in the present case is unmet. In addressing the Government's arguments based on Article 10, cf. Article 269 the wording of Article 269(2) further indicates that the Government's interpretation is erroneous and incompatible with the Regulation's system.
- (136) The Government's interpretation of Article 269 presupposes a "legal bridge" between the absence of the movement rules in the list of Article 269(1) together with the criteria set out in Article 269(2). As such, the Government's interpretation requires a *contra legem* reading of the AHL, contrary to its wording, aim and the deterrent of its effectiveness. As such, this further suggests that the Court could stop its analysis after having considered the listing in Article 269(1), read in conjunction with Article 269(2) letter (b).
- (137) However, for the sake of completeness, the Plaintiff will further assess the interpretation of Article 269(2) below.
- (138) The wording "inconsistent" in letter (b) points to consistency assessment, as known from the proportionality review under primary EEA/EU law. However, contrary to the consistency assessment for primary law, the wording of Article 269(2) implies a consistency assessment within the framework of the Regulation. Therefore, the national measure must be compared to the harmonised rules in the AHL from which it derogates.
- (139) Moreover, "inconsistent" also implies a limitation for how <u>far</u> the national measure can deviate from the harmonised rules in AHL. Since Article 269 represents a derogation from the harmonised rules within the AHL, it must be interpreted strictly. Although the "inconsistent" itself presupposes a specific assessment of the concrete national measure and the particular limitation based on the wording may be difficult to render in general, "inconsistent" in any event must be interpreted to the effect that the national measure cannot be in direct conflict with the movement rules in Article 191 AHL et sea, or other parts of the Regulation.

- (140) Further, the wording "respect" also indicates an additional limitation for how far the national measure can derogate from the AHL. Moreover, the wording sets out that the national measure must respect "the rules laid down in this Regulation", which clearly implies a comparison between the national measure and the AHL as a whole.
- (141) This interpretation is further supported by the context. The first sentence must be read in conjunction with letter (b), which specifically references the rules listed in Article 269(1), whilst the wording of the first sentence is open-ended and does not reference any specific rules in the AHL. In this context, it is underscored that the national movement restrictions go far beyond what is permitted under the AHL and the delegated acts.
- (142) Moreover, Article 269 (2) must be interpreted in a manner which ensures that the *full effectiveness* of the harmonised movement rules in the Regulation (and delegated acts) is achieved. To allow for "disguising" a movement restriction under the pretext of more stringent national measures on, for instance, the "responsibilities" as referred to in Articles 10 to 17 or "approval" (or rather, non-approval) of sites (or operational plans) as referred to in Articles 172 to 190, would make the harmonised movement rules redundant, devoid of meaning and easy to circumvent.
- (143) In any event, even if one were to assume that the movement of fish could be regulated differently at national level in every EEA State based on an extremely "loose" and close to *contra legem* interpretation of Article 10 read in conjunction with Article 269(1)(a) such a (national) restriction would still conflict with and not "respect" the detailed rules on this matter in the Regulation and hinder the harmonised rules on the movement of fish within and between EEA States cf. Article 269(2).
- (144) Neither the exceptions in Article 191 AHL et seq. nor the delegated acts thereof allow for a restriction on planned movement of fish, which is based on the sole discretion of competent national authorities due to hypothetical suspicion of a disease, such a national measure is therefore "inconsistent" with the movement rules. Further, it is a fundamental element in the AHL that it is the Commission's responsibility to adopt additional and more detailed rules on fish movement, which is apparent from Article 191 AHL et seq. An exemption for the EEA States to adopt restrictions on fish movement would not "respect the rules laid down in the Regulation" and, in addition, be "inconsistent" with Article 191 AHL et seq.

- (145) Thus, even in that case, the Regulation must be interpreted as precluding such a deviating (national) restriction not vested in the Regulation itself. Again, it is emphasised that any other interpretation would have implied that the comprehensive and highly detailed rules on the movement of fish and permitted restrictions on such movement would then have lost all of their effectiveness *vis-a-vis* the objective of the AHL of fully harmonising the movement of fish to complete the internal market and been redundant to include in the AHL, as the Government would have been able to circumvent all the extensive and detailed rules simply by referencing Article 10.
- (146) To conclude, the Plaintiff contends that a national restriction on fish movement, such as in the main proceedings, is incompatible with Article 269(2) AHL, and thus, unlawful under EEA law.

5.5 Articles 176, 181 and 183-184 AHL cannot be applied to restrict fish movement.

(147) In the request, the Supreme Court poses the following question:

"Questions may also be asked as to whether the Norwegian Food Safety Authority's decision refusing the application for approval of the operating plan also brings into play the rules on approval of certain aquaculture establishments in Part IV, Title II, Chapter 1, Section 2 (Articles 176–184) of the Animal Health Law, including the rules on withdrawal and suspension of such approvals."⁷⁵

- (148) The Food Safety Authority did not dispute that the criteria in Article 181 AHL were fulfilled when the contested decision was rendered. At the time, the contention was that their powers were entirely discretionary based on Article 269, cf. Article 10 AHL as an (alleged) legal basis. Nonetheless, since the request raises questions regarding the application of Articles 176-184 AHL, it will be assessed in the following.
- (149) As described in pt. 1, the Food Safety Authority has expressly invoked Article 184 AHL as an (alleged) legal basis in a recent decision against the Plaintiff to reject the approval of an establishment (operational plan) solely <u>due</u> to the planned movement of fish itself, which entails a *de facto* restriction on fish movement. For the reasons set out below, Plaintiff contends that this is a manifestly wrongful application of the AHL's provisions regarding approval and, thus, incompatible with the Regulation itself.

⁷⁵ Pt. 31 of the request.

- (150) In essence, the question is thus whether Article 184, cf. Article 181 can be used as a legal basis for denying approval of an operational plan that presupposes a planned movement of clinically healthy fish in <u>full compliance</u> with the AHL's movement provisions under the angle that such a movement would lead to "serious deficiencies" in the establishment (site). In practice, such an interpretation would entail that approval can be withdrawn (or denied) if the operator, such as Plaintiff, wishes to move fish even in cases where all the criteria in Article 191 et seq. and the delegated acts are fulfilled.
- (151) The Plaintiff contends that Articles 176-184 AHL are irrelevant and not applicable to the case since they govern a different situation than fish movement between <u>already approved</u> sites or sites that <u>fulfil</u> the criteria for approval as set out in Article 181 AHL.
- (152) As explained in the following, the Plaintiff contends that Articles 181 and 184 do not apply to the movement of fish and cannot be applied to restrict movement that is planned to take place in full conformity with the AHL's harmonised movement provisions. Fish movement compliant with Article 191 AHL et seq. (and the delegated acts) cannot be classified as "serious deficiencies" within the meaning of Article 184, and this holds true even if the EEA States may adopt more stringent (national) standards for approvals than those set out in the Regulation, cf. Article 269(1)(d).

5.5.1 The wording of Article 184

(153) Article 184, which is entitled "Review, suspension and withdrawal of approvals by the competent authority," reads in extract:

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

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

(154) It follows from the wording that the violation, or deficiency, must concern the "requirements laid down in Article 181(1) and the rules adopted pursuant to Article 181(2)." The wording of Article 184 itself exhaustively sets out that the national competent authority is allowed to reject or withdraw an approval under Article 184 only if there are "serious deficiencies" regarding <u>Articles 181 and 182 AHL</u>.

- (155) As previously stated, these provisions concern the approval of the establishment itself and do not regulate or concern the movement of fish, which is regulated by Article 191 AHL et seq. As the Government's application of Article 184 represents a derogation from the general rules in the AHL when it comes to movement, it must be interpreted narrowly, to the effect that the national authority is precluded from revoking an approval based on an (alleged) deficiency regarding other provisions of the AHL which is not explicitly listed in Article 184, i.e., Article 191 AHL et seq.
- (156) Thus, the wording of Article 184 precludes the national competent authority to reject or withdraw an approval solely based on an operator's planned movement of fish in full compliance with the rules set out in Article 191 AHL et seq.

5.5.2 The systematics of the AHL

- (157) Moreover, the Plaintiff's interpretation is further supported by the systematics of the AHL. As is evident from the cited provisions below, the approval under Articles 181 – 184 AHL is independent of nor contingent on the approval of the fish movement.
- (158) The approval rules in Articles 176 184 are laid out in Part IV, Title II, Chapter 1, which is entitled "Registration, approval, record keeping and registers," hereunder Section 2, entitled "Approval of certain types of aquaculture establishments," whilst the rules on movement of fish are laid in the same part of AHL, but in Chapter 2.
- (159) The structural divide between the approval rules and the rules on movement supports the contention that these sets of rules are separate, and Article 184 cannot be invoked as a basis to restrict fish movement.
- (160) Furthermore, as set out in detail above, the listing in Article 269(1)(a) to (e) further implies that the rules for approvals, which are specifically listed in Article 269(1), and thus only subject to minimum harmonisation, are different and not interlinked with the movement rules, which is not listed in Article 269(1).
- (161) Further supporting the Plaintiff's interpretation is the fact that recital 43 of the AHL discusses the possibility of introducing "higher biosecurity standards" for the establishments (and for approving establishments) and that it should only be conferred on the Commission – in that regard – to lay down "minimum requirements." Contrast this to recitals 147-148 of the AHL, cited further above, where it is clear – as regards the movement of fish – that the competence

to introduce further derogations is exclusive to the Commission. Thus, all derogations and specific requirements for movements of aquatic animals, where the movement rules laid down in the AHL are not sufficient, the implementing powers to lay down special movement rules or derogations are conferred on the Commission and <u>not</u> the EEA States.

- (162) Moreover, it would be contrary to the fully harmonised nature of movement rules as laid down in Article 191 et seq. if Article 184 AHL could be used as a legal basis for national restrictions on fish movement and, as such, circumvent the exhaustive and detailed nature of the movement rules. Such an interpretation is not logical or in line with the structure of the AHL.
- (163) As the cited provision above underscores, it is clear from the systematics of the AHL that the rules concerning registration and approvals in Articles 181 – 184 are independent and separate from the fully harmonised movement rules on fish movement in Article 191 et seq. As such, national authorities cannot base a rejection of approval under Article 184 on the planned movement of fish.

5.5.3 The context of Article 184 AHL

- (164) Moreover, Article 184 must be interpreted in the context in which it occurs. As the Plaintiff will demonstrate below, the approval rules in Article 172 AHL et seq. do not concern restrictions on fish movement but inherently presuppose that the operator plans to move the fish in accordance with Article 191 AHL et seq.
- (165) For instance, Article 176 concerns the "Approval of certain aquaculture establishments." It remains clear that certain aquaculture establishments shall apply to the competent (national) authority for approval in accordance with Article 176(1) under alternative (a) of that provision:

"aquaculture establishments where aquaculture animals are kept <u>with a view to their being moved</u> <u>therefrom</u>, either alive or as products of aquaculture animal origin."

- (166) Approval must be obtained since the fish is kept "with a view to their being moved," demonstrating that the approval rules <u>presuppose</u> a movement of the fish already at the time of the application. In the same vein, Article 176(1) (b) governs "<u>other</u> aquaculture establishments" which pose a significant risk, hereunder due to "(iii) movements of aquaculture animals into and out of the aquaculture establishment concerned."
- (167) Article 176(3) further provides that "operators shall not commence activity at an aquaculture establishment as referred to in paragraph 1 of this Article until that establishment has been

approved in accordance with Article 181(1)." Article 180 comprehensively outlines the information that must be provided to the competent authority. Information about the movement of fish is not explicitly listed in that provision, which seems logical because one of the reasons for mandatory approval is precisely that "aquaculture animals are kept "with a view to their being moved there from" cf. Article 176.

(168) The scope of the approval follows from Article 182. Article 183 outlines the approval procedure. According to Article 183(3), the competent authority <u>shall</u> grant the approval provided that the requirements in Article 181 are fulfilled. All the rules governing approval refer to "the establishment" <u>itself</u>, and no reference is made to the movements of fish from the establishment. Article 184 only concerns the conditions of the establishment after the approval was granted, and not the movement of fish from one establishment to another, is further supported by Article 184(2), which reads in extract:

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

- (169) The wording refers to the conditions in the "establishment." There is nothing in the wording concerning the movement of fish in general or between establishments.
- (170) One illustrative example could be the following regarding the application of the "review clause" in Article 184 and movement of fish: An operator of an already approved establishment that did not have plans to move fish at the time the operating plan was approved sees the need to move fish from one location to another post-approval in the interest of fish health or other operational reasons that had not been foreseen at the outset when the approval was granted. In such situations, should the Food Safety Authority then be competent to withdraw the approval of an operational plan relying on Article 184(2) if all the requirements for the movements of aquatic animals in Articles 191 and 192 et seq. were fulfilled?
- (171) If one were to accept such an interpretation of the approval provisions, the harmonised rules on the movement of fish would have <u>no</u> real substance, and the application of Article 184 in this manner would directly <u>contradict</u> the rules on movement outlined in the AHL, in particular as regards the reference to the movement restrictions in Article 191(2)(b). Also, the exclusive power conferred upon the Commission to lay down further derogations (restrictions) on fish

movement in its delegated acts would, in that case, be entirely <u>redundant</u> and devoid of meaning.

- (172) Adding to that, in a situation where a movement of fish between approved establishments is planned by the operator, again in full compliance with the harmonised rules in the AHL and the delegated acts, it would make very little sense if the AHL had opened for the possibility of rejecting or withdrawing an approval based on such planned movement. This is not only for the reasons provided directly above but also because fish health is not *static* but *dynamic*, as already mentioned and stressed by the Plaintiff above.
- (173) Thus, it can be derived from Article 184's context that the approval rules, hereunder Article 176, already presuppose a movement of fish (in conformity with the movement rules), and as such, further supports the Plaintiff's interpretation that the scope of Articles 181 184 is to approve establishments, and not to regulate future movements compliant with the movement rules in the AHL.

5.5.4 Article 184 must be interpreted to ensure the full effectiveness of the AHL

(174) Moreover, Article 184 must be interpreted to ensure the full effectiveness of the harmonised rules in the AHL. The Plaintiff contends that the Government's interpretation of Article 184 AHL would open the possibility to "camouflage" restrictions on <u>movement</u> under the pretext of not approving the operator on the ground that the facility has "serious deficiencies" or "poses an unacceptable risk as regards the spread of diseases" if the planned movement indeed fully <u>adheres</u> to the strict movement rules in the AHL (and the delegated acts). Applying Article 184 in this manner would deprive the harmonised rules on the movement of fish of their <u>effectiveness</u>.

5.5.5 *Conclusion: Article 184 does not allow for a rejection of an approval the basis of fish movement*

- (175) In simple terms, the Plaintiff contends that the Government cannot be heard with an interpretation that obfuscates the aims, objectives and systematics of the AHL and attempts to "re-introduce" a "flexibility" or a "room of manoeuvre" regarding the movement rules (that is not there) under the pretext of a non-approval (under the registration and approval rules).
- (176) <u>In conclusion</u>, it follows that Articles 176 184 of the Regulation are irrelevant in that none of these provisions can be interpreted as allowing the Government to depart from the harmonised

rules by means of restricting the movement of fish that comply with all the harmonised requirements.

5.6 Article 226

(177) Article 226(1) reads:

"Where a disease other than a listed disease as referred to in point (d) of Article 9(1) constitutes a significant risk for the health of aquatic animals in an EEA State, the EEA State concerned may take national measures to prevent the introduction, or to control the spread, of that disease." (Our emphasis added).

(178) It follows directly from the wording that "other than a listed disease" can justify national measures. The wording clearly implies that suspicion or detected diseases listed cannot justify national measures. As stated in the referral at paras. 29 – 30, the contested decision is grounded in suspicion of ISA, which is a listed disease, cf. Annex II AHL, read in conjunction with Article 5(1)(b) thereof. As such, Article 226 AHL does not apply in the main proceedings and has not been invoked by the Government. Further, no national measures relevant to the present case have been notified to ESA according to Article 226(2).

6 CONCLUSION AND PROPOSED ANSWER TO THE QUESTION REFERRED

- (179) Given the comprehensive harmonisation of the regulations for moving fish in the Regulation and the Commission's delegated acts, the Norwegian Food Safety Authority's application of Section 19 of the Food Act and Section 40 of the AOR with reference to a general precautionary principle as the legal basis for refusing to move fish undoubtedly conflicts with the AHL. The same goes for the Government's application of Article 184 AHL to deny or withdraw applications for operational plans for establishments that fulfil all requirements in Article 181 AHL.
- (180) As already underscored, fish health is not *static*. It is *dynamic*, and the movement of fish planned up to two years ahead (when the approval of the operational plan takes place) does not enable the assessment of the health status in the future at either the location or destination of the fish in line with the very purpose of the AHL's movement provisions. The AHL and the delegated acts require that assessment of movement restrictions and veterinary checks occur as close to the planned movement as possible, both for pre-planned movements and movements that occur due to changed circumstances.

(181) In the light of the above, the Plaintiff considers that the question referred should be answered as follows:

Regulation (EU) 2016/429 and of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law' or 'AHL') in particular Articles 9, 10, 176, 181, 183–184, 191–192, and 269 thereof, read in conjunction with Commission Delegated Regulation (EU) 2020/990 of 28 April 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health and certification requirements for movements within the Union of aquatic animals and products of animal origin from aquatic animals, shall be interpreted as meaning that:

- The EEA States' central veterinary authorities are precluded from prohibiting the movement of clinically healthy farmed fish from one approved aquaculture establishment to another in a situation where there is no detected disease or concrete suspicion of disease in the fish, unless they are subject to the movement restrictions vested in Article 191(2)(b) i) in accordance with the rules laid down in Article 55(1), Article 56, Article 61(1), Articles 62, 64 and 65, point (b) of Article 70(1), Article 74(1), Article 79 and Article 81 and the rules adopted pursuant to Article 55(2), Articles 63 and 67 and Articles 70(3), 71(3), 74(4) and 83(2); or (ii) the emergency measures laid down in Articles 257 and 258 and the rules adopted pursuant to Article 259. EEA States cannot adopt more stringent restrictions on the movement of fish based on Article 269.
- Movement of fish adhering to the movement provisions in the AHL and the Commission's delegated acts does not constitute grounds for refusing or withdrawing the approval of an operating licence for an establishment with reference to Article 184 AHL.

Oslo, 5 July 2024 ADVOKATFIRMAET SIMONSEN VOGT WIIG AS

Jan Magne Langseth Advokat – Admitted to the Supreme Court