To: **Gregg Wood of Maine DEP and interested parties of the public**
From: **David Russell & Marcy Nelson on behalf of the Maine Department of Marine Resources**
Subject: **Preliminary Review of Nordic Aquaculture's discharge as it pertains to pathogens**
Date: **05 February 2020**

Introduction and Disclaimer: At the request of Gregg Wood of the Maine Department of Environmental Protection (DEP), a preliminary review of Nordic Aquaculture's discharge permit application materials and associated Q&A from hearings and pre-file testimony as it pertains to fish pathogen concerns was conducted. Although the discharge and presence of pathogens within a facility are of interest to DEP, particularly in regards to situations wherein chemical therapeutants or antibiotics could be used for their treatment and are thereby of discharge interest; it is the Maine Department of Marine Resources(DMR) that is best suited from a regulatory perspective to set license and import conditions for the express purposes of protecting state resources from aquatic animal pathogens. Nonetheless, the need for pathogen treatment can result in the need to use substances that may enter the environment via a facility's discharge, therefore Maine DEP has a valid interest in evaluating potential pathogen threats associated with the planned activity, especially given the scale of the operation. Although the opinions contained herein should reflect the opinions of Maine DMR, the agency has not concluded its review. As such, this opinion should not be construed to be the final position of Maine DMR. Furthermore, as issuance of the fish cultivation license and permitting of finfish imports for this project are under the jurisdiction of the Maine Department of Marine Resources, as is the authority to regulate the introduction of marine organisms to the coastal waters of the State of Maine, inclusive of the introduction of aquatic pathogens through aquaculture effluents, DMR will issue its own set of requirements after its review is complete.

Maine Aquatic Animal Health Technical Committee:

Maine, in addition to having its own in-house expertise to evaluate risk, also has the Aquatic Animal Health Technical Committee (AAHTC), an established committee appointed jointly by the Commissioners of the Department of Marine Resources and Department of Inland Fisheries and Wildlife(MDIFW). The AAHTC is comprised of aquatic animal health professionals from within and outside of the State of Maine with a composition that is established in the State's aquatic animal health rules in DMR Chapter 24.04(1)[1]. It is currently comprised of veterinarians, epidemiologists, aquatic animal health inspectors, pathologists, and professors from the Maine Department of Marine Resources, the Maine Department of Inland Fisheries and Wildlife, the Maine Department of Agriculture, Conservation and Forestry, the United States Fish and Wildlife Service, NOAA, USDA Animal Plant Health Inspection Services (APHIS), the University of Maine, the Virginia Institute of Marine Science, and individuals from private industry within the State of Maine. The AAHTC is tasked with providing technical advice and recommendations to the Commissioners in several areas, including, but not limited to; criteria for biosecurity and quarantine, procedures for disease and pathogen surveillance, diagnostic protocols and standards, and classification and testing requirements for pathogens of regulatory concern. DMR's fish health rules have provisions that require consultation with the AAHTC for certain imports. Because one of the listed egg sources for the proposed project will trigger the need for consultation, the AAHTC will advise the Commissioner of DMR on the safety of using the proposed source, adequacy of quarantine plans, and the setting of pre

and post import testing requirements. The committee works at the request of DMR and DIFW and has not yet been asked to review the activities associated with the project.

Fish Health Standards: The State of Maine places a high value in safeguarding its natural resources and natural resource-based industries from various threats, including those posed by aquatic animal pathogens. Although DMR and DIFW have specific pathogens that have been classified as being of regulatory concern, both agencies also utilize other pathogen lists in their risk assessments, including those pathogens listed in the Northeast Fish Health Committee Guidelines[2], OIE listed pathogens of the World Organization for Animal Health[3], and lists created by competent authorities of other countries. Pathogen significance varies greatly according to multiple factors including, but not limited to geographical distribution, host range, presence of hosts and/or intermediate hosts, climate match, pathogenicity, and epidemiological traits. Pathogens are classified based on their potential consequences to interests of the State. Although the State takes a highly precautionary approach on the side of protecting natural resources, it also balances its regulations and rules applied to industry in a manner that does not result in costly inconsequential measures of insignificant benefit. In this regard, excessive measures to prevent the release of select pathogens which are regularly introduced to waters of the State or that are established in Maine waters could be pointless in most, but not all, situations. However, the amplification and release of Maine enzootic pathogens that result in localized unnaturally high levels capable of causing harm to wildlife is of concern and such is the reason why certain enzootic pathogens are still highly regulated in aquaculture by the State.

ISAV (Infectious Salmon Anemia virus) commentary: Pre-file commentary received from Bill Bryden suggested that Maine DMR is not concerned about the import of ISAV. Although such may be the case as it specifically relates to risk variables associated with human consumption of infected salmon, such does not represent the overall level of concern that DMR has for ISAV. ISAV has and continues to this day to be the most closely watched and regulated fish pathogen within the State of Maine. Although the virus is not exotic to Maine coastal waters, DMR has kept the virus on its list of "Exotic" pathogens of regulatory concern due to its limited distribution and due to its potential to harm Atlantic salmon interests of the State. The exotic designation gives DMR greater ability to control ISAV outbreaks when they occur as the designation allows for use of mandatory depopulation should such be determined necessary. ISAV, as mentioned in the commentary, has pathogenic and non-pathogenic forms referred to as HPR deleted and HPR0, respectively. Although the non-pathogenic form does not meet Maine's definition of being a pathogen of regulatory concern, the possibility of mutation to a pathogenic form remains a concern and for this reason it was added to DMR's list of "Endemic/Limited Distribution" pathogens of regulatory concern to keep its detection as reportable and for an enhanced ability to regulate. DMR will require evidence of freedom from ISAV for that which is to be imported prior to import and again post import, prior to any fish being transferred from Nordic's quarantine to the main production areas of the facility. Pre and post import testing with highly sensitive molecular screening methods for ISAV, for eggs which are to be imported from Iceland, will be required as will post import screening with cell culture isolation methods. The bar for evidence of freedom from ISAV is set very high.

Both forms of ISAV have been detected in returning Atlantic salmon in the Penobscot River on multiple occasions and years. The pathogen is not exotic to Maine or Penobscot Bay. Due to the pathogen not being novel to Penobscot Bay or other waters of the State, the United States Fish and Wildlife Service disinfects its hatchery effluent water with UV light for those tanks which are used to hold wild collected Atlantic salmon returning to the Penobscot River. Wild salmon with the pathogenic form of ISAV (HPR deleted) are euthanized and those with the non-pathogenic form (HPR0), although not killed, are not utilized for broodstock. Salmon with ISA HPR0 are released back to the river by the USFWS. It is worth mentioning that the USFWS Craig Brook National Fish Hatchery utilizes a 37 micron drum filter for solids filtration followed by a UV dose of 45 mJ/cm^2 on their effluent for the purposes of ISAV biocontainment.[4] In contrast, Nordic Aquafarm's biocontainment plan to filter solids to the 0.4 micron level followed by a UV disinfection dose of 300 mJ/cm^2 is significantly over designed for biocontainment of amplified pathogens of concern.

The communication from DMR with regard to infected salmon for consumer use not being a concern was made based on a risk assessment that included the following;

- The amount of virus shed from handling and washing salmon in household consumer situations is expected to be very small and via routes that do not involve direct introduction to state surface waters where susceptible species congregate.
- Discharge of wash water from household or restaurant consumer use is mostly to onsite septic or municipal waste water treatment plants. Such discharge avenues are not favorable for exposing susceptible host species to an infective dose due to: the small quantities involved, the lack of hosts, the loss of infectivity from treatment processes and time outside of a host, and dilution. In the event ISAV were to survive treatment processes at a municipal waste water treatment plant, the virus would be unlikely to encounter a susceptible host at a dose capable of causing infection.
- The vast majority of salmon sold to the end consumer is in the form of fillets and steaks. The OIE aquatic animal code specifically recommends that such salmon product should not be restricted.[5]
- The virus is only known to cause disease in Atlantic salmon. Although a select few other species can be carriers, the overall host range for the virus is small.[6] Restricting the import of dead Atlantic salmon for human consumption, which DMR does not have the power to regulate, would not result in enhanced protections to the States salmon populations relative to the threat posed by other avenues for its introduction and spread that already exist via natural and anthropogenic routes.

Nordic Aquafarms Effluent Treatment: Any concentrated animal farming operation has the potential to become infected with pathogens, particularly with those that are enzootic to the region in which it is located. Although preventing the introduction of exotic agents is highly feasible via import controls and quarantine, the introduction of enzootic pathogens of lower consequence from the surrounding environment is almost inevitable over time for most operations. However, various facility designs, operating protocols, and contingency plans can make them relatively inconsequential. When a pathogen is introduced into a farming situation, there is a concern that the farmed stock could amplify background levels of enzootic pathogens to levels capable of harming native species in the vicinity of the farm effluent. Due to the proposed scale and location of the Nordic Aquafarms project with respect to

wild salmon populations, the concern of pathogen amplification was raised. Influent and effluent treatment equipment to prevent the introduction and subsequent amplification and release of select enzootic pathogens of concern at levels that would be above that which is naturally expected to be found in state waters is one means of addressing the concern. As the primary concern, from Maine's point of view, is for amplification of select enzootic pathogens that are of greater distribution within the state, effluent treatment at a level to mitigate the most prevalent pathogens of concern is desired. For such purposes, UV treatment at a dose of 30 mJ/cm^2, which is suitable to mitigate the risk from many aquatic pathogens[7], preceded by microscreen filtration at 100 microns would have addressed the primary concerns to a satisfactory level. The Green Lake National Fish Hatchery treats their influent water with a UV dose of 30 mJ[4] to reduce risks associated with their surface water source. Although such a level is not adequate for all pathogens or to completely eliminate susceptible pathogens in an influent or effluent stream with certainty, it is adequate to reduce many general threats to an acceptable level of risk. In a similar fashion, the Maine Department of Inland Fisheries and Wildlife operates 4 facilities with influent UV disinfection of their respective surface water supplies with a UV dose that ranges between 30 and 40 mJ/cm^2.

Nordic Aquafarms, with their plans of using a UV dose of 300 mJ/cm^2 and micron filtration down to 0.4 microns, has proposed a level of effluent treatment that far exceeds regulatory expectations for amplification prevention. Although equipment suited for mitigating the effects of amplification would have been satisfactory, Nordic Aquafarms has opted to use equipment that is much more compatible with that utilized for quarantine systems. Their proposed effluent UV dose is 10 times and their microfiltration is 200 times the minimum level expected for amplification prevention. The level of microfiltration by itself, and without use of UV, is suitable biocontainment for most bacterial pathogens and parasites of concern. The UV dose is enough to address all salmonid pathogens of significance associated with the project. If viewed for the purposes of quarantine treatment, the proposed effluent treatment combination is adequate to address all non-exotic pathogens of regulatory concern. A much higher-level quarantine capability, suitable for the biocontainment of some exotic pathogens, with the addition of an independent more robust effluent treatment process for that discharged from the egg incubation and fry rearing areas prior to discharge into the general effluent treatment plant is also feasible as such would result in redundant biocontainment safeguards.

Enhanced ecological safeguards: It should be noted that Maine DMR and DIFW do not currently require effluent treatment from any aquaculture facility that obtains fish from a qualified source. Of the nineteen land-based aquaculture facilities in the State working with salmonids and that have direct discharge to surface waters of the State, only three utilize effluent UV disinfection[8]. Maine has historically required the use of quarantine systems, with requirements for effluent disinfection and pathogen testing of fish in quarantine, for that which is not from a qualified source. Aquaculture facilities in Maine regularly grow fish in situations wherein there are no mechanisms to prevent the release of amplified pathogens. Although salmonid aquaculture is being conducted at significant scale at multiple locations with no mechanisms to prevent amplification, the industry has had a long track record of operating successfully with little evidence to suggest that harm to wild fish populations is occurring. When compared to net-pen and flow thru aquaculture, the project proposed by Nordic

Aquafarms has a much higher level of environmental separation from the resources of the State of Maine. Import and quarantine controls of the State combined with Nordic Aquafarm's influent treatment plans, biosecurity plans, and effluent biocontainment infrastructure will result in a situation wherein the potential threats posed by the proposed project will be far less than that of current threats for aquatic animal pathogen introduction to State waters.

The need for chemical therapeutants and antibiotics: The potential for the introduction and release of pathogens will be closely regulated by Maine DMR's stringent requirements for import, quarantine, and post import testing. This combined with treatment of influent water, use of batch culture for early rearing phases, segregation of production units, use of biosecurity measures including; restricted staff movements between modules, use of veterinary services, and use of vaccination for select pathogens are some of the means in which Nordic Aquafarms is highly likely to avoid major pathogen problems.

Although Nordic may have no intention of using antibiotics, it would be unwise of them to not include the option as a contingency. In the event a bacterial pathogen requiring treatment were to make it into one of their rearing modules, it would be unethical to allow the fish of that module to succumb to disease by withholding treatment. As the use of antibiotics in food production is now highly regulated in the USA, it is already difficult to get medicated feed in the required size and formulation in a timely manner for treatment. As regulatory approval times for adding substances to a MEPDES permit are not compatible with the need to initiate treatment, when or if the need arises, many farms will add multiple antibiotics and chemicals that are FDA approved for use with food fish to their discharge application even though they may have no need or intention to use them. For many, it is better to have the option to treat than not to treat at all. Just because a substance is listed on an MEPDES permit doesn't mean it will be used.

Other chemicals, particularly formalin, are regularly used in the early life stages of salmonid rearing, particularly for the control of fungal pathogens. Due to the ubiquitous nature of fungus in Maine and elsewhere, the need for fungal treatment is a near certainty, even with the best biosecurity practices. Small quantities will certainly need to be used at Nordic for early rearing phases. Because heterotrophic bacteria of biological filtration systems and waste water treatment systems have an appetite for carbon, formalin is quickly metabolized by such bacteria. Unlike flow thru systems wherein the use of formalin results in its discharge to the environment, its use in a RAS facility such as Nordic will result in non-detectable levels within its discharge.

Virkon is a powerful cleaning and disinfection chemical. It is widely used for biosecurity purposes to disinfect the foot wear of visitors and of staff moving between rearing areas and for disinfecting equipment after use. Its use at an aquaculture facility is not a sign of a disease problem but is rather a sign that good biosecurity practices are being employed.

General Rating of Nordic's RAS Plan as it Relates to Disease

Recirculating aquaculture technology has been used in commercial aquaculture since the 1980's for the production of various fish species from egg thru broodstock. Continual improvements to rearing protocols, development of new and improved technology, and success stories have resulted in RAS being used much more frequently and at increasingly larger scales. Use of RAS in the production of salmonids has generated a significant body of knowledge for what works and what leads to failure. Large salmon producers have utilized RAS to grow their operations successfully and are continuing to invest in RAS for smolt production with over two decades of successful use. However, there are many historical RAS failures and although disease problems are associated with many of them, disease is not the root cause of their failure, but rather the result of using non-biosecure seedstock, use of species not well suited to aquaculture, inadequate system designs and equipment that lead to stressful rearing conditions, and the general practice of cutting biosecurity corners in pursuit of increased profit.

Farm plans that promote success and that avoid major problems of disease include; use of low risk seedstock, production of a species well suited to RAS, overengineering systems to maintain ideal environmental parameters, use of pathogen prevention equipment, use of vaccination as means of insurance, use of regular comprehensive pathogen screening services, use of non-stressful rearing densities and excellent animal welfare practices, and a production layout that is segregated into multiple production units to isolate and minimize the impact of problems should they arise. Nordic Aquafarms certainly has positioned themselves to use such practices and they appear to be on the right track to avoid pathogen problems of significance. To reduce the likelihood of problems Nordic Aquafarms has proposed:

- Seedstock sources of high quality and low pathogen risk. Maine import and quarantine requirements will further reduce risk.
- Atlantic salmon, a species that is well suited to RAS production.
- Working with a highly reputable veterinary service provider that is experienced with RAS, salmon farming, vaccination, and the common aquatic pathogens of Maine and elsewhere.
- System layout and production plans that are compatible with minimizing loss from disease.
- Influent, RAS system loop, and effluent pathogen control equipment that will mitigate pathogen introduction, amplification, and release .
- Facility equipment infrastructure that seems to be over designed for maintaining ideal parameters.
- A system design that appears to have significant built-in operational flexibility.
- Multi-million-dollar equipment, in excess of that needed for production, for the apparent primary purpose of environmental stewardship seems to have been added. Evidence of cost cutting practices at the expense of operational safeguards seems to be absent in their plan.

Operational Flexibility to Maintain Healthy RAS Water Chemistry in Regard to Water Use

In comparing RAS facilities to one another in regard to resources being used and the ability to maintain a healthy rearing environment, the calculation of feed load is very useful. In general, for a RAS system with aerobic biofiltration only, one cubic meter of water must be used for every 4 kg of feed fed. Thus,

any operation that has a feed load less than 4 kg of feed per cubic meter water use is one that is capable of keeping nitrate at acceptable levels to maintain fish health with only aerobic biofiltration. Based on Nordic's annual production level, a feed conversion ratio of 1.2, and their maximum allowed water use, their feed load has an estimate of 3.73 kg of feed per M3 water use. Thus;

- The Nordic MEPDES permit conditions being sought in relation to infrastructure seem to be designed for a high level of operational flexibility which makes it much easier to maintain healthy rearing environments.
- Nordic's plan of using a denitrification filtration step at 8% of the RAS flow does not appear necessary for maintaining acceptable levels of nitrate in their rearing units.
- Inclusion of denitrification filtration allows for maintenance of a higher level of water quality for better fish welfare or may be for the purposes of reducing nitrogen discharge (environmental stewardship).
- Denitrification ability will also allow Nordic to dramatically reduce their intake water volume from Penobscot Bay for significant periods of time, in the event water quality deteriorates in the bay due to adverse events such as storms.
- The technology also allows for lower levels of water use when such is desired. Such reduced water use may be attractive from an energy savings standpoint for heating and cooling on a seasonal basis.

Onsite Seafood Processing

The onsite seafood processing facility and associated effluent treatment plans are sufficient to prevent the release of pathogens of concern. Chlorination of processing waste streams is highly effective for neutralizing many pathogen threats. As chlorine-based disinfection systems are subject to human error and equipment failure, it is insufficient to serve as the only means of preventing the release of exotic pathogens of high consequence should such be present in the fish to be processed. However, when effluent streams are subsequently sent to a robust secondary treatment process, such as Nordic's effluent treatment plant with filtration to 0.4 microns and UV at 300 mJ/cm^2, the risk is inconsequential compared to other avenues for pathogen introduction. If the fish to be processed are only sourced from Nordic Aquafarm's RAS facility to be built in Belfast Maine, the biocontainment plans far exceed the need. The same could also be said for processing any salmon produced within the State of Maine, for seafood wild caught within the Gulf of Maine, and for that which is obtained from land-based salmon farms elsewhere that are documented as being free of exotic pathogens of concern.

The Impact of Good Biosecurity

Given enough time, all land-based food fish production facilities of significance will have fish pathogen issues that require attention. However, facilities with excellent biosecurity and designs experience these issues much less frequently and for that which tends to be of much lower consequence to operational viability. Even facilities with poor biosecurity can operate successfully for periods of time during a startup "honey moon phase", but as disease agents are introduced and compound into bigger problems over time, they have a significant potential to take down an operation financially. In contrast, good

operations have production schemes and contingency plans to address problems quickly before they can compound into bigger problems. Good operators:

- Have their own brood or only source from high quality sources
- Utilize quarantine facilities to verify the quality of the stock they intend to use
- Contract with diagnostic facilities to test seedstock above and beyond regulatory requirements
- Closely monitor fish health to catch problems early
- Use vaccines to proactively protect their stock from that which may bypass biosecurity
- Have contingency plans, production plans, and infrastructure to minimize overall impact
- Utilize batch production methods for early rearing phases with no overlapping of age classes in rearing units, such that pathogen lifecycles can be broken between batches.
- Have segregated production units which allow for individual system shutdown for disinfection and system resetting without the need for an entire facility shutdown. Problems are not allowed to compound or snowball into problems of significance.
- Rarely if ever have the need to use antibiotics
- Would never consider using antibiotics as a "crutch" to address poor biosecurity and husbandry.

The design and operational plans of Nordic Aquafarms is that of a good operator with high levels of biosecurity, system segregation, and contingency plans. Disease issues at the facility are likely to be infrequent, be of a minor nature, and not be at a level that would result in a failed operation. The layout allows for batch production in early phases and the segregation of production in multiple areas which allows for individual system resetting without the need for a facility shutdown should such be needed.

Comments in regards to Bill Bryden concerns

- Effluent disinfection with UV at fish rearing facilities is not a typical requirement for aquaculture operations in Maine. Comments made in regard to the effluent treatment not being fully adequate for quarantine are irrelevant as the primary purpose of treatment, from a regulatory perspective, is for amplification mitigation rather than quarantine. However, if whole facility quarantine was a requirement, the Nordic plan would be adequate for all non-exotic pathogens of concern. It is more than adequate for amplification mitigation.
- ISAV is a highly regulated pathogen in the State of Maine.[9]
- Although ISAV is regulated as an exotic pathogen by Maine, it is not exotic to Maine.
- Although the relative concern of ISAV introduction from consumer use of salmon is very low, there are some concerns in regard to true exotic viruses of very high consequence. Aquatic pathogen introduction risks do exist in our imported consumer food supply. From this perspective, increased local production to the extent imports are decreased could be viewed as being a beneficial side effect of Nordic's production.
- Nordic has not proposed sourcing any eggs from facilities in Norway. Because many facilities in Norway rear their brood in marine net-pens and there are multiple pathogens of regulatory concern prevalent in Norwegian waters, there are almost no facilities in Norway that could satisfy Maine's concerns for import.
- Import will only occur as eyed eggs subject to iodine disinfection.

- The proposed source, form of import, exotic status in Maine, and location of discharge make Whirling Disease irrelevant for this project. Myxobolus cerebralis (Whirling Disease) is not transmitted vertically with iodine disinfected eggs and the pathogen is not present in either Maine or Iceland. Other sources proposed for seedstock are or will be from qualified source hatcheries in regard to all pathogens of regulatory concern. High risk sources are not being proposed for use.
- Saprolegnia is highly ubiquitous to Maine inland waters and is easy to manage in RAS aquaculture. It is typically only a problem for incubating eggs and fry in freshwater, in salmon smolt held in freshwater too long, and as the result of handling injuries. It is not an issue for the marine environment due to lack of salinity tolerance above 2.8 PPT.[11]
- A number of viruses can be vertically transmitted. Thus, the finding of "marine viruses" in freshwater hatcheries is to be expected. Such is the reason why Maine has very strict requirements regarding brood source facility health documentation. As a single lot inspection has some possibility to miss pathogens present at very low prevalence, Maine places much weight on multi-year facility inspection reports.
- The proposed Icelandic brood source for the project is land based and functions as a compartment in the country it is located because it has operating and physical features that segregate its health status from that of the rest of the country. The fish at the facility are subjected to extensive testing, including use of sensitive molecular screening techniques. In addition to testing for typical pathogens of regulatory concern, the facility is also tested for non-listed pathogens which are of increasing concern to some, such as the Piscine Reovirus (PRV).
- Pathogens exotic to Maine and that are of increasing relevance elsewhere are evaluated in import risk assessments. Assessments go beyond that of pathogens which are listed by Maine and include a risk/consequence assessment for those pathogens which are known to be enzootic to the source region.
- Many pathogens of regulatory and non-regulatory concern are of consequence for farmed fish much more so than they are for fish in the wild. Confined rearing and higher levels of stress, compared to that experienced by wild fish, make farmed fish more vulnerable to disease.
- Yellowtail kingfish (*Seriola lalandi*): production of post metamorphosis feed trained marine fish, in contrast to rearing salmon from egg, is very difficult. For many marine species, survival of 35-50% is very common; it is very difficult to get larval fish past metamorphosis and weaned onto a commercial diet. Previously, producers of *Seriola lalandi* were considered lucky if they could achieve survival over 1%. Now, survival over 10% is considered excellent.[10] "Low survival" at Maximus, the supplier for Sashimi Royal, is consistent with that seen amongst other larval fish producers. A high rate of loss during the first weeks of production is due to husbandry variables still being worked out for the species. Post metamorphosis and after fish are trained onto feed, *Seriola lalandi* is a very robust fish that is well suited to RAS. Because it requires better water quality than salmon, Nordic Aquafarm's 3-year record of operation to date with the species, without the use of vaccines, is evidence of having excellent skills for maintaining good water quality and environmental conditions in RAS aquaculture.

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