Hearing response to NOU 2023-18 «Genredigering i en bærekraftig fremtid» from Mowi, Salmar, Benchmark Genetics and AquaGen

Introduction

This document is a response to the public hearing of NOU 2023-18 Genteknologi i en bærekraftig fremtid (gene editing). It is jointly written on behalf of four of the leading selective breeding programs and companies for Atlantic salmon in the world, specifically Mowi, Salmar, Benchmark Genetics, and Aquagen. Together these companies represent the vast majority of salmon egg and genetics supply to the Norwegian and global salmon farming industry.

Salmon aquaculture and sustainable high-quality protein

Farmed Atlantic salmon provides high quality animal protein and essential macro and micronutrients for healthy human diets, including essential Omega-3 fatty acids. Further, the production of salmon compares very favourably in terms of feed conversion, carbon footprint, and freshwater use, versus terrestrial livestock production. As such, salmon aquaculture can form an important part of future food systems to reduce climate change.

Salmon aquaculture is also a key contributor to Norwegian economic growth, contributing 13.1 billion NOK to the Norwegian government's tax revenue in 2021, and is the main industry supporting employment and investment into many rural and coastal communities throughout the country.

Nonetheless, the salmon aquaculture industry faces significant challenges, including those impacting on fish health and welfare, and impacts on the marine environment. Significant innovation and future technological solutions are essential to tackle these challenges, and further improve the overall sustainability of the industry.

Genetics and breeding are cornerstones of sustainable salmon farming

Selective breeding programs for Atlantic salmon has been crucial for the success of developing efficient and sustainable salmon farming in Norway. Since the initiation of the public breeding program by AKVAFORSK at the beginning of the 1970s, continuous genetic improvement has been delivered for key traits, initially focussing on faster growth rate, and subsequently a balanced breeding goal with many traits. In more recent years, the selective breeding of salmon has been performed by a small number of specialist breeding companies (e.g. Aquagen, Benchmark) and integrated companies (e.g. Salmar, Mowi).

The documented benefits of genetic selection show transformative impacts on improved growth rate, improved feed efficiency, and reduced production time in seawater. Furthermore, the positive impacts on improved health and welfare have been demonstrated by the success of reducing the impact of specific diseases, such as Infectious Pancreatic Necrosis, and in more recent years Cardiomyopathy syndrome (amongst others).

The professional family-based breeding programs are highly sustainable, with a focus on many traits and a particular focus on health and welfare traits. These traits include growth efficiency, age at sexual maturation, disease

resistance, survival, and quality traits. The modern programs use the latest technologies, such as genomic selection and – in some cases – cryopreservation of milt to ensure that the genetic makeup of production fish is tailored for high growth, efficiency, survival, and improved health and welfare of the fish. In addition, these programs secure and maintain a broad genetic variation in the breeding populations to facilitate selection response and longevity of the programs.

The potential role of precision breeding technology in salmon breeding

Our companies have reviewed the report 'NOU 2023: 18 (Official Norwegian Report) Gene technology in a sustainable future'. Herein we present our views on the potential role of precision breeding, the consequences of the current regulations, and our principles for the use of the technology in our salmon breeding programs.

We are fully in agreement with the majority of the committee on the point that "Gene technology can contribute significantly to a more sustainable future. However, today's regulations and their implementation create too many obstacles to realize its potential." and we also fully agree with the majority that "it is ethically most proper to facilitate increased use of gene technology, and therefore proposes a significant change of direction that will provide a more predictable, risk-proportional and resource-efficient path from research and innovation to market, for products and organisms developed with gene technology."

Applications of precision breeding techniques, and particularly gene editing, have transformative potential to tackle some of the most pressing health, welfare and environmental challenges facing salmon farming today. All of our companies are undertaking research and development to this end. It is important to note that the focus of these projects is towards applications of precision breeding that have concurrent benefits to health and welfare of the fish, as well as reduced environmental impact.

Examples of ongoing R&D projects involving our companies are:

- Genetic resistance to sea lice. For example, the CrispResist project funded by FHF https://nofima.com/projects/crispresist/ involves understanding the mechanisms by which certain pacific salmon species are resistant to sea lice, and using this knowledge to employ precision breeding methods to increase the resistance of Atlantic salmon to the parasite. Atlantic salmon with genetic resistance to sea lice have potential to transform the industry, tackling one of the most pressing health, welfare, and environmental challenges.
- Genetic resistance to viral pathogens. Our companies undertake projects to discover specific genes and variants which confer resistance to viral pathogens presenting significant challenges to salmon farming. As with the sea lice example, genetic resistance is the ultimate preventative method for infectious diseases, reducing mortality, morbidity, and potentially avoiding stressful handling events for the animals.
- Sterility. Our companies undertake projects aimed at ensuring production animals are sterile. These projects involve both precision breeding and other non-precision breeding technologies. Successful outcomes of

these projects will prevent the problem of precocious maturation in production, and act as a safeguard against genetic introgression of farmed fish with wild counterparts in the case of escapees. As such, we focus on concurrent sterility together with any gene editing applications, to minimise any potential risk of unwanted introgression of PB farmed salmon, and protect the wild salmon gene pool

In addition to these specific targeted R&D pipelines, our companies also undertake R&D on precision breeding methods themselves, including improving the accuracy and scalability of the methods towards a commercial scale. It is important to note that precision breeding technologies are not a replacement for our well-managed selective breeding programs, but rather an addition. Therefore, methods to integrate such technologies into selective breeding operations in a scalable manner are essential to future applications to benefit the industry.

Selective breeding via conventional methods is an effective method to improve all heritable traits, including disease resistance. However, a breeding programme is a compromise between the number of traits included and genetic progress. Atlantic salmon have a long generation interval (3-4 years), meaning that only modest improvements can be expected for each and every trait in a short to medium term timeframe. Furthermore, some traits describe little or no heritability and the only way to improve these are by PB technology. The use of PB technologies can both accelerate the genetic improvement of specific traits such as disease resistance, and allows for the breeding program to put additional emphasis on other traits in the breeding goal, meaning faster genetic progress can be made for those traits also.

It is our opinion that when transformative solutions to improve health and welfare, and reduce environmental impact, are developed through these R&D pipelines, it is our ethical responsibility to ensure a pragmatic and risk-appropriate regulation system to realise the benefits for the industry.

Precision Breeding versus GMO classification

We fully agree with the proposal of the majority to consider changes to a species gene pool, which are considered by the members to be similar to the ones that can be achieved by the use of conventional breeding methods - are classified as precision breeding (PB). This should reflect targeted changes to the species genome which could have occurred via natural mutation, but should not be restricted only to existing naturally occurring variants in the gene pool.

We believe the proposal of the majority is in line with regulatory changes proposed in England, which specifically states “Precision breeding (PB) refers to the use of modern biotechnology to produce a plant or animal with genetic changes that could also have arisen within the existing gene pool, through traditional breeding processes.” Department for Environment Food & Rural Affairs UK.

We agree that such PB changes should be viewed and classified differently to GMO, which should refer to transgenic organisms where foreign DNA is inserted into the species genome. This differentiation is critical to as the current

regulatory system for GMO is prohibitive to realising the benefits of PB technology for the Norwegian aquaculture industry, and would stifle innovation in this area if continued.

In the event that the existing GMO legislation were applied to PB technologies, it would place Norway at a competitive disadvantage to many other regions in the world with pragmatic and progressive regulations of PB technologies, as proposed by the majority. In addition to the practical limitation of the regulatory process for GMO products, the public perception of GMO must be considered, and the negative impact of a GMO label on salmon products will be likely to be damaging to the industry perception and competitiveness.

Since PB organisms would be indistinguishable from non-PB organisms (as follows from the logic that the variant could have occurred naturally in the species gene pool) we strongly agree with the majority that PB products do not have any additional requirements for labelling or traceability.

We believe that the precision breeding and GMO legislation should only apply to heritable changes that result from genetic technology, and not to non-heritable effects. That is why we agree with the majority proposal, which excludes non-heritable changes. This type of genetic technology, that can be used for vaccine production or gene expression modification, is already regulated by other laws. This is consistent with the current trend in the approval and use of DNA and RNA based vaccines, such as the fish vaccine Clynav ™ Elanco and several Covid vaccines currently in use.

Our principles for PB applications

As salmon breeding and production companies we adhere to very strict standards of animal health, welfare and biosecurity. We take responsibility for the animals in our care as an upmost priority. We will therefore apply the same strict principles to the use of PB technologies as for conventional selective breeding technologies.

We fully agree with the committee that ethical justifiability is an overarching concept that includes sustainability and societal utility, and that ethical justifiability is assessed according to four central principles; utility, sustainability, fair distribution and transparency.

As such, we fully support the majority that any risk relating to the use of PB primarily depends on the product's characteristics, and that the risk of a product produced with PB does not differ from the risk of a corresponding product produced using conventional techniques if the genetic changes can be considered to be similar or identical.

We agree that individual approval of PB products should be applied based on a proportional risk-benefit analysis, and such regulation should facilitate timely application of low-risk, high-benefit examples to benefit the industry and society at large. In parallel, such regulation will safeguard against any potential misuse of PB technology, whereby the end result is not in keeping with the aforementioned principles of ethical justifiability. We see that an appropriately qualified independent advisory committee is in place to evaluate the implications for health, welfare, sustainability, and environmental impact of candidate PB products. It is our strong opinion that these decisions should be based on the outcome of the genomic change and resulting trait(s), not on the specific use of the PB methods themselves.

We propose that any candidate PB products are evaluated thoroughly for both off-target mutations (for example by whole genome sequencing), and also that such PB products are robustly tested for potential pleiotropic effects on other traits, particularly those related to health and welfare on the animals.

Authorities and legislation

Finally, we support the opinion of the majority in the Committee in relation to moving the legislation and administrative responsibility for approvals from environmental ministry/agencies to the food authorities and food regulations. This will ensure the Norwegian regulation is align with the way EU organizes the regulations and policies in this matter and will acknowledge that genetically edited food and feed, including livestock and fish, are part of the food system, where gene editing is a breeding tool that expands the existing food production toolbox. Such an organization will enable faster adaptation of the EU regulations, as the majority in the Committee points out.