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Access to and Legal Protection of Aquaculture Genetic Resources: Norwegian Perspectives

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Access to and Legal Protection of Aquaculture Genetic Resources – Norwegian Perspectives [3]

1. Introduction

A central socio-economic challenge in fish breeding arises from issues relating to access to and exclusive rights of genetic resources. Breeding companies need legal or biological protection measures to assure revenues from genetic improvement and investment in genetic material. Fish farmers and fish breeders need access to genetic resources for food production and further development and sustainable use of fish genetic material. How can a balance be created between the need for unencumbered and free access on the one hand, and on the other hand, the need to ensure a right to the results from breeding and research? This question is well-known for plant genetic resources, but has hardly been dealt with for marine genetic resources. Here the aim is to bring together perspectives from international and domestic legal processes with the needs and perceptions of actors in the aquaculture sector.

Aquaculture is one of the fastest growing sectors of food production, with an average increase of nine percent per year (FAO 2004). There are great expectations that the aquatic Blue Revolution may constitute the next wave for enhanced food security in the world (Greer and Harvey 2004:25). Similar to agriculture and livestock husbandry, fish farming involves environmental and socio-economic challenges along with its benefits.[4] It is hoped that a Blue Revolution may circumvent some of the flaws of its predecessor, for instance by basing productivity on a less narrow genetic base, and contributing to equitable benefit sharing, thus putting a greater emphasis on the needs of the poorest farmers. However, only 5-10 % of the total aquaculture production is based on genetically improved material (Gjedrem 2005). This varies between species, but a central question is why the interest for investing in genetic improvement in aquaculture species is so low compared to other domesticated species, e.g. plants and livestock.

Within the plant breeding sector, legal mechanisms for access and exclusive rights have been developed over a long period of time. The most important property rights to genetically improved plant varieties are based upon the plant breeders' rights as set out in the various editions of the International Union for the Protection of New Varieties of Plants (UPOV) conventions since 1961. Plant varieties that are considered as *new, distinct, uniform* and *stable* can be subject to a partly exclusive right to commercial uses. More recently, the UN Food and Agricultural Organisation (FAO) has concluded an International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA 2004) which regulates exchange, access and benefit sharing for some of the most important food plants. While these regimes

[3] The project has been supported by the Norwegian Research Council.
[4] The environmental challenges include hazards relating to introduction of alien species, control of pathogens and diseases, and protection of biodiversity (FAO/COFI, 2003).

are aimed at plants specifically, the Convention on Biological Diversity (CBD, Rio 1992) and the patent system regulate more general aspects relating to genetic resources and innovation. The scope of CBD covers wild species and improved breeding stocks, as well as equitable sharing of benefits derived from the utilization of the world's genetic resources. The patent system applies to inventions in biotechnology and to biological material when the invention fulfils the general patent criteria. Access or exchange of fish genetic resources and legal protection of investments and research in aquaculture have not been addressed extensively (Greer and Harvey 2004: 5).[5]

Fish biology shares some features with plants and some other features with terrestrial farmed animals. There are, however, crucial differences. Aquaculture species such as salmonids and cod have extremely high fecundity and reproductive capacity compared to other farm animals. This feature is more similar to the characteristic of plant species and provides a great potential for breeding and intensive selection. However, plant varieties are often formed as a result of homogenizing processes like inbreeding and vegetative propagation. Accumulation of inbreeding does not seem to impair the viability and performance of plants, as is normally seen in animals. The results are often highly uniform plant varieties, both phenotypically and genetically, that may be characterized e.g. as in terms given by the UPOV *(new, distinct, uniform* and *stable*). Genetic improvement programs will normally aim at generating and testing large numbers of such uniform populations (varieties) and select those that may outperform and replace existing varieties.

Deliberate or unintended inbreeding has been practised in fish breeding – but often with severe inbreeding depression as a result (Kincaid 1983; Eknath and Doyle 1990; Bentsen and Olesen 2002). Fish are more complex organisms than plants and will, like other animal species, usually suffer from inbreeding depression and reduced viability if inbreeding occurs. Furthermore, genetic improvement programs for farmed fish (referred to as breeds or stocks rather than varieties) are usually based on selection of the best performing individuals within the population as parents to the next generation, rather than selection between populations or strains. The larger the genetic variation within the population, the better is the prospect of rapid response to selection. Consequently, genetic improvement programs for fish will aim at minimizing inbreeding and maintaining as much genetic variation as possible within the population. The populations will then not be *uniform* and *stable*, but variable and evolving from generation to generation. Thus, there are important differences between plant and fish populations in terms of phenotypic and genetic characterization. The legal framework that has been developed for protection of plant varieties can therefore hardly be applied to populations of fish.

Nevertheless, the issues of access to, exchange of and exclusive rights to investment and breeding results are important also within the aquaculture sector. Genetic resources are most accessible when everyone can use them for all purposes without restrictions. This

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[5] These issues did not figure among the topics at the two first meetings of the FAO Sub-Committee on Aquaculture (November 2002 and September 2003) and they have not been central to the work of WorldFish Center.

means that there is a latent conflict between free and unconstrained access to genetic resources on the one hand and, on the other hand, the need to protect investments and research efforts against utilisation by others (Tvedt 2005a: 311–344). As fish breeders and fish farmers both work to improve and develop breeds/stocks, the actors in the market are continuously changing position. At times they need free and easy access to new genetic resources; later they need exclusive rights to exploit the economic benefits from their work; when working to improve the breeds/stocks they may again want free and open access to new genetic material (Tvedt 2005c: 75–76). This emphasizes the need for a legal situation that provides a balance between access and exclusive rights to aquatic genetic resources.

A central aim of this article is to study how international and national regulations may contribute to establishing a situation that the aquaculture branch also welcomes. It is the purpose of this article to present and discuss some of the main challenges associated with access to and exclusive rights to fish genetic resources used in aquaculture. In this endeavour we apply three disciplinary approaches, combining biological competence on fish genetic resources and fish breeding with analysis of law and political science. The literature that informs this article is partly drawn from documents and studies from the field of plant genetic resources – as very few studies of fish genetic resources have been conducted.[6]

The work is organised in two parts. First we provide an outline of the rationale for ensuring access to and for using legal measures for protection of breeding materials in aquaculture. In the second part we examine how technological developments and biological features present options and barriers that affect choices open to actors in the aquaculture sector and that relate to access and property right issues to fish genetic resources.

2. Regulation of Access and Exclusive Rights to Genetic Resources

Rationale and Experiences in Reserving Rights to Improved Breeding Material

Several considerations are cited as rationale for introducing some kind of intellectual property rights to biotechnology inventions. One important rational is to secure economic gains in return for heavy investments and thereby stimulating innovation (Crespi 1988). Patents are encouraged as an alternative to secrecy, as the grant of a patent depends upon the disclosure that enables other persons skilled in the same art to reproduce the invention. In effect, knowledge is spread to the public, whereas society compensates the researcher with a time-limited exclusive commercial right to the invention. To obtain a patent, the inventor describes the invention which he wants to patent. In Europe patents are presently granted to nearly all types of inventions including those that build upon biological material.[7] There is an ongoing debate concerning the scope of protection conferred by a patent in biotechnology.[8] The EU Directive regulates this topic, but it remains to be seen how the courts are going to

[6] The exception is Greer and Harvey, 2004.
[7] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, the Patent Directive.

determine the exact scope of a patent on genes. Patent protection is available in fish breeding and fish farming. There are however few examples of patents in this sector. The consequences of introducing patents to this field are not easy to predict.

The need to protect genetic improvements in farmed species arises from the ability of living organisms to pass on their performance traits to the progeny through improved composition of DNA. This means that a buyer/user of the organism may "copy" the performance by reproducing the organism. If the public community does not pay the costs of the improvement efforts, these costs need to be covered by users or other beneficiaries in order to maintain the improvement programs or to stimulate new programs.[9] The extra cash flow that is generated by the improved organisms will have to pass in the opposite direction through the multiplier levels before it may reach the improvement program. The challenge is to secure that a fair proportion of the cash flow really reaches the relevant program.

The strategies traditionally used to secure the funding of genetic improvement programs for farmed species have varied considerably between plants, animals and fish. In plants, the fecundity is normally very high and seed from improved plant varieties may easily and quickly be propagated in large quantities. This facilitates specialized propagation operations as a part of the improvement program, or in close collaboration with it, and organized sales of the improved seed. However, since the product sold to the farmers is able to grow and multiply, it is easy to carry out on-farm propagation of the seed. The main reason for farmers to return to the organized producer to buy new seed has been guarantees against contamination of the seed with diseases, pests or seed from weeds, guarantees regarding the purity of the origin of the commercial seed and the full heterosis effects of hybrid seeds. All these traits are similar in fish but the plant breeders' rights solution is not applicable due to the need for much higher genetic heterogeneity in most commercial fish populations. Fish populations can therefore not meet the criteria under the UPOV convention.

Farm animal species like cattle, horses, sheep and goats, differ from fish in that they have low female fecundity, which limits the possibilities of centralized propagation and sales of genetically improved animals. Here, genetic improvement by e.g. selection has usually been financed by sales of, or hiring out, proven males to the owners of production herds, and by sales of semen from proven superior males for artificial insemination. Poultry and pigs resemble fish, with large female reproductive capacity, but often differ through the shorter generation intervals. Here, private companies have developed hybrid programs based on specialized, protected dam and sire lines with high performing cross-bred progeny. The hybrids may be protected by restricted access to the parent lines.[10] The production farmers

[8] For a profound discussion of practice with regards to the exemption for plant varieties and animal species, see Bryde 2004.

[9] The nucleus population(s) where the improvement program is implemented will normally consist of a limited number of organisms. The genetic improvement will then have been propagated and disseminated through a number of multiplier operations before they are used for production and the products in turn are sold to the consumers.

[10] As private businesses have recently increased their activities in the plant improvement sector, there has been an increasing demand for IPR regulations to prevent unauthorized propagation of the seed beyond the protection offered by hybridisation.

will then normally come back to the breeding operation to buy new animals for each cycle of production. (See next section for discussion of i.a. the applicability of hybrids within the aquaculture sector.) These similarities and differences are important to have in mind when discussing legal aspects to marine genetic resources.

The Rationale for Access to Wild and Improved Breeding Material

Access to fish genetic resources is important for a number of reasons. First, a central rationale for free access is that it may work as a guard against a narrowing genetic base and as such maintain genetic diversity. Different farmers produce under varying conditions with respect to e.g. environment, climate, disease challenges, technology, infrastructure, and governmental legislation. Different stocks may have characteristics that are more suitable for specific production conditions or markets than for others. Therefore, the farmers may supply different markets or market segments. Under a free access regime, it may be possible for breeding programs to acquire brood stock with a wide range of characteristics adapted to their own needs and conditions. Access to genetic resources is essential for future innovations and adaptations within the aquaculture sector.

Second, the legal status of this material is unclear and changing. Improved genetic material may be held by public or private breeding programs, but has until now been available more or less legally for further propagation and/or use in breeding for any buyer of the commercial product (live eggs or fish) from the programs. Typically, organized access to such acquisitions has been subject to a contract between the provider and the user, while unorganised use has probably been widespread, both inside and outside countries. For instance, salmon production in Chile is mainly based on Atlantic salmon (SalmonChile 2005) originally imported in early eighties. In the future, transfer of genetic material may increasingly be a matter between private breeding companies and the users of the material.

Biodiversity represents one of our most valuable resources, although this value is still hard to pin down in economic terms. Greer and Harvey (2004:28) argue that "variations among wild salmon stocks will become increasingly important to the relatively new aquaculture industry as fish farmers continue to look for desirable characteristics to introduce into cultured species". With this in mind, it is apparent that access to both wild and improved genetic resources is valuable.

Evolving Access Legislation and Patent Law

Up until about three decades ago, the situation for all kinds of genetic resources, including collections of wild and improved material in publicly owned genebanks, was that this breeding material was subject to free and open access. From a legal perspective, genetic resources were largely regarded as a Common Heritage of Mankind. This was challenged by the evolving plant breeders' rights regime and altered practices in the patent system. The new biotechnologies have increasingly allowed for innovations in breeding and genetics fulfilling the criteria for patent protection (Bent et al. 1987; Crespi 1988).

In response to this development, the Convention on Biological Diversity (CBD, 1993) introduced national sovereign rights to genetic resources as an attempt to compromise primarily between owners and users of these resources (Rosendal 2000). A parallel process produced the Trade-Related aspects of Intellectual Property Rights (TRIPS) agreement under the World Trade Organisation (WTO), with main objectives to harmonise, strengthen and expand the scope of intellectual property rights (IPR) protection in all technological fields. This includes biotechnology, new breeding and selection methods as well as genetic engineering. TRIPS is said to promote innovation by establishing exclusive private rights to inter alia inventions related to genes through intellectual property rights, while the CBD aims at balancing the uneven distribution of biological resources and biotechnology between the North and the South (Rosendal 2001; 2006). Besides the existing international legislation on patent law under the World Intellectual Property Organisation (WIPO), there are also ongoing negotiations in the Standing Committee in the WIPO for an even higher degree of international harmonisation in this field (Tvedt 2005a: 311-344). In response, access regulations have been proliferating, especially among biodiversity rich, but less industrialised, countries of the south.[11] As pointed out by Greer and Harvey (2004:17), "plant collection in developing countries is a much more controversial issue than collections of aquatic genetic resources in developed countries, but it (i.e. collections of aquatic genetic resources) can be expected to attract greater attention as the demand increases". An important challenge is to develop access regulations that do not hamper development and innovation and to ensure that changes in patent law do not obstruct possibilities for the open access and exchange of genetic resources.

Many countries are developing access regulations. In Norway, a new Act for Nature Diversity proposes that *genetic material* shall be a *common resource* open for everyone to use (NOU 2004:28: 526, 634). This entails that there are no exclusive property rights to genetic material, save when an intellectual property right is granted. Their suggestion is specified as not altering the situation where the owner of biological material has a legitimate right to use the genetic material. The Expert Committee suggests that the government shall have a special role in taking care of this common interest, but does not specify how this shall be carried out. If these suggestions become part of the forthcoming Nature Diversity Act, genetic resources in Norway can be said to be in a *public domain*.[12] A more recent governmental report (NOU 2005: 10) proposes that any utilisation of marine genetic resources must go through a procedure involving the Ministry of Fisheries and suggests the marine genetic resources to be property of the public.[13]

Patent law is also changing at the national level. A further harmonisation of the rules for patenting biotechnological inventions has been enhanced through for instance the EU

[11] See http://www.biodiv.org/programmes/socio-eco/benefit/measures.aspx
[12] For a discussion of the concept public domain to genetic resources see Tvedt 2005a.
[13] The question of property rights to genetic resources, other than intellectual property rights, is not solved in Norwegian legislation (Nordic Council of Ministers 2003; Tvedt 2005b).

Patent Directive.[14] The exact scope of to what a patent grants an exclusive right remains to be seen, as this has not been legally tried in Norway. It remains to be seen how patent practice will develop.

3. Types of Biological and Legal Protection and How to Balance Access Regimes

The fish-farming sector as a whole is characterised by rapid market fluctuations; with accompanying rapid bonanzas and great losses. In salmon, the relatively long time interval (two to three years) between acquisition of roe and marketing makes salmon farming very vulnerable to market fluctuations compared to most agriculture crop production where seeds will yield a harvest the same or following year. Terrestrial animal husbandry is similar to fish farming in this respect, but the vulnerability of this sector in Norway is reduced because these farmers may cooperate within primarily domestic markets. Farmed fish is largely produced for international markets and this tends to complicate co-operation strategies for the farmers. The evolving need for legal protection measures is partly explained by the expectations that breeding material will become more expensive.[15] There may also be future needs for external acquisitions of breeding materials, as new diseases turn up or new characteristics are demanded (e.g. disease resistant characteristics).[16]

In the following we look into various strategies to protect breeding and research results. For each type of strategy, we comment on how the method may presumably affect investment returns, innovation, access for other users and genetic diversity. Until now, most animal breeding programs have relied on various biologically-based strategies to encourage the users of their genetic material to deal directly with the program.

Biological Protection

Continuous upgrading: The most common strategy in aquaculture breeding programs is continuous upgrading of the material. Since genetic improvement in most breeding programs is based on generation-by-generation selection of the best breeders within the population, every new generation is expected to perform better than the previous ones.[17] Most aquaculture breeding programs can easily gain control of the sales of the latest generation, and if the genetic progress and service are good enough, this is often sufficient to entice the producers to come back to the source and pay extra.

[14] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions.

[15] This is because the present prices are very low due to increased competition and high production and supply of salmon roe.

[16] These genes for such traits may be found in wild materials or other improved stocks and failing to include such characteristics due to e.g. high royalty rates would mean to be quickly out of business. Pointed out by participants during Fish Breeders' Round Table, Håholmen, Norway,17 June, 2004.

[17] In aquaculture organisms, the response to single trait selection for growth performance is often in the range of 10-15% per generation (Gjedrem 1997).

The sold material may of course be grown to sexual maturation and be reproduced by the buyer without the knowledge of the supplier, but the reproduced material will then always lag behind by at least one generation compared to the material supplied directly from the breeding program. However, since it is possible for anyone to acquire such outdated material unauthorized, it must be considered as *de facto* accessible material. This will of course augment access for all breeding programs or other actors in the industry to a wide range of well-performing genetic materials, and thus widen the potential genetic base for the programs and counteract loss of genetic variation. On the other hand, it will be difficult for a superior program to gain a large competitive advantage, since other programs may hitchhike (with some delay) on its genetic progress. This may increase the focus of the breeding programs on marketing and service/support rather than on improving the genetic progress. To protect against unauthorized propagation and use of second or later generations of progeny from a breeding program, the solution today is to integrate the breeding program with a complete in-house production chain until slaughtering, or by marketing sterile seed for grow-out.[18]

Cross-breeding and hybrids: In plant species, it is relatively easy to produce a large number of inbred lines and to test-cross various combinations to identify hybrids that express significant heterosis effects.[19] The heterosis effects will be gradually lost in the progeny generations if the hybrids are reproduced. Again, this will encourage the users of the material to come back to the source to buy seed for each new cycle of production. Denying access to and secrecy about the parent lines will protect them from being used by others and the parent lines may not be regenerated from the commercial hybrids. However, the commercial hybrids may still be reproduced and the progeny may be used for production.[20] In farm animals, the cross-breeding strategy is mainly used in highly prolific species like poultry and pigs, where parent lines and hybrids may be propagated without spending vast resources on keeping large numbers of female brood stock. Still, the costs of producing a variety of parent lines and performing test-crosses among them are much higher in animal species than in plants, and the degree of inbreeding in the parent lines will generally be lower (i.e. the heterogeneity within the lines will be higher) because of the limitations arising from harmful inbreeding depression. Consequently, animal hybrid programs tend to rely less on frequent replacement

[18] "The high reproductive rate makes it easy to build up a new population and similarly easy to supply the market; in turn it is difficult to protect the materials – but also more needed. The danger is that this will dissuade investments; as the competitors may so easily catch up with you – all the more need for legal protection." Hein van der Stein, SyGen, at *Fish Breeders' Round Table*, Håholmen, June 2004.

[19] Heterosis occurs when a hybrid performs better than the parent lines, and is often more pronounced when the parent lines are inbred.

[20] Denying external access to the parent lines will protect them from piracy, and the parent lines may not be regenerated from the commercial hybrids. However, the commercial hybrids may still be reproduced and the progeny may be used for production. The loss of performance in the progeny will depend on the magnitude of the original heterosis. If the progeny generations may not be protected by legal measures, the genetic material of the progeny of the hybrids will be available for other users or breeding programs as described above for selection programs/continuous upgrading.

of parent strains and more on improvement by selection within existing parent strains, as in ordinary selection programs.[21]

In aquaculture breeding, applied hybrid programs are scarce. As in plants, the high female fecundity makes it feasible to produce and test-cross large numbers of distinct parent lines and mass-produce commercial hybrids. However, cross-breeding experiments with stocks in aquaculture species have until now largely failed to detect major or applicable heterosis effects (Gjerde and Refstie 1984; Gjerde 1988; Bentsen et al. 1998). The gain from cross-breeding in aquaculture is typically lower than the response after only one generation of selection in a simple selection program. Possibly, deliberate inbreeding in the parent lines may increase the heterosis, but this strategy is expected to encounter the same problems with inbreeding depression in the parent lines as in other farm animals. Hybrid programs to improve female fecundity, as in poultry and pigs, are less interesting in aquaculture species, where the fecundity is excessive and depressed fecundity has not been a problem.

A separate cross-breeding strategy, which currently is increasingly of interest in salmon breeding, does not depend on heterosis effects. It is the crossing of parents from different populations with distinct performance traits (e.g. fast growth in one population, late sexual maturation in another, resistance to a disease in a third etc.) to combine the desired traits in the crossbred production animals. Basically, this approach is not expected to result in an overall improvement of production animals compared to an ordinary selection program where the desired traits are considered simultaneously during the selection. However, a breeding program with several such distinct populations may produce progeny with a variety of combinations of traits, depending on the customers demand, and this may attract buyers with specific needs. Here, continuous progress by selection is needed within each of the parent populations to maintain the advantage of buying seed from the program. Still, on-farm reproduction of the crossbred progeny will be feasible without loss of performance.

Sterile production animals: In commercial plant breeding, it has been suggested to protect new varieties by inducing sterility in the products at harvest and thus prevent unauthorized propagation. In the absence of applicable natural procedures, approaches involving artificial transfer of novel gene constructs have been investigated. The technology has not yet been applied commercially, both because of public skepticism and because of immature technology.

In several aquaculture species (unlike farmed plants and land animals), applicable methods are available for commercial scale propagation of sterile production animals (Pepper 1991; Sutterlin and Collier 1991, Felip et al. 2001). The methods are based on applying a

[21] In addition to exploiting some degree of heterosis, the main objective of such hybrid programs is usually to increase female fecundity, which may be adversely affected by selection for increased growth. The cost of holding breeding females is a major expense in poultry and pig production. The total gain of this design is usually sufficient to make the grow-out farmer come back to the organized suppliers of hybrid animals. However, on-farm reproduction by mating commercial hybrid animals is possible and usually legal, and outsiders may use such animals as a genetic source.

shock (temperature, pressure or chemicals) to the eggs in the hatchery, and were developed for salmonids to prevent degradation of meat quality that is caused by precocious sexual maturation. Sterile production animals are routinely used in some production systems today, e.g. in rainbow trout in France (Bonnet et al. 1999). The methods have not been applied in Norwegian salmon aquaculture, partly due to lack of consumer acceptance, but also due to reduced problems with precocious maturation in recent, fast growing generations (because of shorter production cycles) and problems with unwanted side effects on productivity. It has been shown that sexual maturation in salmon is a booster for growth performance several months before sexual maturity becomes a problem (Gjerde et al. 1994). Sterile individuals may consequently grow more slowly towards the end of the production cycle and thus perform poorly.

Legal Protection

Branding and trademarks: Traditionally, the approach to seek legal property rights of genetically improved populations of fish has been to register product names and trademarks. Strictly speaking, this will not protect the genetic material from being propagated and used by outsiders, but only prevent unauthorized use of the registered name. Branding can be combined with additional measures such as biological protection strategies like continuous upgrading or crossbreeding of the material, or with high quality management of the seed production process, good customer support and services, and high profile information and marketing strategies. Customers may then gain safety and production benefits from returning to the branded sources. Of all the strategies, this seems most relevant for the current situation. An appreciated superiority of the material from a branded source will justify a higher price for the material and consequently reward investments and stimulate innovation. However, the prices in many fish seed markets, such as the salmon smolt market, are influenced by large fluctuations in prices on the end product, and consequently by variable willingness and ability to pay a premium price for quality seed. Branding is a strategy that builds upon trust and reputation in the market, rather than protection of the genetic material itself. Hence, it will not hamper access to genetic material for further research and development.

Material transfer agreements: Private law contracts between seller and buyer have traditionally been the most common strategy for regulating trade and transfer of livestock. Here, the breeding program supplies the user with genetically improved brood stock or semen on conditions involving e.g. financial returns to the breeding program and limitations on the use of the material. In prolific farm animals like poultry and pigs, the industry often consists of separate specialised operations conducted by different companies. It is therefore common that breeding programs focus on the breeding operation and formalize collaboration with selected, skilled multipliers through material transfer agreements (MTA).

In most aquaculture species, the organization of production is similar to that of poultry and pigs, with several separate, specialized levels. Because of the even higher reproductive capacity, the multiplier level may usually be managed by a small number of hatcheries/juvenile producers. This facilitates the integration of the multiplier level into the operations of the breeding program. However, some well-established breeding programs have abandoned this strategy and rely on MTAs between the breeding program and independent, specialized multiplier operations. Brood stock may be sold to multipliers under contracted time restrictions on the use of the genetic material and the brand, and with limitations on mating regimes, mixing with other stocks and use of progeny generations as brood stock. Possible financial benefits arising from a successful and competitive strategy in the breeding nucleus may be partly channelled back from the multipliers through a contracted royalty fee on each egg or juvenile sold.

However, the experiences with this type of MTAs are mixed.[22] There have been problems with control, enforcement and monitoring of the terms in the agreements with the multipliers, and instances of contract violations had occurred. One problem seems to be difficulties in tracing and verifying the number and origin of marketed seed. Another challenge is that it is only legally binding for the two parties signing the agreement and not third parties. Thus, this legal strategy does not ensure an exclusive right to the genetic material in relation to all potential users, only with respect to the contracting party (Tvedt 2006: 192–193). To secure investments in breeding, this must be combined with strong rules restricting further distribution of the material. However, enforcing such rights to the commercial progeny sold by the multipliers is difficult with the current limited tracing opportunities or would hamper access. This strategy can better be enforced in transparent markets with a limited number of potential users of the improved material. Genetic material representing older generations in the breeding program will be more or less available for common use. This may therefore widen the potential genetic base for diverse breeding programs and counteract loss of genetic variation.

Patents: An invention may entail a product or a process related to biological material. As mentioned earlier, there are two narrowly defined exemptions from patent protection. If the process that is described in the patent application is a process consisting "entirely of natural phenomena such as crossing or selection", it is not patentable. However, "entirely" is a severe legal term. If the process combines a biological process with only a very low level of technological, non-biological knowledge, also a partly biological process can be patented. This will probably be the most common case for patents in the fish breeding sector, as the pure biological processes, such as selection and crossbreeding, will be known to everyone and thus often form a part of the *prior art*. The second exemption entails that "animal varieties" cannot be patented. The term animal variety is not easily applied in fish breeding, where varieties is seldom referred to, but rather *stocks* or *populations* are the relevant terms. When a process is patented, the exclusive right also covers results directly produced from that process.

[22] See report by Rosendal, Olesen, Bentsen, Tvedt & Bryde (2005).

To be granted a patent, the invention must fulfil the patent criteria; it must be regarded *novel*, involve a sufficient level of *inventive step* and have a use (*industrial applicable*). One reason why patents have not been applied extensively in the aquaculture sector might be that it is difficult to fulfil the patent criteria. This might be due to lack of knowledge about which gene variants or genotypes are present in superior animals. The isolation of a naturally occurring gene can be regarded as an invention that fulfils the patent criteria. (The genes may be patented through e.g. patents on a selection test based on the gene sequence, transgenic animal or a marker gene.) Thus, increased knowledge about the genome of each fish species will increase the applicability of the patent system for protecting the commercial use of such knowledge. Gene technology may reduce the barriers to patenting inventions, but has so far not been much applied in animal breeding in spite of high expectations for a long period of time.

An unsolved question in practice as well as in patent theory is what a patent to a naturally occurring gene covers. The EU patent directive specifies that: "The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics." This refers to the coverage of a patent when the patented gene is transferred to new organisms. It does not solve the question of the scope of the protection for naturally occurring genes as long as they are not transferred to another organism. Noiville (1999) emphasizes that patents on natural occurring genes have no effect on traditional breeders. "Patent holders are not able to claim rights on farm animals naturally carrying this gene; they may only claim rights on the use they proposed of this gene". However, she focuses on the risks of the patent law in traditional breeding: Competition between patent holder and traditional breeders when e.g. a company sells genetically modified animals without authorization from the traditional breed used and the problem with broad patents. The scope of the protection should (ideally) encompass all that the inventor has added to the state of the art, but nothing more. If it covers more than the addition to the state of the art, the patent protection is too broad. It is assumed that *broad patents* may hamper access to breeding stocks, as this will make the activities too costly for smaller companies. The problem with *broad patents* is that they lead to a situation where it is difficult for other inventors to come up with new solutions and inventions, to *invent around* the patented invention. To invent around means to find a new and presumably better way to solve the same or similar technical problem. Patents on biological subject matter, including genetic material from fish, might be particularly difficult to invent around if there is only one gene coding for a particular trait.[23] Possibly, such broad patents may hinder further technical development. Similarly, if there are many patents in one field of technology, it may become difficult and costly for new inventors to obtain licences from all patent holders. Each patent grants an exclusive right. Thus, each patent holder must agree to license his invention to

[23] The identification of this problem is contested. Li Westerlund (2002) claims that if patents to naturally occurring genes are not made comprehensive, it will be too easy to invent around and thus avoid the patent.

others if they shall use the invention in commercial activities legally. Such practical and monetary obstacles may hinder the development of new inventions in a technical field.

Patenting has also been recommended as a preventive strategy to prevent others from patenting the same invention. This is, however, a costly and insecure strategy. To publish the new invention or new knowledge may be a better strategy, as it brings the knowledge into the public domain and thus prevents others from patenting it. There is an increasing awareness that patenting in the life sciences may actually lead to reduced innovation and initiatives are emerging to resolve the problem. Various initiatives are emerging which aim to find options that do not hamper research and development within basic research.[24] This will, however, include that the innovation or knowledge will become available to the public. When it is published it can no longer be kept a secret. This eliminates the possibility to use trade secrets as protection strategy (discussed below). The use of patents in a breeding program is a very costly process, both to achieve and to enforce. This strategy may therefore be best suited for larger actors within a technological sector.

Even if the patent system is applicable for the fish breeding sector, there are essential legal and biological barriers linked to patenting as a strategy for securing investments in fish genetic improvement programs. Gene transfer and other gene modifications could provide a strong protection mechanism to aid enforcement, but this strategy is hardly compatible with restrictive Norwegian views on genetically modified animals.

Sui generis for fish populations: There are still no Animal Breeders' Rights similar to plant breeders' rights (PBR). There are however international processes considering such possibilities. The difficult question is how such a system could be designed. The major danger in this process is that such a system would borrow or use experiences from the plant sector without taking sufficiently into account the special features of the fish breeding and farming sectors. As shown in the introduction, most fish breeding systems are dependent on outbred, heterogeneous populations and are hence unsuited to fulfil the plant breeders' rights criteria of *new, distinct, uniform* and *stable*.[25] Perhaps this reflects a need for a specially adapted type of intellectual property system for the particular needs of aquaculture breeds. In legal literature this is called a sui generis system. This can be explained as a system specially adapted to the unique features of that particular type of subject matter. It would need to

[24] One such initiative is BiOS (Biological Innovation for Open Society), which proposes to use the communications and data transfer opportunities of the internet to build useful information connections throughout the worldwide community of problem solvers, so that an innovator working on a crop improvement in a developing country can become aware of an advance elsewhere that could be harnessed together with local means of production for use in solving a local problem. A coordinated aim is to build a legally and normative "protected commons" of intellectual property, on a precedent afforded by 'open source' software development. http://www.cambia.org/daisy/cambia/583.html

[25] These are the criteria for Plant Breeders Rights according to UPOV-91 Article 5.

address the questions of what should be protected,[26] criteria for obtaining protection and to what extent the right should be exclusive.

Other Protection

Trade secrets: To obtain exclusivity by the use of trade secrets, the genetic material needs to be confined or made unavailable for competitors. Trade secrets do not guarantee an exclusive right as does a patent. In a breeding program, subjects for trade secrets could be the breeding nucleus, procedures for data recording, data processing, or selection and mating of the animals. However, because the product (the commercial seed) may usually be copied without knowledge about the trade secrets, simply by growing and reproducing the animals, secrecy about the procedures alone will not provide exclusivity to the genetic material resulting from the activities. Secrecy could be obtained by keeping the parent lines in a cross-breeding program, by marketing sterile commercial seed, or by reserving the material for in-house production through the entire production cycle until slaughtering. The strategy will still be vulnerable, however, since it is difficult to achieve full security against leakage of the genetic material and difficult to prove that material occurring outside the confinement descends from unauthorized brood stock. Also, if all the actors should use a strict trade secret approach, this could hamper access and exchange of genetic resources.

Unless the secret procedures result in really remarkable advantages in the performance of the commercial seed, trade secrets are not expected to affect financial returns or genetic variability in the farmed stocks differently from other competitive measures. Trade secrets with great effects are bound to attract attention and attempts at copying. Altogether, trade secrets are a rather insecure strategy by which to ensure a monopoly right.

Enforcement Strategies

A critical issue for enforcement of many protection methods is the possibility to control illegal use and document the origin of e.g. fish produced or reproduced illegally. Gene technology and biochemical methods together with databases have already been applied for such tracing or pedigree control.

Allele frequencies: In both wild and farmed stocks, populations are often discriminated from each other based on differences in the frequency of various alleles[27] (Verspoor and McCarthy 1997). The method is suitable for discrimination between groups of fish, but may normally not be used to assign individuals to a particular population. The application of this method to trace a population from one generation to another requires random mating of a rather large number of representative parents. This is normally not the case in farmed populations, and

[26] The subject matter protected could hardly be varieties as in UPOV because "fish varieties" is hardly used as a biological criterion or term in aquaculture. However, a term covering heterogenous stocks or breeding populations may be applied.

[27] A gene may occur in different variants, called alleles.

particularly not if the propagation is not controlled and authorized. Small numbers of selected and possibly related breeders may be used and even crossed with other populations, and this may result in a complete change in allele frequencies in the progeny generation.

Marker genes: Unique alleles may occur in populations that have been genetically isolated over many generations. Individuals that are carrying the unique allele may then be assigned with certainty to this particular population. Most farmed populations have not been isolated long enough to develop unique alleles. However, a very rare allele may have been transferred from one of the wild progenitor populations. If such an allele may be identified in or deliberately crossed into the farmed population, the frequency of the allele may be increased by selection to an unusually high frequency, or even to fixation. Even if the allele may occur naturally at low incidences outside the population, high frequencies of the allele in a farmed stock could be used to trace unauthorized use of brood stock from the breeding program. However, to achieve a significant increase in the marker frequency, the selection in the breeding nucleus has to focus on the marker allele for several generations. This may stop or slow down the genetic progress for important production traits, increase the risk of inbreeding, and cause the breeding program to lag behind compared to competing programs.

Truly unique marker genes may alternatively be introduced in a breeding population by means of artificial gene transfer. Even if the introduced marker does not necessarily code for any effects in the recipient organisms, the organisms will probably have to be legally considered to be genetically modified organisms and the use will be restricted accordingly. Novel gene constructs that have originally been introduced into the organism to improve the performance will also in most cases serve as unique marker genes for the GMO population.

DNA fingerprinting/profiling: Recent developments in molecular genetic technologies based on highly variable DNA sequences like micro satellites or single nucleotide polymorphisms (SNP) have made it possible to trace the ancestors of an individual.[28] A breeding program may then sample commercial seed from the market and test whether the material descends from brood stock produced by the breeding program. This will require that the program has secured a tissue sample from each individual parent fish that has been provided from the breeding nucleus, that the tissue samples are analysed in the laboratory, and that the DNA fingerprints are stored in a database. To trace a random individual from the commercial seed market or from grow-out farms with sufficient accuracy, a rather extensive laboratory analysis is required of the DNA from both the sampled individuals and the ancestor candidates (see e.g. Hayes et al. 2005). Furthermore, the logistics from the production of fertilized eggs to the commercial seed market or the grow-out farms need to be transparent and documented if the hatchery source of the sampled seed shall be identified. This would be a rather expensive and laborious exercise.

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[28] Using the DNA fingerprinting approach to trace the source of escaped farmed salmon that are recaptured in coastal waters and salmon rivers has been suggested and discussed. (Havforskningsinstituttet 2004).

Mandatory certificates: The increased consumer awareness of the origin and production history of food products has resulted in a demand for documented traceability of the products. For aquaculture products, the initial focus may be on the grow-out farms. However, there is a history of public interest in the genetic origin of aquaculture stocks and the operation of aquaculture genetic improvement programs that may result in a request for traceability all the way back to the breeding nucleus. Food products that may be traced back to breeding programs with a documented practice that is conceived as clean, natural, and environmentally friendly, may gain a competitive advantage. In an international context, national regulations that ensure traceability all the way back to the breeding nucleus may also increase the competitiveness of the national industry. Most likely, such traceability systems would be based on certificates following each step of transaction in the production process, and would require logistics and procedures by the producers during each phase of production to keep track of the origin of the material.

To be accepted as reliable, such certificates would probably need to be verifiable. For this purpose, tracing by DNA fingerprinting may be a feasible technology. It would require that tissue samples are collected, frozen and stored from all commercial brood stock in the breeding nucleus and at the hatcheries. If the certificates include information about the genetic origin of the male and female used to produce the commercial seed (alternatively a small number of possible parents), verification by DNA fingerprinting would be affordable, since only a limited number of tissue samples need to be analysed. The traceability system may then be used to ensure that each breeder is awarded according to the material transfer agreement for the use of their brood stock. The system will be universal if pedigree certificates are made mandatory for all hatcheries and grow-out farmers. A further extension could be that pedigree certificates are made mandatory also for the parents of the brood stock used by the hatcheries. This will allow tracing of the genetic origin if commercial grow-out fish from one program are illegally used to produce commercial brood stock by competing breeding programs. It may be relatively easy to establish such a system on the national level, but an international system will be more challenging to initiate and enforce.

4. Discussion and Conclusion

The maturing aquaculture sector is currently facing several changes and challenges. One of the most far reaching changes may originate in the emerging international and domestic legislation and regulations for access and protection of genetic materials. We started out with the research question of how a balance can be created between the need for unencumbered and free access on the one hand, and the need to ensure a right to the results from breeding and research on the other.

Our analysis has indicated how protection measures may affect access to and innovation concerning aquatic genetic resources. Let us briefly sum up the evaluation of different protection methods with respect to verification, feasibility, access for other users, and genetic diversity. The strength of the protection system is associated with its ability to achieve verification and monitoring. The costs of the protection system are linked to its feasibility, as high costs will be prohibitive for most actors. We argue that both aspects will be central in guaranteeing a return of investment costs for claimholders. Returning investment costs is an important factor for stimulating innovation. On the other hand, we argue that some degree of access for other users of breeding material will also be important for enhancing innovation.

The mechanisms currently used to secure the income of the programs are *continuous upgrading* of the brood stock and *MTA contracts* with collaborating multiplier hatcheries and seed producers, combined with various *branding* strategies. *MTA contracts* are largely characterised by inadequate control and verification mechanisms, which have left the breeders in an unfortunate position for gleaning the value of their improved material. The option that provides the strongest protection mechanism – *patents* – has no proven applications in populations improved by selection alone, but may be highly relevant e.g. in populations that are genetically modified by artificial gene transfer. However, genetically modified fish are still incompatible with the choice of consumers in most relevant markets. *Hybridisation* is an option that gives weak protection for the breeders, while not detrimentally affecting the activities of other breeders or the genetic variability in the gene pool at large. *Branding* and *mandatory certificates of origin* represent the two options that come closest to balancing the concerns for stimulating innovations and access, while not involving adverse effects on biodiversity. *Trademark*, one of the most widely applied types of intellectual property right for foods, provides a strong control mechanism, while at the same time not posing any barriers to utilization of genetic material in general. It does, however, necessitate successful investment in and application of marketing aimed at international markets. Most actors might be better off with a system of *mandatory certificates of origin* that may be verified by DNA analysis of stored tissue samples from all brood stock. This would provide a strong verification mechanism at reasonable cost, and may be combined with *MTA contracts* and *trademarks/branding*. Moreover, as the property right is not linked to particular traits or specified genes, this option would not hinder access to genetic material for other breeders nor would it have an inherent tendency towards a dwindling genetic pool. The particular situation for fish breeding suggests that there is a need for developing a sui generis property right particularly adapted to the needs of the branch. More legal research in close cooperation with the sector itself is necessary to outline how such a system can be framed to take care of the particular needs.

Regardless of the choice of protection for improved material, all actors would benefit from a legal system of free access to wild genetic material. Further examination of this issue is needed, as this study concludes with two pertinent questions: First, we need to know how the current models for genetic improvement in aquaculture will perform in the face of recent changes in the domestic and international regulations on access and legal protection. The second question is whether new farmed species will experience a similar development of genetic improvement programs as that which has been seen in the salmon industry, or if new incentives will be required.

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