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Access to and protection of aquaculture genetic resources -structures and strategies in Norwegian aquaculture

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1 **Access to and protection of aquaculture genetic resources -**  
2 **structures and strategies in Norwegian aquaculture**

3

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10

11 **Abstract**

12 Breeding companies need protection for genetic material to assure revenues from genetic  
13 improvement and investment. Fish farmers and fish breeders need access to genetic resources  
14 for food production and further development and sustainable use of fish genetic material. In  
15 Norway, access legislation is now in the process of being developed. The objective of this  
16 paper is to discuss some of the main challenges associated with access to and protection of  
17 fish genetic resources in aquaculture. In an interdisciplinary study, we combine expertise on  
18 fish breeding and genetic resources with that on law and political science regarding regimes  
19 for resource management. Our material is drawn from a number of interviews with  
20 individuals directly involved in fish breeding and farming. Our most significant finding is that  
21 there is a discrepancy between the knowledge of farmers and breeders with respect to access  
22 and legal rights to genetic resources and the actual possibilities and limits offered by today's  
23 and forthcoming legislation. In order to maximize the industry's potential, there seems to be a  
24 need for information about access and legal rights to genetic resources. Market consolidations  
25 and privatisation are among the factors that are recognised as most important in changing the

26 ground rules within the sector. Although the similar history of the plant and agricultural sector  
27 does not seem to have a high visibility among fish farmers and breeders, most are becoming  
28 more concerned with the questions of access to and protection of the wild and improved  
29 breeding material that is central to their trade. This realisation is predominantly linked to  
30 external use of Norwegian salmon genetic resources, as most breeders are still confident in  
31 the superiority of their own breeding populations. Nevertheless, the breeders also  
32 acknowledge their vulnerability, should access to new and improved materials or traits  
33 become severely restricted. The predominant view among our respondents is that the sector  
34 needs to find a balance between access to breeding material and protection of proprietary  
35 innovations in fish breeding. Coupled with this view is an emerging realisation that the value  
36 of improved breeding material invariably is underestimated, leaving the farmers to reap most  
37 of the added value from fish breeding and farming. Against this background, an interest in  
38 finding some way of capturing the value of the improved stocks is emerging among the fish  
39 breeders.

40

41 *Keywords:* Fish breeding, Farm animals, Intellectual property rights, Legal protection,  
42 International conventions, Atlantic salmon, *Salmo salar*

43

#### 44 **1. Introduction**

45 A challenge in fish breeding rises from issues of access and exclusive rights to genetic  
46 resources. Breeding companies need some form of legal or biological protection measures to  
47 assure revenues from genetic improvement and investment in genetic material. Fish farmers  
48 and fish breeders need access to genetic resources for food production and further  
49 development and sustainable use of fish genetic material. How can a balance be created

50 between the need for unencumbered and free access on the one hand and the need to ensure a  
51 right to the results from breeding and research on the other?

52 The objective of this paper is to discuss some of the main challenges associated with  
53 access to and protection of fish genetic resources in aquaculture based on international and  
54 domestic regulations and interviews with representatives from fish breeding companies in  
55 Norway. We will present three dimensions that presumably affect choices pertaining to  
56 protection and the scope for access to fish genetic resources: First we look at international  
57 and domestic regulations and awareness among fish farmers and breeders about the emerging  
58 regulations for genetic resources. The second dimension represents the evolving structures  
59 within the aquaculture sector itself. Size, private or public ownership and funding may affect  
60 how actors regard their strategic option. Third, we examine how technological developments  
61 and biological features present options and barriers, which also will affect choices relating to  
62 access and property rights issues pertaining to fish genetic resources. In this third section, we  
63 discuss in depth the options available.

64 Only 5-10% of total aquaculture production is based on genetic material that has been  
65 improved by systematic family selection programs (Gjedrem et al., 2005; Gjedrem, 2005).  
66 This varies between species, but a central question is why the interest for investing in genetic  
67 improvement in aquaculture species is so low compared to other domesticated species, e.g.  
68 plants and livestock.

69 Within the plant breeding sector, legal mechanisms for access and exclusive rights have  
70 been developed over a long period of time. For example, the US Plant Patent Act dates back to  
71 1930 (Hallerman and Kapuscinski, 1990). The most important property rights to genetically  
72 improved plant varieties are based upon the plant breeders' rights as set out in the various  
73 editions of the International Union for the Protection of New Varieties of Plants (UPOV)  
74 conventions since 1961. Plant varieties that are considered as *new, distinct, uniform* and

75 *stable* can be subject to a partly exclusive right to commercial uses. More recently, the UN  
76 Food and Agricultural Organisation (FAO) has concluded an International Treaty for Plant  
77 Genetic Resources for Food and Agriculture<sup>1</sup> (ITPGRFA, 2004), which regulates exchange,  
78 access and benefit sharing for some of the most important food plants. While these regimes  
79 are aimed at plants specifically, the Convention on Biological Diversity (CBD, Rio 1992<sup>2</sup>)  
80 and the patent system regulate more general aspects relating to our case study. The scope of  
81 the CBD covers both wild species and improved breeding stocks, and equitable sharing of  
82 benefits derived from the use of world's genetic resources. Patents apply to inventions in  
83 biotechnology and to biological material when the invention fulfils the general patent criteria  
84 of novelty, practical usefulness and non-obviousness (Benson, 1986; Office of Technology  
85 Assessment, 1989; Hallerman and Kapuscinski, 1990). Access or exchange of fish genetic  
86 resources and legal protection of investments and research in aquaculture have not been  
87 addressed extensively (Greer and Harvey, 2005; p. 5). However, Rosendal et al. (2006)  
88 recently outlined the rationale for ensuring access to and use of legal measures for protection  
89 of breeding materials in aquaculture.

90 As emphasized by Rosendal et al. (2006), fish biology shares some features with  
91 plants and some other features with terrestrial farmed animals. The extremely high fecundity  
92 and reproductive capacity is more similar to the characteristics for plant species and provides  
93 a great potential for breeding and intensive selection. However, plant varieties are often  
94 formed as a result of homogenizing processes like inbreeding and vegetative propagation.  
95 Accumulation of inbreeding does not seem to impair the viability and performance of selfing  
96 plants as is normally seen in outbreeding animals. The results are often highly uniform plant

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<sup>1</sup> FAO International Treaty on Plant Genetic Resources for Food and Agriculture, signed for adoption in Rome 2001. For more information, see [http://pgrc3.agr.ca/itpgrfa/info\\_e.html](http://pgrc3.agr.ca/itpgrfa/info_e.html).

<sup>2</sup> Convention on Biological Diversity, signed in Rio de Janeiro in 1992, entered into force in 1993, presently ratified by 189 parties/member states. For further information, see [www.biodiv.org](http://www.biodiv.org).

97 varieties, both phenotypically and genetically, that may be characterized in terms given by  
98 the UPOV (*new, distinct, uniform and stable*).

99 Deliberate or unintended inbreeding has been practised in fish breeding – but often  
100 with severe inbreeding depression as a result (Kincaid, 1983; Eknath and Doyle, 1990;  
101 Bentsen and Olesen, 2000). Genetic improvement programs for fish will aim at minimizing  
102 inbreeding and maintaining as much genetic variation as possible within the population.  
103 Hence, the populations will not be *uniform and stable*, but variable and evolving from  
104 generation to generation. Thus, there are important differences between plant and fish  
105 populations in terms of phenotypic and genetic characterization. The legal framework that  
106 has been developed for protection of plant varieties can therefore not be applied directly to  
107 fish populations.

108 Nevertheless, the issues of access to, exchange of and exclusive rights to investment  
109 and breeding results are important also within the aquaculture sector. There is a latent  
110 conflict between free and unconstrained access to genetic resources and on the need to  
111 protect investments and research efforts against the utilisation by others (Tvedt, 2005a, pp.  
112 311-344). For example, a fish breeder who develops a new breed is dependent on collecting  
113 genetic material from wild stocks or from other bases of improved breeding stock – the  
114 breeder needs access. When a new and improved breed is developed, the breeder needs to  
115 ensure a right to his efforts by preventing others from unauthorized use of his improved  
116 genetic material. The actors in the market may change position as they at one time need free  
117 and easy access to new genetic resources, and later need exclusive rights to exploit the  
118 economic benefits from their work (Tvedt, 2005c, pp. 75-76). This conflict emphasizes the  
119 need for a legal situation that provides a balance between access and exclusive rights to  
120 aquatic genetic resources.

121

122 **2. Regulation of access and exclusive rights to genetic resources**123 *Reserving rights to improved breeding material*

124 Several considerations are cited as rationale for introducing some kind of intellectual property  
125 rights to biotechnology inventions (Crespi, 1988; Office of Technology Assessment, 1989;  
126 Hallerman and Kapuscinski, 1990; Rosendal et al., 2006). One important rationale is to secure  
127 economic gains in return for heavy investments and thereby stimulating innovation (Crespi,  
128 1988). Patents are encouraged as an alternative to secrecy, as the grant of a patent depends  
129 upon the disclosure that enables other persons skilled in the same art to reproduce the  
130 invention. In effect, knowledge is spread to the public, whereas society compensates the  
131 researcher with a time-limited exclusive commercial right to the invention. In Europe, patents  
132 are presently granted to nearly all types of inventions including those that build upon  
133 biological material (Directive 98/44/EC, the Patent Directive). Noiville (1999) analysed  
134 impacts of the EU Directive and patent law on farm animal breeding and selection. The EU  
135 Directive regulates this topic, but it remains to be seen how the courts are going to determine  
136 the exact scope of a patent on genes. Patent protection is available for fish breeding and fish  
137 farming. There are, however, only few examples of patents in this sector (e.g. triploid oysters,  
138 genetic disease resistance marker in salmon and transgenic salmon). In Norway, there is so far  
139 only a few patents that may have a direct effect on breeding options in the future, AquaGen's  
140 patent on determination of viral disease resistance of salmon by MHC sequences (patent NO  
141 317342) and two on transgenic fish (patent NO 321650 and application NO 20064420). The  
142 consequences of introducing patents to this field are not easy to predict (Hallerman and  
143 Kapuscinski, 1990).

144 Fish breeders need to protect their genetic improvements in farmed organisms in  
145 order to prevent unauthorized reproduction ("copying") on their breeding material, and

146 further use and marketing of e.g. the resulting offspring (roe and fingerlings). If the public  
147 does not pay the costs of the genetic improvement efforts, the costs need to be covered by  
148 users or other beneficiaries to maintain the improvement programs or to stimulate the start of  
149 new programs. The challenge is to ensure that a fair proportion of the cash flow really  
150 reaches the relevant program.

151         The strategies traditionally used to secure the funding of genetic improvement  
152 programs for farmed species have varied considerably between plants, animals and fishes  
153 (Rosendal et al., 2006). In plants, the fecundity is normally very high and seed from  
154 improved plant varieties may easily and quickly be propagated in large quantities. However,  
155 farmers return to the breeder/seed producer to buy new seed that has then been guaranteed  
156 against contamination of the seed with diseases, pests or seed from weeds, and guarantees  
157 regarding the purity of the origin and the full heterosis effects in the case of hybrid varieties.  
158 This is also the case for fish, but “breeders’ rights” is not applicable due to the need for much  
159 higher genetic heterogeneity in most commercial fish populations. Fish populations can  
160 therefore not meet the criteria under the UPOV convention.

161         Rosendal et al. (2006) described and discussed different biologically-based protection  
162 strategies as well as legal measures for protecting genetic resources in aquaculture.  
163 Continuous upgrading of the material through genetic improvement combined with private  
164 law contracts between seller (breeding company) and buyer (e.g. multiplier) has been the  
165 common strategy in aquaculture. Crossbreeding and hybrids, sterile production animals,  
166 branding/trademarks, patents and specially adapted type of intellectual property system (*sui*  
167 *generis* in legal literature) for fish may be other options for protecting genetic resources in  
168 aquaculture.

169

170 *Access to wild and improved breeding material*

171 Access to fish genetic resources is important for a number of reasons (Rosendal et al., 2006).

172 It may work as a guard against a narrowing genetic base and as such maintain genetic

173 diversity. Different stocks may have characteristics that are more suitable for specific

174 production conditions or markets than for others. Under a free access regime, it may be

175 possible for breeding programs to acquire brood stock with a wide range of characteristics

176 adapted to their own needs and conditions. Access to genetic resources is essential for future

177 innovations and adaptations within the aquaculture sector.

178 However, the legal status of both wild and improved genetic material is unclear and

179 changing (Rosendal et al., 2006). Improved genetic material may be held by public or private

180 breeding programs, but has until now been more or less legally available for further

181 propagation and/or use in breeding for any buyer of the commercial product (live eggs or

182 fish) from the programs. Typically, organized access to such acquisitions has been subject to

183 a contract between the provider and the user, while unorganised use has been difficult to

184 prevent and hence may have occurred, both inside and outside Norway. For example, the

185 biggest Norwegian salmon breeding company, AquaGen, at first prohibited all export of their

186 genetic material. In 1998, they started an organized export of their genetic material in order

187 to control the extensive export of Atlantic salmon that was already taking place. The strong

188 consolidations of the industry into big multinational farming companies at that time also

189 enforced this decision (pers. Comm., Svein Hjeldnes, AquaGen). Future transfer of genetic

190 material will largely be a matter between private breeding companies and the users of the

191 material. Biodiversity represents one of our most valuable resources, although this value is

192 still hard to quantify in economic terms. Greer and Harvey (2004, p. 28) argue that

193 “variations among wild salmon stocks will become increasingly important to the relatively

194 new aquaculture industry as fish farmers continue to look for desirable characteristics to

195 introduce into cultured species". In addition, the already improved Atlantic salmon genetic  
196 material represents a valuable resource for Norway. This has been one of the most important  
197 contributions to the strong competitiveness of Norwegian salmon on the world market. The  
198 Norwegian salmon stocks, including the wild stocks, constitute valuable genetic resources  
199 that can be further developed and utilised. From this it follows that access to both wild and  
200 improved genetic resources is valuable.

201

202 *Evolving access legislation and patent law*

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

210 In response to this development, the Convention on Biological Diversity (CBD, 1992)  
211 introduced national sovereign rights to genetic resources as an attempt to compromise  
212 between primary owners and users of these resources (Rosendal, 2000). A parallel process  
213 produced the Trade-Related aspects of Intellectual Property Rights<sup>3</sup> (TRIPS) agreement  
214 under the World Trade Organisation (WTO), with the main objectives to harmonise,  
215 strengthen and expand the scope of intellectual property rights (IPR) protection in all  
216 technological fields. This includes biotechnology and new or improved breeding and selection  
217 methods as well as genetic engineering. TRIPS is said to promote innovation by establishing  
218 exclusive private rights to *inter alia* genetic resources through intellectual property rights,

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<sup>3</sup> For details, see [http://www.wto.org/english/tratop\\_e/trips\\_e/trips\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/trips_e.htm)

219 while the CBD aims at balancing the skewed distribution of biological resources and  
220 biotechnology between the North and the South (Rosendal, 2001; 2005). Besides the existing  
221 international legislation on patent law under the World Intellectual Property Organisation<sup>4</sup>  
222 (WIPO), there are also ongoing negotiations in the Standing Committee in the WIPO for an  
223 even higher degree of international harmonisation in this field (Tvedt, 2005a, pp. 311-344). In  
224 response, access regulations have been proliferating, especially among biodiversity rich, but  
225 less industrialised countries of the South. As pointed out by Greer and Harvey (2004, p.17),  
226 “plant collection in developing countries is a much more controversial issue than collections  
227 of aquatic genetic resources in developed countries, but it (aquatic collections) can be  
228 expected to attract greater attention as the demand increases”. In general, the fish breeding as  
229 well as the breeders are less organised in the developing world. As a response to a  
230 strengthened IPR protection of genetic material (e.g. by patenting), they may in theory also  
231 take advantage of this and obtain control of their own material. Because patents are  
232 dependent on technology development and are relatively expensive to obtain and enforce,  
233 only well organized and big companies with sufficient economic power can take fully  
234 advantage of strengthened IPR protection. Hence, they can restrict the activity of the weaker  
235 breeders in the third world, who will probably become the injured party. An important  
236 challenge for Norway, as well as for other countries, is to develop access regulations that do  
237 not hamper development and innovation and to ensure that changes in patent law do not close  
238 possibilities for the open access and exchange of genetic resources.

239

240 *Norwegian legislation*

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<sup>4</sup> The World Intellectual Property Organization is a specialized agency of the United Nations. It is dedicated to developing a balanced and accessible international intellectual property system, which rewards creativity, stimulates innovation and contributes to economic development while safeguarding the public interest. See [http://www.wipo.int/about-wipo/en/what\\_is\\_wipo.html](http://www.wipo.int/about-wipo/en/what_is_wipo.html).

241 Access legislation is now in the process of being developed in Norway. An Expert  
242 Committee proposed a new Act for Nature Diversity stating that *genetic material* is a  
243 *common resource* open for everyone to use (NOU, 2004<sup>5</sup>). This entails that there are no  
244 exclusive property rights to genetic material, save when an intellectual property right is  
245 granted. If these suggestions become part of the forthcoming Nature Diversity Act, then  
246 genetic resources in Norway can be said to be in a *public domain*. However, a more recent  
247 statement from a governmental appointed expert committee (NOU, 2005) proposes that any  
248 utilisation of marine genetic resources must go through a procedure involving the Ministry of  
249 Fisheries. The question of property rights to genetic resources, other than intellectual  
250 property rights, is still not solved in Norwegian legislation (Nordic Council of Ministers,  
251 2003; Tvedt, 2005b).

252 Norway implemented the EU Patent Directive in 2003. The exact scope of what a  
253 patent grants an exclusive right to remains to be seen, as this has not been legally tried in  
254 Norway, and it remains to be seen how patent practice will develop.

255 Concerns have been expressed that the Norwegian aquaculture industry may become  
256 dependent on external companies and must pay royalties for using interesting salmon genetic  
257 material originating from Norway (Gjerstad, 2000; Fish Farming International, 2000). For  
258 instance, commercial breeders may find a useful gene in a wild salmon stock, patent an  
259 isolated or modified expression of this material, and go on to demand monopoly prices from  
260 (other) Norwegian actors that use that gene or knowledge about the gene. Patenting of genes  
261 by Norwegian players was presented as the solution to this problem. In such a scenario,  
262 commercial actors may obtain wild genetic material free of charge, due to the legal status of  
263 genetic resources being *common resources* according to the draft Nature Diversity Act or due  
264 to the lack of access regulation.

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265

266 **3. Methods and materials**

267 In order to present and discuss some of the main challenges associated with access to and  
268 exclusive rights to fish genetic resources in aquaculture, we applied three disciplinary  
269 approaches. We combined biological expertise in fish genetic resources and fish breeding  
270 with expertise in law and in political science. The literature that informed this article was  
271 partly drawn from documents and studies from the field of plant genetic resources – as very  
272 few studies of fish genetic resources have been conducted. The other main part of our  
273 material is drawn from a number of interviews with individuals directly involved in fish  
274 breeding and farming. In order to achieve a manageable selection, our interviewees were  
275 limited to Norwegians directly involved in fish breeding, which in some instances are also  
276 involved in fish farming. The four respondents represented breeding companies providing  
277 practically all of the roe and smolt for salmon farming in Norway. As the universe of  
278 breeding companies is rather small, our interviews have covered all but two small companies.  
279 A high degree of confidentiality was claimed by and granted the respondents, and hence,  
280 hindering us from presenting a list of the companies that we interviewed. Prior to the  
281 interview, a short introduction and questionnaire was sent to the respondents (see Appendix  
282 1).

283 The following topics were focused upon in the questionnaire and during the interviews:

- 284 • The emerging domestic and international regulations of genetic resources.
- 285 • Evolving structures in the aquaculture sector. How size, private or public ownership  
286 and funding may affect options for strategies.

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<sup>5</sup> Norges offentlige utredninger (Norwegian Governmental Reports) NOU 2004:28, pp. 526, 634

- 287       • Technological developments and biological features that affect choices relating to  
288       access to and protection of fish genetic resources.

289

290       We also build on discussions within the Fish Breeders Round Table, organised by  
291       AKVAFORSK in June 2004.

292             Norwegian aquaculture is chosen as a case in our study. Norway played a leadership  
293       role in the international negotiations that led to evolving norms and regulations for access and  
294       benefit sharing of genetic resources within the framework of the Convention on Biological  
295       Diversity (CBD). Norway is among the first developed countries to embark on a legislative  
296       process for regulating access to these resources. In addition, the research team is  
297       geographically close to the people involved. As many countries are facing challenges similar  
298       to those confronting the Norwegian aquaculture sector, our findings may be relevant to a  
299       broader audience.

300

#### 301       **4. Results**

##### 302       *Evolving regulations affecting access and protection*

303       In the course of our interviews, we did not find a high degree of awareness about the *domestic*  
304       legislative process that is taking place. To the extent that our respondents were familiar with  
305       the evolving legislation, they expressed positive views to the Norwegian Expert Committee  
306       (NOU 2004:28) and its approach to access to wild material. Similarly, the respondents were in  
307       general not familiar with the evolving *international* norms and regulations on intellectual  
308       property rights to genetic materials or with the evolving access regulatory regimes. Those  
309       who did recognise the emerging regimes, however, had clear opinions about their utility:  
310       “There must be a balance of strength between intellectual property rights (IPR) and access

311 regulations. Strong patents in the form as seen in the EU Patent Directive must somehow be  
312 balanced with strong access regulation to prevent that genetic resources currently shared are  
313 controlled commercially by a few companies”.

314 To the extent that our interviewees had knowledge of the domestic and international  
315 regulations, they did not immediately perceive a high degree of utility. First, the experiences  
316 with the evolving property rights regimes were that they were “highly complex and currently  
317 considered to be of low relevance for most players in the field of applied genetic  
318 improvement in aquaculture”. Moreover, “If strict (patent) regulations are implemented, this  
319 may severely limit the developments in this field, since few players have the size and  
320 economic strength to pursue key patents. This may thus limit and possibly exclude activity by  
321 the many small and economically vulnerable players in the sector today”. One respondent  
322 emphasised that patenting in vaccines and medicines was a much greater challenge than  
323 patenting of breeding materials. Increased use of patents in the pharmaceutical sector was  
324 seen to create problems for farmers by e.g. postponing and preventing further development of  
325 drugs or vaccines.

326 Others held that regulations on access and protection were indeed necessary and  
327 patenting was recognised as a way to promote innovation and investments. With a view to  
328 evolving legislation on intellectual property rights, however, the main problem was  
329 formulated as “How and what can we patent in salmon breeding?”

330 As for Norwegian salmon, it was maintained that patenting was far too late, anyway: “This  
331 train has left the station. It is too late to harvest the fruits from Norwegian salmon breeding or  
332 to regulate access to Norwegian salmon genetic resources”. Both wild and improved breeding  
333 materials for salmon have already been spread to a great number of breeders world wide.

334 *Changing structures in the aquaculture sector affecting access and protection*

335         The evolving need for legal measures for protection of genetically improved material  
336 is partly explained by the expectation that breeding material will become more expensive. In  
337 response to what our respondents view as the most important factors instigating change, they  
338 also pointed to organisational and market-related factors. “The early initiatives in this field  
339 were in the form of sector-wide joint venture approaches for mutual benefits, in many cases  
340 supported by strong public funding. As aquaculture productions have matured, the  
341 commercial interests in controlling salmon seed stocks have led to the establishment of  
342 several, strongly competing commercial companies”.

343         Contrasting aquaculture with plant genetic resources in agriculture, it is pointed out  
344 that “Monsanto is large with many small farms as customers, while we are small with larger  
345 fish farmer customers. However, this may change in the future”. This contrast emphasizes  
346 how the differences among the sectors affect the legal strategies, and that there might be a  
347 correlation between market power and the focus on how important it is to secure such a  
348 dominant position by exclusive rights. This also points to the more uncertain trend of whether  
349 industry integration will come to encompass additional parts of the production chain.<sup>6</sup> This  
350 has been a trend in other sectors of bio-production. Until now, various strategies have been  
351 used by the larger salmon farming companies to secure the seed supply, from in-house  
352 breeding programs via minority ownership in specialized programs to purchase contracts in  
353 the seed market.

354         During the course of our interviews, it became clear that essentially all the leading  
355 breeding companies have great confidence in their competitive edge over their counterparts.  
356 In effect, due to having access to superior genetic materials, they think that they do not need  
357 to seek legal protection of the material: “Today we do not need to buy. We already have the

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<sup>6</sup> As pointed out by Morten Rye, at Fish Breeders Round Table, June 2004.

358 best material". As priority has been on avoiding inbreeding, selection has been focused on a  
359 great number of characteristics and many families. In effect, there has been little need for  
360 new material, little perceived need for access, and little perceived need for exclusive property  
361 rights. Another explanation for the low interest in legal protection is that the advanced  
362 breeding programmes (based on testing and selection of families) have not documented and  
363 marketed well enough effects on growth rate and age at sexual maturity (the prioritised traits  
364 for most fish farmers) compared to results achieved more inexpensively by phenotype  
365 selection. In turn, actors may not always realise the value in more costly breeding activities  
366 and breeding stocks where more traits (e.g. carcass quality and disease resistance) are also  
367 taken into account. Large fish farming companies increasingly tend to rely on a strategy of  
368 buying stocks from specialized breeding companies and invest in marketing rather than in  
369 uncertain breeding programmes.

370 At the same time, our respondents all assumed that this situation is about to change, as  
371 future developments may make legal measures necessary. It is admitted that there may be  
372 future needs for external acquisitions of breeding materials as new diseases turn up or new  
373 characteristics are demanded (e.g. disease resistance characteristics).<sup>7</sup>

374

375 *Technological developments and biological features affecting access and protection*

376 When speaking about legal protection, most respondents had some type of tracking system in  
377 mind for control and monitoring of contracts, rather than patenting of specific products.

378 Securing breeding or research results through patents or trademarks was considered

379 cumbersome, inefficient and expensive. The situation today is that most fish breeding

380 companies in Norway sign contracts with cooperating multipliers that propagate their genetic

381 material for further sale to the industry, where the multipliers agree that the material cannot  
382 be utilised for further breeding or sold for breeding purposes. However, private law  
383 agreements may not prevent the material from being acquired without authorization by  
384 breeders in for example Chile and other competing countries or by domestic competitors. The  
385 respondents (salmon breeders) experienced problems with control, enforcement and  
386 monitoring of the terms of the private material transfer agreements (MTA) with the  
387 multipliers, and instances of contract violations had occurred.

388

## 389 **5. Discussion**

### 390 *Evolving regulations affecting access and protection*

391 A great variety of Norwegian salmon genetic resources are already acquired and in  
392 use by both Norwegian and foreign breeders, e.g. in Chile. Hence, the effects of Norwegian  
393 access regulations would arguably be limited, and it may be too late to reverse the situation,  
394 except for novel improvements. However, for future acquisition of fish genetic resources  
395 from other species in early phases of farming (cod, halibut, etc.) it is not too late to regulate  
396 access to wild material, as a similar international exchange has not taken place for these other  
397 species of fish. Also, as mentioned above, the MTAs do not ensure the breeders rights  
398 sufficiently, and that there is a need for improving the regulation.

399 Let us take a closer look at patents of *improved fish* in the breeding industry. Patents  
400 of fish genetic resources are already regulated in Norway through the Norwegian Patent Act.  
401 As far as we have been able to ascertain, it is so far only the larger corporations that have  
402 concrete plans for using patents to protect aquatic genetic material. However, these large-  
403 scale actors also show great reluctance to apply for patents, and point to the situation in

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<sup>7</sup> 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. One respondent's

404 international regulations: “There is already too much skepticism in the public opinion. If  
405 these sentiments were around at the time of plant breeders’ rights (PBR), they would  
406 probably not have emerged”.<sup>8</sup> This indicates that industry does not believe in trying to  
407 influence policy and regulatory developments in this field. Drawing from the experiences in  
408 the seeds sector, however, it would seem that this pessimistic view has little empirical  
409 support. This is demonstrated by both plant breeders’ rights and patent systems that have  
410 recently been strengthened worldwide – in spite of opposition by a large public opinion.  
411 While this may appear a bit paradoxical, the bottom line seems to relate to the problems  
412 encountered in tailoring protection systems to the specific characteristics of fish genetic  
413 resources.

414

#### 415 *Changing structures in the aquaculture sector affecting access and protection*

416 In Norway, effective breeding programs for most farm animals were established in the early  
417 1960s as cooperative joint actions between farmers, the slaughter and dairy industries, and  
418 the state. Animal breeding was considered a means to provide food more efficiently as a  
419 public good. Similarly, Norwegian salmon and rainbow trout breeding programs were started  
420 in 1971 by the non-profit research institute AKVAFORSK with public financing (Gjøen and  
421 Bentsen, 1997). The base populations for these programs were collected from Norwegian  
422 rivers (Atlantic salmon) and from Scandinavian farmed populations (rainbow trout). Inspired  
423 by the cooperative success for farm animals, these breeding populations for Atlantic salmon  
424 and rainbow trout were transferred in 1985-1989 to the Norwegian Salmon Breeding  
425 Association under the ownership of the Norwegian salmon farmers’ organizations. However,  
426 as a result of the critical economic development in the late 1980s, ending with the bankruptcy  
427 of the Fish Farmers Sale Organisation, this activity was transferred to a private, limited

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statement 2 June, 2004.

428 company in 1992 (at present, *AquaGen*). In the meantime, public support for Norwegian farm  
429 animal breeding decreased, reflecting a political will to privatize breeding and genetic  
430 resources. A counter-trend is a recent initiative from the Ministry of Fisheries to fund the  
431 establishment of a breeding program for cod at the Norwegian Institute of Fisheries and  
432 Aquaculture Research in Tromsø. A similar case may arise with public funding of halibut  
433 breeding at the Bodø University College in Nordland County. These cases show that there is  
434 still a willingness to finance development of genetic resources in Norway, at least in the  
435 districts of Northern Norway.

436         The genetic material of salmon originally collected and developed by AKVAFORSK  
437 has dominated Norwegian fish farming until recently. However, several other breeding  
438 programs have been operating in parallel most of the time, usually with a distinct genetic  
439 origin from Norwegian river stocks. The *AquaGen* breeding programs were until some years  
440 ago the only full-scale family-based breeding program, while the smaller programs were  
441 based on phenotype selection. Today, some of the early phenotype selection programs have  
442 been developed into full-scale family selection programs and are now covering about half of  
443 the total Norwegian salmonid farming market (*SalmoBreed and Rauma*).

444         The fish-farming sector as a whole is characterised by rapid market fluctuations with  
445 accompanying bonanzas and great losses. The relatively long time interval (two to three  
446 years) between acquisition of roe and marketing of salmon makes salmon farming very  
447 vulnerable to market fluctuations compared to most agricultural crop production, where seeds  
448 will yield a harvest the same or following year. Terrestrial animal husbandry is similar to fish  
449 in this respect, but the vulnerability of the terrestrial sector in Norway is reduced because  
450 Norwegian farmers can cooperate within primarily domestic markets. Farmed fish is largely

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<sup>8</sup> Argued by Hein van der Stein, SyGen, *Fish Breeders Round Table*, June 2004.

451 produced for international markets, and this tends to complicate cooperative strategies for the  
452 farmers.

453         Summing up, we found that the market and the structural changes within the sector  
454 itself constitute major factors instigating change in the perceptions of issues regarding access  
455 and protection. At the same time, we also found that the incentives for capitalising on  
456 breeding materials have been virtually non-existent, due to low roe prices and low  
457 profitability for improved breeding material, a trend that does not seem to be changing in the  
458 near future. This seems a paradox when considered against the valuable public good of  
459 faster-growing and hence cheaper salmon resulting from the breeding programs. It also  
460 illustrates the challenge of securing a fair sharing of the benefits from genetic improvement  
461 among consumers, farmers and breeders.

462         Our results have further demonstrated a small, but growing concern about rights to  
463 germplasm on the part of the breeding companies involved. In the following section we will  
464 discuss the applicability and wider effects of various forms of protection, given the nature of  
465 fish farming and fish genetic resources as well as the technology available or being  
466 developed.

467

468 *Types of biological and legal protection and how to balance access regimes*

469 In the following, we will discuss various strategies, available technology and fish biology for  
470 protecting breeding and research results, taking into account the options presented by  
471 Rosendal et al. (2006) and examples and experiences among our interviewees. We will  
472 address how the method may presumably affect investment returns, innovation, access for  
473 other users and genetic diversity. A more elaborate discussion of the legal and biological  
474 aspects relating to the various options is presented by Rosendal et al. (2006). Until now, most

475 animal breeding programs have relied on various biologically based strategies to encourage  
476 the users of their genetic material to deal directly with the program.

477

478 *Biological protection*

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

486 The material sold may, of course, be illegally reproduced by the buyer without the  
487 knowledge of the supplier. However, the reproduced material will always lag behind in  
488 performance by at least one generation compared to the material supplied directly from the  
489 breeding program. However, it will have to be considered as *de facto* free-access material,  
490 because it will be possible for anyone to acquire such unauthorized outdated material. This  
491 will, of course, benefit the access for all breeding programs or other actors in the industry to a  
492 wide range of well-performing genetic materials. Thus, it may widen the potential genetic  
493 base for the programs and counteract loss of genetic variation. On the other hand, it will be  
494 difficult for a superior program to gain a large competitive advantage, since other programs  
495 may hitchhike (with some delay) on its genetic progress. This may increase the focus by the  
496 breeding programs on marketing and service/support rather than on increasing the genetic  
497 progress.

498

499 Crossbreeding and hybrids: In plant species, it is relatively easy to produce a large number of  
500 inbred lines and to testcross various combinations to identify crossbreds that express  
501 significant heterosis effects. The heterosis effects will be gradually lost in the progeny  
502 generations if the hybrids are reproduced. Denying access to the parent lines will protect  
503 them from piracy. However, the commercial hybrids may still be reproduced and the progeny  
504 may be used for production.

505 In aquaculture breeding, applied crossbreeding programs are scarce. Crossbreeding  
506 experiments with stocks in aquaculture species have until now, with some exceptions (e.g. for  
507 common carp; Wohlfarth, 1993 and for channel catfish; Dunham et al., 1983), failed to detect  
508 major or applicable heterosis effects (Gjerde and Refstie, 1984; Gjerde, 1988; Bentsen et al.,  
509 1998, Gjerde et al., 2002). The gain from crossbreeding in aquaculture is typically lower than  
510 the response after only one generation of selection in a simple selection program.

511 A separate crossbreeding strategy, which is becoming increasingly topical in salmon  
512 breeding, does not depend on heterosis effects. It is the crossing of parents from different  
513 populations with distinct performance traits to combine the desired traits in the crossbred  
514 production animals. A breeding program with several such distinct populations may produce  
515 progeny with a variety of combinations of traits, depending on the customers' demand, and  
516 this genetic material may attract buyers with specific needs. Still, on-farm reproduction of the  
517 crossbred progeny will be feasible without loss of performance.

518

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

523 applied commercially, both because of public skepticism and because of immature  
524 technology.

525 In several aquaculture species (unlike farmed plants and land animals), applicable  
526 methods are available for commercial-scale propagation of sterile production animals  
527 (Pepper, 1991; Sutterlin and Collier, 1991, Felip et al., 2001, Nell, 2002). Sterile production  
528 animals are routinely used in some production systems today, e.g. in rainbow trout in France  
529 (Bonnet et al., 1999) and pacific oyster (Nell, 2002) to avoid problems with sexual  
530 maturation and spawning. The methods have not been applied in Norwegian salmon farming  
531 due to consumer skepticism to chromosome manipulated organisms, minor problems with  
532 precocious sexual maturation in the salmon farming and the undesirable side effects of  
533 triploidy on productivity (lower growth and yields, O'Flynn et al., 1997).

534

### 535 *Legal protection*

536 Branding: Traditionally, the approach for seeking legal property rights for genetically  
537 improved populations of fish has been to register product names and trademarks. Strictly, this  
538 will not protect the genetic material from being propagated and used by outsiders, but only  
539 prevent unauthorized use of the registered name. Branding can be combined with additional  
540 measures such as biological protection strategies like continuous upgrading or crossbreeding  
541 of the material, or with high quality management of the seed production process, good  
542 customer support and services, and high profile information and marketing strategies. Then  
543 the customers may find safety and production benefits from returning to the branded sources.  
544 Our respondents seemed to conceive this strategy as the most relevant for the current  
545 situation although it does not hamper access to genetic material for further research and  
546 development unless it is combined with MTAs.

547

548 Material transfer agreements: Private legal contracts between seller and buyer have  
549 traditionally been the most common means for regulating trade and transfer of livestock.  
550 Here, the breeding program supplies the user with genetically improved broodstock or semen  
551 on conditions involving e.g. financial returns to the breeding program and limitations on the  
552 use of the material. For prolific farm animals, like poultry and pigs, the industry often  
553 consists of separate specialised operations conducted by different companies. Therefore, it is  
554 common that breeding programs focus on the breeding operation and formalize collaboration  
555 with selected, skilled multipliers through MTA.

556 For aquaculture species with advanced and more demanding breeding programs (e.g.  
557 for salmon), the organization of production is similar to that of poultry and pigs, with several  
558 separate, specialized levels. Because of the even higher reproductive capacity, the multiplier  
559 level may be managed by a small number of hatcheries/juvenile producers. This facilitates  
560 both integration of the multiplier level in the breeding program as well as MTAs between the  
561 breeding program and independent, specialized multiplier operations. Possible financial  
562 benefits arising from a successful and competitive strategy in the breeding nucleus may be  
563 partly channeled back from the multipliers through a contracted royalty fee on each egg or  
564 juvenile sold.

565 However, the experience with this type of MTAs among some of our respondents was  
566 mixed. There have been problems with control, enforcement and monitoring of the terms of  
567 the agreements with the multipliers, and instances of contract violations have occurred. One  
568 problem seems to be the difficulties in tracing and verifying the number and origin of  
569 marketed seed. Another challenge is that it is only legally binding for the two parties signing  
570 the agreement and not for any third parties. To secure investments in breeding, this approach  
571 must be combined with strong rules on restricting further distribution of the material and

572 improved tracing opportunities. Genetic material representing older generations in the  
573 breeding program will be more or less legally available for common use. This may, therefore,  
574 widen the potential genetic base for diverse breeding programs and counteract loss of genetic  
575 variation.

576

577 Patents: The invention to be patented may entail either a product or a process related to  
578 biological material. However, there are two narrowly defined exemptions from patent  
579 protection. If the process that is described in the patent application is a process that is consisting  
580 “entirely of natural phenomena such as crossing or selection”, it is not patentable. However,  
581 “entirely” is a severe legal term. If the process combines a biological process only with a  
582 very low level of technological, non-biological knowledge, it can also be patented. This will  
583 probably be the most common case for patents in the fish breeding sector, as the pure  
584 biological processes, such as selection and crossbreeding, will be known to everyone and thus  
585 form a part of the *prior art*. The second exemption entails that “animal varieties” cannot be  
586 patented. The term animal variety is not unambiguous in fish breeding, where we rarely talk  
587 about varieties, but rather about stocks. When a process is patented, the exclusive right also  
588 covers results directly produced from that process.

589 To be granted a patent, the invention must fulfill the patent criteria; it must be regarded  
590 *novel*, involve a sufficient level of *inventive step* and have a use (*industrially applicable*). One  
591 reason why patents have not been applied extensively to the aquaculture sector might be that it is  
592 difficult to fulfill the patent criteria. This might be due to lack of knowledge about which gene  
593 variants or genotypes are present in superior animals. However, according to the Patent  
594 Directive in EU, isolation of a naturally occurring gene is regarded as an invention that fulfils  
595 the patent criteria, and such patents may indirectly affect fish breeding. Rothschild et al  
596 (2003) list several examples of patents involving common methods, genes and genetic

597 markers in livestock. The genes may directly or indirectly be patented through e.g. patents on  
598 a gene sequence, major gene affecting an important trait, a genetic marker, method for  
599 identifying a genetic marker or a transgenic animal. A scan of Norwegian fish patents in 2007  
600 only revealed three such patents, one involved a genetic marker for disease resistance (Patent  
601 NO 317342) and two on transgenic fish (patent NO 321650 and application NO 20064420).  
602 Thus, increased knowledge about the genome of each fish species will increase the  
603 applicability of the patent system for protecting the commercial use of such knowledge. Gene  
604 technology may reduce the barriers to patenting inventions, but has so far not been much  
605 applied in animal breeding in spite of high expectations for a long period. Another problem  
606 with patenting genes in breeding populations may be the long time from application to  
607 granting a patent, while there is a continuous genetic improvement from selection  
608 programmes. For species with low generation interval, a moderate non-recurrent genetic  
609 improvement by a gene exchange or transfer may be passed over by a couple of generations  
610 of selection in a modern breeding programme. Hence, patents affecting the fish breeding  
611 options severely may either be related to genes with large effects on important traits, e.g. on  
612 the gene itself or on technical processes on selecting for such genes, (via e.g. marker genes  
613 linked to it). The latter selection technology may also be of temporary value if it is not wider  
614 than concerning a specific gene, because it will be irrelevant when the favourable gene  
615 variant eventually is fixed. Patented transgenic fish must also show long-term competitive  
616 benefits with respect to consumer price (producer costs) and product quality in order to affect  
617 breeders' options for access and protection significantly. If so, transgenic technology will  
618 facilitate protection through patenting in the same way as other gene technology mentioned  
619 above.

620 An unsolved question in practice as well as in patent theory is what a patent to a  
621 naturally occurring gene covers. The patent directive specifies that: "The protection conferred

622 by a patent on a biological material possessing specific characteristics as a result of the  
623 invention shall extend to any biological material derived from that biological material  
624 through propagation or multiplication in an identical or divergent form and possessing those  
625 same characteristics.” This refers to the coverage of a patent when the patented gene is  
626 transferred to new organisms. It does not cover the question of the scope of the protection for  
627 natural occurring genes as long as they are not transferred to another organism. Noiville  
628 (1999) emphasizes that patents on natural occurring genes have no effect on traditional  
629 breeders. “Patent holders are not able to claim rights on farm animals naturally carrying this  
630 gene; they may only claim rights on the use they proposed of this gene”. However, she  
631 focuses on the risks of the patent law in the traditional breeding: Competition between patent  
632 holder and traditional breeders when e.g. a company sells genetically modified animals  
633 without the breeders’ permission to use their genetic material (breed, strain or stock) and the  
634 problem with broad patents, also discussed here below. Rye (2000) also stressed the problem  
635 of the lack of legal mechanisms for sharing the benefits between a patent holder and the  
636 breeder or owner of the fish population making the origin of the patented gene or animal. The  
637 scope of the protection should (from an ideal perspective) encompass all that the inventor has  
638 added to the state of the art, but nothing more. If it covers more than the addition to the state  
639 of the art, the patent protection is too broad. It is assumed that *broad patents* may hamper  
640 access to breeding stocks, as this will make the activities too costly for smaller companies.  
641 Broad patents may cause difficulties for other inventors to come up with new solutions and  
642 inventions, to “invent around” the patented invention. Patents on genetic material from fish  
643 might be particularly difficult to invent around if there is only one set of genes coding for a  
644 particular trait. Similarly, if there are many patents in one field of technology, it may become  
645 difficult and costly for new inventors to obtain licenses from all patent holders. Such  
646 practical and monetary obstacles may hinder the development of new inventions in a

647 technical field. Patenting has also been recommended as a preventive strategy to prevent  
648 others from patenting the same invention (Fish Farming International, 2000; Gjerstad, 2000).  
649 This is, however, a costly and insecure strategy. To publish the new invention or new  
650 knowledge may be a better strategy, as it brings the knowledge into the public domain and  
651 thus prevents others from patenting it. The use of patents in a breeding program is a very  
652 costly process, both in terms of achieving and enforcing the patent. This strategy may be best  
653 suited for larger companies within a technological sector.

654 Even if the patent system is applicable for the fish breeding sector, there are essential  
655 legal and biological barriers linked to patenting as a strategy for securing investments in fish  
656 genetic improvement programs. Gene transfer and other gene modifications could provide a  
657 strong protection mechanism to aid enforcement, but this strategy is hardly compatible with  
658 restrictive Norwegian and some EU-countries' views on genetically modified animals.  
659 However, if competitive gene modified animals are patented and approved for aquaculture  
660 production abroad, it will probably reduce the Norwegian farmers' and breeders' export of  
661 such unmodified fish and genetic material, respectively. Some Norwegian farmers and  
662 breeders are also multinational and may move their production to other countries and adapt  
663 the production to these countries' legislation if they get access to the preferred gene modified  
664 fish. This may in turn have negative effects on the fish farming activity in Norway if it fails  
665 to compensate by serving other market segments by e.g. GMO-free labeling.

666 Romstad and Stokstad (2005) discuss market power and patenting of genetic  
667 resources. As mentioned above, the potential for exercising market power is tied to the  
668 possibility to exclude access and the availability/threat of substitutes. When the degree of  
669 monopoly increases, the possibility to provide the products for a price larger than the  
670 production cost increases. Furthermore, the use of market power and cost of exclusion can  
671 make private provision less efficient than an ideal public provision.

672

673 *Sui generis* for fish populations: There are still no Animal Breeders' Rights similar to plant  
674 breeders' rights (PBR). There are however international processes looking at such  
675 possibilities. The difficult question is how such a system could be designed. The major danger  
676 in this process is that such a system would borrow or use experiences from the plant sector  
677 without taking sufficiently into account the special features of the fish breeding and farming  
678 sector. As shown in the introduction, most fish breeding systems are dependent on  
679 heterogeneous populations and hence unsuited to fulfill the plant breeders' rights criteria of  
680 *new, distinct, uniform* and *stable*. Perhaps this reflects a need for a specially adapted type of  
681 intellectual property system for aquaculture breeds. In legal literature this is called a *sui*  
682 *generis* system. Such a system should address what can be protected, criteria for obtaining  
683 protection and the extent of exclusive rights that can be obtained.

684

685 *Other protection*

686 Trade secrets: To obtain exclusivity by the use of trade secrets, the genetic material needs to  
687 be confined or made unavailable for competitors. Trade secrets do not guarantee an exclusive  
688 right in a similar manner as does a patent. In a breeding program, subjects for trade secrets  
689 could be the breeding nucleus, procedures for data recording, data processing, or selection  
690 and mating of the animals. However, because the product (the commercial seed) may usually  
691 be copied without knowledge about the trade secrets, simply by growing and reproducing the  
692 animals, secrecy about the procedures will not alone provide exclusivity to the genetic  
693 material resulting from the activities. Also, if all the actors should use a strict trade secret  
694 approach, this could hamper access and exchange of genetic resources.

695 Trade secrets with large effects are bound to attract attention and attempts at copying,  
696 and competitors may even patent the leaked secret. Altogether, trade secrets are a rather  
697 insecure strategy to ensure a monopoly right in the aquaculture context.

698

699 *Enforcement strategies*

700 Tracing and documentation of possible unauthorized use of genetic material:

701 A critical issue for enforcement of many protection methods is the possibility to  
702 control illegal use and document the origin of e.g. fish produced or reproduced illegally.  
703 Gene technology and biochemical methods together with databases have already been  
704 applied for such tracing or pedigree control, and Rosendal et al. (2006) described methods  
705 based on allele frequencies, marker genes, DNA fingerprinting/profiling and certificates of  
706 origin. The latter two were considered the most relevant for documenting the origin of fish  
707 reproduced illegally. To trace a random individual from the commercial seed market or from  
708 grow-out farms with sufficient accuracy, a rather extensive laboratory analysis is required of  
709 the DNA from both the sampled individuals and the ancestor candidates (see e.g. Hayes et  
710 al., 2005). Furthermore, the logistics from the production of fertilized eggs to the commercial  
711 seed market or the grow-out farms need to be transparent and documented if the hatchery  
712 source of the sampled seed is to be identified. This would be a rather expensive and laborious  
713 exercise.

714 The increased consumer awareness of the origin and production history of food  
715 products has resulted in a demand for traceable products. Food products, that may be traced  
716 back to breeding programs with a documented practice that is conceived as clean, natural and  
717 environmental friendly, may gain a competitive advantage. In an international context,

718 national regulations that ensure traceability all the way back to the breeding nucleus may also  
719 increase the competitiveness of the national industry.

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

736

### 737 **Conclusion and implications**

738 There is a discrepancy between the knowledge of farmers and breeders with respect to access  
739 and legal rights to genetic resources and the actual possibilities and limits offered by evolving  
740 legislation. The Norwegian aquaculture sector is characterised by small breeding companies  
741 engaged in competition in international markets. This may help to explain why they have  
742 been rather unsuccessful in developing common positions and accessing relevant political

743 decision-making processes both for national and international law-making processes. In order  
744 to maximize the industry's potential, there seems to be a need for information about access  
745 and legal rights to genetic resources, and further research on how this can be optimized.

746         The maturing aquaculture sector is currently facing several changes and challenges.  
747 One of the most far-reaching changes may originate in the emerging international and  
748 domestic legislation and regulations for access and protection of genetic materials. However,  
749 there are equally strong internal factors driving the changes in aquaculture. Market  
750 consolidations and privatisation are among the factors that the actors themselves recognise as  
751 most important in changing the ground rules within the sector. Even though the emerging sets  
752 of legislation do not seem to have a high visibility among the relevant groups, most are  
753 becoming more concerned with the questions of access and exclusive rights to the wild and  
754 improved breeding material that is central to their trade. This realisation is predominantly  
755 linked to external use of Norwegian salmon genetic resources, as most breeders are still  
756 confident in the superiority of their own breeders' lines. Nevertheless, the breeders also  
757 acknowledge their vulnerability, should access to new and improved materials or traits  
758 become severely restricted. For these reasons, the predominant view among our respondents  
759 is that the sector needs to find a balance between access to breeding material and protection  
760 of its own innovations in fish breeding. This proper balance is not discussed either in patent  
761 law or in the two domestic law proposals. Coupled with this view is an emerging  
762 understanding that the value of improved breeding material is invariably underestimated,  
763 leaving the farmers (during the peaks of seller's market) to reap most of the added value from  
764 fish breeding and farming.

765         Protection measures may affect access to and innovation concerning marine genetic  
766 resources. Different protection methods are evaluated above with respect to verification,  
767 feasibility, access for other users, and genetic diversity. The strength of the protection system

768 is associated with its ability to achieve verification and monitoring. The costs of the  
769 protection system are linked to its feasibility, as high costs will be prohibitive for most actors.  
770 Both aspects will probably be central in guaranteeing a return of investment costs for  
771 claimholders, and returning investment costs is an important factor for stimulating  
772 innovation. On the other hand, some degree of access for other users of breeding material  
773 will also be important for enhancing innovation.

774 Currently, the mechanisms used to secure the income of the programs are *continuous*  
775 *upgrading* of the broodstock and *MTA contracts* with collaborating multiplier hatcheries and  
776 seed producers, combined with various *branding* strategies. *MTA contracts* are hindered by  
777 inadequate control and verification mechanisms, which have left the breeders in an  
778 unfortunate position for capturing the value of their improved material. The option that  
779 provides for the strongest protection mechanism – *securing patents* – has no proven  
780 applications in populations improved by selection alone, but may be highly relevant e.g. in  
781 populations that are genetically modified by artificial gene transfer. *Branding* and *mandatory*  
782 *certificates of origin* represent the two options that come closest to balancing the concerns for  
783 stimulating innovations and access, while not involving adverse effects on biodiversity. A  
784 system of *mandatory certificates of origin* that may be verified by DNA analysis of stored  
785 tissue samples from all broodstock would provide a strong verification mechanism at  
786 reasonable costs, and may be combined with *MTA contracts* and *branding*. Moreover, this  
787 option would not hinder access to genetic material for other breeders nor would it have an  
788 inherent tendency to dwindle the genetic pool. The particular situation for fish breeding  
789 suggests that there is a need for developing a *sui generis* property right particularly adapted  
790 to the needs of the branch. More legal research is necessary to outline how such a system can  
791 be framed to take care of the particular needs of the sector.

792           Regardless of the choice of protection for improved material, all actors would benefit  
793 from a legal system of free access to wild genetic material. This view is largely reflected in  
794 the proposal for a Norwegian Nature Diversity Act, where free access to genetic resources  
795 from the wild and from public collections receives a central place. However, there is a need  
796 for maintaining this public resource, which the proposed draft act seems to underestimate.  
797 Further examination of this issue is needed as this study concludes with two pertinent  
798 questions: Will the current model for genetic improvement in salmon endure the changes in  
799 the structure of the salmon farming industry and the emerging IPR regimes? Will other  
800 farmed species experience a similar development of genetic improvement programs as what  
801 has been seen in the salmon industry, or will new incentives be required? Furthermore, these  
802 issues are also highly relevant for developing countries, where the largest proportion of world  
803 aquaculture production is taking place, and where production of e.g. carps and tilapia, is very  
804 important for many small scale farmers and households involved in aquaculture. These issues  
805 and implications for the third world are not considered here due to the complexity, extend  
806 and specific conditions involved. However, it is a very important question requiring further  
807 examination.

808

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811

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ACCEPTED MANUSCRIPT

917 **Appendix 1**

918

919 **Questionnaire: Access to and protection of aquatic genetic resources**

920

921 **Background & introduction**

922

923 1. The organisation / enterprise

924 1.1. Please describe your type of institution / enterprise in terms of profit / non-profit, private /  
925 public, national/international owners, primarily research / commercial goals, organisation.

926

927 2. The collection

928 Please describe the fish genetic material – with a focus on salmon:

929 2.1 Are samples (genetic material) collected from natural environments, from gene banks,  
930 exchanged with other breeders?

931 2.2 Do the activities involve international or domestic exchange of aquatic genetic resources?

932 2.3 Please describe the utilisation of the collection: Scientific and economic purpose, terms of  
933 exchange, licensing / royalties.

934

935 **Perceptions and orientation to case questions**

936

937 3. Access to and protection of propagating material

938 3.1 What is your need or plans for exchange of genetic material? E.g. crossing with fish from  
939 other domestic or international breeding populations, gene banks or wild populations? Is there  
940 a need for improved access to genetic material?

941

942 3.2 Is there a need for protecting this genetic (propagating) material through some type of  
943 intellectual property rights (IPR) system (patents, trade marks), agreements on royalty or  
944 other technological/biological method?

945

946 3.3 Do you see any practical possibilities for applying a legal protection of your genetic  
947 material against unauthorised breeding (e.g. by applying DNA-fingerprinting for  
948 identification of fish origin, organisational possibilities in the company, patenting of genes or  
949 fish or by genetic engineering (GMO))? If so, what strategies do you see are possible, and  
950 which would you prefer.

951

952 3.4. Do you have any plans for implementing such protection strategy as mentioned above?

953

#### 954 4. Actors/stakeholders/industry's positions /interests

955 4.1 Have your and/or your sector's interests / positions regarding questions of access to  
956 genetic material changed over time?

957 4.2 Have your and/or your sector's interests / positions regarding questions of protection of  
958 genetic material changed over time?

959 4.3 Which are the most important factors that have led to eventual changes? Technological,  
960 biological, organisational, market etc?

961

#### 962 5. Exploring changes in positions

963 In general, access regulations are tightening while intellectual property rights (IPR) protection  
964 is strengthened. At the same time, users of genetic resources are generally opposed to  
965 cumbersome access regulations and in favour of a wider scope for protection through IPR  
966 legislation.

967 5.1 Is there a need for strengthened access regulations within your field?

968 5.2 Is there a need for strengthened IPR systems within your field?

969 5.3 Are access regulations in any way likely to enhance or hamper transactions with aquatic  
970 genetic resources in your field of activities?

971 5.4 Are strengthened IPR systems in any way likely to enhance or hamper innovation  
972 involving aquatic genetic resources in your field of activities?

973 5.5 How do you perceive *access* to decision-making processes (through e.g. hearings of  
974 regulation proposals) relevant to the evolving regulatory framework – and has this changed  
975 over time?

976

977 6. Comparative view with related sectors and other regions

978 With regard to the perceptions of access to and protection of aquatic genetic resources:

979 6.1 How do you perceive ‘your’ sector to respond to the situation: Are there national  
980 differences, technological differences, or differences in size that will affect unity in the  
981 sector?

982 6.2 Do you perceive a harmonisation process with related enterprises in other countries (such  
983 as Chile, Canada, Scotland, other regions)?

984 6.3 Which do you perceive as the most important factors accounting for differences in  
985 competitiveness between Norwegian companies in your sector and comparative European and  
986 other foreign or multinational companies?

987

988 7. Perceptions of international regulations and domestic legislation

989 7.1 Are you familiar with the evolving international regulatory frameworks?

990 Access and benefit sharing regulations: CBD, Bonn Guidelines, MTA (Material transfer  
991 Agreement).

992 Intellectual property rights systems: TRIPS of the WTO, other options.  
993 7.2 Are you familiar with the evolving domestic (Norwegian, other country) legislation  
994 pertaining to access to and protection of genetic resources?  
995 Access regulation: In Norway novel legislation is to be proposed by Biomangfoldlovutvalget.  
996 Intellectual property rights systems: Norwegian acceptance of the EU Patent Directive.  
997 7.3 If so, how is your perception of and experience with the regulatory frameworks –  
998 preferred alternatives? Does it or will it promote development, utilization and innovation in  
999 your sector?  
1000  
1001  
1002