

5 DISSEMINATION OF GENETICALLY IMPROVED STRAINS AND MATERIAL TRANSFER AGREEMENTS ⁵⁰

5.1 Introduction

This section covers both (i) the transfer of genetically improved strains from one country to another and (ii) the multiplication and dissemination of germplasm within countries. Although related, there are also issues specific to each and they are therefore dealt with separately.

Article 9.1.2 of the Code of Conduct for Responsible Fisheries requires that “*States should promote the responsible development and management of aquaculture, including an advance evaluation of the effects of aquaculture development on genetic diversity and ecosystem integrity, based on the best available scientific information*”. In Article 9.3, it continues: “*States should conserve genetic diversity and maintain integrity of aquatic communities... should cooperate in the elaboration, adoption and implementation of international codes of practice and procedures for introductions and transfers...*” and “*minimize the risks of disease transfer and other adverse effects on wild and cultured stocks...*”. Technical guidelines for implementation of Article 9 (Aquaculture Development) of the Code were developed in 1997⁵¹ and a wide range of instruments and tools has since been elaborated in the pursuit of responsible and sustainable aquaculture development. These guidelines also strive for consistency with the Convention on Biological Diversity⁵² (see also Chapter 2) and other policy advisories designed to ensure wise use of wild and improved genetic resources.⁵³

The following sections give general guidance on the dissemination of genetically improved strains between and within countries, with particular

⁵⁰ Contributed by R. E. Brummett, M. C. M. Beveridge, R. W. Ponzoni, R. J. Lawton and D. M. Bartley
⁵¹ FAO (1997). Aquaculture Development. *FAO Technical Guidelines for Responsible Fisheries*. No. 5, <ftp://ftp.fao.org/docrep/fao/003/W4493e/W4493e00.pdf>.

⁵² <http://www.cbd.int/default.shtml>

⁵³ ICES (2004) *Code of Practice on the Introductions and Transfers of Marine Organisms* <http://www.ices.dk/reports/general/2004/ICESCOP2004.pdf>; Hewitt, C.L., Campbell, M.L. & Gollasch, S. (2006). *Alien Species in Aquaculture. Considerations for Responsible Use*. <http://www.iucn.org/dbtw-wpd/edocs/2006-036.pdf>. IUCN, Gland, Switzerland; WorldFish Center (2002) *Nairobi Declaration on Aquatic Biodiversity and Use of Genetically Improved and Alien Species for Aquaculture in Africa*. http://www.worldfishcenter.org/cms/list_article.aspx?catID=39&ddlID=109. WorldFish Center (2003) *Dhaka Declaration on Ecological Risk Assessment of Genetically Improved dFish*, http://www.worldfishcenter.org/Pubs/Dhaka%20booklet/Dhaka_booklet.pdf

reference to lines of fish improved through traditional selective breeding, as opposed to living modified organisms (LMO's)⁵⁴ or transgenic hybrids, which might be better considered as alien species introductions. These guidelines should serve as a starting point for the development of more situation-specific guidelines. The information provided is of technical nature, which is the focus of these guidelines. It does not cover some policy and legal aspects, such as access and benefit-sharing or intellectual property, that also regulate access to, and conditions to use, fish genetic resources.

As mentioned before, this chapter does not focus on the exchange of wild genetic resources, which may be provided to other countries for the purposes of research, breeding and training for aquaculture. Exchange mechanisms for genetic resources for food and agriculture in other sectors, such as crops, have so far received much more international attention than fish genetic resources for aquaculture. These mechanisms normally detail the rights and obligations of the provider and recipient with respect to the materials being transferred. Similar trends could be expected in aquaculture as exchange of fish genetic resources will increase in the next years with breeding programmes developing all over the world.

5.2 Transfer of an improved strain to another country

5.2.1 Introduction

The Code promotes the use of the *Code of Practice on the Introductions and Transfers of Marine Organisms 2004 developed by the International Council for the Exploration of the Sea (ICES) and Technical Guidelines on the Responsible Use and Control of Alien Species on the purposeful movement of fish from one country to another and encourage states to make these transfers in such a way that risks to indigenous biological and genetic diversity are minimized. There have been numerous documented cases of competition, predation, disease transfer and habitat damage resulting from the introduction of alien species and these should be treated with utmost caution.*⁵⁵ In the case of selected lines, there is evidence from salmonids that modified gene

⁵⁴ The Cartagena Protocol on Biosafety defines an LMO as an organism resulting from direct DNA manipulations or the fusion of cells from outside of a taxonomic family.

⁵⁵ Sindermann, C.J. 1993. Disease risks associated with importation of non-indigenous marine animals. *Marine Fisheries Review*, **54**, 1-10; McVicar, A. H. (1997) Disease and parasite implications of the coexistence of wild and cultured salmon populations. *ICES Journal of Marine Science*, **54**, 998-1008.

frequencies in fishes planted for stock enhancement or used in aquaculture can, when released into the wild and crossed with the wild genome, reduce the whole lifetime fitness of indigenous populations of the same or closely related species through genetic introgression (i.e. introduction of alleles into the wild population from the improved strain).⁵⁶

5.2.2 *Guidance on transfer*

Rather than local, regional or international political boundaries, the biologically more important geographical unit to consider when contemplating a transfer of improved aquatic germplasm is the watershed.⁵⁷ Although government agencies should take into consideration both transfers within and from outside the country, a proposed transfer of fish within a watershed across political boundaries might be considered less critically than a transfer from one watershed to another within the same political jurisdiction or country.

In the absence of a dedicated national authority for germplasm transfers, requests for the introduction of improved lines should be made to the highest responsible fisheries official in the importing country (e.g., Director of Fisheries, Environment or Agriculture) on the basis of a sound environmental impact assessment (EIA) and cost: benefit analysis.

EIA guidelines and the analysis of potential negative costs associated with any importation should take into consideration:

- The presence of potentially valuable conspecific genetic diversity in the specific watershed to which the new material is to be imported.
- The presence of other rare or endangered aquatic biodiversity that might be negatively impacted by the introduction.
- The presence of suitable indigenous local species or genetic improvement strategies of existing farmed fish to use as an alternative introduction.

⁵⁶ McGinnity *et al.* 2003. Fitness reduction and potential extinction of wild populations of Atlantic salmon, *Salmo salar*, as a result of interactions with escaped farmed salmon. *Proceedings of the Royal Society of London, Series B*, **270**: 2443-2450; Jonsson, B. and Jonsson, B. (2006) Cultured salmon in nature: a review of their ecology and interactions with wild fish. *ICES Journal of Marine Science* **63**: 1162-1181; Verspoor, E., Stradmeyer, L., Neilsen, J. L. (eds.). 2007. *The Atlantic Salmon. Genetics, Conservation and Management*. Blackwells, Oxford.

⁵⁷ The term watershed is used here to refer to interconnected waterbodies, which may be defined at a catchment or sub catchment level.

The ICES Code recommends a framework for the introduction of aquatic organisms covering both alien species and improved lines. The Code is conceptually simple and contains the requirements that any person, agency or business planning to use non-indigenous germplasm should follow. The requirements start with the preparation of a proposal that will be reviewed by an independent body. The results of the review will be communicated back to the proponents for approval, revision or rejection. If the proposal to introduce a new species is approved, then the Code calls for fish health management, monitoring and reporting.

5.2.3 Material Transfer Agreements (MTAs)

If the request for introduction is approved, the transfer should be consistent with relevant international and national laws such as those related to access and benefit-sharing, property rights or biosecurity. The conditions to access and use such genetic material are normally set through a Material Transfer Agreement. The MTA should be certified by the national empowering body of the importing country and communicated to the FAO Database on Introductions of Aquatic Species (DIAS).⁵⁸

Material transfer agreements can be legally binding agreements that are generally drawn up to document and describe conditions for the transfer of tangible biological materials, including material used in research and genetically improved fish, from one entity to another. An example of an MTA is shown in Annex 5.1.

5.2.4 Protocols for transfer

The following protocols are based on international codes of practice, which may include one or more of the existing protocols of the different countries, and are included to serve as general guidelines. They may be seen as an addition to the individual national requirements, or they may form the basis for elements of national regulations.

5.2.4.1 Exporting (transferring) country or organization

Appended to the Material Transfer Agreement should be specific technical information concerning the requested germplasm, particularly:

⁵⁸ FAO Database on Introductions of Aquatic Species (DIAS) <http://www.fao.org/fi/website/FISearch.do?dom=introsp>, FishBase (<http://www.fishbase.org>)

- scientific and local names of the transferred stock;
- salient features of the transferred stock that make it desirable for importation;
- intended use of the transferred stock and the exact location of that use;
- number of individuals transferred,
- number and type (e.g. full sib, half sibs) of families represented in the transfer;
- age or ontological state (e.g. egg, larvae, post-larvae, swim-up fry, fingerling) of transferred individuals;
- disease and/or pathogen exposure history of the stock;
- genotypic and phenotypic sex of the transferred stock (e.g. normal females, normal males, normal mixed sex, genetically mixed sex but phenotypically all male – hormone treated).

The material to be transferred must be accompanied with a veterinary certification of freedom from prescribed parasites, pathogens and any other biota issued by a competent authority. Shipment water, if any, should be clean and free from suspended particulate matter. If possible, the transferred stock should be disinfected prior to shipment.

Most of this information should have been provided in the original proposal requesting importation of the species into the country. It can be duplicated with the MTA to help ensure compliance with the conditions of the agreement.

5.2.4.2 Importing (receiving) country or organization

A major concern for importing countries is fish health and the prevention of trans-boundary pathogens. Relevant sections of Technical Guidelines⁵⁹ on the subject call for a national aquatic animal health strategy and are summarized here. A formalized national aquatic animal health strategy provides countries with a “road map”, based on national needs and priorities, for achieving the desired aquatic animal health status. The components of a national strategy include: pathogens to be considered, disease diagnosis, health certification and quarantine measures, disease zoning, disease surveillance and reporting, contingency planning, import risk analysis, policy frameworks and regional capacity building.

⁵⁹ FAO. 2007. Aquaculture Development. 2. Health management for responsible movement of live aquatic animals. FAO Technical Guidelines for Responsible Fisheries. No. 5. Suppl. 2. Rome, FAO. <ftp://ftp.fao.org/docrep/fao/010/a1108e/a1108e00.pdf>

Consistent with the World Trade Organization (WTO) and the *Agreement on the application of sanitary and phytosanitary measures* (SPS Agreement), all countries reserve the right to take sanitary and phytosanitary measures necessary for the protection of human, animal, or plant life. In determining the appropriate level of protection (ALOP), relevant economic, social and ecological factors have to be taken into account.

Whenever possible, rather than adult brood fish, stocks should be imported as eggs or as other early life history stages. The longer a fish lives, the more likely it is to come into contact with a pathogen. Also, early life history stages carry less sub-clinical infections than adults, they are easier to maintain in quarantine and eggs cannot transmit certain pathogens, e.g. gill parasites.

Prior to importation, qualified personnel in the importing country should consult the World Organization for Animal Health (OIE) which is the World Trade Organization's standard setting body for fish pathogens, existing literature and disease networking services⁶⁰ to identify possible areas for concern in regards to fish health. Every effort should be made to obtain fish from accredited hatcheries that practice good fish health management and ensure the quality of the exporting country's veterinary certification. Upon arrival, shipments should be examined for freedom from prescribed pathogens, e.g. those officially listed by OIE, parasites and other unapproved biological material, such as hitchhiking species for which import was not requested. If diseases are identified, the shipment should be destroyed and disposed of in an appropriate manner, unless effective treatment can be guaranteed.

Quarantine should maintain a group of aquatic animals in isolation with no direct or indirect contact with other aquatic animals, in order to undergo observation for a specified length of time and, if appropriate, testing and treatment, including proper treatment of the effluent waters⁶¹. The level of quarantine should relate to the risk of disease spread. First time importation of alien species, or species collected from the wild or sources of unknown health status, may require more stringent quarantine levels.

⁶⁰ http://www.oie.int/eng/ea_index.htm; Permanent Advisory Network for Diseases in Aquaculture (PANDA; <http://www.europanda.net/>), Aquatic Animal Pathogen and Quarantine Information System (AAPQIS, <http://www.aapqis.org/main/main.asp>).

⁶¹ OIE. 2005. *Aquatic animal health code*. 8th Edn. Paris.
http://www.oie.int/eng/normes/fcode/A_summry.htm

It should be understood that physical inspection and quarantine are of only limited effectiveness in preventing transfer of pathogens. Any bacteria or virus to which the imported stock is already immune or only displays sub-clinical symptoms, i.e. appears healthy, can be detected through experimentation and immunoassay but will not be eradicated by holding in isolation. Testing and observation in quarantine may involve co-habitation experiments with local species or placing quarantine animals under increased stress to see if disease problems arise.

Nevertheless, quarantine does give authorities the opportunity to observe the stock for a period of time, which might give indications of problems. Quarantine in an appropriate facility should be for a period of at least 28 days but must be determined by the specific pathogens under consideration. Upon arrival in quarantine, introductions should be disinfected in a prophylactic bath and, if feasible, put on an oral course of broad-spectrum antibiotics. All water, packing materials, containers or other associated shipping materials should be sterilized or destroyed.

Quarantine sites must be secure against escapes and discharges of water. Water must be safely disposed of. If the quarantine unit suffers a disease outbreak treatment is sometimes possible. However chemical therapy can cause other problems such as antibiotic resistance and should be used under expert advice. When the outbreak cannot be controlled, diseased stocks should be destroyed and disposed of after sterilization in an approved manner. Water quality at the quarantine unit should be monitored at regular intervals and periodic checks for introducible parasites and diseases carried out. A list of known parasites, diseases and pathogens should be maintained and the exporter advised in case of unexpected occurrence of parasites or pathogens.

Original imports should not be transferred to natural environments. The ICES Code recommends distributing only the F1 generation of imported species following quarantine of the original parents.

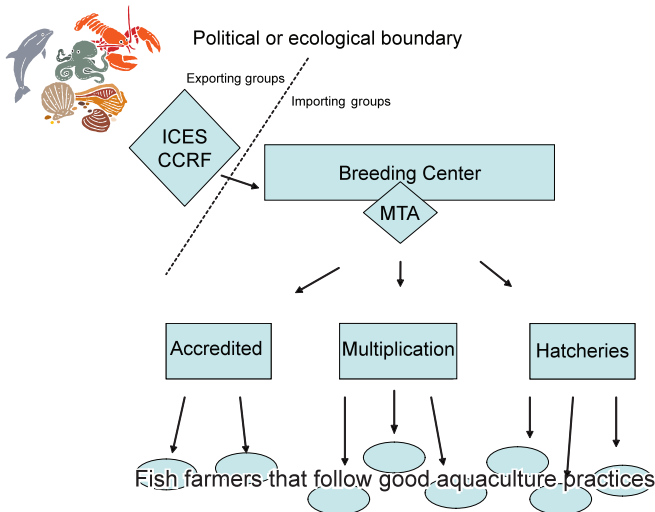
Zoning areas of aquaculture use and conservation (Chapter 9) also apply to fish health management. Countries may establish zones where certain pathogens are known to exist and disease free zones; zones should be based on ecological criteria rather than on political boundaries. Movement of animals between zones where the same pathogens exist or from a disease free zone would not be problematic. Animals may not be moved from a zone having pathogens that are absent in the receiving zone.

5.3 Dissemination of an improved strain within a country as part of a rational aquaculture development strategy

Given that original imports should not be transferred to natural environments, a process of multiplication must be carried out prior to the dissemination of seed from genetically improved strains.⁶² Improved strains should be disseminated through a system of accredited hatcheries and breeding centers (Figure 5.1). Accreditation of hatcheries that function as multipliers of the improved stocks from the breeding centers should be carried out by an evaluation team of the regional breeding centre. Accredited hatcheries

Figure 5.1

Dissemination system for the introduction and use of genetically improved strains in aquaculture. Diamonds represent guidelines and codes of practice that should be followed before dissemination. There should be no movement of germplasm except as noted by the arrows. MTA = Material Transfer Agreement; ICES and CCRF refer to the recommendations and guidance in the International Council for the Exploration of the Sea Code of Practice on Introductions and the FAO Code of Conduct for Responsible Fisheries, respectively.



⁶² *Pioneering Fish Genetic Resource Management and Seed Dissemination Programmes for Africa: adapting principles of selective breeding to the improvement of aquaculture in the Volta Basin. Workshop Proceedings, 27-30 March 2007, FAO, Rome.*

must meet technical requirements established by the evaluation team and have an agreement with the breeding center concerning standard operating management and dissemination procedures.

The main objective of developing a hatchery accreditation system is to ensure implementation of guidelines on maintaining genetic quality of fingerlings supplied by the hatcheries to farmers and safeguarding native genetic resources. It is recommended that:

- In order to receive genetically improved seed hatchery operators must apply for accreditation to the breeding center; the application would be reviewed on the basis of a set of criteria that could include the elements listed here as well as other relevant information (e.g. facilities, experience, location, earlier performance).
- Brood stock would be supplied by breeding centers to the accredited hatchery and replaced following a well defined protocol and on a needs basis.
- Hatcheries being considered for accreditation should be well managed and follow best aquaculture practices according to the judgment of qualified technical staff.
- A system of good record keeping of supplied brood stock or fry to the hatchery should be implemented.
- A system to monitor distribution of fingerlings from accredited hatcheries to producers should be implemented in order to monitor the geographical distribution of genetically improved stocks. This would enable assessments of potential economical and environmental impacts of the improved strains being disseminated.
- Hatcheries should implement quality control measures, and their accreditation status should be regularly reviewed.

5.4 Discussion

There has been considerable movement of alien species and strains for aquaculture purposes,⁶³ but very little evaluation of their impacts, either good or bad.⁶⁴ Governments are requested to maintain records on the introduction and subsequent distribution of alien species and genetically improved stocks

⁶³ FAO Database on Introductions of Aquatic Species (DIAS) <http://www.fao.org/fi/website/FISearch.do?dom=introsp>, FishBase (<http://www.fishbase.org>)

⁶⁴ A notable exception is, *An Impact Evaluation of the Development of Genetically Improved Farmed Tilapia and Their Dissemination in Selected Countries* by Asian Development Bank. ADB 2005; available at www.adb.org/publications.

in their countries and to report the information to FAO. FAO maintains a Database of Introductions of Aquatic Species (DIAS) that also contains information on impacts. The coverage of alien species is increasing and allows for better decisions on introducing alien species; there is no comparable information source on the impacts of genetically improved strains.

Many movements of improved stocks and alien species are poorly controlled, even though there is wide recognition that control is needed due to the risks involved. The Hazard Analysis and Critical Control Point Approach (HACCP)⁶⁵ is being promoted by the aquarium trade and fish and wildlife scientists in some areas, primarily to reduce risks of importing countries bringing in hitchhikers and pathogens and to improve public awareness. HACCP is also being promoted by salmon farmers in order to reduce the likelihood of escapes. MTAs present a way of helping improve controls, but to date they have been little used in aquaculture and fisheries transfers.

⁶⁵ See http://seagrant.umn.edu/downloads/ais-haccp_manual.pdf for guidance on applying the HACCP principles to aquatic invasive species.

Annex 5.1

*Material Transfer Agreement*¹

The following example of a Material Transfer Agreement is based on one currently used by the WorldFish Center.

To: The request for improved germplasm should be made to a competent authority that has legal and political authority to disseminate the material.

I/we order the following material:

A list of material being requested should be attached here including the detailed description of the material, its intended use and location of use as listed in the text.

I/we agree

- to abide by the provisions in the Convention on Biological Diversity;
- to preclude further distribution of germplasm to locations at which it could have adverse environmental impact;
- not to claim ownership over the material received, nor to seek intellectual property rights over that germplasm or related information;
- to ensure that any subsequent person or institution to whom I/we make samples of the germplasm available, is bound by the same provision;
- that the responsibility to comply with country's biosafety and import regulations and any of the recipient country's rules governing the release of genetic material, is entirely mine/ours;
- to follow the quarantine protocols suggested by the FAO Technical Guidelines on Health Management for Responsible Movement of Live Aquatic Animals and the WorldFish Center;
- that when germplasm is transferred beyond the boundaries of our country, we will abide by the relevant international codes and guidelines, e.g. the CCRF, ICES, and the OIE.

Date:

Name of person or institution requesting the germplasm:

Address:

Shipping address (if different from the above):

Authorized signature:

¹ From the International Network for Genetics in Aquaculture (INGA) www.worldfishcenter.org

6 ECONOMIC CONSIDERATIONS RELEVANT TO GENETIC IMPROVEMENT PROGRAMMES⁶⁶

6.1 Evidence about genetic improvement

In terrestrial animal and plant species genetic improvement programmes have made a substantial contribution to productivity increases and to industry viability. By contrast, most aquaculture stocks in current use in developing countries are genetically similar or inferior to wild, undomesticated counterparts.^{67 68} There is evidence indicating that genetic improvement programmes implemented in aquatic animal species can have the same positive effect they have had in livestock and crops. The Genetically Improved Farmed Tilapia (GIFT)⁶⁹ (*Oreochromis niloticus*) and Jayanti rohu⁷⁰ (*Labeo rohita*) are two examples in developing countries; The genetic improvement programmes implemented in these two species were modeled on the successful project with Atlantic salmon (*Salmo salar*) initiated in the 1970s in Norway. These improved strains are very appealing and valuable to farmers due to their greater growth and survival rates.

6.2 Limiting factors to the widespread adoption of the technology

Proof about genetic improvement can be easily obtained under controlled, experimental conditions, in which a set of necessary records are systematically kept. However, the ‘visibility’ of genetic gains in aquatic animals under farming conditions is extremely low. Important traits from a production viewpoint, such as growth rate, survival, and freedom from disease, are not only influenced by genetics, but also, and to a large extent, by the environment. This makes it difficult, if not impossible, to precisely ascertain the cause of observed changes in the production system. Furthermore, genetic

⁶⁶ Contributed by Raul W. Ponzoni.

⁶⁷ Eknath, A.E. 1991. Simple broodstock management to control indirect selection and inbreeding: Indian carp example. NAGA, The ICLARM Quarterly 738: 13-14.

⁶⁸ Brummett, R.E., Angoni, D.E. and Pouomogne V. 2004. On-farm and on-station comparison of wild and domesticated Cameroonian populations of *Oreochromis niloticus*. Aquaculture 242, 157-164.

⁶⁹ Gupta, M. and Acosta B. 2004. From drawing board to dining table: The success story of the GIFT project. NAGA, WorldFish Center Quarterly 27, (3&4), 4-14.

⁷⁰ Mahapatra, K., Jana, R.K., Saha, J.N., Gjerde, B. and Sarangi N. 2006. Lessons from the breeding program of Rohu. In: Ponzoni, R.W., Acosta, B., Ponniah, A.G. (eds.), Development of aquatic animal genetic improvement and dissemination programs: Current status and action plans, WorldFish Center Conference Proceedings 73, Penang, Malaysia, pp. 34-40.

improvement programmes require an initial investment, as well as recurrent annual expenditure to run them. In view of these costs, government institutions may remain unconvinced about the wisdom to invest in such programmes unless clear benefits to the nation can be confidently anticipated. In order to generate information that can assist in making logical decisions about genetic improvement, economic considerations at two critical levels have to be made, namely, when defining the programme's breeding objectives, and when assessing the costs and benefits of implementing the programme within a reasonable time horizon. These two levels are, of course, related, but they are best dealt with separately.

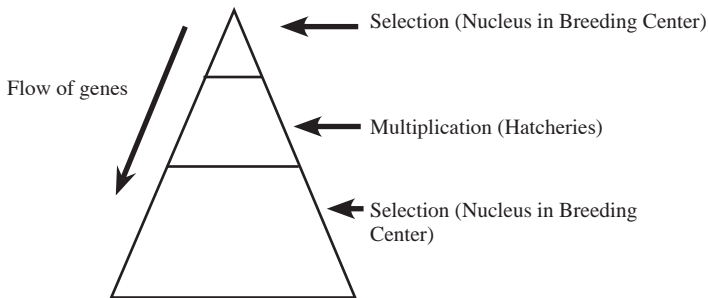
6.3 Breeding objectives

In animal production, genetic improvement typically takes place in a very small fraction of the population. The genetic improvement achieved in that 'elite' or 'nucleus' of superior animals is multiplied and disseminated to the production systems (Chapter 5). The flow of genes is graphically illustrated in Figure 6.1. The implementation of a genetic improvement programme in a relatively small number of animals can be enough to service a very large population involved in production. The nucleus supplies brood stock to hatcheries (multipliers of genetically improved stock). In turn, the fry produced by hatcheries are grown out in the production sector.

With this industry structure (Figure 6.1; see also Chapter 5) farmers produce virtually all the fish for consumption. Hence, the breeding objective must be

Figure 6.1

Flow of genes from the Nucleus in the Breeding Center to the production system.



defined according to farmers' interests, considering the nucleus and the dependent hatcheries as sectors servicing farmers. The biological traits included in the breeding objective must be those that influence profit, i.e. income, expense, or both, at the farm level. They are shown for a simple case in Table 6.1.

A profit equation has the form:

$$\text{Profit (P)} = \text{Income} - \text{Expense}$$

This equation can be expressed as a function of the biological traits in Table 1. Scaling it up to a production unit of 1000 fish stocked we may write:

$$P = 1000 [(W) (S/100) (\text{price per unit weight of fish}) - \text{FI} (\text{price per unit weight of feed})] - K$$

where: W is weight at harvest, S is the percent survival to harvest time, FI is the total amount of feed consumed per fish to harvest time, and K represents fixed costs. Fixed costs are those that a producer incurs in no matter what the level of production is, and can be ignored when deriving the economic value for each trait. This equation enables the estimation of the economic value for each trait in the breeding objective. The economic values usually differ between traits because of the unit of measurement, their expression in the production system, and because of their relative economic importance. For instance, survival rate is expressed in all fish stocked, but market weight in only those that survive to market. Also, if the feed price is low (high) relative to fish price, then feed intake will have a lower (greater) economic value than harvest weight.

Assigning economic values to the traits in the breeding objective enables the calculation of genetic gains in economic units. The inclusion of traits associated with expense as well as those associated with income is very

Table 6.1 Biological traits included in the breeding objective.

Effect on profit	Trait	Logic for inclusion
Income	Harvest weight (W)	Fish are marketed on a weight basis, heavier fish generally fetch a greater price. Fast growing fish will reach a particular weight faster than slow growing fish.
	Survival rate (S)	Greater survival results in a greater number of fish available for consumption or for sale.
Expense	Feed intake (FI)	Feed is a major production cost. Greater growth rate may result in greater feed consumption.

important because if only income traits are included, the economic worth of genetic gain may be overestimated. The economic values for each trait can be evaluated numerically by computing the difference $P^* - P$, where P is the profit at the average value for all traits, and P^* is the corresponding value after increasing the trait in question by one unit, while leaving the other traits at the average value. Using the equation for P above, we find that the economic values for W , S and FI are US\$0.85, US\$3.00 and - US\$0.56, respectively.

6.4 Costs and benefits of a genetic improvement programme

Whereas there are several ways of manipulating the genetics of aquatic animals (e.g. polyploidy, cross-breeding), selective breeding is the only approach whereby the gains achieved can be multiplied, transmitted to other animals and passed on from generation to generation. This paper focuses exclusively on selective breeding. Annual responses to selection often look negligible when compared with the gains that may be achieved through expansion, improved nutrition and intensification of the production system. However, response to selection measured in one population does not provide a good measure of the potential impact of genetic gains. With an adequate industry structure, the small but cumulative responses to selection achieved in a nucleus undergoing genetic improvement, can be passed over to a multiplier tier of hatcheries and in turn, from hatcheries to farmers (Figure 6.1; Figure 5.1 Chapter 5). This potential for expression of small accumulated changes in thousands or millions of animals is what makes genetic improvement programmes one of the most powerful and cheapest means of increasing the efficiency of aquaculture.

6.5 Factors affecting the economic benefit and the benefit/cost ratio of genetic improvement programmes

There is an established methodology that is generally used in studies about the economic consequences of implementing a genetic improvement programme.⁷¹ The results of such studies are dependant on the assumptions made about the numerous factors that may affect the outcome. Table 6.2 lists such factors and provides numerical values that cover a range of plausible scenarios. In practice, one can test the robustness of the assumptions made by testing the sensitivity of the results to realistic deviations from such

⁷¹ Ponzoni R.W., Nguyen, H.N. and Hooi Ling Khaw. 2007. Investment appraisal of genetic improvement programs in Nile tilapia (*Oreochromis niloticus*). *Aquaculture* 269, 187-199.

assumptions. The values shown in Table 6.2 were used in the calculation of the economic benefit (EB) and benefit/cost ratio (BCR) resulting from the genetic improvement programme. When several values are shown for a given parameter, the one in bold was used as a reference to generate “base results” (Table 6.3), other values being used in the sensitivity analysis (see section 6.8).

6.6 General usefulness of the results

The conduct of economic appraisals of genetic improvement programmes

Table 6.2 Parameter values for economic evaluation of selective breeding programme.

Parameter	Value(s) ^a
Economic parameters	
Initial investment in programme	50 000, 75 000 , 100 000 US\$
Discount rate	0.05 , 0.10, 0.15 d (fraction)
Discount factor	Computed from d values $r = 1 / (1+d)$
Annual (recurrent) costs	30 000, 60 000 , 90 000 US\$
Price of fish (farm gate)	0.001 , 0.0015, 0.002 US\$/g
Cost of feed	0.00056 US\$/g
Number of years over which scheme is evaluated	10 years
Biological parameter	
Generation interval in females	1.0 year
Generation interval in males	1.0 year
Heritability estimates	W values = 0.2, 0.3 , 0.4; S values = 0.05, 0.08 , 0.12; FI values = 0.16, 0.25 , 0.3
Cumulative feed intake	400 g
Operational parameters	
Year when first returns are obtained	2 , 3, 4 years
Number of fish marketed for slaughter/year ^b	(1) 2.205; (2) 6.6248 ; (3) 47.32; (4) 338.0 in millions
Harvest weight	300 g
Survival rate	85 %

^a When several values are presented, the value in bold was used as a reference to generate “base results”, whereas the other values were used in the sensitivity analysis.

^b The figures correspond to different reproductive technological levels, from a very low one, to higher ones. Level 1 corresponds to poor management and natural spawning in ponds; Level 2 is as Level 1 but with good management; Level 3 uses reproduction in hapas, egg collection from the mouths of females and artificial incubation in the nucleus, and natural spawning with good management in hatcheries; Level 4 assumes that reproduction in hapas (as described for Level 3) is used in both the nucleus and in hatcheries.

Table 6.3 Discounted cash flow ($d = 5\%$), economic benefit and benefit/cost ratio for the base situation.

Year	Discount factor	Discounted returns	Discounted costs (000's US\$)	Economic benefit (000's US\$)	Benefit/cost ratio
0	1.0	0	0	-75	-
1	0.952	0	57.14	-132.14	0
2	0.907	130.56	111.56	-56.01	0.7
3	0.864	379.23	163.39	140.84	1.6
4	0.823	734.48	212.76	446.73	2.6
5	0.784	1 185.60	259.77	850.83	3.5
6	0.746	1 722.64	304.54	1 343.10	4.5
7	0.711	2 336.40	347.18	1 914.21	5.5
8	0.677	3 018.35	387.80	2 555.56	6.5
9	0.645	3 760.62	426.47	3 259.15	7.5
10	0.614	4 555.90	463.30	4 017.60	8.5

is especially useful from a national perspective, where decision-makers will focus on the calculation of what additional wealth to the nation would emerge from the implementation of such a programme. The findings are also applicable to a vertically integrated firm controlling the nucleus breeding center, the hatcheries and the production sector (Figure 6.1). The results strongly suggest that very favorable returns on investment can be obtained from genetic improvement (Table 6.3). Even for the very conservative values assumed for the base level of factors in Table 2, EB and BCR were extremely favorable, at four million US\$ and 8.5, respectively, after 10 years of programme implementation. The “break-even point”, that is, the moment when profit turns from negative to positive, occurs in year 3.

6.7 Positioning the base parameter values in a real life context

The base parameter values were chosen here to represent a very conservative scenario. For instance, when both fish price and reproductive efficiency were set close to the lower limit of the values that can be expected, EB turned from negative to positive by the third year of programme implementation (Table 6.3), and by year 10 the BCR was 8.5. In practice, the fish price is likely to be greater, and using very simple and inexpensive technology the reproductive efficiency of the fish can be greater. Hence, the EB and BCR obtained with the base parameter values should be taken as the minimum that can be expected from a genetic improvement programme such as the one in question.

6.8 Sensitivity analysis

The factors that can affect EB and BCR (Table 6.2) may be grouped into three categories: (i) Biological (heritability values, accounting for feed intake), (ii) Economic (initial investment, annual cost, discount rate, price of fish), and (iii) Operational (year when first return occurs, reproductive efficiency).

6.8.1 Biological parameters

The effects of two biological factors were studied, namely, the heritability values for the traits in the breeding objective, and the approach taken regarding feed intake. Greater heritabilities resulted in greater genetic gain and consequently in greater EB and BCR. Partly, the heritability value is a property of the trait and the population in question, but it may be improved by reducing the environmental variance by managerial means. Although EB and BCR were only moderately sensitive to rather large variations in the heritabilities, management practices that may lead to reduced environmental variance in the nucleus should be adopted whenever possible. The production of progeny from synchronized spawnings and its grow-out in standard and uniform conditions are examples of such practices.

With regards to feed intake, despite a lack of genetic parameters for this trait in most cultured species, it should be included in the breeding objective because generally feed is a major cost in aquaculture production. The parameter values used for feed intake were based on a number of assumptions, but note that ignoring feed intake involves more radical assumptions, namely, that feed requirements do not increase with greater growth rate, or that the cost of the additional feed is zero; the latter assumption is certainly not correct. With regards to the former, there is experimental evidence indicating that in Atlantic salmon there is a correlated response in feed intake, as well as in feed efficiency, to selection for growth rate.⁷² Also, in brown trout (*S. trutta*) there is a correlated response in feed intake, but there is no change in the efficiency of feed utilization.⁷³ These experimental results, coupled with the importance of feed costs in the production system, provide ample justification for the inclusion of the trait in the breeding objective. Ignoring feed intake in the breeding objective would result in a gross overestimate of the benefit of a

⁷² Thodesen, J. 1999. Selection for improved feed utilization in Atlantic salmon. Doctor Sci. Thesis, Agricultural University of Norway, 108 pp.

⁷³ Mambrini, M., Labbe, L., Randriamanantsoa, F. and Boujard, T. 2006. Response of growth selected brown trout (*Salmo trutta*) to challenging feeding conditions. *Aquaculture* 252, 429-440.

genetic improvement programme emphasizing growth rate. This result is consistent with what is observed in terrestrial animal species.⁷⁴ Although it is unlikely that feed intake will be measured in any breeding programmes in developing countries, the estimation of phenotypic and genetic parameters for this trait by research institutions would be highly desirable to increase our confidence on the parameter values used for genetic evaluations and in predicting responses to selection.⁷⁵

6.8.2 Economic parameters

EB and BCR were both insensitive to the magnitude of the initial investment, whereas the annual cost of the programme had a greater effect on BCR than on EB. By contrast, discount rate, had a greater effect on EB than on BCR. The discount rate (d , Table 6.2) is the interest rate used in calculating the present value of expected future benefits and costs. The discount factor ($1/(1+d)^y$, Table 6.2) is the factor that transforms expected benefits or costs in any future 'y' year into present value terms. The choice of a discount rate in a study such as this is always open to debate. In the present context the costs and benefits are being assessed from the viewpoint of society as a whole (as distinct from an individual firm or person), and the discounting technique is used to express such costs and benefits in terms of net present value. This net present value can then be compared to that obtained from alternative uses of the limited resources a nation may presently have for investment. In the present case, despite the assumed low reproductive rate, even at a high discount rate of 15 percent EB remained highly positive and BCR was about 75 percent of that for the base situation.

The price of fish had a large effect on both EB and BCR. Although prices are most often beyond planners' and farmers' control, bigger fish often fetch greater prices in the market, so an added (and not accounted for) benefit of the selection programme could be better prices in the future.

6.8.3 Operational efficiency

The year when first returns occur is likely to be a reflection of how soon the programme gets fully underway, including the distribution of stock to hatcheries. There may be delays in the latter activities despite on-going

⁷⁴ Ponzoni, R.W. 1992. Genetic improvement of hair sheep. FAO Animal Production and Health Paper no. 101, 168 pp. (Rome, Italy).

⁷⁵ Doupe, R.G., Lymbery, A.J. 2003. Toward the genetic improvement of feed conversion efficiency in fish. *J. World Aquacult. Soc.* 34, 245-254.

genetic gain in the nucleus. The earlier returns occur, the better, but even with a delay of two years EB and BCR were still highly favorable.

The reproductive efficiency assumed for the base situation (Table 6.2) was considered to be the lowest level at which a genetic improvement programme should be entertained, and one that can be easily improved with readily available and affordable technology. Despite this it resulted in a very favorable EB and a BCR of 8.5 after 10 years (Table 6.3). Reproductive efficiency Level 3 can be achieved with simple and inexpensive technology, and it can be easily targeted in a national genetic improvement programme. In Level 4 with even more improved reproductive efficiency both EB and BCR increased in an extraordinary manner. It may be argued that to achieve a greater reproductive efficiency in hatcheries an additional government investment would be required to transfer technology to hatchery managers. Modeling showed that despite substantial additional investment to train hatchery personnel, EB and BCR were still very favorable and worth the investment.

6.8.4 Summary of sensitivity analysis

- Management practices in the nucleus that may reduce environmental variance and thus increase heritabilities are likely to have a moderate effect on profitability.
- The cost of increased feed intake as a correlated response to selection for greater growth rate should be taken into consideration to avoid gross over-estimations of the EB and BCR of the programme.
- Initial investment, annual costs and choice of discount rate are likely to have a relatively small effect on EB and BCR, whereas the effect of the price of fish can be substantial.
- The earlier the first returns are achieved the greater EB and BCR will be. However, the greatest contribution to EB and BCR came from improvements in the reproductive efficiency at the level of both the nucleus and the hatcheries. This last factor, reproductive efficiency, is the one likely to have the greatest impact on EB and BCR.

6.9 Chance of success

The results presented in the earlier sections are of a deterministic nature (use of mathematical equations to predict results) implicitly assuming a total certainty of outcomes. However, genetic improvement by selection is a stochastic process, involving sampling of genes when the parents of each generation are chosen and when those parents produce progeny. A way of assessing the

Table 6.4 Upper and lower limits (95 % probability) for EB and BCR for the different levels of reproductive efficiency.

Reproductive efficiency^A	Limit for EB and BCR	EB (millions US\$)	BCR
Level 1	Upper	1.17	3.17
	Lower	0.79	2.46
Level 2	Upper	4.60	9.53
	Lower	3.44	7.40
Level 3	Upper	36.11	68.08
	Lower	27.90	52.82
Level 4	Upper	261.25	486.32
	Lower	202.56	377.30

^A See Table 6.2 for definition of Levels 1 to 4.

probability of success of a genetic improvement programme is by looking at the anticipated variability in response to selection.⁷⁶ The coefficient of variation calculated using equations provided by Nicholas (1989) was low enough to inspire confidence in the programme's outcome, and if confidence limits were set for EB and BCR these fell within favorable values even for the lowest level of reproduction studied (Table 6.4). Therefore, the risk of failure due to technical reasons is extremely low. Of course, failure due to natural disasters or to lack of continuity of purpose can occur but it is very difficult to deal with this kind of causes in a systematic manner.

6.10 Concluding remarks

Economic considerations in genetic improvement programmes are necessary in order to logically assign relative emphasis to different traits in the breeding objective. In turn, these enable the assessment of the economic impact of the programme on industry as a whole. The methodology used illustrates the multiplicity of factors that can influence the impact of a genetic improvement programme. The factors to which the economic benefit and the benefit/cost ratio are most sensitive can be identified and given greatest attention Both EB and BCR were most sensitive to reproductive efficiency in the nucleus

⁷⁶ Nicholas, F.W. 1989. Incorporation of new reproductive technology in genetic improvement programmes. In Hill, W.G. Mackay, T.F.C. (eds), Evolution and animal breeding, CAB International, Wallingford, U.K., pp. 203-209.

and in hatcheries, a factor that determines the number of fish upon which the genetic improvement is expressed. This quantitative finding is consistent with the generalized perception that multiplication and dissemination of improved strains or breeds is of paramount importance in a comprehensive approach to genetic improvement. The model (see footnote 71) can be used to investigate other factors that one may suspect will influence the outcome of a genetic improvement programme (e.g. less frequent transfer of brood stock to hatcheries, expression of only a fraction of the selection response in the nucleus in the production environment due to genotype by environment interaction). It can be used 'in reverse', to examine the wisdom of setting up a genetic improvement programme for hatchery and production sectors of specific sizes.

With conservative reproductive efficiencies (Level 2 in Table 6.1), attractive EB and BCR values of over four million US\$ and 8.5, respectively, can be obtained. Implementing available, proven, and inexpensive reproductive technology (Level 3 in Table 6.1) resulted in EB and BCR increases to over 32 million US\$ and 60, respectively. With easily cultured species (e.g. tilapia), because of its feasibility and impact reproductive efficiency Level 3 should be the initial target in national genetic improvement programmes, with a view to upgrading to Level 4 as skills in hatcheries are enhanced.

From a national viewpoint, investing in genetic improvement programmes in cultured aquatic animals is a wise decision. Additionally, the availability to producers of a "high performing" strain can act as a stimulus to the adoption of better practices in other areas (management, nutrition, animal health, marketing).

7 RISK ASSESSMENT AND MONITORING IN GENETIC IMPROVEMENT PROGRAMMES⁷⁷

7.1 Introduction

Genetic improvement programmes (Chapters 4, 5 and 6) raise the need to assess and manage ecological risks imposed by intentional introductions and unintended escapes of improved organisms into aquatic ecosystems. Ecological risk assessment and management is fundamentally a social process guided by scientific information and analysis. The importance of human values is clear in the definitions of risk assessment terms:

- **Risk** refers to the likelihood of harm occurring from a specified hazard or set of hazards.
- **Harm** refers to undesirable consequences to humans and the things that they value.
- **Hazard** refers to an event that has the potential to produce harm.

Risk assessment processes in natural resource arenas, therefore, often incorporate stakeholder⁷⁸ deliberations with scientific analysis. International expert consultations co-led by the FAO have identified some important elements of ecological risk assessments for genetically improved fish⁷⁹ and an international team has produced the first global synthesis of current approaches and methodologies.⁸⁰

⁷⁷ Contributed by Anne R. Kapuscinski.

⁷⁸ Anyone who has an interest in an issue, or anyone who shares the burden of the risks resulting from a particular decision. An individual or representative of a group affected by or affecting the issues in question.

⁷⁹ Gupta, M.V.; Bartley, D.M.; Acosta, B.O. (eds). 2004. *Use of genetically improved and alien species for aquaculture and conservation of aquatic biodiversity in Africa*. WorldFish Center Contribution No. 1707. Penang, Malaysia. 107 pp. Nairobi Declaration in Gupta *et al.*, 2004.

WorldFish Center. 2003. Dhaka Declaration on Ecological Risk Assessment of Genetically Improved Fish. WorldFish Center Contribution No. 1704, Penang, Malaysia.

Pullin, R.S.V.; Bartley, D.M.; Kooiman, J. (eds). 1999. *Towards policies for conservation and sustainable use of aquatic genetic resources*. ICLARM Conf. Proc. 59, 277 pp.

⁸⁰ This chapter represents and draws extensively from the work of 44 natural and social scientists and policy specialists from 19 countries, begun at a workshop at the WorldFish Center in 2005 and published in a refereed book. They concluded that their synthesis of risk assessment and management methodologies applies broadly to different kinds of genetically improved lines in aquaculture. Kapuscinski, A. R.; Hayes, K.R; Li, S; Dana, G. (eds). 2007. *Environmental risk assessment of genetically modified organisms: Volume 3, methodologies for transgenic fish*. CAB International, Wallingford, UK, 304 pp.

These guidelines address predictive risk assessment, in order to predict the likelihood and consequences of potentially harmful events before and during dissemination of genetically improved fish. The focus is on possible ecological harm to wild populations of aquatic species or the ecosystems that support these species; ecological harm can involve undesirable changes at the genetic, population, community or ecosystem level. The guidelines also address risk management, including monitoring, as part of dissemination programmes.

7.2 The Code of Conduct

Genetic improvement programmes should not undermine the goals of conserving genetic diversity in wild aquatic species and protecting the integrity of aquatic communities and ecosystems, as stated in Articles 6.2, 7.2.2., 9.1.2, 9.31 and 9.3.5 of the Code of Conduct. Stakeholder participation in the risk assessment process is supported by Articles 6.13 and 6.16. Article 9.1.2 gives a clear basis for incorporating ecological risk assessment and management into genetic improvement programmes:

States should promote responsible development and management of aquaculture, including an advance evaluation of the effects of aquaculture development on genetic diversity and ecosystem integrity, based on best available scientific information.

7.3 Principles

7.3.1 Frameworks for ecological risk assessment and management differ across nations but all effective frameworks contain similar systematic steps that build upon each other.⁸¹

7.3.2 The entire ecological risk assessment and management process should integrate interdisciplinary scientific analysis with multi-stakeholder deliberation.

⁸¹ Hayes, K.R.; Kapuscinski, A.R.; Dana, G.; Li, S.; Devlin, R.H. 2007. Introduction to environmental risk assessment for transgenic fish. Pages 1-28 in Kapuscinski *et al.* (eds) (see footnote 80).
Nelson, K.C.; Basiao, Z.; Cooper, A.M.; Dey, M.; Lorenzo Hernandez, M.; Kunawasen, S.; Li, S.; Fonticciella, D.; Ratner, B.D.; Toledo, M.I.; Leelapatra, W. 2007. Problem formulation and options assessment: science-guided deliberation in risk assessment of transgenic fish. Pages 29-60 in Kapuscinski *et al.* (eds) (see footnote 80).

Credible frameworks for risk assessment and management have certain steps in common (Table 7.1). Responsible agencies should identify who will conduct the various steps in their risk assessment and management framework, identify required areas of expertise, identify relevant stakeholders and decide on how to involve experts and stakeholders in the process.⁸² In linking scientific analysis with multi-stakeholder deliberation, each political jurisdiction will need to determine the level of stakeholder participation that fits with its society and available resources. Transparent and equitable deliberation among relevant stakeholders can enhance legitimacy and public trust of the risk assessment conclusions and risk management recommendations and improve the quality of the assessment because it:

- allows all concerns to be recognized;
- incorporates stakeholders' important knowledge about the system, such as information about wild fish in the area, which may be unknown to the technically oriented risk analysts;
- incorporates perspectives of stakeholders at key points in the process; and
- assures that risk assessment conclusions and risk management approaches are meaningful to the stakeholders.

7.3.3 Each ecological risk assessment should be organized around a hazard chain of events that starts with potential entry of the genetically altered organisms into the ecosystem and defines the subsequent events that pose potential harm.

The need to assess genetic risks and other ecological risks stems from the changes in genetic makeup and traits of the genetically altered organism. Numerous steps in a risk assessment will require empirical data on these changes compared to the population(s) currently farmed in the geographical area and compared to any wild relatives⁸³ in the aquatic ecosystem, and how those changes might or might not lead to ecological harm. Figure 7.1 presents a generalized example of a chain of events that would have to occur to end up with ecological harm.

⁸² For further information on incorporating multi-stakeholder deliberations: Hayes *et al.* 2007 and Nelson *et al.*, 2007 (see footnote 81); and Nelson, K.C.; Banker, M.J. 2007. *Problem formulation and options assessment handbook: A guide to the PFOA process and how to integrate it into environmental risk assessment (ERA) of genetically modified organisms (GMOs)*. GMO-ERA Project. Available at: www.gmoera.umn.edu.

⁸³ Any species in the ecosystem with which the genetically altered fish can interbreed, including the same species as the genetically altered fish or a closely-related species.

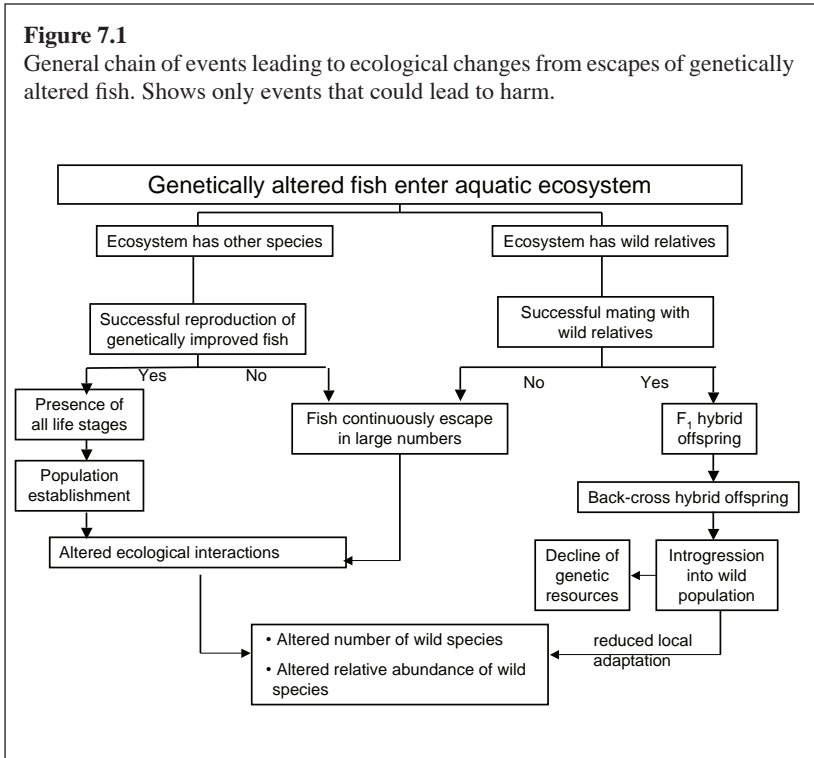
Table 7.1 Steps found in most risk assessment and management frameworks. Stakeholder participation should be integrated with technical analysis throughout, particularly to address questions in italics.*

Multi stakeholder deliberation integrated at key points in each step	STEP	KEY QUESTIONS ADDRESSED AT THIS STEP
	Risk Assessment	Identify and prioritize hazards
Risk estimation	Estimate exposure to each prioritized hazard, and likelihood of harm resulting from hazard exposure.	What is the hazard exposure and how likely is the hazard? What would be the harms of realization of the hazard and how severe are they?
Estimation is quantitative (when possible), semi-quantitative, or qualitative.		What are conclusions of the risk assessment (matrix of estimated likelihood of harm plotted against severity of harm)? How certain is the knowledge used to identify hazards, estimate likelihood, and predict harms? Which uncertainties can be eliminated? Which uncertainties need to be treated throughout the assessment?
Identify and analyze uncertainties		
Risk Management	Risk reduction planning	What can be done to reduce risk to acceptable levels, either by reducing the likelihood or mitigating the consequences? Are the risk reduction measures acceptable?
Implementation of plan		
Monitoring		Are the monitoring activities acceptable? How effective are the implemented measures for risk reduction? Are they as good, better or worse than planned for?
Remedial action		What remedial (corrective) action will be pursued if findings are unacceptable? Did the action adequately resolve the concern(s)?

* Hayes *et al.*, 2007 and Nelson *et al.*, 2007 (see footnote 81); Nelson and Banker, 2007 (see footnote 82).

Figure 7.1

General chain of events leading to ecological changes from escapes of genetically altered fish. Shows only events that could lead to harm.



7.3.4 Early in the risk assessment process, relevant experts and stakeholders should deliberate to describe the event chain of concern, identify and prioritize the hazards and harms along the chain, and agree on acceptable levels of risk.

These outcomes from deliberations among relevant experts and potentially affected interested stakeholders give decision-makers a socially trusted basis for allocating limited resources on assessing the higher priority hazards and harms. The rest of the risk assessment and management process thus focuses on the selected priority hazards (Table 7.1).⁸⁴

⁸⁴ Further guidance on prioritizing hazards is in Hayes *et al.*, 2007 (see footnote 81).

7.3.5 Focus the risk assessment and management on measurable end points for the prioritized hazards.

It is essential to carefully choose measurable end points for the ecological changes that stakeholders and analysts have agreed are undesirable.⁸⁵ Risk analysts can then focus on estimating the likelihood and severity of harm for each endpoint (Figure 7.2). Risk assessment end points (what the risk assessment is trying to protect) should be identified for each prioritized hazard along the event chain (Figure 7.1). When it is difficult to assess an end point of main interest, risk analysts should identify and assess measurement end points (what they can actually measure) that are good scientific indicators of whether a specific ecological harm will or will not occur. For example, if genetically altered fish prey on a wild species which stakeholders agree to protect at a specific abundance level (assessment endpoint), it may be easier to assess effects on survival of wild adults (measurement endpoint) than to predict changes in overall abundance of the wild species.

Figure 7.2

Schematic of a qualitative risk assessment matrix for estimates of likelihood (vertical axis) and severity (horizontal axis) of harm. Quantitative risk assessments are preferable to qualitative or semi-quantitative assessments but require more data.

Likelihood of harm	Frequent				Greatest risk
	Almost never	Lowest risk			
		Very low			Very high
		Severity of harm			

⁸⁵ End points explicitly express the valued elements of the ecosystem that the interested parties are trying to protect by performing the ecological risk assessment (Hayes *et al.*, 2007, see footnote 81).

The ability to provide honest and accurate predictions of risk diminishes as the length of the hazard event chain increases due to increasingly complex and cascading interactions between the genetically altered organisms and wild species and their habitats. Thus, it is wise to establish a careful balance between reality, complexity and stakeholder concerns by choosing assessment end points that are clearly relevant to these concerns, but occur earlier (rather than later) in event chains. An interdisciplinary team of experts should define endpoints (preferably through deliberations with multiple stakeholders) and identify appropriate assessment methods and existing data. Relevant expertise will vary case-by-case and would ideally include aquatic biologists and ecologists and persons trained in risk assessment methods.

7.3.6 Case-by-case risk assessment and management

Any culture programme can change the genetic makeup and traits of the cultured organisms (Chapter 3 & 4). No method of genetic improvement inherently poses greater or lesser environmental risks than other methods. Instead, risks need to be assessed case-by-case, based on characteristics of the aquaculture production system (especially its patterns and frequency of escapes into nature), the genetically altered organisms and the potentially affected ecosystems.⁸⁶

7.4 Assessing genetic effects⁸⁷

Gene flow from genetically altered individuals to wild relatives is a major process through which genetically altered fish may affect wild fish populations. The main concerns are whether gene flow results in introgression (incorporation) of genes from the improved organisms into wild gene pools, and whether this leads to harmful genetic and ecological consequences (Figure 7.1). Risk assessors should assess end points in a chain of events that must occur to end up with introgression. They can do this by partitioning the assessment into two major endpoints, entry and introgression; and further partitioning these into sub-component events that should be easier to assess than treating entry or introgression as a single variable.⁸⁸

⁸⁶ There is broad agreement on the need for case-by-case ecological risk assessment; e.g. the Cartagena Protocol on Biosafety, Article 15 and Annex III. See also Bellagio Statement in Pullin, R.S.V.; Bartley, D.M.; Kooiman, J. (eds). 1999. *Towards policies for conservation and sustainable use of aquatic genetic resources*. ICLARM Conf. Proc. 59, 277 pp.

⁸⁷ Kapuscinski, A.R.; Hard, J.J.; Paulson, K.; Neira, R.; Ponniah, A.; Kamonrat, W; Mwanja, W; Fleming, I.A.; Gallardo, J.; Devlin, R. H.; Trisak, J. 2007. Approaches to assessing gene flow. Pages 112-150 in Kapuscinski *et al.* (eds) (see footnote 80).

⁸⁸ Extensive guidance for assessing sub-components is in Kapuscinski *et al.*, 2007 (see footnote 87).

Predicting the likelihood and genetic effects of these events requires data on how the genetic alteration affects the fitness⁸⁹ of the farmed fish, and on how that fitness might change if fish escape into the environment and interbreed with wild relatives in the environment. Also required are specific baseline data about the wild relatives, such as population genetic structure and spatial distribution of breeding adults. It can be a daunting task to collect case-specific empirical data for assessing all sub-components of gene flow. To reduce data needs, risk analysts can pursue a step-by-step strategy of assuming that a specific event leading to entry or introgression will occur (instead of obtaining data to estimate its likelihood) and then proceed to estimating the next event in the chain.⁹⁰

Introgression of altered genotypes into wild populations could result in several declines in genetic resources (Figure 7.1): altered frequencies of native alleles, loss of genetic distinctiveness, or loss of genetic variation in the affected wild population. Introgression could lead to outbreeding depression due to disruption of co-adapted gene complexes of the wild population. These genetic changes can reduce the fitness of wild populations and reduce their ability to adapt to environmental change such as climate change or habitat transformation (e.g. from dams or other construction). Such risks are of particular concern for wild populations already in decline or in a species' center of origin.

7.5 Assessing ecological effects⁹¹

Genetically altered organisms may have ecological effects beyond their possible effects on the genetics of wild populations (Figure 7.1). Ecological effects are even possible when there is no interbreeding of farmed fish with wild populations. Adding a new element to an ecosystem can trigger the ecosystem to shift from an initial state to a new state. The purpose of assessing ecological risks is to predict whether a new state might occur that involves socially undesired changes for instance, species extinctions, altered population abundance, and or altered ecosystem functions.

⁸⁹ The degree to which an organism succeeds at passing on its genes to future generations. Fitness is determined by the joint effect of key traits spanning the entire life cycle of the organism, such as juvenile and adult viability, fecundity, fertility, mating success, and age at sexual maturity. Muir, W.M.; Howard, R.D. 2001. Fitness components and ecological risk of transgenic release: a model using Japanese medaka (*Oryzias latipes*). *American Naturalist* 158:1-16.

⁹⁰ Guidance for this strategy appears in Kapuscinski *et al.*, 2007 (see footnote 87).

⁹¹ Devlin, R.H.; Sundström, L.F.; Johnsson, J.I.; I.A Fleming, I.A.; Hayes, K.R.; Ojwang, W.O.; Bambaradeniya, C.; Zakaraia-Ismail, M. 2007. Assessing ecological effects of transgenic fish prior to entry into nature. Pages 151-187 in Kapuscinski *et al.*, (eds) (see footnote 80).

Predictive assessment of ecological risks should involve four phases that build upon each other.⁹²

- (1) characterize specific biotic and abiotic properties of the receiving ecosystem(s) that the genetically altered fish might affect;
- (2) measure intended and unintended changes in traits of the genetically altered fish, focusing on changes that could alter their interactions with the ecosystem;
- (3) determine anticipated interactions between the genetically altered fish and the ecosystem, such as interference competition with another fish species or grazing of aquatic vegetation; and
- (4) estimate the scale and likelihood of ecological effects resulting from each interaction of the genetically altered fish with the ecosystem.

In each phase, assessors should integrate information from several sources including experts and appropriate stakeholders; baseline data about potential receiving ecosystems (e.g. from field surveys); and empirical data from well-designed experiments that incorporate semi-natural conditions. Risk assessors should determine appropriate confinement of genetically altered fish in risk assessment experiments,⁹³ taking into consideration available resources and current unknowns about these fish. Even when applying this systematic four-phase approach, predictive risk assessment of ecological effects will be a complex task involving significant sources of uncertainty. Genetically altered fish may behave differently in risk assessment experiments than in nature, especially due to genotype-environment interactions, reducing the value of applying the results to natural environments. Studies to obtain case-specific data on ecological consequences should simulate a range of ecological conditions representative of the potentially affected aquatic ecosystem.

7.6 Uncertainty analysis⁹⁴

All risk assessments are subject to uncertainty. The reliability of an ecological risk assessment depends on identifying and treating the various sources of uncertainty. To ‘treat’ an uncertainty means to analyse, eliminate (resolve) or carry it through the chains of calculations and judgments of the entire

⁹² Extensive guidance for carrying out each phase appears in Devlin *et al.*, 2007 (see footnote 91).

⁹³ Guidance on semi-natural experiments and confined experiments appears in Kapuscinski *et al.*, 2007, chapters 5, 6 and 8 (see footnote 80).

⁹⁴ Hayes, K.R.; Regan, H.M.; Burgman, M.A. 2007. Introduction to the concepts and methods of uncertainty analysis. Pages 188-208 in Kapuscinski *et al.*, (eds) (see footnote 80).

risk assessment. Systematic identification and treatment of uncertainties can help inform when to apply a precautionary approach (Chapter 11). Different types of uncertainty arise from different mechanisms and risk analysts have developed appropriate mathematical and qualitative methods to identify, treat and communicate each type.⁹⁵ It is critically important to build capacity and practical experience in applying these methods to risk assessment of genetically altered fish. Parties responsible for carrying out ecological risk assessments should receive training to:

- identify uncertainties through appropriate stakeholder-expert deliberation methods;
- treat the uncertainties using appropriate methods or recruit properly trained experts to do this;
- understand the results from treating each identified uncertainty; and
- represent and communicate the uncertainty treatments in a reliable and transparent manner.

7.7 Ecological risk management

Ecological risk management aims to reduce identified risks to acceptable levels.⁹⁶ It can include confinement measures and monitoring programs. When a risk assessment identifies likely but manageable risks, a risk management plan should be developed and implemented as an integral part of dissemination of genetically improved fish. Risk management plans should be based on conclusions from a risk assessment so that they focus on the prioritized risks and are backed by the shared understanding among those who participated in the assessment.

7.7.1 Confinement of genetically altered organisms⁹⁷

No confinement method is 100% effective, so risk managers should consider the use of multiple and reinforcing confinement measures and best management practices⁹⁸ for confinement. Multiple confinement methods may be needed

⁹⁵ A summary of methods to treat sources of uncertainty is in Hayes *et al.*, 2007 (see footnote 94).

⁹⁶ Using multi-stakeholder deliberations to agree upon acceptable levels of reduced risk will increase social acceptance of the decision.

⁹⁷ Mair, G.C.; Nam, Y.K.; Solar., I.I. 2007. Risk management: Reducing risk through confinement of transgenic fish. Pages 209-238 in Kapuscinski *et al.*, (eds) (see footnote 80).

⁹⁸ Best management practices will vary depending on the aquaculture system and may be very difficult to implement in resource-poor contexts. General guidance on best management practices is in Mair *et al.*, 2007 (see footnote 97).

to reduce the number of escapees from an aquaculture system to acceptable levels. Confinement measures can focus on preventing escapes or reducing effects if escapes occur. Physical barriers e.g., lethal water temperatures or pH; mechanical barriers e.g., screens; and geographical barriers e.g., raising a marine species in an inland closed seawater system (Chapter 9) can be used to prevent escapes. Biological barriers, such as induced triploidy which makes adults of some fish species functionally sterile, can be used to reduce gene flow (thus reduce genetic risks) and population establishment (thus reduce ecological risks). But sterilization does not eliminate all environmental risks. Escaped, sterile fish might still compete with wild fish for limited resources or engage in courtship and spawning behavior, disrupting breeding in wild populations.⁹⁹

7.7.2 Monitoring for presence and ecological effects of genetically altered organisms.¹⁰⁰

The best way to detect escapes and early signs of undesired ecological changes is through a well-designed monitoring program that integrates typical fisheries field sampling methods with statistical techniques and uses DNA-based genetic markers to detect genetically altered individuals. Monitoring should be designed to detect one or more end points at various ecological levels:

1. presence of genetically altered individuals in the ecosystem;
2. presence of first-generation hybrid offspring (from successful reproduction between escapees and wild relatives);
3. presence of back-cross hybrid offspring (from successful reproduction between first-generation hybrids and wild relatives);
4. presence of genetically altered individuals at all life stages;
5. population change of both genetically altered and wild individuals; and
6. changes in the number of local aquatic species and their relative abundance.

End points 1-5 may occur over one to several generations after genetically altered fish enter an ecosystem, allowing relatively early detection of ecological effects. It is easier and faster to detect these end points than to

⁹⁹ Agricultural Biotechnology Research Advisory Committee (ABRAC). 1995. *Performance Standards for Safely Conducting Research with Genetically Modified Fish and Shellfish*. Parts I and II, USDA, Office of Agricultural Biotechnology, Washington D.C. Available at: www.isb.vt.edu/perfstands/psmain.cfm

¹⁰⁰ Senanan, W.; Hard, J.J.; Alcivar-Warren, A.; Trisak, J.; Zakaria-Ismail, M.; Lorenzo Hernandez, M. 2007. Risk management: post-approval monitoring and remediation. Pages 239-271 in Kapuscinski, A.R. *et al.* (eds) (see footnote 80).

monitor for community-level changes in species composition (end point 6). This last end point may take many generations to manifest, is harder to detect, and could also result from other hazards (e.g. habitat damage), making it difficult to distinguish effects due to the genetically altered organisms. For example, relatively early detection of genetically altered fish at all life stages in a monitored area (end point 4) would indicate that these individuals are reproducing well enough to interact extensively with other species. Longer-duration and more complex monitoring would be needed to determine whether interactions between these genetically altered fish and other species lead to undesired changes in fish community composition (end point 6).

Early monitoring can allow remedial responses (or contingency plans in Chapter 11) at the earliest point possible. Remedial responses may include improving confinement measures, removing genetically altered fish from the wild (rarely feasible and likely quite costly) and restricting further use of the genetically altered fish in aquaculture. Decision makers should realize that it is extremely difficult and costly to remedy adverse ecological effects once they have become widespread. Monitoring can also confirm a risk assessment's conclusion of ecological safety. A monitoring programme should have a high probability to detect changes that actually occur by using *inter alia* appropriate sampling designs, scientific tools and data analyses.¹⁰¹

7.8 Constraints and opportunities

Ecological risk assessment and management of genetically altered fish are complex and demand considerable resources. Methodologies are evolving and practical experience with them is limited. The need to build human and institutional capacity is widespread. Major needs are to.¹⁰²

- fill key gaps in baseline ecological and genetic data and improve access to existing databases;
- further develop broadly useable methods for ecological risk assessment and management of genetically altered fish;
- develop in-depth risk assessment training programs for persons needed to run risk assessment processes (managers, scientists, facilitators), as well as to help policy-makers understand how outcomes can inform their decision-making;

¹⁰¹ Extensive guidance on these aspects of monitoring is in Senanan *et al.*, 2007 (see footnote 100).

¹⁰² Nairobi Declaration, Dhaka Declaration (see footnote 2); Kapuscinski *et al.* (eds), 2007 (see footnote 80).

- strengthen international collaborations for conducting risk assessment studies under semi-natural and confined conditions;
- strengthen institutional frameworks needed to govern risk decision-making in this area; and
- promote networks among relevant institutions, as well as international cooperative programs to address the above needs.

Efforts to meet these needs will also assist in the conservation of aquatic biodiversity and responsible development of aquaculture. Better baseline data on key components of natural fish communities (e.g. on genetic diversity of wild populations and on factors affecting species composition) can help prioritize efforts in aquatic biodiversity conservation, inform the design of aquaculture zones and conservation zones (Chapter 9), and inform strategies for climate change adaptation in the fisheries sector. Other concerns about ecological impacts of aquaculture (e.g. raising alien species or effluent discharges) and other development activities (e.g. dam construction) require systematic risk assessment frameworks and some similar methodologies. Thus, broadly useable methods and training programmes will improve ecological risk assessment in the aquatic sector in general.

7.9 Conclusion

Ecological risk assessment of genetically improved fish before their dissemination, and ecological monitoring after dissemination, is necessary to achieve broad benefits without undermining the conservation of aquatic biodiversity. Systematic risk assessment approaches allow policy-makers to focus limited resources for risk assessment on the highest priority issues. Appropriate scientific techniques should be incorporated with multi-stakeholder deliberations. This makes it possible to reach agreement on the prioritized hazards, utilize the most relevant existing knowledge, focus tests and data collection on filling the most important information gaps, apply uncertainty analysis to improve the quality of the conclusions, and improve understanding of the issues and social trust in the risk assessment process and conclusions. Well-designed monitoring is essential for detecting early signs of undesired effects of genetically altered fish in natural ecosystems. Effective monitoring, however, is complex and requires considerable technical expertise and a long-term commitment.

Risk assessment and management is a complicated endeavor and has not been used extensively in aquaculture. As aquaculture expands and uses more genetically improved organisms, there is an urgent need to refine and apply risk

analysis processes involving scientists, multi-stakeholders and government regulatory agencies. Pro-active risk assessment and management can help steer aquaculture of genetically improved organisms towards practices that protect nature while supporting successful fish farming.

8 CULTURE-BASED FISHERIES¹⁰³

8.1 General principles

For the purpose of these guidelines, culture-based fisheries (CBF) mean capture fisheries that are maintained by stocking with material raised within aquaculture installations. The “material” is usually early life-history stages, but may also include juveniles or adults. There are three broad categories of CBF:

1. Those where the stocked material is meant to breed with each other and with the local species, thus increasing or re-establishing the local stocks;
2. Those where the stocked material is meant to breed with each other, but not with local species, thus creating a new fishery stock;
3. Those where the stocked material is not meant to breed at all.

Terminology suggested by an international group working on coastal fisheries suggests use of

- restocking, the release of cultured juveniles into wild population(s) to restore severely depleted spawning biomass to a level where it can once again provide regular, substantial yields;
- stock enhancement, the release of cultured juveniles into wild population(s) to augment the natural supply of juveniles and optimize harvests by overcoming recruitment limitation; and
- sea ranching, the release of cultured juveniles into unenclosed marine and estuarine environments for harvest at a larger size in “put, grow and take” operations.

In order to manage genetic resources effectively in CBF, it is essential to understand which of the above objectives are being sought. It is recognized that these categories are not discrete. For example fish in category 3 may breed. This is not the measure of CBF success, but must be factored into risk analysis. Success of culture-based fisheries will depend on the social, economic, and ecological contexts in which they are applied. The use of hatcheries to support fisheries is a fishery management tactic that must be integrated into an overall management plan for the fishery or water body. Simply releasing organisms into a water body with no provisions for resource management, no control of fishers and fishing practices, and no protection of habitat will not succeed. The guidelines given here focus on genetic resources management in CBF.

¹⁰³ Contributed by Devin M. Bartley.

8.2 Genetic resource management plan for culture-based fisheries

The use of hatchery-raised organisms in fishery management has often not met the desired objectives of increasing fishery production. This is partially because aquaculturists produce young fish that survive well in the hatchery, but then releases them to survive in completely different wild environments (Chapter 3). A domesticated fish that is adapted to regular feedings on formulated diets will not survive well in most natural habitats. Therefore, a genetic resource management plan for CBF must be very different from the breed improvement plans outlined in chapters 4-6. General management plans are outlined below for the three main categories of CBF.

8.2.1 Culture-based fisheries where the stocked material is meant to breed with the local species

When the CBF objective is to restock or increase natural reproduction of natural populations of local species, genetic resources management should strive to recreate the natural level of genetic diversity in the stocked material. The hatchery environment should be as natural as possible so that no artificial selection pressures are introduced. This requires choosing the correct strain to stock, as well as modifying hatchery and grow-out techniques to minimize artificial or inadvertent selection.

8.2.1.1 Choosing the correct stock

The material to be stocked should match the genetic diversity of the natural populations. This is best achieved by using wild-caught broodstock. If wild broodstock are in short supply, as in the case of many endangered or locally extinct natural populations, genetic stock identification should be used to identify a very similar stock. Where genetic data are not available for stock identification, surrogate information can be used, e.g. choose stocks from same aquatic habitat (water body or specific watercourse, such as a tributary) with similar life history, growth, color, shape and behaviour characters. Transfers of stocks among different watersheds or ecoregions is to be avoided. Broodstock management (Chapter 3) to optimize effective population size and reduce genetic drift should be followed as soon as brood fish are ready to be mated.

For long-term programmes it is desirable to develop a rotational breeding plan where broodstock are used to produce material for stocking, they are then released back into the wild, and then new broodstock are brought into

the hatchery. The timing of this rotation will depend on the success of the programme and the availability of natural broodstock. For species that spawn only once (e.g. Pacific salmon) or where killing broodfish is necessary for achieving fertilization (e.g. some sturgeons) this rotation will not apply.

8.2.1.2 Choosing the correct hatchery procedures

Fish will adapt in the short term to hatchery management practices and, in the longer-term, hatchery conditions will exert selective pressures on them (Chapter 3). Hatchery procedures should be designed so as to minimize these influences (i.e. to reduce domestication selection) when the stocked material is meant to survive and/or to breed in the wild. Guidelines on specific breeding protocols to minimize inbreeding and loss of genetic diversity are discussed in Chapter 3.

Typical modifications to hatcheries to decrease artificial selection include:

- Provision of live food, from the wild if possible, rather than formulated feed;
- Provision of more natural habitat with gravel, plants, and shelters, rather than sterile tanks and raceways;
- Provision of limited amount of predators to teach predator avoidance;
- Natural light/dark cycles;
- Release of younger fish that have not adapted to hatchery conditions. However, this should be assessed as older fish may survive better;
- Spawn fish over the entire spawning season (i.e. do not simply collect lots of spawn when convenient in order to meet production goals);
- Do not transfer fish among hatcheries that are located in different watersheds or tributaries in order to meet production goals.

8.2.2 Culture-based fisheries where the stocked material is meant to breed with each other, but not with local species

This can arise when the fish stocked for CBF have different reproductive strategies from local species, because they are different species or, if the same as the local species, have different migration patterns or other behaviour, such as mate preferences. The most common example is the regular stocking for CBF of alien species or of specific strains of fish, such as salmon. If fertile fish are being released to breed, self-sustaining populations would be expected to develop thus negating the need for continued stocking.

The release of viable alien fish that are capable of reproducing is considered the most risk-prone type of stock enhancement (Chapter 7). Management of these stocks requires in-depth knowledge of the genetics and natural history of a species or stock. Even then, the natural history characters and behaviour of a strain may change when it encounters a new environment. Guidelines have been created to advise on responsible procedures on the use of alien species (Chapter 5).¹⁰⁴ Assuming that these guidelines have been followed and that CBF based on alien fish have been determined to be an acceptable management option, a stock should be chosen that has appropriate behavioural characteristics (e.g., timing and location of migration), and genetic resources management measures should be planned and implemented to optimize N_e and avoid domestication selection (see Chapter 3).

8.2.3 Culture-based fisheries where the stocked material is not meant to breed

In many CBF there is no intention or possibility of creating self-sustaining populations. In these circumstances, genetic resource management should strive to optimize productivity and reduce negative impacts on the ecosystem. The production of sterile fish is the best means to reduce the chance of stocked fish breeding with local species. Creation of triploids, i.e. adding another set of chromosomes, is the most common method of producing sterile fish. Triploidy can be induced by temperature, pressure or chemical treatments to fish gametes and developing embryos. This is easily accomplished in many species such as oysters, salmon and trout, but difficult on a commercial scale for others, such as tilapia.

The release of individuals of a single sex, i.e. monosex, has also been used to reduce chance of reproduction. Monosex groups can be made either by genetic manipulation or by administering sex hormones at the proper time. Combining induced triploidy with monosex production would further reduce chance of unwanted breeding.

Monitoring of the stocked material is necessary to ensure that the hatchery is producing the desired product (i.e. that the stocked material is all triploids or all of the desired sex).

¹⁰⁴ For example, International Council for the Exploration of the Sea ICES Code of Practice on the Introductions and Transfers of Marine Organisms 2004. www.ices.dk/reports/general/2004/ICESCOP2004.pdf

It is also possible to control breeding by controlling fishing effort and through choice of habitat that is stocked. Fish are often stocked in temporary waterbodies that dry up before they can reproduce, in enclosed water bodies that lack connection to critical spawning habitats, or in areas with intense fishing pressure where 100% of the stocked fish are taken. However, these conditions are not always 100% effective at preventing all reproduction, because some fish may move to areas where reproduction is possible or fishing less intense. The use of sterile fish in these circumstances would further reduce the chance of unwanted reproduction.

8.3 Monitoring, assessments and reporting

As with all fisheries, monitoring of CBF is essential and for this the stocked material must be identifiable. Hatchery marking programmes are being mandated in many parts of the world to assess hatcheries' contributions to CBF. Physical tags can identify initial contributions, but if stocked fish reproduce in the wild only genetic tags can indicate hatcheries' contributions to subsequent generations. Increase in abundance of stocked species is sometimes, but not always, an indicator of hatchery contribution to a fishery; favourable changes in the environment or better fishery management may also promote natural increases.

Additionally, stocked fish have in some cases been shown to displace local con-specific stocks. This is a situation to be avoided and another reason why the ability to differentiate among hatchery and wild stocks is important in the overall assessment of stocking as a management strategy.

A precautionary approach to developing CBF requires the development of reference points (Chapter 11); target reference points to indicate desirable situations a fish farm will strive to achieve and limit reference points to indicate conditions to be avoided and then regular monitoring to see to what extents the reference points are met. The reference points should relate to stated objectives, risk assessment and measures of success (see Chapter 11).

Where hatcheries release viable organisms that are capable of reproduction in order to support CBF, there is the possibility that self-sustaining populations will develop and thus negate the need for further stocking. This might be especially true in recovery programmes for endangered species that would combine stocking with habitat improvement and improved legislation. Monitoring and honest discussions with stakeholders are required to determine whether further stocking is still needed after self-sustaining populations have been established.

FAO collects information on the numbers and species that are released into open waterbodies, including natural waterbodies, semi-natural waterbodies such as reservoirs, and other managed waters such as rice fields. In order to evaluate the contributions of CBF to national and global fishery production, hatchery managers should convey comprehensive and timely information on all releases for CBF to their national statistics offices, for forwarding to FAO.