In the line beginning "18 U.S.C. 477" by inserting ", 2B5.2" immediately following "2B5.1";

In the line beginning "18 U.S.C. 496 by deleting "2T3.1" and inserting in lieu thereof "2F1.1";

In the line beginning "18 U.S.C. 545" by deleting "2Q2.2" and inserting in lieu thereof "2Q2.1";

In the line beginning "18 U.S.C. 549" by inserting "2B1.1," immediately before "2T3.1" and by inserting ", 2T3.2" following "2T3.1";

In the line beginning "18 U.S.C. 551" by inserting "2]1.2," immediately before "2T3.1";

In the line beginning "18 U.S.C. 642" by inserting ", 2B5.2" following "2B5.1";

By deleting:

"18 U.S.C. 666(a)	2B1.1, 2C1.1, 2C1.2, 2F1.1",

and by inserting in lieu thereof:

"18 U.S.C. 666(a)(1)(A)	2B1.1, 2F1.1
18 U.S.C. 666(a)(1)(B)	2C1.1, 2C1.2
18 U.S.C. 666(a)(1)(C)	2C1.1, 2C1.2";

In the line beginning "18 U.S.C. 755" by deleting ", 2X2.1";

In the line beginning "18 U.S.C. 756" by deleting ", 2X2.1";

In the line beginning "18 U.S.C. 757" by deleting ", 2X2.1";

In the line beginning "18 U.S.C. 842(a)" by deleting ", (h), (i)" by inserting in lieu thereof "–(g)";

In the line beginning "18 U.S.C. 844(f)" by inserting ", 2X1.1" following "2K1.4";

By deleting:

"18 U.S.C. 922(a) (1)–(5)	2K2.3
18 U.S.C. 922(6)	2K2.1
18 U.S.C. 922(b) (1)–(3)	2K2.3
18 U.S.C. 922(d)	2K2.3
18 U.S.C. 922(g)	2K2.1
18 U.S.C. 922(h)	2K2.1
18 U.S.C. 922(i)	2B1.2, 2K2.3
18 U.S.C. 922(j)	2B1.2, 2K2.3
18 U.S.C. 922(k)	2K2.3
18 U.S.C. 922(l)	2K2.3
18 U.S.C. 922(n)	2K2.1
18 U.S.C. 923	2K2.3
18 U.S.C. 924(c)	2K2.4",

and by inserting in lieu thereof:

"18 U.S.C. 922(a)(1)	2K2.1, 2K2.2
18 U.S.C. 922(a)(2)	2K2.2
18 U.S.C. 922(a)(3)	2K2.1
18 U.S.C. 922(a)(4)	2K2.1
18 U.S.C. 922(a)(5)	2K2.2
18 U.S.C. 922(a)(6)	2K2.1
18 U.S.C. 922(b)–(d)	2K2.2
18 U.S.C. 922(e)	2K2.1, 2K2.2
18 U.S.C. 922(f)	2K2.1, 2K2.2
18 U.S.C. 922(g)	2K2.1
18 U.S.C. 922(h)	2K2.1
18 U.S.C. 922(i)–(l)	2K2.1, 2K2.2
18 U.S.C. 922(m)	2K2.2
18 U.S.C. 922(n)	2K2.1
18 U.S.C. 922(o)	2K2.1, 2K2.2
18 U.S.C. 923(a)	2K2.2
18 U.S.C. 924(a)(1)(A)	2K2.2
18 U.S.C. 924(a)(1)(C)	2K2.1, 2K2.2
18 U.S.C. 924(a)(3)(A)	2K2.2
18 U.S.C. 924(b)	2K2.3
18 U.S.C. 924(c)	2K2.4
18 U.S.C. 924(f)	2K2.3
18 U.S.C. 924(g)	2K2.3";

In the line beginning "18 U.S.C. 1012" by inserting "2C1.3," immediately before "2F1.1";

In the line beginning "18 U.S.C. 1028" by inserting ", 2L2.4" following "2L2.3";

By inserting in the appropriate place according to statutory title and section number "18 U.S.C. 1201(c),(d) 2X1.1";

In the line beginning "18 U.S.C. 1362" by inserting ", 2K1.4" following "2B1.3";

In the line beginning "18 U.S.C. "1363" by inserting ", 2K1.4" following "2B1.3";

In the line beginning "18 U.S.C. 1426" by inserting ", 2L2.2" following "2L2.1";

In the line beginning "18 U.S.C. 1460" by inserting "2G2.2," immediately before "2G3.1";

In the line beginning "18 U.S.C. 1512(a)" by inserting "2A1.3," following "2A1.2,";

In the line beginning "18 U.S.C. 1512(b) by inserting "2A1.2," immediately before "2A2.2";

In the line beginning "18 U.S.C. 1704" by inserting ", 2F1.1" following "2B5.2";

In the line beginning "18 U.S.C. 1751(c)" by inserting ", 2X1.1" following "2A4.1";

In the line beginning "18 U.S.C. 1751(d)" by inserting ", 2X1.1" following "2A4.1";

In the line beginning "18 U.S.C. 1909" by inserting "2C1.3," immediately before "2C1.4";

In the line beginning "18 U.S.C. 1951" by deleting "2B3.1, 2B3.2, 2C1.1,";

In the line beginning "18 U.S.C. 1952A" by deleting "2A2.1,";

In the line beginning "18 U.S.C. 1958" by deleting "2A2.1,";

In the line beginning "18 U.S.C. 2271" by deleting "2F1.1,";

By deleting "18 U.S.C. 4082(d) 2P1.1";

by deleting:

"26 U.S.C. 5861(a)	2K2.3
26 U.S.C. 5861(b)-(1)	2K2.2",

and by inserting in lieu thereof:

"26 U.S.C. 5861(a)	2K2.2
26 U.S.C. 5861(b)	2K2.1
26 U.S.C. 5861(c)	2K2.1
26 U.S.C. 5861(d)	2K2.1
26 U.S.C. 5861(e)	2K2.2
26 U.S.C. 5861(f)	2K2.2
26 U.S.C. 5861(g)	2K2.2
26 U.S.C. 5861(h)	2K2.1
26 U.S.C. 5861(i)	2K2.1
26 U.S.C. 5861(j)	2K2.1, 2K2.2
26 U.S.C. 5861(k)	2K2.1
26 U.S.C. 5861(l)	2K2.2";

and in the line beginning "26 U.S.C. 5871" by deleting "2K2.2, 2K2.3" and inserting in lieu thereof "2A2.1, 2A2.2".

Reason for Amendment: This amendment conforms the statutory index to amended guidelines, and makes the statutory index more comprehensive.

[FR Doc. 90–3519 Filed 2–15–90; 8:45 am]

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federal register

Friday
February 16, 1990

Part III

Department of Agriculture

Cooperative State Research Service

Research Proposed on Transgenic Fish; Publication of Environmental Assessment; Notice of Opportunity for Public Comment

DEPARTMENT OF AGRICULTURE

Cooperative State Research Service

Research Proposal on Transgenic Fish; Publication of Environmental Assessment

AGENCY: Cooperative State Research Service, USDA.

ACTION: Notice of opportunity for public comment on environmental assessment and proposed FONSI.

SUMMARY: The Cooperative State Research Service (CSRS) advises the public through this notice that an environmental assessment (EA) and proposed finding of no significant impact (FONSI) have been prepared concerning a proposal submitted by the Alabama Agricultural Experiment Station to conduct research on carp which have been genetically modified using recombinant deoxyribonucleic acid (DNA) technology. The research would be carried out in a fish hatchery facility and in outdoor research ponds located in Lee County, Auburn, Alabama. Funding for the research would be provided from CSRS through the Hatch Act.

The EA and proposed FONSI are published immediately following this notice. Public comment is welcomed. The EA provides a basis for concluding that measures proposed to prevent escape of the transgenic carp and fertilized eggs from the test site are adequate, and that the research will not have a significant impact on the quality of the human environment.

The EA has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4331 et seq.), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1509), and (3) U.S. Department of Agriculture (USDA) regulations implementing NEPA (7 CFR part 1b).

DATES: Comments must be received by March 19, 1990.

ADDRESSES: Written comments may be submitted to Dr. Daniel Jones, Deputy Director, Office of Agricultural Biotechnology, U.S. Department of Agriculture, room 321–A, Administration Building, 14th and Independence Avenue SW., Washington, DC, 20250.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel Jones at the above address, or telephone (202) 447–9165.

Done at Washington, DC, this 9th day of February, 1990.

John Patrick Jordan,

Administrator, Cooperative State Research Service.

PROPOSED FINDING OF NO SIGNIFICANT IMPACT

Research on Transgenic Carp in Confined Outdoor Ponds To Be Conducted at the Alabama Agricultural Experiment Station (AAES); Auburn University, Auburn, Alabama

AAES has requested U.S. Department of Agriculture funding of a research proposal to conduct an experiment in confined outdoor ponds with a scaleless variant of common carp (Cyprinus carpio), termed "mirror" carp, which have been genetically modified by the chromosomal insertion of a cloning vector, pRSV–2. The pRSV–2 contains a gene for rainbow trout growth hormone, and the Rous sarcoma virus (RSV) long terminal repeat sequence, termed "RSV promoter", which provides an efficient molecular recognition site for initiating the production of rainbow trout growth hormone in the experimental carp. These genetically modified fish are referred to as "transgenic" carp because they contain genetic material from a source different from the parents. AAES proposes to artificially spawn brood transgenic carp, produced in earlier research studies, indoors and to conduct studies of the offspring in 10 confined outdoor ponds located at AAES, Auburn, Lee County, Alabama.

The purpose of the research is to (1) evaluate the effects of the trout growth hormone gene on the reproductive capacity of brood carp, (2) determine whether offspring of these carp inherit the trout growth hormone gene, and (3) determine what are the effects of the inherited gene on the survival, growth rate, and behavior of the offspring. The research will develop basic information that may in the future be useful in developing improved fish species for commercial aquaculture through the use of recombinant deoxyribonucleic acid (DNA) technology.

The environmental assessment of the research analyzes the following three alternatives for conducting the research.

Alternative 1—Rearing offspring/fry in outdoor ponds under confinement conditions proposed by AAES in their submission of February 8, 1989 (AAES Proposal).

Alternative 2—Rearing offspring/fry in outdoor research ponds under confinement conditions preferred by USDA (USDA preferred action). This alternative was developed during the environmental assessment process in consultation with AAES and other fisheries science and ecology experts.

Alternative 3—Rearing offspring/fry indoors (No action). Alternative 3 is a presumed outcome if USDA denies funding for the proposed research.

Details of these alternatives and the environmental analysis are found in the attached Environmental Assessment. Based on the analysis, I have tentatively determined that Alternative 2 is the preferred action for achieving the objectives of the research. Alternative 2 provides an acceptable experimental procedure which contains adequate measures to prevent the release of experimental fish into the local environment and, therefore, the research carried out under these conditions will have no significant impact on the quality of the human environment.

This preliminary finding of no significant impact (FONSI) is based on the following factors:

1. It is uncertain what the immediate consequences would be on the Saugahatchee Creek watershed if the experimental fish were to escape the AAES facilities because the effect of the rainbow trout growth hormone gene on the ability of the carp to survive and become established in the local environment is not known. However, indications are that they could become a successfully established population and interbreed with existing common carp in the watershed. Because of their gregarious spawning activity and feeding habits, carp can adversely affect water quality, aquatic vegetation and indigenous organisms in the ecosystem. Adequate measures to prevent release of transgenic carp from AAES are necessary to mitigate any potentially significant adverse environmental impacts.

2. Alternative 2 provides adequate measures to prevent release of the experimental carp taking into account the following significant factors.

a. Weather conditions. Measures are provided to prevent escape of live experimental carp even though unusual rainfall and flood conditions may occur during the experimental period. The levees surrounding the experimental ponds are at least 0.8 feet above the estimated 100 year flood height of Saugahatchee Creek, which is the nearest natural body of water to the experimental ponds. Configuration of the levees will allow any flood water to dissipate first over an extensive pond area that does not contain the experimental transgenic carp.

An agricultural meteorologist will monitor weather forecasts provided by a National Oceanographic and

Atmospheric Administration weather station at Auburn University, and apprise AAES immediately of any prediction for severe flooding conditions. The research protocol contains emergency termination procedures for the experiment, should termination become necessary. These include treating the ponds with rotenone, a fast acting respiratory fish poison, in accordance with use conditions approved by the U.S. Environmental Protection Agency and the Alabama Department of Environmental Management. A decision on emergency termination will be made in consultation with the Alabama Department of Conservation and Natural Resources, if time permits.

Precautions are included to prevent heavy rainfall from causing the experimental ponds to overflow into the drainage canal. All ponds containing the transgenic carp will drain into two catch basin ponds through an overflow pipe 4 inches in diameter with a maximum flow rate of 9,500 gallons per hour. Distance between the overflow pipe and the top of the dikes surrounding each pond is 18 inches. Maximum rainfall in one month, recorded over 100 years, is 18 inches. Ponds initially will be filled with water 5 inches below the overflow pipe. If, due to evaporation and lack of rainfall, it becomes necessary to add water to the experimental ponds they will not be filled above 5 inches below the overflow pipe. Human failure to cut off the water at this point, still would not overflow the ponds because the diameter of the inlet pipe is only 1 inch with a maximum flow rate of 3,000 gallons, less if more than one pond is being filled. Overflow pipes between the ponds will have a box filters attached on each side with an open top 6 inches above the pipe to ensure that if the filters become clogged water will flow to the catch basin ponds and not flood over the dike.

Water in the catch basin ponds will be treated with rotenone and detoxified with potassium permanganate prior to discharge into the drainage canal leading to Saugahatchee Creek. Inlet water pipes for the experimental ponds will be filtered to prevent contamination of the water supply. The overflow pipes between the ponds will contain filters on both sides; the drainpipes of the catch basin ponds will also contain a filter. In addition, water discharged from the catch basin ponds, after treatment with rotenone and detoxification with potassium permanganate, will pass through a filter box before entering the environment. The mesh size of all filters initially will be 250 microns, which is adequate to contain the smallest fry. The size of the filters will be increased as the carp grow to reduce risk of clogging and breaking. An appropriate inspection and maintenance protocol for the filters is provided.

b. Predators. Adequate measures exist to prevent escape of the carp from the experimental ponds by birds and other terrestrial predators. These measures, by restricting access of predators to the ponds, also will prevent any harm to predators from exposure to rotenone-treated water or contact with the transgenic carp. Ponds containing experimental carp and the two catch basin ponds will be surrounded by a locked chain link fence 8 feet high and topped with two strands of barbed wire. This fence will be anchored with a concrete base. One-half inch polyethylene bird netting will be installed on the chain link fence and across the top, completely enclosing the experimental site. An additional $\frac{1}{16}$ inch wire screen perimeter fence, 18 inches high, will be installed on the chain link fence. The combination of these barriers will prevent access by birds, small animals such as snakes, frogs and rodents, and larger animals, such as muskrats and raccoons. The barriers will be formally inspected weekly, the inspection recorded, and any necessary repair will be made promptly. In addition, staff engaged in the research will be present daily and will immediately report any observed deficiency in the barriers.

The thickness of the levees/dikes, regular mowing, and inspection procedures will mitigate possible damage to the dikes by burrowing animals. The dike on one side of the perimeter of the experimental area, which is adjacent to a drainage canal, is 10 feet thick at the top and 40 feet thick at the base. Most of the remaining perimeter is contiguous terrain nestled into a hillside. The remaining perimeter has dikes averaging 7.5 feet thick above the water level (minimum of 6 feet) and tapering to 30 feet thick at the base. These narrower dikes are adjacent to additional research ponds, thus facilitating the detection and removal of burrowing animals that threaten to breech the security of the ponds containing the experimental fish. Levees and dikes will be formally inspected weekly, the inspection documented, and any necessary repairs promptly made. Burrowing predators have rarely been sighted at AAES and will be promptly removed if found.

c. Theft by humans. The above described locked enclosure of the experimental site, its location some distance from any public road, and lighting of the area will discourage human access, except by authorized personnel associated with the research. Persons with authorized access will have been examined on their understanding of the importance of precautions contained in the research protocol to prevent escape of the fish from the test site. At least one trained person associated with the project will be present intermittently during the day to report any attempt at unauthorized access. University police will patrol the area at least twice a night and log each security check. No measures would provide an absolute guarantee of preventing a deliberate human theft, but reasonable precautions to prevent theft are included in the protocol together with public information activities seeking public cooperation.

3. Procedures proposed for the use of rotenone and detoxification of rotenone-treated water with potassium permanganate before discharge mitigate any adverse effects of these chemicals on the environment. Tricaine methanesulfonate will be used for the humane sacrifice of the fish. The amount of rotenone or tricaine methanesulfonate in the sacrificed fish to be buried on the premises at AAES will be small and will not have an adverse impact on the environment.

4. The size of the experiment and limited area of the experimental site (approximately one acre) make it feasible to supervise the research and implementation of mitigation measures.

5. It is highly improbable that adverse effects will result from the use of a viral DNA sequence in the genetic modification of the carp. The viral sequence used in the modification to promote expression of the rainbow trout growth hormone gene, known as the long terminal repeat (LTR), is derived from the avian RNA-tumor virus, Rous sarcoma virus (RSV). The LTR represents less than 10% of the viral genome and does not code for or express any protein. A complete copy of the genome of the avian virus is not present in the transgenic carp, and latent retroviruses or oncogenes that the LTR might activate are not known to occur in this species. The LTR is believed to function in the integration of DNA into a host chromosome, as well as in promoting the expression of genes placed under its control. It is not expected to promote expression of other genes in the carp. No impacts on human health or safety are anticipated from contact with the carp containing this RSV–LTR promoter. Furthermore, precautions taken to prevent escape of

the carp or contact with other fish or birds, mitigate any significant impacts, although none are anticipated, that might be associated with the RSV–LTR promoter.

Dated: February 9, 1990.

John Patrick Jordan,

Administrator, Cooperative State Research Service.

Environmental Assessment of Research on Transgenic Carp in Confined Outdoor Ponds

Proposed by the Alabama Agricultural Experiment Station, Auburn University, Auburn, Alabama

Prepared by Office of Agricultural Biotechnology, Office of the Secretary, U.S. Department of Agriculture

John Patrick Jordan,

Administrator, Cooperative State Research Service.

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Environmental Assessment

I. Abstract

The Alabama Agricultural Experiment Station (AAES) has requested U.S. Department of Agriculture (USDA) funding of a research proposal to conduct experiments with a partially scaleless variant of common carp, termed "mirror" carp, which have been genetically modified by the use of recombinant deoxyribonucleic acid (DNA) technology. The transformation of the mirror carp was accomplished by the chromosomal insertion of DNA from a cloning vector, pRSV–2, introduced by microinjection into cells at an early stage of embryo development. The recombinant plasmid, pRSV–2, contained a gene for rainbow trout growth hormone under the promotional control of the long terminal repeat (LTR) from Rous sarcoma virus (RSV) and additional apparently non-functional flanking sequences of bacterial DNA used in construction of the pBR322-based plasmid. The LTR, a non-infectious regulatory sequence of DNA derived from RSV-ribonucleic acid (RNA), functions as an efficient recognition site for initiation of synthesis of the rainbow trout growth hormone protein in transgenic carp. Carp containing genetic material from a source other than the parents are termed "transgenic" carp. AAES proposes to artificially spawn transgenic carp, available from previous research, indoors, and to study the performance of their offspring in confined outdoor ponds located at their research facility in Auburn, Lee County, Alabama.

In accordance with the National Environmental Policy Act and implementing regulations, this environmental assessment examines possible effects of the proposed research on the quality of the human environment taking into account mitigation measures to minimize these effects. Three alternatives for the research are discussed: (1) The AAES proposal, (2) the USDA preferred action, which includes some modifications of measures proposed by AAES to prevent release of the experimental fish into the environment, and (3) probable action if USDA denies funding for the research.

II. Purpose and Need

2.1 Introduction

The Alabama Agricultural Experiment Station (AAES) has requested U.S. Department of Agriculture (USDA) funding of a research proposal to conduct experiments with carp, which have been genetically modified by the use of recombinant deoxyribonucleic acid (DNA) technology, in outdoor research ponds. The ponds are located on the AAES research facility in Auburn, Lee County, Alabama. Funding is contingent on approval by the Administrator of the Cooperative State Research Service (CSRS), who must consider whether that action may have a significant impact on the quality of the human environment as required by the National Environmental Policy Act (NEPA) and the implementing regulations.

The carp that will be used in the proposed research are a partially scaleless mutant form of common carp (*Cyprinus carpio*), termed "Israeli" or "mirror" carp. Mirror carp have been transformed by the chromosomal insertion of DNA from a cloning vector, pRSV–2, introduced by microinjection into cells at an early stage of embryo development. The recombinant plasmid, pRSV–2, contained the gene for rainbow trout growth hormone under the promotional control of the long terminal repeat (LTR) from Rous sarcoma virus (RSV) and additional apparently non-functional flanking sequences of bacterial DNA used in construction of the pBR322-based plasmid. The LTR, a non-infectious regulatory sequence of DNA derived from RSV–RNA, functions as an efficient recognition site for initiation of synthesis of rainbow trout growth hormone protein in transgenic carp. Carp containing genetic material from a source other than the parents are termed "transgenic" carp.

The purpose of the research is to evaluate the effects of the trout growth hormone gene on the reproductive capacity of brood carp, determine whether the offspring inherit the trout growth hormone gene, and determine what the effects of the inherited gene are on the survival, growth rate, and behavior of the offspring. This research project is part of a research program at AAES to develop basic information that may, in the future, be useful in developing improved fish species for commercial aquaculture.

In earlier indoor experiments with the transgenic carp at AAES, more than half of the carp died and the remaining carp failed to reach a physiological state that would allow spawning. After receiving approval from Auburn University's Institutional Biosafety Committee (IBC), AAES placed the remaining 5 male and 4 female transgenic carp, which were between one and two years of age, into outdoor research ponds, segregated by sex. These ponds were determined by Auburn University's IBC to meet containment conditions required by the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) (1). AAES scientists believe this more natural pond environment will allow the transgenic carp to reach a physiological state for spawning.

When the carp are ready to spawn they will be brought indoors where they will be placed in sex-segregated tanks and artificially spawned. The fertilized eggs will be incubated indoors and the larvae will be maintained in indoor tanks for about 3 to 7 days after yolk-sac

absorption until they are at least 0.5 centimeter long, at which time they will be placed in confined outdoor ponds. For purposes of this EA, the term "fry" means the young transgenic carp when they have grown to at least 0.5 centimeter long.

A total of 50,000 fry are proposed for placement in 10 outdoor ponds, 5,000 fry stocked in each 0.1 acre pond. When the fry have grown to about 30 grams (3–4 months of age), the population density will be reduced to a total of 300 fish per pond, including both transgenic carp and control (non-transgenic) carp. These fish will be heat branded for identification. The fish will be grown for one year and then the experiment will be terminated before the fish reach sexual maturity.

Details of the proposed experiment are presented in Section 2.4 of this Environmental Assessment (EA). Mitigation measures to prevent release of the fish into the environment are discussed in section III.

The EA presents scientific data and other information evaluated by USDA concerning the potential environmental impact of the proposed research and the alternatives considered and their potential environmental impacts.

2.2 Need for Conducting the Research in Outdoor Ponds

AAES scientists believe that an outdoor pond environment will ensure a higher survival rate of transgenic fish, enhance their spawning ability, and increase the validity of the research findings on growth rate and behavior. A pond environment also will permit research with a larger number of fish, thus increasing the statistical validity of the results of the research.

2.2.1 Survival Rate

In past AAES experiments, both transgenic and non-transgenic "mirror" carp reared indoors exhibited high mortality rates. More than half of the transgenic carp one to two years of age died indoors. Outdoor ponds provide a more natural and healthy environment conducive to a survival rate greater than in indoor tanks, and allow the use of a larger number of fish in the study.

2.2.2 Spawning Ability

Transgenic "mirror" carp reared indoors at AAES did not achieve a physiological state for spawning. A similar lack of reproductive health was observed in controls, so the condition of the fish does not appear to be an effect of the introduced gene. AAES scientists believe that placing the mature brood fish in sex-segregated outdoor ponds will provide an environment appropriate for the fish to reach spawning condition.

2.2.3 Utility of the Research

The proposed pond environment more closely resembles the environment in which many fish are reared commercially. Although it is premature to speculate on development of transgenic fish for commercial use, the applicability of basic research information on performance is enhanced if that research is conducted in an environment that more closely simulates a commercial setting. It is important to evaluate the offspring in outdoor ponds because of genotype-environment interactions (2, 3). Performance of a genotype will vary with the environment, and would be expected to differ in indoor tanks and outdoor ponds.

2.3 USDA Regulations and Review Process

The National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3121) designates the Department of Agriculture as the lead agency of the Federal Government for agricultural research, extension, and teaching in the food and agricultural sciences. The Act, through a 1985 amendment by the Food Security Act (Pub. L. No. 99–198, 1403, 99 Stat. 852), specifically directs the Secretary of Agriculture to establish appropriate controls for the development and use of the application of biotechnology to agriculture. To assist it in fulfilling those obligations, USDA has established a Federal advisory committee, the Agricultural Biotechnology Research Advisory Committee (ABRAC), to provide advice to the Department on matters of biosafety.

2.3.1 Research Funding Programs

Within USDA, the Cooperative State Research Service (CSRS) administers Federal funding of agricultural research under both a competitive research grants program and a cooperative funding program in conjunction with state agricultural experiment stations as authorized by the Hatch Act. Under the cooperative program, state agricultural experiment stations are apportioned funds for broad areas of investigation based on rural and farm populations within the state. Federal funds are matched by state funding. AAES has requested approval of Hatch Act funding to continue its research with transgenic carp, including rearing offspring in outdoor ponds.

2.3.2 Funding Agency Policy on Recombinant DNA Research

USDA regulations [7 CFR 3015.205(b)(3)] stipulate that as a condition of every USDA grant or cooperative agreement to institutions of higher learning, the recipient will assume primary responsibility for implementing proper conduct of recombinant DNA research, and it will comply with current NIH Guidelines for Research Involving Recombinant DNA Molecules. CSRS, in implementing the USDA regulations, requires that any recombinant DNA research be submitted to CSRS for approval and be accompanied by documentation that the institution's biosafety committee has approved the experiment (4). AAES has provided documentation that Auburn University's Institutional Biosafety Committee (IBC) concurs, pending further review by ABRAC, that the biosafety measures proposed by AAES for the pond experiments appear adequate for containment of the transgenic fish (memorandum of February 3, 1989 to Dr. Lowell Frobish, Director of AAES, from Dr. Paul Lemke, Chairman of Auburn University's IBC at that time).

2.3.3 Why USDA Conducted the Biosafety Review

Auburn University's IBC has determined that AAES has complied with Section III.B.4 of the NIH Guidelines in its laboratory experiments with the transgenic fish and placement of brood fish in outdoor ponds. Section III.B.4. of the NIH Guidelines is included in Appendix 4 of this EA. These research conditions also meet specifications for containment described in a draft revision to the NIH Guidelines (Appendix Q) pertaining to research involving whole animals. Appendix 4 of this EA provides a relevant excerpt from a proposed version of Appendix Q, which was published in the Federal Register on December 30, 1988 (52 FR 29800).

The question may arise as to whether placing the transgenic fry in outdoor research ponds, as proposed by AAES, constitutes deliberate release into the environment under the NIH Guidelines. Before a deliberate release experiment can be undertaken, Section III.A. of the NIH Guidelines requires that NIH publish relevant information on the proposed experiment in the Federal Register providing 30 days for comment, that the Recombinant DNA Advisory Committee of NIH review the experiment, and that NIH grant an approval. In reviewing this EA, NIH has

taken the position that the proposed research is not a deliberate release experiment because the fish containing recombinant DNA are confined in contained facilities (holding ponds), and there is no plan to release the fish outside such facilities.

Although USDA requires adherence to the NIH Guidelines as a condition of funding, it has an independent obligation in its funding decisions and under the National Agricultural Research, Extension, and Teaching Policy Act, to ensure that appropriate controls are applied in research involving agricultural biotechnology. The Department also must ensure that its actions fully comply with its obligations under the National Environmental Policy Act. Because the AAES proposal is the first one involving research with transgenic fish in outdoor ponds considered for funding by USDA, and because of the Department's statutory obligations explained above, USDA has sought advice from ABRAC as part of its review of the proposal and has prepared this EA to be published for a 30 day comment period, before deciding whether to approve funding for the experiment under the Hatch Act.

2.3.4 USDA Review Process

AAES initially submitted a proposal to CSRS for approval that encompassed a broad scope of research involving transgenic carp and catfish produced by the use of several different cloning vectors. This proposal was evaluated by six fisheries science peer reviewers, including a scientist from the U.S. Fish and Wildlife Service. Written comments from the reviewers were discussed with AAES scientists by USDA representatives that visited Auburn in March 1988. In January 1989, at the request of AAES, USDA scientists from CSRS, the Agricultural Research Service, and the Forest Service visited AAES, to discuss biosafety and environmental considerations with AAES scientists, and to advise AAES regarding their plans to submit a revised proposal to USDA. AAES had decided to narrow the scope of their original proposal to the study of transgenic carp containing rainbow trout growth hormone gene, and to modify and expand the protocol for confinement of fish in the outdoor ponds. The revised proposal was submitted on February 8, 1989 to the Director of the Office of Agricultural Biotechnology (OAB), USDA for review. The Director of OAB serves as the Executive Secretary to ABRAC. The Administrator of CSRS in consultation with the Director of OAB had decided that an ABRAC review of the proposal and a recommendation on the biosafety aspects of the experiment would be useful to CSRS in its evaluation and decision regarding funding.

2.3.4.1 USDA Advisory Committee and Public Meeting

At a public meeting on March 22–23, 1989, ABRAC reviewed the biosafety and confinement provisions of the AAES proposal, described as Alternative 1 in Section 3.1 of this EA. ABRAC also considered comments previously submitted by six fisheries science peer reviewers on the initial AAES proposal involving both transgenic carp and catfish.

Besides the AAES principal investigator, those attending the March meeting included representatives of the U.S. Environmental Protection Agency, USDA/Animal and Plant Health Inspection Service, Council on Environmental Quality, National Wildlife Federation, American Society for Microbiology, Industrial Biotechnology Association, Hill and Knowlton, Animal Health Institute, Science Magazine, Bio/Technology Magazine, Des Moines Register, and Washington Aquafarm Letter. Several representatives from these organizations offered specific oral and written comments on the AAES proposal.

2.3.4.2 Advisory Committee Recommendation

After considering information presented at the public meeting of March 23, 1989, ABRAC recommended that the confinement conditions for the outdoor ponds and other safety measures described in the AAES proposal are sufficient to protect human health and the environment. This recommendation was provided to the Administrator of CSRS.

2.3.4.3 Preparation of the Environmental Assessment

At the request of CSRS, OAB in consultation with a large number of experts analyzed the environmental impacts of the proposed research, considered alternatives, and prepared this EA. During the preparation of the EA, concerns were raised about some of the confinement conditions for the research. These concerns were discussed with AAES researchers, and AAES agreed to modify the protocol as described in Alternative 2 (The USDA preferred action), Section 4.2 of the EA. In developing and evaluating this alternative, site visits were made to AAES by several scientists from USDA, a scientist from the U.S. Fish and Wildlife Service, five non-government fisheries science experts, and a water management engineer.

2.4 The Proposed Research and Protocols

2.4.1 Experimental Design

The experimental design consists of three phases: bringing brood fish into spawning condition (phase 1 in progress); spawning the fish, incubating the eggs, and growing the larvae (phase 2), and rearing the fry (phase 3). Phase 1 has not been funded by USDA. If USDA denies funding, the experiment could be terminated if AAES so desires.

2.4.1.1 Bringing Brood Fish Into Spawning Condition (Phase 1)

Five male and four female mature brood transgenic carp, heat branded for identification, are currently being maintained in two outdoor ponds, segregated by sex, until they reach a condition for spawning. This phase of the experiment is being conducted in accordance with Section III.B.4 of the NIH Guidelines, since it is not considered to be a deliberate release into the environment. Auburn University's Institutional Biosafety Committee has determined that the outdoor pond conditions for the brood fish are adequate to prevent escape of the fish into the local environment.

2.4.1.2 Spawning the Fish and Growing the Larvae (Phase 2)

When the nine transgenic fish are ready for spawning, they will be brought indoors to a hatchery facility and kept in sex-segregated tanks for artificial spawning. The females will each be given an injection of carp pituitary extract (0.4 mg/kg body weight) followed in 12 hours by a second injection (3.6 mg/kg body weight) to induce ovulation. When the fish ovulate, eggs will be stripped into a bowl. Sperm will be extracted from the males over the eggs, salt water will be added to the mixture, and the contents of the bowl will be transferred to an aerated tank to incubate the fertilized eggs. The larvae will be grown in aerated indoor tanks for about 3–7 days after yolk-sac absorption until they are at least 0.5 centimeters (cm) long, at which time they will be placed in outdoor research ponds as described below.

When survival of an adequate number of offspring in the ponds is assured, the brood fish will be given a lethal dose of tricaine methanesulfonate (MS–222), and the carcasses will be frozen for subsequent tissue analysis. Tricaine methanesulfonate is an anesthetic

approved by the U. S. Food and Drug Administration for temporary immobilization of fish, and is the drug recommended by fish pathologists for humane sacrifice of fish used for research purposes. The hatchery conditions under which Phase 2 will be carried out have been determined by Auburn University's local IBC to meet containment requirements of the NIH Guidelines.

2.4.1.3 Rearing the Fry (Phase 3)

When the offspring measure at least 0.5 cm, termed "fry", a total of 50,000 fry will be stocked in 10 outdoor ponds, 5,000 fry per 0.1 acre pond. The ponds are marked in the shaded area of Figure 1, as pond numbers R–3 through R–12. Stocking of the ponds will proceed one pond at a time as fry resulting from various matings are produced in the hatchery. Fry will be transferred from the hatchery to the ponds by truck in covered containers. During stocking of the ponds, when the fry are about two weeks old, 50 fry per mating will be sacrificed to determine inheritance of rainbow trout growth hormone gene. Confirmation that a sufficient number of transgenic fry have been stocked, is a prerequisite for continuing the experiment.

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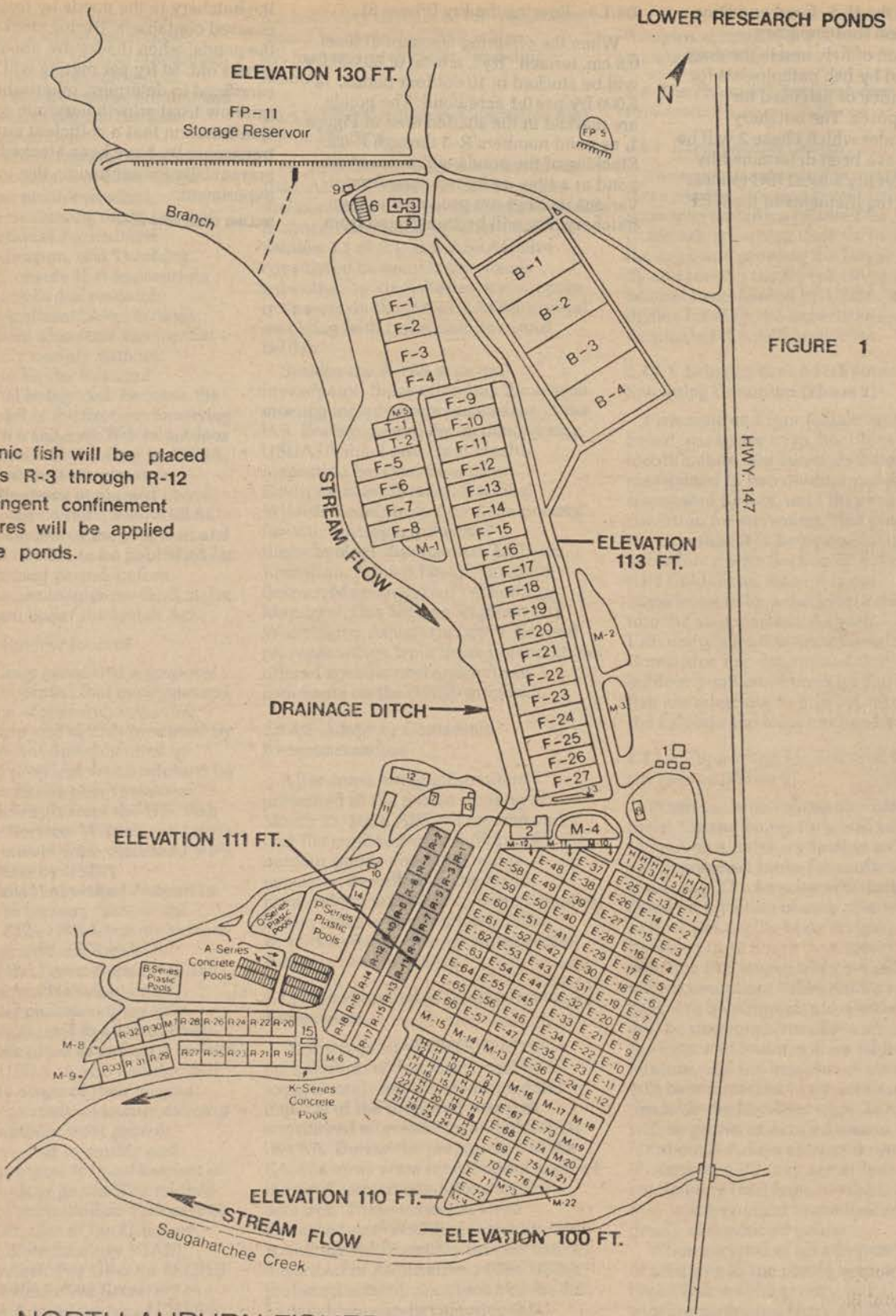

FIGURE 1

Transgenic fish will be placed in ponds R-3 through R-12 and stringent confinement procedures will be applied to those ponds.

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At about 3 months of age when the fish weigh approximately 30 grams, the population density will be reduced to 300 fish per pond for a total of 3,000 fish. This will be accomplished one pond at a time within the pond enclosure. First, the fish will be seined and held in the seining net at the end of the pond. Then, within the pond enclosure, about 400 of the fish will be individually weighed, fin clipped for DNA analysis, heat branded for identification, and held in a separate net in the pond until the results of the DNA analyses are completed. Based on the analyses, a total of 300 of the sampled fish, including transgenic and non-transgenic controls, will be selected for continuation of the experiment in that pond. It is expected that not all of the offspring will contain the rainbow trout growth hormone gene. Those fry that do not contain the gene will be selected as controls for the experiment. Excess fish will be transferred, using a small net, to a 200–300 gallon tank brought into the enclosed pond area to which a lethal dose of anesthesia MS–222 has been added. The sacrificed fish and treated water in the tank will be transported by truck to a suitable site on the AAES premises where the fish will be buried and the water poured on the ground.

Fish remaining in the experiment will be grown for one year, and the experiment will be terminated before the fish are sexually mature. During the experiment, a monthly inventory of the fish will be taken, and their growth and development will be monitored. At termination the fish will be harvested, given a lethal dose of anesthesia MS–222, and buried on the AAES premises in the manner described previously. AAES may wish to retain 30–40 of the transgenic fish for future research. Conditions under which some fish may be retained will be determined at a future time, after considering any pertinent new information that has been developed. No fish will be retained unless USDA approves the conditions under which they are retained. USDA approval will be contingent upon those conditions presenting no significant deviation that would alter the findings in this environmental assessment.

Protocols for minimizing potential for escape of the fish during experimentation are presented in Section III of this EA.

2.5 Background

2.5.1 Carp Biology and Ecology

2.5.1.1 General Biology

A member of the minnow family (Cyprinidae), carp are native to Asia and were introduced into North America in the 1880's. Mirror carp are a partially scaled, genetically selected form of the common carp (*Cyprinus carpio*). Mature adult carp frequently exceed 10 pounds in weight and 2 feet in length. The normal life span seldom exceeds 20 years.

2.5.1.2 Reproduction and Fecundity

Sexual maturity varies with sex and growing conditions. The range for reaching sexual maturity is 1 to 5 years. The average male carp matures in 2 years with female carp usually reaching sexual maturity within 3 years. However, carp may mature earlier under controlled growing conditions. Spawning is temperature dependent. Most spawning occurs throughout the spring and early summer once water temperature reaches 63 °F (5). Spawning will cease at temperatures above 81 °F (5). Spawning begins with the adults congregating in groups in water 1 to 2 feet deep. During spawning several males may pursue a female, and the associated pursuit often splashes the water and roils the bottom sediments. Several hundred thousand to millions of eggs can be released by an individual female. The eggs sink and adhere to the bottom or to vegetation. Hatching time is temperature dependent. For example, eggs hatch in less than 3 days at 77 °F, but in cooler water may take 4 to 12 days to hatch (6). Newly hatched larvae are less than 0.2 inch long and remain attached to vegetation until they have completely absorbed their yolk sacs. This generally occurs by the fifth day.

2.5.1.3 Feeding and Growth

Carp commonly feed by rooting on the bottom and sucking up quantities of silt which are then expelled as food items are selected from the water (5). The disruption of the sediments up to 5 inches deep during feeding causes substantial increases in water turbidity (7), and can have an adverse effect on the plant communities within the carp feeding areas. The mechanisms of these effects are by either the physical uprooting of aquatic plants, or the blockage of sunlight by the turbidity which causes the plants to die (8). However, other studies have shown that when carp were present in low densities, water turbidity was not significantly increased (9). Common carp prefer aquatic insects and invertebrates as food items, and seldom selectively graze on plants as is the habit with grass carp (*Ctenopharyngodon idella*).

Carp in natural systems often grow to 7 inches in the first year, with successive growth highly variable and dependent upon environmental and genetic variables.

2.5.1.4 Ecology

The gregarious spawning activities, disruptive feeding habits, and propensity of carp to displace existing fish species have all contributed to carp becoming the most often cited nuisance introduced fish in North America (10).

The displacement of existing fish populations when carp are introduced into a system is seldom caused by a direct competition for food, but rather the displacement is caused by carp physically disrupting the habitats used by the existing fish populations. Fish that rely on sight to capture prey are disrupted when carp feeding and spawning activities increase the water turbidity. Those fish that rely on aquatic plants to provide shelter from predation, or who feed upon the animals that colonize the plants, are displaced when the carp uproot the plant stands as they feed. Many species of fish deposit their eggs directly on the sediments during spawning. The eggs are then vulnerable to incidental ingestion by carp, or to burial as the sediments which the carp suck up during feeding settle through the water column. The above displacements occur most commonly in those systems that support mature carp (11).

Carp can also coexist with other warm water fish species, and often thrive in situations where water pollution has resulted in the decline of less tolerant native fish populations (12). In addition, carp can provide beneficial effects to an aquatic system by uprooting nuisance vegetation, and as juveniles, providing forage to certain game fish (8).

2.5.1.5 Mirror Carp

Mirror carp are sometimes seen in waters of North America (5). In large populations of carp, many unusual patterns of scaling and color occur infrequently along with the predominant wild type. Data on crosses of carp with different scale cover show that the continuous pattern of scaling in common carp dominates over the "mirror" type of scale distribution (13).

The pleiotropic action of the "scale" gene in carp affects survival. Decreased survival of carp carrying the "nude" carp gene is a result of the unfavorable action of this gene upon a large number of traits, some of which are shown in the following table (13). Growth rate, ability to regenerate fins, and survival are expressed as percentages of the value in scaled carp taken for 100.

Indices	Scaled carp	Mirror carp
Growth rate	100	83-94
Mean No. gill lamellae	8.86	8.35
Ability to regenerate fins	100	76
Hemoglobin, percent	9.02	8.87
Survival (optimum conditions)	100	91-98
Survival (unfavorable conditions)	100	93-95

2.5.2 Genetic Modification of the Mirror Carp

The genetic transformation of the mirror carp was accomplished by the chromosomal insertion of DNA from a cloning vector, pRSV-2. The recombinant plasmid, pRSV-2 contained the gene for rainbow trout growth hormone (rtGH) under the promotional control of the long terminal repeat (LTR) from Rous sarcoma virus (RSV) and additional apparently non-functional flanking sequences used in construction of the pBR322-derived plasmid. See Figure 2. The LTR, a non-infectious regulatory sequence of DNA derived from RSV-RNA, functions as an efficient molecular recognition site for initiation of synthesis of rtGH protein in transgenic carp.

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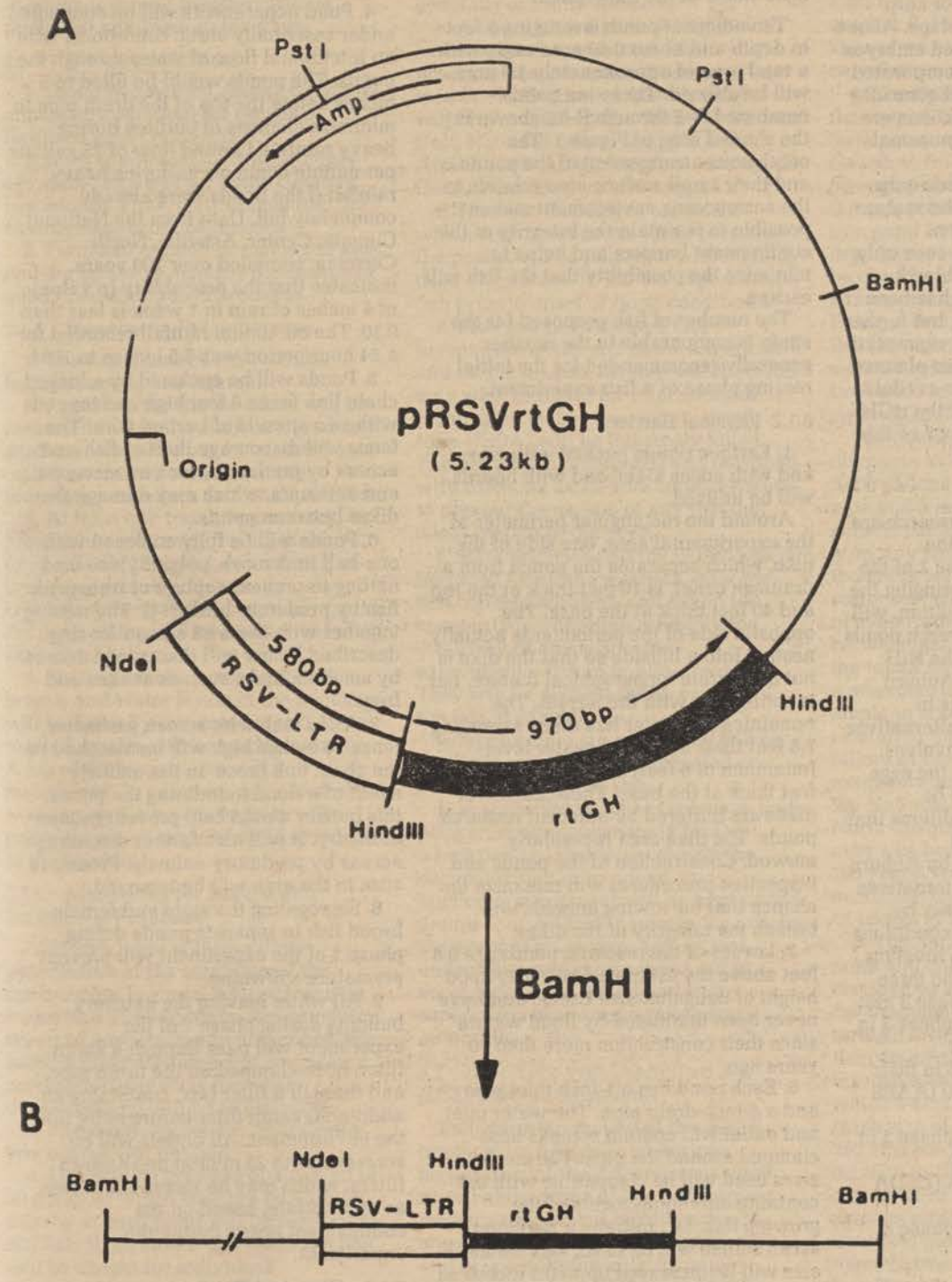
FIGURE 2. Structure of RSV Rainbow trout growth hormone recombinant plasmid. (A) Circular pRSVrtGH containing the rtGHcDNA (970 bp) at the Hind III site, along with RSV-LTR promoter (580 bp). (B) Bam HI linearized recombinant plasmid (5.23 kb) used for microinjection.



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Further technical details and references on the construction of the pRSV–2 are given in Appendix 1 of this EA.

The recombinant DNA was linearized (Figure 2) prior to microinjection, and 10^6–10^8 copies of the genetic material were microinjected into mirror carp embryos at the 1, 2 or 4 cell stage. About 30 percent of the microinjected embryos survived. About 5 percent incorporated from 1 to 5 copies of the rtGH gene into their chromosomes. The insertions are typical of a single copy chromosomal integration at multiple sites.

All of the resulting transgenic carp tested expressed both carp and mature rainbow trout growth hormone. Expression of rtGH has been seen only in red blood cells and not in blood serum. Not every carp tissue has been tested for expression to date, but further assessment of the rtGH gene expression and other biological effects are planned in the proposed research. The available evidence of the expression of the rtGH gene is presented in Appendix 2 of this EA.

III. Alternatives

Three alternatives to the research are considered in this EA. All of the alternatives assume that phase 1 of the experiment, which involves bringing the brood fish into spawning condition, will be carried out in outdoor research ponds meeting the requirements of the NIH Guidelines and approved by Auburn University's IBC. This phase is in progress. Similarly all of the alternatives assume that phase 2, which involves spawning the fish, incubating the eggs and growth of the larvae, will be conducted indoors under conditions that meet requirements of the NIH Guidelines and are approved by Auburn University's IBC. The three alternatives considered are defined primarily by variation in the experimental conditions for conducting phase 3, which involves rearing of the offspring/fry. The three alternatives considered for phase 3 are:

Alternative 1—Conducting phase 3 in outdoor research ponds under conditions proposed by AAES in their submission of February 8, 1989 (AAES proposal);

Alternative 2—Conducting phase 3 in outdoor research ponds under conditions preferred by USDA (USDA preferred action); and

Alternative 3—Conducting phase 3 indoors (No action).

3.1 Description of Alternative 1

In developing the protocol for the research, AAES considered various alternative measures to reduce the possibility of escape of the fish from the outdoor research ponds or hatchery. After consulting with a number of experts before submitting their proposal to USDA for a review by ABRAC, AAES included the following confinement measures in the proposed action.

3.1.1 Scale of the Experiment

Ten adjacent ponds averaging 3 feet in depth and about 0.10 acre each, with a total area of approximately 1.0 acre, will be utilized. These are ponds numbered R–3 through R–12 shown in the shaded area of Figure 1. The contiguous arrangement of the ponds and their small surface area relative to the surrounding environment makes it possible to maintain the integrity of the confinement barriers and helps to minimize the possibility that the fish will escape.

The number of fish proposed for the study is comparable to the number generally recommended for the initial rearing phase of a fish experiment.

3.1.2 Physical Barriers

1. Earthen ponds packed with clay, and with edges stabilized with boards will be utilized.

Around the rectangular perimeter of the experimental area, one side of the dike, which separates the ponds from a drainage canal, is 10 feet thick at the top and 40 feet thick at the base. The opposite side of the perimeter is actually nestled into a hillside so that the dike is not a separate topographical feature, but is contiguous with the terrain. The remaining perimeter has dikes averaging 7.5 feet thick above the water level (minimum of 6 feet) and tapering to 30 feet thick at the base. These narrower dikes are buffered by adjacent research ponds. The dike area is regularly mowed. Construction of the ponds and inspection procedures will minimize the chance that burrowing animals will breach the integrity of the dikes.

2. Levees of the research ponds are 0.8 feet above the estimated 100-year flood height of Saugahatchee Creek, and have never been inundated by flood waters since their construction more than 30 years ago.

3. Each pond has a 1-inch inlet pipe and a 4-inch drain pipe. The water inlet and outlet will contain screens hose-clamped around the pipe. The mesh sizes used will be compatible with the containment requirements of the growing fish, i.e., initially a 25 micron saran screen will be used, and the mesh size will be increased up to 0.5 inches as the fry grow. When screens larger than 500 microns are appropriate, these will be made of hard plastic securely clamped to the pipe. Water is discharged from the ponds into an adjacent open drainage canal through a common drain pipe servicing each pair of ponds. Just before entering the drainage canal, the discharged water will go through 1 of 5 filter boxes in which a screen of appropriate mesh size is stapled to a wooden frame.

4. Pond experiments will be conducted under essentially static conditions, with no intentional flow of water through the ponds. The ponds would be filled to 5 inches below the top of the drain pipe to minimize chances of outflow during heavy rainfall. Limited flow of 25 gallons per minute could occur during heavy rainfall if the ponds were already completely full. Data from the National Climatic Center, Ashville, North Carolina, compiled over 100 years indicates that the probability (p value) of 4 inches of rain in 1 week is less than 0.10. The maximum rainfall recorded for a 24 hour period was 8.5 inches in 1964.

5. Ponds will be enclosed by a locked chain link fence 8 feet high and topped with two strands of barbed wire. The fence will discourage theft of fish and access by predators, such as raccoons and muskrats, which may damage the dikes between ponds.

6. Ponds will be fully enclosed with one-half inch mesh, polyethylene bird netting to prevent capture of transgenic fish by predatory birds (14). The netting together with the wire screen fencing described below will discourage access by small animals, such as snakes and frogs.

7. A 1/16 inch wire screen perimeter fence 18 inches high will be attached to the chain link fence. In the unlikely event of a flood inundating the ponds, this barrier would help prevent escape of the fry. It will also further discourage access by predatory animals. Predators seen in the area will be removed.

8. Segregating the male and female brood fish in separate ponds during phase 1 of the experiment will prevent premature spawning.

9. All water leaving the hatchery building during phase 2 of the experiment will pass through a saran filter, hose-clamped on the drain pipe, and through a filter box, containing an additional saran filter before entry into the environment. All outlets will be screened with 25 micron mesh saran filters, which may be increased in size, as appropriate, based on the confinement needs during the experiment.

3.1.3 Chemical Barriers

At termination of the experiment the fish will be harvested, humanely sacrificed using MS–222, and the ponds drained. Any remaining water will be

poisoned with rotenone at a dose calculated to ensure that all fish not harvested have been killed.

Rotenone is a respiratory poison commonly used to kill fish (15). When exposed to light and air, rotenone undergoes decomposition so that ponds in which it is used normally can be restocked in a week to ten days.

3.1.4 Biological Barriers

1. Brood fish will be spawned indoors, minimizing potential for escape of fertilized eggs and larvae.

2. Carp sperm and unfertilized eggs are viable in water for approximately one minute. Thus, their escape into the environment is not of concern.

3. Fertilized eggs of carp in water sink and are adhesive, making the escape of unhatched embryos improbable.

3.1.5 Security and Maintenance

1. The experimental area will be locked, posted, and lighted.

2. Access to the test facilities will be restricted to faculty, staff, and graduate students who have been instructed and tested on their knowledge of the biosafety procedures in this experiment.

3. At least one trained person will be present intermittently during the day, 7 days a week, to report any attempt at breaching security. University police will patrol the area at least twice during the night. A log will be maintained of all security checks.

4. Netting, fences, screens, filters, levees, and water levels in the ponds will be formally inspected weekly. Any needed repairs will be made promptly. A log of the inspections will be maintained. In addition, personnel working on the premises daily will promptly report any observed deficiency in the barriers.

3.1.6 Monitoring for Escape and Emergency Response

Although there will be a daily observation of the condition of the confinement barriers, a formal weekly inspection of all barriers, and prompt repair of any damage to prevent escape, monitoring procedures and emergency notification protocols have been developed and will be implemented.

1. The following specific monitoring procedures will be used:

a. Fish will be branded at a weight of 30 grams at which time the population density in each pond will be reduced to 300 fish. Each month thereafter the fish will be caught for individual measurements, which will provide a monthly indication of the surviving number of fish in each pond. Rate of maturation and sexual development will be observed to ensure that the experiment is terminated before the fish are able to spawn.

b. Only fish with distinctive features for ease of recognition will be used in the study. For example, the "mirror" carp used in this study are only partially scaled whereas carp found in the wild generally are fully scaled.

c. An agricultural meteorologist will be designated to inform AAES whenever the prospect of severe weather is forecasted. Weather data will be provided by the Weather Service Unit, National Oceanographic and Atmospheric Administration, located on the Auburn University Campus.

d. If severe flooding is predicted which might breach the levee barriers, the ponds will be poisoned with a lethal dose of rotenone to kill the experimental fish prior to onset of flood conditions.

e. Fish will be harvested and inventoried at the end of the experiment, and all but a small number which AAES may wish to retain for future studies (contingent on subsequent approval from USDA) will be humanely killed. The ponds will be drained and poisoned with rotenone as an additional measure to prevent the escape of any fish that might remain in the pond.

f. State agencies and the public will be informed about the research, how the fish can be identified, and asked to cooperate by reporting promptly the discovery of any suspected experimental fish in public streams. They will be warned not to eat any of the fish, if caught.

g. Appropriate state agencies will be notified promptly of any reported or suspected escape of fish.

h. A sufficient supply of rotenone and potassium permanganate ($KMnO_4$), which can be used to accelerate the decomposition of rotenone, and applicator equipment will be kept on the premises of AAES for emergency use. In the event of an escape, any actions undertaken would be carried out in accordance with the advice and supervision of the appropriate state authorities.

3.2 Description of Alternative 2—(USDA preferred action)

Following the review of the AAES proposal by ABRAC and during preparation of the EA, concerns were raised about some of the confinement measures presented in Alternative 1 above. In response to these concerns and in consultation with fisheries science experts, AAES agreed to the following modifications in the protocol presented in Alternative 1, to further reduce the potential for escape of the fish. Alternative 1 with these modifications is the USDA preferred action.

3.2.1 Physical Barrier modification

1. Use the same 10 ponds proposed in Alternative 1 for rearing the fry (pond numbers R–3 through R–12 shown in Figure 1), but add two ponds (pond number R–13 and R–14 shown in Figure 1) to serve as catch basins, one pond for each five ponds containing fry.

2. Construct a new overflow system that interconnects the ponds and terminates in the two catch basin ponds Overflow from pond R3 would flow through pond R5, through pond R7, through pond R9, through pond R11, and into pond R13, which would normally be dry. An identical overflow system would be used for ponds R4, R6, R8, R10 and R12 emptying into catch basin pond R14. Existing drain pipes for pond numbers R–3 through R–12 containing experimental fish will be capped on both ends to prevent any water from entering or flowing through these pipes.

The overflow pipes will be 4 inches in diameter. With a maximum flow rate of 3,000 gallons per hour for the 1 inch inlet pipe and a maximum flow rate of 9,500 gallons per hour through the overflow pipe, any risks from accidentally adding too much water to the ponds when water replacement is necessary because of evaporation, is mitigated. Distance between the top of the overflow pipe to the top of the dike will be maintained at a minimum of 18 inches. This distance is ample to accommodate unusual levels of rainfall in the event of a short term failure of the overflow pipes to carry off excess water. According to reports of the National Climatic Center in Ashville, North Carolina, the maximum rainfall over a 24 hour period (recorded for over 100 years) was 8.5 inches in 1964; the maximum monthly rainfall recorded was 18 inches in 1961.

3. The outlet drain of each catch basin pond will contain a screen, hose-clamped to the pipe. Just before entering the drainage canal, water exiting through a common drain pipe servicing the two catch basin ponds will pass through a wooden frame filter box on which a screen has been stapled. The mesh size of the screens initially will be 250 microns, and will be increased up to 0.5 inch as the fry grow. Saran filters will be used up to 500 microns; larger screens will be of hard plastic. The overflow pipes installed through the dikes between ponds will have wooden box filters on each end of the pipe, to prevent fish from passing from one pond to another. The box filter will be mounted on stakes at the edge of the dike. It will consist of a wooden box

frame to which a screen of appropriate mesh size, as described above, is stapled to the bottom and sides. The top of the box filter will be left open. A rubber gasket will be used to seal the pipe where it enters the box filter. The box filter will be positioned so that the open top is no more than 6 inches above the pipe opening. In the event that the screen becomes clogged, this opening will assure that water and fish will pass to the catch basin ponds for poisoning and not over the dike to the drainage canal.

The minimum size filter of 250 microns is adequate to prevent escape of the smallest fish stocked in the ponds, and is less likely to become clogged and break than the 25 micron, minimum size filter proposed in Alternative 1. Filters of mesh size less than 0.25 inches will be inspected and cleaned daily. Those with mesh size equal to or greater than 0.25 inches will be inspected and cleaned weekly.

4. The dike between the experimental ponds and the drainage canal will be rebuilt so that:

a. The dike is at least 6 inches higher than the dike on the opposite side of the drainage canal. This will allow any flood water to dissipate first over ponds that do not contain the experimental transgenic carp.

b. The dike is at least 6 inches higher than the dikes (i) between the experimental ponds, and (ii) between the experimental ponds and the catch basin ponds. This will allow any overflow, should it occur, to pass into the catch basin pond and not to the drainage canal.

With these modifications in the dikes and drainage system there is little chance that heavy rainfall would cause overflow of the experimental ponds into the adjacent drainage canal. Emergency termination procedures will be implemented if, in monitoring of weather conditions, severe rainfall is predicted to cause unusual flood conditions. The decision to terminate will be made by the Director of AAES or a senior staff member in his absence. If time permits, AAES will consult with the Alabama Department of Conservation and Natural Resources regarding termination.

The modification of the drainage system, coupled with the water treatment modifications and termination procedures described below, reduce dependence on filters to prevent escape of experimental fish, and mitigate risks if those filters were to break.

5. The chain link fence, 18 inch high perimeter wire mesh fence, and polyethylene netting described in Alternative 1 will be extended to enclose the two catch basin ponds as well as the experimental ponds. The gates and the fences connected to the gates will have a metal screen or plate attached. The screen or plate will allow the gates to open while maintaining the integrity of the confinement barriers. The bottom of the fence surrounding the ponds containing the experimental fish and catch basin ponds will be anchored in a cement footer.

These barriers will improve security and discourage access by unauthorized persons or by predators to ponds containing the experimental fish as well as the catch basin ponds.

6. Fry will be transported from the hatchery to the ponds in plastic buckets with lids. After transporting the fry, the plastic buckets and trucks will be washed out at a place where any fry that escaped from the buckets will not be washed into a drainage canal or creek.

3.2.2 Chemical Barrier Modification

1. Catch basin ponds (ponds into which all experimental ponds drain) will be treated with rotenone in accordance with Federal and state requirements to prevent any accidental release of the experimental fish into Saugahatchee Creek. A group of bioassay carp will be placed in a cage in the pond to confirm efficacy of the poison. The rotenone-treated water will be detoxified before release into the drainage canal leading to Saugahatchee Creek. Rotenone may be detoxified either by sunlight (16) or by the addition of a chemical oxidant, potassium permanganate ($KMnO_4$) (17). The use of $KMnO_4$ at the concentration needed to detoxify the rotenone, followed by a short period of about 24 hours for complete oxidation of the rotenone, does not pose an environmental risk. Oxidation is complete when the water, which turns purple on addition of the permanganate, changes to brown. AAES has contacted the the Alabama Department of Environmental Management on its proposed use of rotenone, as required under the U.S. Environmental Protection Agency's reregistration standard for the use of rotenone. The Department notified Dr. John Plumb, Auburn University, in a letter dated November 15, 1989, that the proposed use of rotenone is acceptable, and a permit is not required because the facility produces less than 45,454 kilograms, harvest weight, of aquatic animals per year.

2. At termination of the experiment, the experimental fish will be removed from the ponds. The water remaining in the ponds will be treated with rotenone to kill any remaining experimental fish. A group of bioassay carp will be placed in a cage in the pond to confirm efficacy of the poison. The rotenone-treated water will be detoxified with $KMnO_4$ and the rotenone allowed to completely oxidize prior to the ponds being drained.

3.2.3 Hatchery Modification

1. The hatchery facility will be locked to restrict unauthorized entry and posted to alert anyone entering it that special procedures must be followed.

2. A fine screen that will retain eggs and newly hatched larvae will be placed over all the floor drains in the room used for incubation and hatching. Also, a weighted screen of appropriate mesh size will be placed over the tanks. These screens will prevent young fish from jumping or sloshing out of the tanks, falling into the floor drains, and potentially escaping into the environment if the drain filters were to fail.

3. Hatchery water will be discharged through a pipe into a catch basin pond. The rate of flow from the hatchery will allow static conditions, i.e., no drainage, in the catch basin pond during the incubation of the eggs. Rotenone will be applied in the catch basin pond every four days, in accordance with registered use conditions. A daily bioassay will be conducted to confirm the efficacy of the poison by placing carp in a cage into the pond. After a sufficient time period has elapsed for any escaped eggs to hatch and the larvae to be killed by the rotenone, the water will be detoxified by the addition of $KMnO_4$, and the rotenone allowed to completely oxidize prior to discharge. Because rotenone is not an effective poison for fish eggs, it is necessary to continue rotenone poisoning until any eggs that may have escaped have hatched.

Hatchery procedures will conform to all containment requirements of Auburn University's IBC.

3.2.4 Other Modifications

1. After the facilities have been modified and prior to spawning in the hatchery, USDA will inspect the facilities to assure compliance with all requirements described for Alternative 2. Water level in the ponds will be lowered for the inspection in accordance with instructions from the inspection team.

2. AAES will develop written instructions regarding routine monitoring, maintenance and security checks. Written instructions will also be developed for the chemical treatment of the catch basin ponds and associated bioassays, and for emergency termination procedures.

3. In the case of a known or suspected escape of transgenic carp, the drainage canal leaving the Auburn Fisheries Research Unit will be blocked with a net. Rotenone will be applied to the full length of the drainage canal in accordance with a written protocol conforming to Federal and state rotenone use requirements. Immediately behind the net the rotenone will be detoxified by the addition of $KMnO_4$.

4. Auburn University's IBC has agreed to conduct unscheduled inspections of the facility and AAES compliance with prescribed operating procedures in the protocol, during the course of the experiment. The IBC will determine how often inspections should be made.

3.3 Description of Alternative 3—(No action)

If USDA denies funding of the research and advises AAES that it does not believe transgenic carp offspring should be placed in outdoor ponds, AAES may decide to continue its current experiments under the following conditions until the research is no longer productive.

Phase 1. Bringing the brood fish into spawning condition in sex-segregated in outdoor ponds,

Phase 2. Artificially spawning the fish indoors, and

Phase 3. Rearing the offspring/fry in aerated indoor tanks.

This third phase, i.e., rearing the offspring/fry in indoor tanks distinguishes Alternative 3 from Alternatives 1 and 2. Because of limitations in the number of fish that can be raised indoors at the AAES facilities—currently no more than about 100 fish can be reared to the adult stage—and the history of poor survival of mirror carp at AAES under these conditions, the expected number of offspring that could be studied would be significantly less compared to Alternatives 1 and 2. Consequently, the utility of the research would be significantly curtailed.

Presumably, measures that AAES would use to prevent escape of the fish would be determined by Auburn University's IBC, in accordance with the NIH Guidelines. Without specific knowledge of these measures, their effectiveness in preventing escape of experimental fish and eggs compared to Alternatives 1 and 2 can not be evaluated. Indoor research, however, would reduce concern about weather conditions and wildlife predators contributing to an unplanned release of the experimental fish.

IV. Affected Environment

4.1 Research Facilities

Research pond facilities at AAES are located on a tract of AAES land approximately 4 miles north of the campus of Auburn University. Approximately 1600 acres of the tract have been set aside primarily for research and teaching in aquaculture and inland fisheries. Constructed on the Fisheries Research unit are 235 earthen ponds comprising approximately 222 acres of water. The ponds range in size from 0.05 acre to 22 acres. Located near the ponds are service buildings, equipment storage buildings, shops, feed and fertilizer storage, and a large fish holding/handling building. A fish processing/technology laboratory, a fish reproduction laboratory, and a fish nutrition laboratory are also located on the area.

4.2 Local Aquatic Ecosystem

The nearest natural body of water is Saugahatchee Creek which passes within approximately 400 yards of the AAES research ponds. The ponds and a portion of the creek are shown in Figure 1. Saugahatchee Creek originates approximately 3 miles northeast of the AAES and flows for over 45 creek miles before draining into the Tallapoosa River system at Yates Reservoir. The flow characteristics of Saugahatchee Creek are irregular and depend upon factors such as release from Saugahatchee Reservoir, rainfall, temperature, and outflow from municipal and industrial users located in Auburn and Opelika. Rivers in Alabama overflow about once per year on the average (18), with March the month with the greatest flood frequency (19). The tops of the levees of the research ponds are at least 0.8 feet above the estimated 100 year flood height for Saugahatchee Creek. Even under drought conditions flow would still be present in Saugahatchee Creek (20).

Saugahatchee Creek is a low order stream with intermediate water quality compared to neighboring streams (18). Water quality is oligotrophic in Yates Reservoir, the receiving water body of Saugahatchee Creek (21). Water temperatures have been infrequently collected, but reported values range from 10 °C in January to 24 °C in June (18) with up to a 7 °C variation in temperature occurring in as short of an interval as 12 days (20). The plant community in Saugahatchee Creek is dominated by lush periphytic and planktonic algal growths (18). Midges are the most common invertebrates in the creek (18). The fish community in Saugahatchee Creek is diverse with minnows (mostly *Notropis* spp.) comprising about 67 percent and centracids (mostly bass and bluegills) comprising about 26 percent of the fish community (18). Mirror carp (*Cyprinus carpio*), the subject of the proposed test, have not been reported as such from Saugahatchee Creek, however, the creek does support a resident population of the non-mutant form of this carp (21,22). In addition, other non-native carp, including grass carp (*Ctenopharyngodon idella*), silver carp (*Hypopthalmichthys molitrix*), and bighead carp (*Aristichthys nobilis*) have either become established in Saugahatchee Creek or migrated to bodies of water up to 200 miles downstream (18,21). The source of introductions of these exotic species has not been established, although they have been used for research purposes in the United States. This experience indicates the need for adequate measures to prevent the unplanned release of fish used for experimentation. No endangered or threatened species have been reported from Saugahatchee Creek (23).

V. Environmental Consequences

5.1 Introduction

It is uncertain what the immediate influence would be on the Saugahatchee Creek watershed if the transgenic and control mirror carp used in the proposed research were to escape the AAES facilities, but indications are that these carp could become a successfully established population. Interbreeding with the existing common carp assemblages would also be likely given the habitat and water temperatures that are favorable to carp spawning in the creek. The long-term effects of a transgenic mirror carp escape cannot be entirely predicted, but it is unlikely that they would differ in nature from those impacts observed from the introduction of common carp into the United States. However, the anticipated altered performance in growth rate of the transgenic mirror carp does suggest the likelihood of ecological impact on the existing aquatic ecosystem once an escape occurs. Whether the genetic transformation of the mirror carp would affect their ability to survive in Saugahatchee Creek is unknown.

5.2 Vegetation

The vegetation of Saugahatchee Creek could be adversely affected due to feeding behavior, a shading effect from water turbidity, and direct consumption should the experimental carp escape the AAES and become an established population. However, severe damage to

vegetation by carp has most often been reported in shallow still waters (8). Apart from the behavior of the fish, the presence of the rtGH gene itself will not impact aquatic vegetation. Given the precautions contained in protocol for the USDA preferred action (Alternative 2) to prevent escape of the experimental fish, significant impacts on aquatic vegetation are not anticipated.

Rotenone, a natural plant product derived from *Tephrosia vogelii* and related plants, has not been shown to be toxic to any aquatic or terrestrial plants (24).

5.3 Water Quality

The water quality of Saugahatchee Creek could be adversely affected by the increase in turbidity and nutrient resuspensions caused by the spawning and foraging activities of mirror carp should the carp escape the AAES. Apart from the expected behavioral characteristics of mirror carp, the presence of the rtGH gene itself in mirror carp is not expected to impact water quality. Given the precautions contained in the protocol of the USDA preferred action to prevent the escape of the experimental fish, significant impacts on water quality are not expected.

Rotenone is a respiratory poison that has varying degrees of toxicity toward invertebrates and vertebrates such as birds, reptiles, and mammals (15, 25). Therefore, its presence in water would be detrimental to water quality. Gilderhus et al. (26), have determined the half-life of rotenone in freshwater as 13.9 hours at 24 °C and 83.9 hours at 0 °C. The proposed use of rotenone in accordance with the EPA registration and subsequent detoxification procedures for the rotenone treated water will prevent rotenone from being released into local waters and affecting water quality.

5.4 Indigenous Organisms

The indigenous organisms in the Saugahatchee Creek ecosystem could be adversely affected by the physical disruption of the habitat and competition for food caused by the transgenic mirror carp should they escape the AAES and become an established population. Whether mirror carp containing the rtGH gene would have a competitive advantage over other carp or fish populations in this creek is unknown, but the potential may be more adverse than the release of non-transgenic mirror carp. The transgenic carp would be sexually compatible with indigenous non-transgenic common carp in Saugahatchee Creek.

The impact of Rous sarcoma virus (RSV) long terminal repeat sequence (referred to as the RSV–LTR) on indigenous waterfowl and fish populations is unknown, but no adverse effects are anticipated. Although RSV is an avian pathogen that induces tumors, the RSV–LTR sequence alone does not represent the entire viral genome and cannot replicate and initiate an infection independently. Potential risks of the RSV–LTR that have been considered are: (i) Possible activation of other genes, particularly oncogenes, (ii) transactivation of LTR by other gene products, (ii) induction of immunological intolerance to other retroviruses, and (iv) possible recombination with fish retroviruses. Each of these potential risks is discussed in more detail in Appendix 3. Given the precautions contained in the USDA preferred action to prevent escape of fish or their contact with waterfowl in the experimental ponds, and the lack of evidence suggesting the occurence of any of the above potential risks, significant impacts associated with the RSV–LTR are not anticipated.

Rotenone is a potent fish poison. Release of rotenone into the Saugahatchee Creek would be extremely detrimental to indigenous fish stocks. In addition, rotenone has been shown to be toxic to aquatic and terrestrial invertebrates (27, 24). Rotenone is less toxic to birds. The oral LD_{50} for mallards and pheasants is greater than 1 g/kg. Procedures for the planned use of rotenone are such that no adverse effect on indigenous organisms is expected.

Burial of experimental fish killed with rotenone or with tricaine methanesulfonate, MS–222, will have no adverse effect on the environment. The amount of rotenone and MS–222 per fish is small. The rotenone is chemically bonded to intracellular components of the fish. Therefore, free rotenone would not exist at the burial site. MS–222 is commonly used in fisheries research for humane sacrifice.

5.5 Human Health and Safety

No impacts on human health or safety are expected from contact with the transgenic carp. However, if the transgenic fish escape and are caught they should not be eaten because food safety has not been fully documented. No risk is expected from the rtGH gene itself. The gene is a very small part of the carp genetic makeup, and the resulting protein hormone occurs at low levels and is non-toxic and the same protein that occurs naturally in rainbow trout. An rtGH gene in carp could have unintended secondary effects by way of positional or other effects on the carp genes that hypothetically could affect food safety. With the precautions included in the protocol to prevent escape of the experimental fish, the unique physical characteristics of mirror carp, and the public information activities which AAES plans to undertake, significant impacts on human health from fish consumption are not expected to occur.

Rotenone has a human oral LD_{50} of 2.85 g/kg. In general, this value is similar to other toxicity values for mammals. If all label instructions for the use of rotenone are followed and the detoxification procedures are adhered to, then no human health risk is envisioned from the use of rotenone.

5.6 Socioeconomic Impacts

Research with transgenic carp is at an early stage of development. Any prediction of possible commercial application that may eventually evolve from the research would be highly speculative. Assessment of socioeconomic impacts at this time would be premature and meaningless. Precautions in the protocol for the USDA preferred action to prevent escape of the transgenic carp and the opportunity for these fish to be captured and used in commercial production mitigate the possibility of socioeconomic impacts.

5.7 Cumulative Impacts

No cumulative impacts are expected to arise from the experiment, if the precautions and procedures described in Alternative 2 are followed.

VI. Conclusions

No significant impact on the quality of the human environment is expected if the mitigation measures in the study protocol as modified in Alternative 2 (USDA preferred action) are carried out. While Alternative 1 also provides substantial mitigation, it provides less assurance that fish will not escape and a greater potential risk of adverse impacts on the environment. Because the precise conditions under which AAES may elect to continue research if USDA does not approve the research are speculative (Alternative 3), conclusions about the environmental consequences and comparison of this alternative with other alternatives likewise would be speculative.

VII. Public Notification

The AAES has worked diligently to communicate broadly the nature and expectations of the proposed research project to genetically transform fish

species of scientific and economic importance. Public communication has taken place through international, national and state newspaper coverage including The New York Times, television coverage, scientific reports in meetings and journals, experiment station publications and lectures, and consultations with State, Federal and interest-group representatives concerned with the consequences of the research.

Also, USDA will publish this EA in the Federal Register, providing a 30 day public comment period. Copies of the EA will be sent to persons who previously expressed an interest.

7.1 Persons and Agencies Consulted

(1) Dr. William Gartland, National Institutes for Allergy and Infectious Diseases, National Institutes of Health.

(2) Nelson A. Wivel, M.D., Office of Recombinant DNA Activities, National Institutes of Health.

(3) Dr. John Fulkerson, Dr. William Carlson, Dr. Meryl Broussard, and Dr. David McKenzie, Cooperative State Research Service, USDA.

(4) Dr. Douglas Bolt and Dr. Richard Parry, Agricultural Research Service, USDA.

(5) Michael L. Werner, Esq., Animal and Plant Health Inspection Service, USDA.

(6) Dr. James McCann, National Fishery Research Laboratory, U.S. Fish and Wild Life Service, Gainesville, Florida.

(7) Dr. J. R. MacMillian, Dr. Graham Purchase, and Dr. Jonathan Pote, Mississippi State University.

(8) Dr. William Wolters, Louisiana State University.

(9) Dr. Anne Kapuscinski and Dr. George Spangler, University of Minnesota.

(10) Dr. Dennis Powers and Dr. Thomas Chen, Molecular Geneticists, Johns Hopkins University.

(11) Dr. Tim Townes, Molecular Geneticist, University of Alabama, Birmingham.

(12) Dr. Curtis Bird, Chairman, Institutional Biosafety Committee, Auburn University.

(13) Dr. David Bisaro, former Chairman, Institutional Biosafety Committee, Auburn University, currently at Ohio State University.

(14) Dr. Paul Lemke, former Chairman, Institutional Biosafety Committee, Auburn University.

(15) Mr. Ron Kriel, Environmental Safety Officer, Auburn University.

(16) Ms. Jane Rissler and Dr. Rudy Rosen, National Wildlife Federation.

(17) Mr. C.E. White and Mr. Charles Kelly, Alabama Department of Conservation and Natural Resources.

(18) Mr. Doug Schofield, Alabama Wildlife Federation.

(19) Mr. Dennis Holcomb and Mr. Robert Wattendorf, Florida Game and Freshwater Fish Commission.

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Dr. Sue Tolin, Department of Plant Pathology, Physiology, and Weed Science, Virginia Polytechnic Institute and State University.

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Appendix 1—Assembly and Structure of the Genetic Construct

The genetic construct used in the transgenic carp studies, denoted as pRSVLTR-rtGH cDNA, was assembled as follows. A Bam HI–Hind III fragment

containing GH cDNA sequences coding for the mature rainbow trout GH1 was isolated from pAF51 (Agellon and Chen, 1986). The DNA was blunt-ended and inserted into the Sal I site of plasmid pRSV–2 (Gorman, et al., 1982). The resulting construct (5.2 Kb), pRSVLTR-rtGH cDNA, contains 580 bp of the LTR sequence, 970 bp of the cDNA rtGH sequence and 3.7 Kbp of the pRSV flanking sequence. The 5' end of the GH cDNA sequence is linked to the RSV–LTR promoter by a 13 bp fragment corresponding [to] the multiple cloning site. The construct was linearized with Bam HI for microinjection into carp embryos.

The structure of the genetic construct is shown in Figure 2.

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Agellon, L. B. and T. T. Chen. 1986. Rainbow Trout Growth Hormone: Molecular Cloning of cDNA and Expressions in *Escherichia coli*. DNA Vol. 5 (6) pp. 463–471.

Gorman, C. M., G. D. Merlin, M. C. Willingham, I. Pastan, and B. H. Howard. 1982. The Rous Sarcoma Virus Long Terminal Repeat is a Strong Promoter when Introducted into a Variety of Eukaryotic Cells by DNA-mediated Transfection. Proc. Natl. Acad. Sci. USA Vol. 79, pp. 6777–6781.

Appendix 2—Incorporation and Expression of the Genetic Construct in Transgenic Carp

The number of integrated copies of the gene ranges from 1–5. The insertions are typical of a single copy integration at multiple sites. The transgenic carp express mature rainbow trout growth hormone polypeptide in their red blood cells, but not in their serum. The investigators have not examined other tissues, but they anticipate that there is expression in other cell types as well.

The expression results in an increased growth rate of about 20 percent in the transgenic carp. The morphology and behavior of the transgenic carp appears to be unaffected. The observed frequency of deformities exhibited by the transgenic carp in the laboratory is not different from normal controls.

The investigators do not anticipate any other changes in the transgenic carp besides the expression of the rainbow trout growth hormone and the increased growth rate, although they will measure several other traits. These will include (1) Rate of fertilization, (2) hatching percentage, (3) growth and survival to two weeks, (4) growth and survival to 3 months, (5) growth and survival to 15 months, (6) expression of the RSVrtGHcDNA gene, (7) tissue distribution of expression, (8) inheritance of the gene, (9) morphology, (10) ease of capture by seine and ease of handling, (11) if disease or other stresses occur and their relative effects, (12) dressing percentage, (13) body composition, (14) age at sexual maturity, (15) rate of sexual maturation, and (16) fecundity. Other observations of a subjective nature on behavior will be made.

Dot blot data (Figure 3) and Southern blot data (Figure 4) are presented as evidence of genomic incorporation of the genetic construct shown in Figure 2.

Evidence of rainbow trout growth hormone in red blood cells of transgenic carp is presented in Figure 5.

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FIGURE 3. Dot Blot analysis of genomic DNA isolated from the presumptive transgenic (pRSVrtGHcDNA-1) Common carp. Genomic DNA (18 µg) isolated from pectoral fin was denatured and spotted onto a nylon membrane along with pRSVrtGH standards of 30 pg (a), 60 pg (b) and 150 pg (c), corresponding to 1, 2, and 5 copies of the integrated gene. Genomic DNA from non-transgenic carp (d and e) was included as negative control.

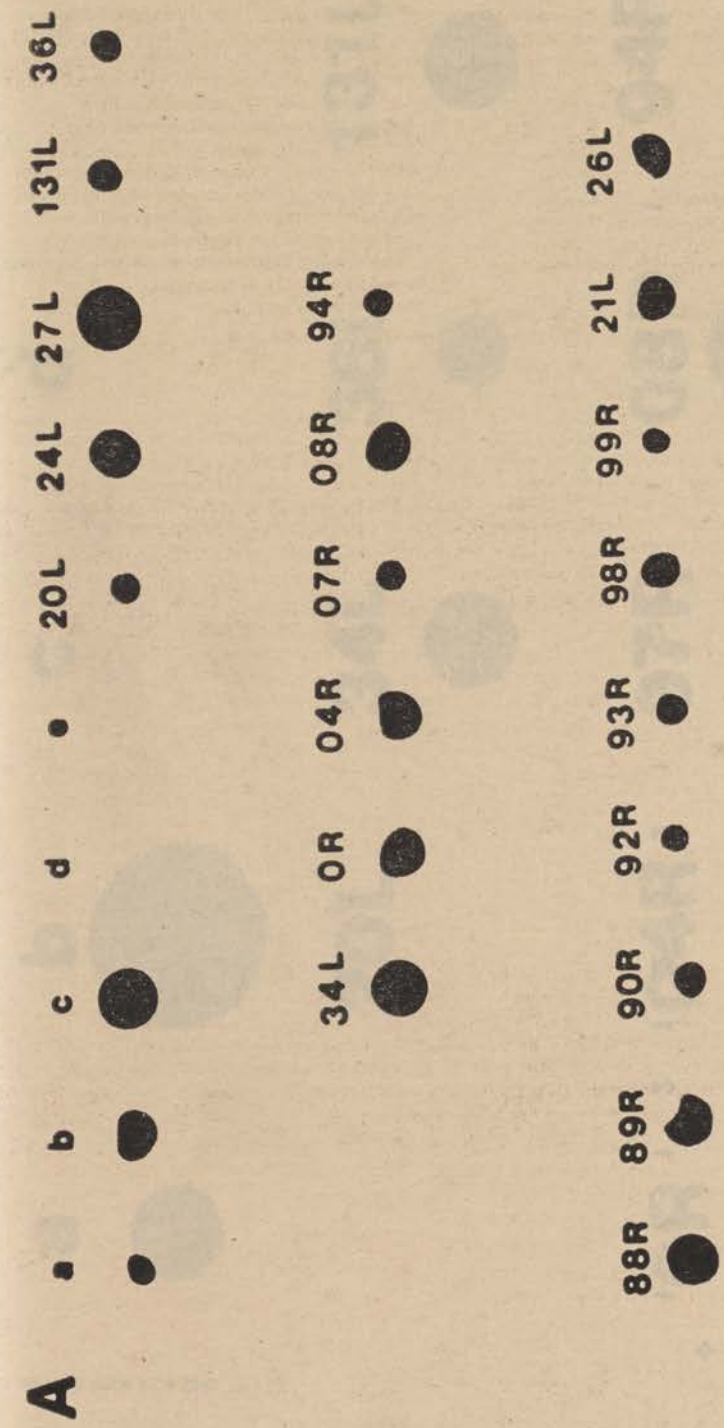


FIGURE 4. Southern Blot analysis of genomic DNA isolated from the presumptive transgenic (pRSVrtGHcDNA-1) Common carp. BAM HI (a) and HIND III (b) digested genomic DNA (18 µg) was electrophoresed on a 0.8% agarose gel, transferred to a nylon membrane and hybridized either with probe 1 (580 bp LTR of RSV) or probe 2 (890 bp HIND III-HIND III fragment containing the rtGHcDNA).

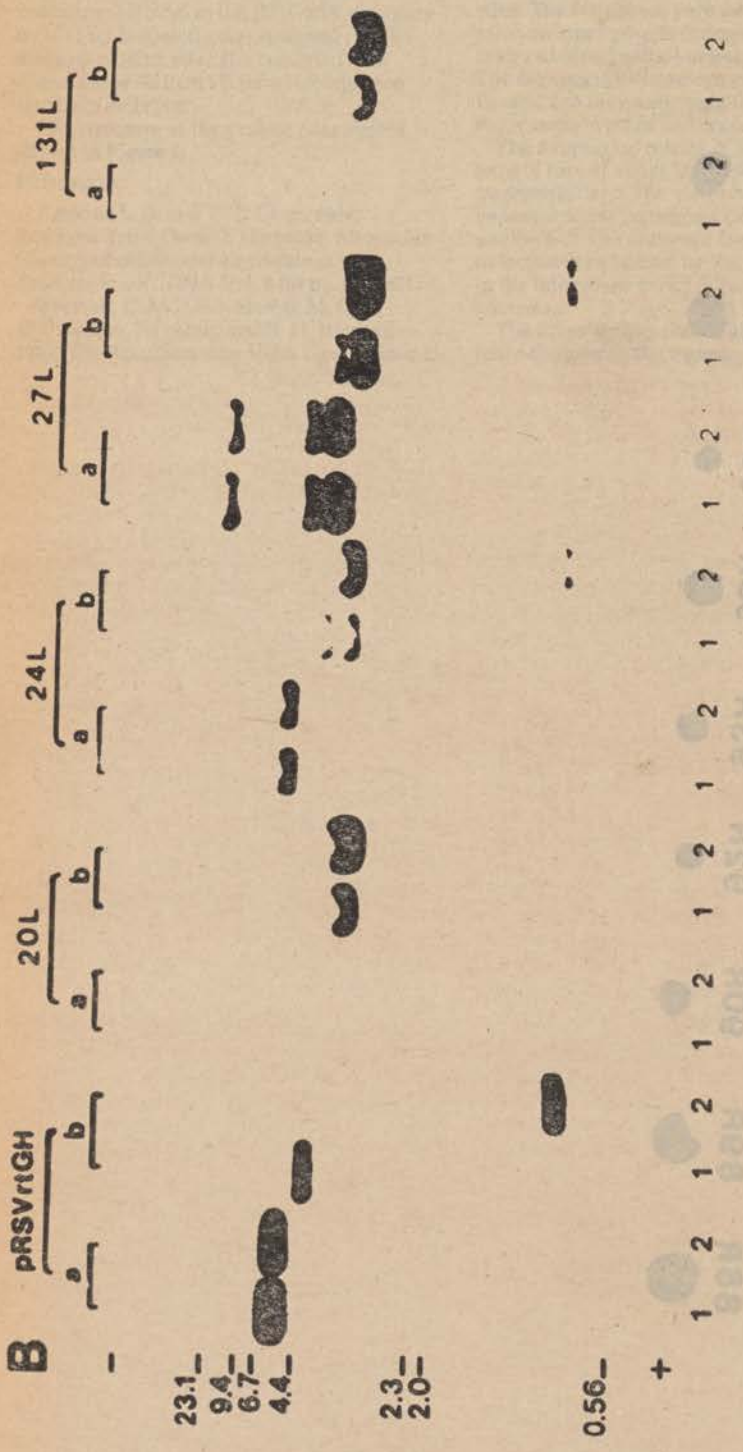
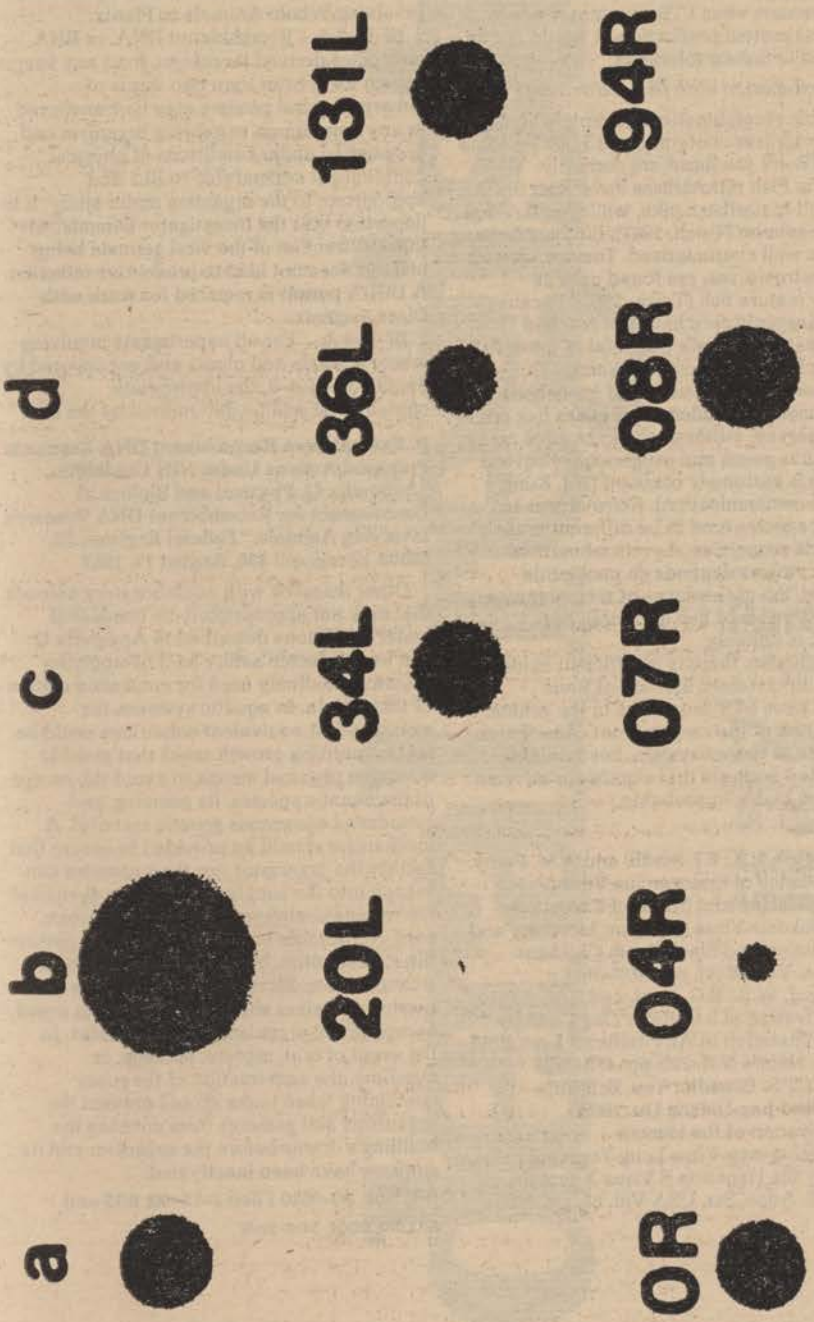


FIGURE 5. Detection of Rainbow trout growth hormone (rtGH) in red blood cells of transgenic carp. Red blood cell extracts from transgenic carp were immobilized on a Terasaki plate, and bound to iodine-125 labeled goat anti-rabbit IgG. Rainbow Trout pituitary extract [0.1 g (a) and 0.2 g (b)] was included as positive control and normal carp red blood extract (c AND d) as negative control.



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Appendix 3—Potential Risks of Using the RSV Promoter in Transgenic Fish

There is currently little or no scientific information available regarding the possible interaction of the RSV–LTR genetic sequence with endogenous fish retroviral infections. As an alternative, Dr. R. L. Witter of the Agricultural Research Service has supplied information on inherited retroviral genes in chickens, the primary biological host of the Rous sarcoma virus. That information facilitates consideration of the following four types of potential risk of using the RSV promoter in transgenic fish.

1. *Activation of other genes*

Retroviral integration in somatic cells may prompt tumor induction through activation of host oncogenes, a function of the 3' LTR which acts like an enhancer (Hayward, et al., 1981). Integration sites near the oncogenes are most effective. This phenomenon is specific for certain viral strains. LTR's from exogenous avian leukosis viruses are more efficient than those from endogenous viruses. Oncogenes are highly conserved and are undoubtedly present in the common carp. It is possible that the Rous sarcoma virus LTR might activate host oncogenes, causing neoplastic disease. However, no such disease has been observed by the investigators. This type of disease would be detected through pathologic examinations and would be manifested through increased mortality in transgenic animals. In no way would this pose a danger to humans handling the fish. Because a complete virus is not present, there is no risk of transmission through contact with the fish or through consumption in the unlikely event the fish escape confinement. Risks to the ecosystem seem small since, if this inserted gene decreases fitness, it may be self limiting in nature.

2. *Transactivation of LTR by other gene products*

Integrated LTR's can be activated by various molecules, including proteins produced by viruses of the herpes and other groups, to function as a promoter (Seto, et al., 1988). It is possible that such proteins, if present, might transactivate the Rous sarcoma virus LTR in common carp. If so, the main effect probably would be an increase in the output of trout growth hormone. If this proved to be the case, little danger would be expected to occur. However, experiments should be monitored for evidence of unusual gene expression that might be related to environmental transactivating factors.

3. *Immunological tolerance leading to increased susceptibility to retroviral infection*

Integrated retroviruses may express gene products that serve to reduce the ability of animals to respond immunologically to later infection with exogenous retroviruses of similar serotypes (Crittenden, et al., 1984). This requires the production of retroviral protein antigens. Because expression of the Rous sarcoma virus LTR does not result in retroviral protein production, it would not be expected to induce tolerance.

4. *Recombination with fish retroviruses*

Possible recombinational events whereby fish retroviruses containing the Rous sarcoma virus LTR are produced are currently unknown. Fish retroviruses have been described in northern pike, walleye pike, and Atlantic salmon (Teich, 1982), but they have not been well characterized. Tumors, caused by fish retroviruses, are found only in sexually mature fish (Teich, 1982). Because these transgenic carp have not reached sexual maturity, tumor potential of these fish is still unknown. Among chickens, spontaneous recombination of exogenous retroviruses with endogenous genes has not been observed, although chickens have many endogenous genes and exogenous retroviral infection is extremely common (H.J. Kung, personal communication). Retroviruses in different species tend to be different in their nucleotide sequences. As recombination between viruses depends on nucleotide homology, the occurrences of recombination between viruses of fish and birds, for example, is unlikely.

In conclusion, there is insufficient evidence to say with certainty that use of Rous sarcoma virus LTR sequences in the genetic modification of the carp will not cause harm to humans or the ecosystem, but available information suggests that significant adverse effects are highly improbable.

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Appendix 4—I. Excerpt From NIH Guidelines for Research Involving Recombinant DNA Molecules—Federal Register, 51, 16961, May 7, 1986

III–B–4. Recombinant DNA Experiments Involving Whole Animals or Plants

III–B–4–a. Recombinant DNA, or RNA molecules derived therefrom, from any source except for greater than two thirds of a eukaryotic viral genome may be transferred to any non-human vertebrate organism and propagated under conditions of physical containment comparable to BL1 and appropriate to the organism under study. It is important that the investigator demonstrate that the fraction of the viral genome being utilized does not lead to productive infection. A USDA permit is required for work with Class 5 agents.

III–B–4–b. For all experiments involving whole animals and plants and not covered by Section III–B–4–a, the appropriate containment will be determined by the IBC.

II. Excerpt from Recombinant DNA Research; Proposed Actions Under NIH Guidelines, "Appendix Q, Physical and Biological Containment for Recombinant DNA Research Involving Animals," Federal Register, 52, 29800, paragraph 338, August 11, 1987

Other research with nonlaboratory animals that may not appropriately be conducted under conditions described in Appendix Q can be conducted safety [sic] by applying practices routinely used for controlled culture of these biota. In aquatic systems, for example, BL1 equivalent conditions could be met by utilizing growth tanks that provide adequate physical means to avoid the escape of the aquatic species, its gametes, and introduced exogenous genetic material. A mechanism should be provided to ensure that neither the organisms nor their gametes can escape into the supply or discharge system of the rearing container (e.g., tank, aquarium, etc.). Acceptable barriers include appropriate filter, irradiation, heat treatment, chemical treatment, etc. Moreover, the top of the rearing container should be covered to avoid escape of the organism and its gametes. In the event of tank rupture, leakage, or overflow, the construction of the room containing these tanks should prevent the organisms and gametes from entering the building's drains before the organism and its gametes have been inactivated.

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federal register

Friday
February 16, 1990

Part IV

Department of State

48 CFR Parts 601, 605, and 607 et al.
Acquisition Regulations, Miscellaneous Amendments; Final Rule

DEPARTMENT OF STATE

48 CFR Parts 601, 605, 607, 608, 609, 622, 623, 625, 632, 636, 637, 648, and 653.

[State Acquisition Circular 88-1]

Department of State Acquisition Regulation; Miscellaneous Amendments

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: State Acquisition Circular (SAC) 88-1, amends the Department of State Acquisition Regulation (DOSAR):

(1) In consideration of some of the changes made to the Federal Acquisition Regulation (FAR) by Federal Acquisition Circulars (FAC's) 84-34 through 84-50;

(2) By designating appropriate officials where the FAR prescribes "agency head" or "agency head or designee."

(3) By revising the authority designation in part 636.

(4) By correcting editorial errors in part 601.

(5) By correcting the table of contents for part 653 by removing section 653.107, which was included in error;

(6) By amending the Table of Contents for part 609 to reflect the revised title of section 609.404 (for FAR 9.404, as included in FAC 84-46);

Items (4), (5), and (6) are considered strictly editorial in nature.

EFFECTIVE DATES: February 16, 1990.

FOR FURTHER INFORMATION CONTACT: James Tyckoski, Office of the Procurement Executive (703) 875-7046.

SUPPLEMENTARY INFORMATION: The changes being made by SAC 88-1 do not constitute "significant revisions" as defined at FAR 1.501-1; therefore, public comment has not been solicited pursuant to FAR 1.501-3(a). This action is exempt from the requirements of Executive Order 12291 by OMB Circular 85-7. It will not have an impact on a substantial number of small entities, nor does it establish any information collection as contemplated by the Regulatory Flexibility Act and Paperwork Reduction Act.

List of Subjects in 48 CFR 601, 605, 607, 608, 609, 622, 623, 625, 632, 636, 637, 648, and 653

Government procurement.

Dated: January 23, 1990.

John J. Conway,

Procurement Executive.

For the reasons set out in the Preamble, Chapter 6 of Title 48 of the Code of Federal Regulations is amended as follows:

1. The authority citation for parts 601, 605, 607, 608, 609, 622, 623, 625, 632, 636, 637, 048, and 653 continues to read as follows:

Authority: 22 U.S.C. 2658; 40 U.S.C. 486(c); 48 CFR subpart 1.3.

PART 601—DEPARTMENT OF STATE ACQUISITION REGULATIONS SYSTEM

601.602-1 [Amended]

2. Section 601.602-1(c) is amended by adding "a contract" after "terminate" and by revising "ben" to read "been".

PART 605—PUBLICIZING CONTRACT ACTIONS

4. Part 605 is amended by adding subpart 605.4, consisting of sections 605.404 and 605.404-1 to read as follows:

Subpart 605.4—Release of Information

605.404 Release of long-range acquisition estimates.
605.404-1 Release procedures.

Subpart 605.4—Release of Information

605.404 Release of long-range acquisition estimates.

605.404-1 Release procedures.

The Procurement Executive is the agency head's designee for the purposes of FAR 5.404-1(a) and the agency head for the purposes of FAR 5.404-1(b).

5. A new part 607 consisting of subpart 607.1 and section 607.103 is added to read as follows:

PART 607—ACQUISITION PLANNING

Authority: 22 U.S.C. 2658; 40 U.S.C. 486(c); 48 CFR subpart 1.3.

Subpart 607.1—Acquisition Plans

607.103 Agency-head responsibilities.

The Procurement Executive is the agency head's designee for the purposes of FAR 7.103.

PART 608—REQUIRED SOURCES OF SUPPLIES AND SERVICES

6. Part 608 is amended by adding subpart 608.3 consisting of section 608.302 to read as follows:

Subpart 608.3—Acquisition of Utility Service

608.302 Applicability.

The Procurement Executive is the agency head for the purposes of FAR 8.302(d)(2)(i).

PART 609—CONTRACTOR QUALIFICATIONS

7. Section 609.404 is amended by revising the section heading as follows:

609.404 Parties excluded from procurement programs.

PART 622—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

8. Part 622 is amended by adding subpart 622.3, consisting of section 622.302; adding subpart 622.4, consisting of sections 622.404, 622.404-3, 622.404-6, 622.404-7, 622.404-11, 622.406, 622.406-1, 622.406-8, 622.406-9, 622.406-10, 622.406-11, and 622.406-12; adding section 622.1308 to subpart 622.13; and adding section 622.1408 to subpart 622.14 to read as follows:

Subpart 622.3—Contract Work Hours and Safety Standards Act

603.302 Liquidated damages and overtime pay.

Subpart 622.4—Labor Standards For Contracts Involving Construction

622.404 Davis-Bacon Act wage determinations.
622.404-3 Procedures for requesting wage determinations.
622.404-6 Modifications of wage determinations.
622.404-7 Correction of wage determinations containing clerical errors.
622.404-11 Wage determination appeals.
622.406 Administration and enforcement.
622.406-1 Policy.
622.406-8 Investigations.
622.406-9 Withholding from or suspension of contract payments.
622.406-10 Disposition of disputes concerning construction contract labor standards enforcement.
622.406-11 Contract terminations.
622.406-12 Cooperation with the Department of Labor.
622.1308 Contract clauses.
622.1408 Contract clause.

622.302 Liquidated damages and overtime pay.

The authority to make the determination prescribed in FAR 22.302(c) is delegated, without power of redelegation, to the head of the contracting activity.

622.404 Davis-Bacon Act wage determinations.

622.404-3 Procedures for requesting wage determinations.

The cognizant contracting activity (see 601.603-70) is the contracting agency for the purposes of FAR 22.404-3(b) and (e)

622.404-6 Modifications of wage determinations.

The cognizant contracting activity is the contracting agency for the purposes of FAR 22.404-6.

622.404-7 Correction of wage determinations containing clerical errors.

The cognizant contracting activity is the contracting agency for the purposes of FAR 22.404-7.

622.404-11 Wage determination appeals.

The cognizant contracting activity is the contracting agency for the purposes of FAR 22.404-11.

622.406 Administration and enforcement.

622.406-1 Policy.

The cognizant contracting activity is the contracting agency for the purposes of FAR 22.406-1(a).

622.406-8 Investigations.

(a) The chief of the contracting activity is responsible for conducting labor standards investigations as prescribed in FAR 22.406-8(a).

(d) The Procurement Executive is the agency head's designee for the purposes of FAR 22.406-8(d).

622.406-9 Withholding from or suspension of contract payments.

The authority to suspend contract payments pursuant to FAR 22.406-9(b) is delegated, without power of redelegation, to the head of the contracting activity.

622.406-10 Disposition of disputes concerning construction contract labor standards enforcement.

The cognizant contracting activity is the contracting agency for the purposes of FAR 22.406-10(b).

622.406-11 Contract terminations.

The cognizant contracting activity is the contracting agency for the purposes of FAR 22.406-11.

622.406-12 Cooperation with the Department of Labor.

Any information furnished to the Department of Labor pursuant to FAR 22.406-12(a) shall be submitted through the head of the contracting activity.

622.1308 Contract clauses.

The Procurement Executive is the agency head for the purposes of FAR 22.1308 (a)(2) and (c).

622.1408 Contract clause.

The Procurement Executive is the agency head for the purposes of FAR 22.1408.

PART 623—ENVIRONMENT, CONSERVATION, OCCUPATIONAL SAFETY, AND DRUG-FREE WORKPLACE

9. Part 623 is amended by revising the title to read as set forth above and adding a new subpart 623.5, consisting of section 623.506 to read as follows:

Subpart 623.5—Drug-Free Workplace

623.506 Suspension of payments, termination of contract, and debarment and suspension actions.

The authority to approve the determination prescribed in FAR 23.506(e) is reserved to the Secretary of State.

PART 625—FOREIGN ACQUISITION

10. Part 625 is amended by revising subpart 625.9 consisting of section 625.901 and adding subpart 625.10, consisting of section 625.1003, to read as follows:

Subpart 625.9—Additional Foreign Acquisition Clauses

625.901 Omission of examination of records clause.

The Procurement Executive is the agency head for the purposes of FAR 25.901.

Subpart 625.10—Sanctions for Violations of Export Controls

625.1003 Exceptions.

The Procurement Executive is the agency head's designee for the purposes of FAR 25.1003(b).

PART 632—CONTRACT FINANCING

11. Part 632 is amended by adding subpart 632.9 consisting of section 632.903 to read as follows:

Subpart 632.9—Prompt Payment

632.903 Policy.

The authority to make the determination prescribed in FAR 32.903 is delegated, without power of redelegation, to the head of the contracting activity. Before making a determination concerning early invoice and contract financing payments, the head of the contracting activity shall consult with the Office of Fiscal Operations director, or designee.

PART 636—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS

12. Part 636 is amended by revising section 636.602 to read as follows:

636.602 Selection of firms for architect-engineer contracts.

The authority to select Architect-Engineers prescribed in FAR 36.602 is delegated, with power to redelegate, to the head of the contracting activity.

PART 637—SERVICE CONTRACTING

13. Part 637 is amended by adding section 637.110 in numerical order under subpart 637.1 to read as follows:

637.110 Solicitation provisions and contract clauses.

(f) Use of the clause at 52.237-8, Severance Payments to Foreign Nationals Employed Under a Service Contract Performed Outside the United States, is mandatory for DOS solicitations and contracts for services which may be performed in whole or in part outside the United States, and for which cost analysis is performed (see FAR 15.805-3).

PART 648—VALUE ENGINEERING

14. Part 648 is amended by revising section 648.102, and adding subpart 648.2 consisting of section 648.201 to read as follows:

648.102 Policies.

(a) The authority to grant exemptions prescribed in FAR 48.102(a), or to extend future contract savings or sharing pursuant to FAR 48.102(g), is delegated, without power of redelegation, to the head of the contracting activity (see 601.603-70).

Subpart 648.2—Contract Clauses

648.201 Clauses for supply or service contracts.

The authority to determine exemptions prescribed in FAR 48.201(a)(6) is delegated, without power of redelegation, to the head of the contracting activity.

PART 653—FORMS

653.107 [Removed]

15. Part 653 is amended by removing section 653.107.

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