



Transgenic fish: is a new policy framework necessary for a new technology?

Nathaniel Logar*, Leslie K. Pollock

*Graduate Program in Environmental Studies, University of Colorado at Boulder,
Campus Box 397, Boulder, CO 80309-0397, USA*

Abstract

Worldwide, transgenic fish have emerged as a means of more efficiently meeting demand for seafood. At this time, the environmental impacts of raising transgenic fish remain uncertain and resistance to their commercial production appears to exist among consumers in some countries. Regulatory approval of the first transgenic fish for human consumption is currently being considered by the U.S. and Canadian governments. This paper examines the U.S. Food and Drug Administration's (FDA) approval process for transgenic fish and finds if it will likely prohibit effective regulation of this fish, consequently risking the environmental health of aquatic ecosystems. Additionally, the closed-door process causes three problems: (1) concerned interests do not have access to information and are thus forced to rely on speculation, (2) the process is unable to take into account the values of the public and (3) any opportunity for meaningful public comment on environmental impacts is lost. We propose that policy makers consider creating a regulatory framework that is capable of addressing the unique environmental risks posed by transgenic fish and incorporating public participation into the process. This paper briefly examines possible frameworks and mechanisms for public participation and suggests the most promising alternatives.

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1. Introduction

In 1999, AquaBounty Inc., submitted a proposal to the U.S. Food and Drug Administration (FDA) for approval of the first transgenic¹ fish for human consumption: the *AquaAdvantage* salmon. This application triggered a new regulatory approval process by the FDA. Given the potentially precedent-setting nature of the decision faced by the FDA, this paper examines the current process for approving transgenic fish. We find that the current process will likely prohibit effective regulation of such fish, consequently risking the environmental health of aquatic ecosystems. Furthermore, the process is not open or

democratic. A better process would include regulations specific to the unique situation posed by transgenic fish and establish a clear mechanism for the incorporation of public values through public participation.

1.1. Emergence of transgenic products

Worldwide, demand for fish continues to increase at a higher rate than wild fish populations can support on their own. By the late 1990s, worldwide consumption of fish per capita had almost tripled since 1960 (FAO, 2001). During the same period, the annual global fish catch plateaued at approximately 95 million metric tonnes (FAO, 2001); the Food and Agriculture Organization expects this stagnation to continue into the future (FAO, 2002). To meet the demand and ease the pressure on natural fisheries, commercial aquaculture – fish farming – grew rapidly as a cost effective alternative to traditional fisheries (Naylor et al., 2000), with aquaculture's contribution to global supplies of fish, mollusks and crustaceans increasing from 3.9% of total production by weight in 1970 to 27.3% in 2000 (FAO, 2002).

* Corresponding author. Tel.: +1 303 440 1269; fax: +1 303 492 5207.
E-mail address: logar@colorado.edu (N. Logar).

¹ The term “transgenic” refers to “an individual in which a transgene [an isolated gene sequence used to transform an organism] has been integrated into its genome” (Food and Agricultural Organization, 2004, http://www.fao.org/biotech/index_glossary.asp?lang=en). Commonly refers to genes from one organism that have been inserted into the genome of another organism.

Global aquaculture production doubled between 1987 and 1997 (FAO, 1999) and rose from 28.6 million metric tonnes in 1997 to more than 37 million metric tonnes in 2001 (FAO, 2002). Aquaculture is now the fastest growing animal food production sector in the world with 70% of its future growth expected to occur in China (FAO, 2002). The U.S. Department of Commerce set a goal to increase the value of domestic aquaculture production from the current US\$ 900 million to US\$ 5 billion annually by 2025 (USDOC, 2002).

Beyond traditional aquaculture, transgenic fish provide a possible means for meeting seafood demand more efficiently. For example, AquaBounty estimates that its *AquaAdvantage* salmon, a modified Atlantic salmon, reach commercial size in one-third of the time required for non-transgenic salmon (Fletcher et al., 2001). The faster growth of each generation can lead to increased production per unit time along with savings on total food per pound of meat produced (AquaBounty, 2002). The company uses a growth hormone and an antifreeze protein to increase the salmon's feeding efficiency and tolerance for cold waters. The potential to produce three fish generations for every one produced now would present significant economic benefits for commercial fish farmers.

Private industry around the world is developing nearly 20 species of transgenic fish and shellfish, including catfish, carp, oysters and trout (FAO, 1999). To date, no country has approved any of these species for commercial production or human consumption. The FDA's consideration of the *AquaAdvantage* salmon is the first such case (AquaBounty has also applied for approval permission in Canada). However, widespread use of genetically modified organisms (GMOs), primarily plants, is already common. GMOs consist of over 28% of corn and 68% of soybeans grown in the U.S. (USDA, 2001), and 11% and 55%, respectively, of these crops worldwide (FAO, 2004). The U.S. cultivates nearly two-thirds of the world's transgenic crops. GMOs are generally regarded by international food organizations as important for meeting future food demands, especially in the developing world (FAO, 2001).

1.2. Concerns over transgenic organisms

1.2.1. Environmental effects

Scientists are just beginning to question the impacts of transgenic fish on native fish populations and aquatic ecosystems. If farmed using the traditional method, where farmers raise the fish to maturity in open water net pens, transgenic salmon will likely escape and come into contact with wild populations (NRC, 2002). Farmed salmon escape from these pens on a regular basis and will inevitably continue to do so. Ecological research on transgenic fish began only recently, and scientists have not reached any conclusions on the effects of escapees. Muir and Howard (1999) studied the effects of growth-enhanced transgenic fish, which would have a mating advantage due to their

larger size. When Muir and Howard (1999) modeled the impact of the transgenic fish on native populations, the model predicted the decimation of a local native population upon introduction of only a small number of transgenic individuals. Faster growth and tolerance for cold may provide escaped transgenic salmon with a competitive edge over wild populations (Hallerman and Kapuscinski, 1992a). Hallerman and Kapuscinski (1992b) posited that the domesticated traits of aquaculture-raised fish already might risk the genetic base of wild relatives, even before considering the potential of passing on a transgenic trait. The creators of *AquaAdvantage*, claim their salmon will be sterile, greatly reducing environmental risks that would result from interbreeding in the wild (Fletcher et al., 2001). Achieving 100% sterility, however, is next to impossible. Because the development of transgenic fish species is in its relative infancy, the science examining their potential effects on the natural environment is still emerging.

Accidental release of *AquaAdvantage* fish could potentially harm other species beyond the native salmon populations. Although there is a lack of conclusive data supporting ecosystem harm stemming from exposure to transgenic fish, scientists have posited reasons that escaped transgenic salmon could adversely impact whole communities or ecosystems. Kapuscinski and Hallerman (1990) write that with the removal of the wild fish population from an area, predator–prey relationships could change so that the wild fish no longer controls populations of prey species and predators that depend on population are at risk of food deprivation. Furthermore, a U.S. National Research Council Report (2002, p. 85) posits that, “use of genetically engineered animals could harm the environment indirectly by changing demand for feed, number of animals used, or amount of resulting waste, and by the effects of wastes containing novel gene products on microbial and insect ecologies.” In this case, the animals could exacerbate the impacts of fish farming without even considering the extra risk stemming from escape.

1.2.2. Public opinion

In the U.S., contrary to the prevailing thought that consumers are not concerned with biotechnology, the issues surrounding its use may be becoming more contentious (Priest, 2000; NSB, 2002), with opposing interests fighting over the hearts and minds of Americans through the mass media (NSB, 2002). Public opinion data regarding Americans' attitudes towards genetic engineering and biotechnology generally show a decline in support for such technologies over past 5–15 years (NSB, 2002; Priest, 2000). According to a poll performed by the International Food Information Council, a group supported by food, beverage and agricultural industries, the percentage of people who believe “biotechnology will provide benefits” declined from 78% in 1997 to 61% in 2001 (IFIC, 2002). Furthermore, in a survey performed for the Pew Initiative on Food and Biotechnology, 65% of consumers disagreed with the idea of

creating transgenic fish to improve efficiency of production (Pew, 2001). A 2003 survey suggests, Americans are far less comfortable with genetic modification of animals than plants (Mellman Group, 2003). These numbers suggest divisions amongst Americans regarding different uses of biotechnology and that their opinions are likely to change over time.

Internationally, the Food and Agriculture Organization (2004) reports, “public attitudes to agricultural biotechnology differ widely across countries, with people from Europe generally expressing more negative views than those from the Americas, Asia and Oceania” (p. 77). In a global poll conducted by Environics International in 2000 of respondents in 34 countries, Indonesia (81%), Cuba (79%) and Thailand (72%) had the most positive responses to the question of whether the benefits of using biotechnology to genetically modify crops for pest resistance outweigh the risks, while Greece (22%), France (22%) and Japan (33%) displayed the most negative responses (66% of Americans responded favorably to the question) (FAO, 2004). FAO noted a general trend that respondents in poorer countries tended to show more support than those in wealthier countries, with some exceptions. Further, 62% of all respondents worldwide opposed the application of biotechnology to increase farm animal productivity, while 71% approved of its application to create pest-resistant crops (FAO, 2004).

Worldwide, some of those concerned with biotechnology and genetic engineering act as vocal opponents to further development of transgenic organisms—plants and animals alike. Environmental and consumer groups, such as Greenpeace, Friends of the Earth and The Center for Food Safety, are running campaigns to ban or postpone uses of transgenic organisms (Greenpeace, 2004; FOE, 2004; CFS, 2004). Further, consumers in Europe successfully convinced the European Union to enact a virtual ban on new transgenic crops (Reuters, 2002). Non-governmental organizations are building resistance to growing GM crops and are questioning whether GM is in fact the answer to food shortage problems in some developing countries as well, including Brazil and India (Aubert, 2000). In September 2002, approximately 200 restaurants and other businesses in the U.S. signed a pledge to boycott transgenic fish, joining supermarkets – Trader Joe’s, Wild Oats, Whole Foods – who have pledged to banish goods containing transgenics from their shelves (Kay, 2002).

As with any discussion of public opinion, it is important to note the dynamic nature of public thought. Public opinion is likely to change “as more information is made available about the benefits, risks, societal impacts, and other factors relevant to acceptance of the technology in question” (Frewer, 2003; p. 323). Generalizing about public opinion also inevitably fails to take consumer’s value systems into account (Frewer, 2003)—understanding the “why” behind the responses.

In summary, given the growing demand for fish worldwide and the respondent growth of commercial aquaculture, transgenic fish provide a potential solution for meeting this

demand in a cost effective manner. However, the effects of introducing such species into the environment could be significant and are largely unknown. In addition, public opinion throughout the world and in the U.S. regarding transgenic organisms is divided and appears to be changing. As we will argue, the U.S. regulatory approval process – in fact, any governmental approval process – needs to account for these issues.

2. The current U.S. approval process

To date, neither the FDA nor the U.S. Congress has developed regulations or legislation specific to transgenic fish or animals. In 1986, the Reagan administration published “Coordinated Framework on the Regulation of Biotechnology (1986),” which mandated that all regulation of biotechnology products occur within preexisting laws and regulations. Because the Coordinated Framework provides jurisdiction for biotechnology regulation based on ultimate use (Hallerman and Kapuscinski, 1990), the U.S. Food and Drug Administration (FDA, 2004) reinterprets the Federal Food, Drug and Cosmetic Act (FFDCA, 2004) to provide it with authority over all transgenic fish and animals before they can be marketed for human or animal consumption. As such, the FDA has decided to treat both the *AquAdvantage* salmon’s altered hormones and the genetic modifications made to the fish as a “New Animal Drug” under regulations laid out in the FFDCA (21 U.S.C. 360b). Although the genetic modifications in animals or fish are not a drug in the traditional sense, they fall under the FDA’s definition of “drug” as a material that will “affect the structure or any function of the body of animals” (21 U.S.C. 321(g)(1)). Evaluation of New Animal Drug applications falls under the purview of the FDA’s Center for Veterinary Medicine. Fitting transgenic animals into this regulatory framework has raised objections or concerns from members of a National Research Council committee responsible for investigating science-based concerns over animal biotechnology (NRC, 2002), and environmental and consumer advocacy groups (Goldburg, 2002; UCS, 2001). These parties voiced concerns that Congress did not anticipate that the New Animal Drug regulations would be used to evaluate the unique risks posed by transgenic animals when it passed the FFDCA. It appears that policy makers originally created New Animal Drug regulations to address new substances such as antibiotics for cows or pets. Therefore, it is unclear whether the current regulatory framework can adequately ensure consideration of the new scientific problems posed by transgenic fish and animals. We will further examine these issues in the next section.

2.1. Evaluating environmental risks

As a government agency, the FDA must abide by the provisions of the National Environmental Policy Act of 1969

(NEPA, 1969), which directs all federal agencies to prepare a “detailed statement” for every “major Federal action(s) significantly affecting the quality of the human environment” (42 U.S.C. 4332). The primary means by which the FDA complies with NEPA is the creation and consideration of environmental impact documents submitted by an applicant in the form of an Environmental Assessment (EA), or the production of a more thorough Environmental Impact Statement. All applications or petitions to the FDA must address the environmental impacts of their product or claim exemption from the process (21 CFR 25.15(a)). However, NEPA does not mandate specific outcomes; it merely requires that agencies engage in the process of considering environmental impacts of their major actions. Based on a careful reading of the FFDCA and the FDA’s regulations for considering environmental impacts, it is unclear whether the FDA has the express authority to act upon a finding of significant environmental impact, that is, whether it can reject an application solely on environmental grounds. This concern has been raised by the U.S. National Research Council (2002) and the Pew Initiative on Food and Biotechnology (2003) as well. According to a senior regulatory review scientist in the FDA, the agency also considers this question unresolved, and it will ultimately be decided by the courts in their interpretation of the scope of NEPA (Matheson, 2004).

2.1.1. Drawbacks of the current regulatory framework when examining environmental risk

The current regulatory framework, as outlined above, is unable to ensure that the broad range of potential ecological impacts posed by transgenic fish and animals undergoes thorough assessment. A thorough assessment would include the examination of all reasonably foreseeable risks posed by the transgenic fish to the entire ecosystem – and all of its components – into which it would be introduced, whether deliberately or accidentally. There are several ways in which the current framework falls short of this.

First, the wording contained in the regulatory framework lacks necessary specificity. For example, in the FFDCA, although the approval process for a New Animal Drug considers the parameter of “safety,” the statute contains no clear definition of what constitutes “safe.” The FFDCA indicates that a New Animal Drug is to be considered “unsafe” until it is approved (21 U.S.C. 360b(a)(1)), and the definition of a New Animal Drug is listed as one that is not recognized as “safe and effective” for use under the conditions listed in the product’s labeling (21 U.S.C. 321(v)(1)). But the exact parameters for concluding a transgenic fish or animal is “safe” are unclear. The only definition for “safety” found in the FFDCA maintains that it “has reference to the health of man or animal” (21 U.S.C. 321(u)). Furthermore, in the NRC report examining science-based concerns related to animal biotechnology, the scientists found the FFDCA’s loose wording and lack of specific provisions for the assessment of “safety” neither

provide clear guidance for the FDA on how to deal with its considerations of environmental health, nor give an idea of what level of environmental risk is deemed “safe” (NRC, 2002). The FFDCA leaves the FDA to make a decision on acceptable environmental risk with little to no guidance on the criteria for doing so.

Another equally vexing question lies beyond the safety question: what exactly is the FDA determining the safety of, when approving or rejecting a New Animal Drug application? The FDA has internally interpreted the FFDCA as providing it with the authority to consider environmental risks to the health of animals other than the one upon which the “drug” acts (CEQ/OSTP, 2001). According to the FDA, this would include examining impacts the transgenic animal might have on the health of an entire ecosystem (CEQ/OSTP, 2001), which is beyond the normal scope of consideration for most New Animal Drug applications. One problem with relying on the FDA’s current interpretation of the FFDCA for both of these scenarios is that these internal interpretations of the language are not codified in any way and therefore can be altered at any time. Legislation might guarantee that changes in the prevailing attitudes at the FDA could not lead to a shift in policy toward one with reduced rigor with regard to these issues, subsequently leaving critical questions of environmental risk answered.

Second, the language in the FDA’s New Animal Drug provisions (21 CFR 5) for implementing NEPA lack specificity when applied to transgenic fish or animals, since they were not written with these organisms in mind. For example, when directing what information belongs in an Environmental Assessment, the regulations state the EA shall focus on relevant environmental issues “relating to the use and disposal from use of FDA-regulated articles ...” (emphasis added) (21 CFR 25.40). These guidelines set a narrow scope for evaluating environmental impacts of transgenic fish and animals, and fail to direct the agency to examine environmental impacts of the fish on any ecosystem into which it would be introduced. In another example, some provisions in the FDA regulations would exempt a New Animal Drug application from environmental review if the FDA considers the drug to be another version of a previously approved animal drug (21 CFR 25.33). This might allow a new species of transgenic fish to be approved with the same type of genetic modification as a previously approved transgenic fish of another species, even though the new transgenic fish species might have profoundly different environmental impacts.

Third, the protocol for preparing the Environmental Assessment invites the opportunity for the applicant to misrepresent the environmental risks of the transgenic fish or animal under evaluation (even assuming there is no intent to do so). The regulations allow, in fact require, the applicant to submit the EA. This is a bit like allowing the seller of a home to provide the buyer with the inspection report. A seller has much less incentive to tell the buyer about the rotting floor beams than an independent inspector would. Although the

FDA is ultimately responsible for the content in the EA, the applicant's natural bias may have already shaped the presentation of the environmental risks in a way that might unfairly give it an advantage.

Finally, the FDA's Center for Veterinary Medicine does not appear to possess scientists or managers on staff with the highly specific expertise necessary to analyze the environmental risks unique to transgenic fish or animals. Although the FDA employs highly qualified scientists, its staff does not appear to include people with expertise in population genetics, for example, which will be important for the consideration of impacts of transgenic fish (FDA/CVM, 2003; NRC, 2002). NEPA states that the agency responsible for preparing the detailed statement "shall consult" with other agencies with jurisdiction over impacted areas or having special expertise (42 U.S.C. 4332); however, there is no language requiring such consultation in the FDA's implementing regulations. For species protected under the Endangered Species Act (ESA), when seeking to approve an action that might impact a threatened or endangered species, the FDA must consult with the National Marine Fisheries Service (NMFS) and/or the Fish & Wildlife Service (FWS). This is the case for the *AquAdvantage* salmon, a modified Atlantic salmon which may come in contact with the endangered wild Atlantic salmon. However, in circumstances where genetic lines for other species of fish not protected by the ESA are under consideration for FDA approval, it is unclear whether there is an obvious mechanism in place to ensure that these agencies, or other scientists with appropriate expertise, will be involved in assessing the potential ecological impacts that could result from release into the environment.

2.2. Accounting for public opinion

The FDA approval process for New Animal Drugs takes place almost entirely behind closed doors. The FDCA and the *Trade Secrets Act* (2004) prohibit the FDA from sharing any information with the public before a decision is made on an application, in the interest of protecting the applicant's trade secrets (21 U.S.C. 331(j); 18 U.S.C. 1905). The FDA cannot even disclose the existence of an application for approval until after publication of that approval in the Federal Register (21 CFR 514.11). Although the FDCA forbids the FDA from disclosing the application, the sponsor of the application may do so. However, even if the sponsor acknowledges the application, "no data or information contained in the (FDA's application) file is available for public disclosure before such approval is published," except in limited circumstances (21 CFR 514.11(d)). These requirements effectively shut the public out of discussions surrounding the approval of transgenic fish and animals. This results in three problems: (1) concerned interests do not have access to information and are thus forced to rely on speculative rhetoric, (2) the process is unable to take into account the values of the public and (3) any opportunity for

meaningful public comment on environmental impacts is lost.

First, as mentioned earlier, Americans' support for transgenic organisms has eroded down to 61% from 78% since 1997, as the controversy over genetic engineering has become more prominent (IFIC, 2002). In addition, consumer and environmental groups in the U.S. and elsewhere have targeted transgenic products in their campaigns and are communicating their concerns to their supporters and the general public. Under the current laws, these citizens are denied access to official information regarding the FDA's evaluation of these organisms. Absent this information, groups are forced to argue their positions based on rumor or speculation regarding the potential impacts of transgenic animals. One group, the Union of Concerned Scientists, acknowledges that their information is "pieced together from newspapers, science magazines and to a limited degree, industry sources" (UCS, 2001). Because of the dearth of information available from official sources such as the FDA, consumers are forced to turn to interest groups and media reports that are necessarily based on this speculation. Therefore, in the case of applications for transgenic animals, the public has no obvious source of "good" information at their disposal.

Second, the current process cannot consider the values, norms and preferences of the citizens whom the approval of a transgenic animal will ultimately affect, whether it is through consuming a transgenic fish, the possibility of watching a wild place suffer harm from its introduction, or paying less for seafood at the grocery store. Why should the public contribute to this process? Certainly a process, such as the FDA's approval of a new food or drug is one that requires primary reliance on science and verifiable data; a majority vote of the people would not be appropriate. However, science alone cannot answer all the questions relating to approving transgenic fish and animals. For example, what constitutes acceptable risk to the environment from transgenic fish and animals? What role should the values of society play in the decision? Those working at FDA bring their own values and risk perceptions to the table, but these values and perceptions are not necessarily representative of the larger public (Wagle, 2000). As Frewer (2003) explains,

"It has been argued that the ways technical risk experts and lay people think about the risks associated with different hazards are very different . . . It might be predicted that risk communication based on technical information alone would appear irrelevant to the general public, as it would not address their real concerns" (p. 321).

While the procedures of peer review and publication serve as quality control for most research, the FDA process lacks any public review to ensure rigorous science (Kapuscinski, 2002). In addition, according to a number of policy specialists, including DeLeon (1988), Dryzek (1990) and Stone (1997), "the failures of most public policies have

occurred today because of their inability to incorporate social norms and values in policymaking processes and thus in policy outcomes” (Wagle, 2000; p. 212). Thus, FDA experts assessing risk without input from outside sources might see the issue only through the lenses of their own disciplines, while the general public may perceive other risks that the experts may have overlooked or not recognized. Although some of these risks may be negligible under the scrutiny of current scientific methods, the concern of the public could drive the success of the policy. The FDA’s regulations make the consideration and incorporation of these values more difficult than in an open process.

Third, the current framework denies both the public the opportunity to provide input during the assessment of environmental impacts and the FDA the chance to receive potentially valuable input from the public and outside scientists. NEPA’s goals include public airing of an agency’s consideration of impacts and soliciting input from the public (42 U.S.C. 4341). However, the FDA’s disclosure guidelines protecting trade secrets conflict with, and in fact trump, public participation as included in NEPA. In fact, the FDA’s regulations deny consumers and uninvolved scientists the opportunity to comment on the application, EA or EIS until after the FDA renders a decision on the application. The regulations state that public comments can form the basis for a reconsideration of an approval by the FDA, but by that time, the damage could already be inflicted, especially if the approved animal has already been released into the environment. Waiting until after the application has been approved to take comments means the FDA will forego the potentially valuable contributions of a concerned public while making a decision on an application.

The FDA’s process for approving transgenic fish may not be able to address the unique challenges posed by the new technology. With regard to environmental impacts, even if the process were able to thoroughly identify relevant impacts, the FDA may not be able to base its approval or rejection on this information. Additionally, the lack of public input creates a dearth of good information for the public, a potential gulf between the FDA’s and the public’s perception of acceptable risk, and a loss of scientific and public input on the application. If the process is left in its current state, resulting decisions could harm consumers, the aquaculture and biotech industries, or the environment.

3. Proposed alternatives

As demonstrated, the current regulatory framework, which places transgenic fish under the FDA’s New Animal Drug provisions, risks the environmental health of aquatic ecosystems because it may prohibit effective regulation of these fish. Further, by excluding the public during the review of a New Animal Drug application, the process fails to meet democratic standards.

In order to successfully remedy these problems, we propose that policy makers consider placing transgenic fish under a different regulatory framework that addresses all the risks posed by such fish, and is more democratic. Any such framework should include the following four items:

- (1) Express authority for the FDA to assess the harm posed to the environment by transgenic fish, including the larger ecosystems into which such fish may be introduced, and to make decisions on applications based on such harm. This would help clear up any confusion surrounding the FDA’s authority to examine environmental impacts of transgenic fish. It would also allow the development of a definition of “safety” as it applies to transgenic fish, and NEPA regulations specific to transgenic fish.
- (2) A means for ensuring the FDA’s consultation with other agencies – such as FWS and NMFS – and/or scientists with relevant expertise. Such a requirement would guarantee that the appropriate scientific expertise is utilized when examining environmental risks of transgenic fish.
- (3) A requirement that the FDA analyze each new genetic strain of transgenic fish. According to population geneticist William Muir, the unique nature of every transgenic strain makes this necessary for an accurate assessment of environmental risk (Reichhardt, 2000).
- (4) A means for incorporating public participation into the process before an application is approved, and increasing the overall transparency of the process.

What should this regulatory framework look like? We will briefly consider three alternatives for managing transgenic fish: (1) keeping transgenic fish within New Animal Drug regulations, (2) considering transgenic fish under another established category at FDA and (3) creating a new regulatory framework within FDA specifically for transgenic fish. All three alternatives keep the primary responsibility for regulating transgenic fish within the FDA.² Since the issues surrounding incorporation of public participation will likely be similar for all three alternatives, we will consider them separately after the discussion of the alternatives.

3.1. Alternative 1: transgenic fish as new animal drug

This alternative would keep the regulation of transgenic fish within the New Animal Drug guidelines by redefining “New Animal Drug” to include the constructs specific to transgenic fish, and creating a new subsection within the

² We limited the discussion of alternatives to the FDA for two reasons: (1) this is where GM fish are currently regulated and (2) it is beyond the scope of this paper to conduct a thorough analysis of the effects of placing such responsibility with another agency. In addition, the discussion of alternatives is limited to regulations affecting transgenic fish and does not include other transgenic animals.

FFDCA's New Animal Drug section solely addressing transgenic fish. At least one U.S. Senator has thus far attempted to address the problems with the FDA process in this manner.³ Regarding our first criterion, the FDA could be given express authority to examine the environmental effects of transgenic fish within the transgenic fish-specific section of the New Animal Drug regulations. Policy makers would have to be careful when extending this authority to be sure not to require it of all New Animal Drugs, as this could significantly increase the FDA's responsibilities without warrant. Further, the NEPA guidelines for New Animal Drugs could be rewritten to include a separate section on consideration of transgenic fish. The second and third criteria could be met under this framework by including language in the transgenic fish-specific section that addresses them.

It is unclear, however, that it makes sense to fit transgenic fish into the New Animal Drug category. They are not, after all, animal drugs in the traditional sense. In order to satisfy our criteria, the regulations must be changed to the point where they will look quite different from those for all other New Animal Drugs.

3.2. *Alternative 2: transgenic fish as "substantial equivalent" or food additive*

A second option for regulating transgenic fish is to place them under another category of substance within FDA where we might find a better fit. Considering transgenic fish as a "substantial equivalent" is one such option. The federal government currently regulates transgenic agricultural crops as a "substantial equivalent" to conventional food, where transgenic crops are treated the same as their conventional counterparts (Pew, 2003). The FDA could treat transgenic fish in this manner as well. Environmental regulations would be the same as those for traditional aquaculture, where the responsible agencies evaluate impacts only at the site-specific level. This might work fine for considering environmental harm and incorporating public opinion into specific decisions. Yet, since "substantial equivalents" can go straight to market, there would be a total lack of premarket consideration of environmental impacts or public opinion. Given the dearth of information available on the impacts of transgenic fish and the newness of the technology, this option is clearly unfit when considering our criteria of environmental protection and democratic standards.

Some have suggested that the FDA consider genetic modifications in transgenic fish as a food additive (CFS, 2004). The FFDCA defines a food additive as "any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component of, or otherwise affecting the

characteristics of any food" (21 U.S.C. 321(s)). Once approved, producers of a food additive may use it repeatedly without further approval by the FDA. Therefore, approving a genetic modification such as those in transgenic fish could potentially result in the usage of such genetic modifications in different species of fish without any review prior to their introduction to the market and the environment.

Further, in determining the "safety" of a food additive, the FDA must consider (1) consumption of the substance, (2) cumulative effect of the substance in the diet and (3) appropriate safety factors as determined by those trained to evaluate food and food ingredients (emphasis added) (21 CFR 170.3(i)). Nowhere in the regulations for food additives are there considerations for the additive's effect on the environment. Understandably, the regulations focus specifically on food safety for human and animal consumption. In fact, it appears that the regulations would apply to the genetic construct itself as opposed to the fish or animal of which it is a part. A question arises: how then, when assessing environmental impacts, would scientists evaluate the effects of transgenic fish on an ecosystem when food additive regulations restrict them to examining only its genetic mutation?

We also must ask if it is possible to satisfy our criteria under this framework. Arguably, policy makers could write transgenic fish-specific regulations that satisfy our criteria into the food additive regulations (similar to Alternative 1 with respect to New Animal Drug regulations). However, the same issue arises: since the subsection addressing transgenic fish within the food additive regulations would look substantially different from the rest of the regulations (including a separate definition of safety), the FDA would effectively treat transgenic fish differently from a food additive. Therefore, does it make sense to include them within food additives? Once again, there may be an institutional reason to do so, but given the fact that the FDA already chose to treat them as a New Animal Drug and not a food additive, we doubt this is the right option.

3.3. *Alternative 3: new regulatory framework*

In their current states, the FDA's existing regulatory frameworks, including those for New Animal Drugs, "substantial equivalents" and food additives, do not ensure adequate evaluation of the unique risks associated with transgenic fish. In addition, in order to meet our criteria, it appears the government would have to create new regulations in order to fit transgenic fish into these frameworks, rendering their consideration quite different from other members of their group. Therefore, we propose a third alternative: creating a new framework within the Federal Food, Drug and Cosmetics Act that solely addresses transgenic fish.

This new framework could be found within the FFDCA under the heading, "Transgenic Fish, Crustaceans and Mollusks," and include: provisions giving FDA express

³ The Genetically Engineered Foods Act of 2002 (S. 3095) was introduced by Senator Richard Durbin in October 2002. It had not been voted on as of this printing.

authority to assess ecosystem impacts of transgenic fish and to use this criteria to make decisions on applications; a requirement that FDA consult with appropriate scientific experts; a requirement that FDA analyze each new genetic strain of transgenic fish; and, as will be discussed in the following section, a means for incorporating public opinion into the process before approval of an application. Under such a framework, policy makers would simply be free to address the unique risks posed by transgenic fish and legislate accordingly. This alternative involves challenges both logistical, e.g., determining which department within the FDA should have primary authority, and political. In fact, the very question of whether the FDA is the appropriate agency to handle regulation of transgenic fish would be on the table. For the purposes of this study, we assume that it is.

3.4. Public participation

We will now turn to the challenge of meeting our fourth criterion: incorporating public participation into the process before approval of a transgenic fish species, and increasing the overall transparency of the process. Including this criterion will correct the non-participatory nature of the FDA's current approval process. To review, we have shown that the exclusion of public participation results in: (1) the public's inability to access information concerning specific transgenic animals under consideration, (2) the FDA's lack of data on social values, norms and preferences when making the approval decision and (3) lost opportunity for the public to comment on environmental impacts. In order to make the process more democratic, the new regulatory framework – in whatever form it ultimately takes – should include specific provisions to incorporate public participation. Including such participation in the process will remedy the identified problems in the following ways. First, providing access to information regarding an application eliminates the need for interest groups to rely on speculation when formulating their positions in relation to transgenic animals. Making this information public also opens up the opportunity for the public to seek it out in order to find accurate information.

Second, creation of a public process is more likely to inspire confidence and an increased sense of fairness among constituents compared to the current closed-door method. From a focus group-based study on natural resource decision making, researchers found that notification of citizens by the regulatory agencies, along with providing citizen participation in decisions, had a significant impact on the public acceptance of the outcome (Smith and McDonough, 2000). The designers of the study found that secretive processes lead to less acceptance of decisions by the public. Furthermore, at times the focus groups felt that agencies allowed comments but failed to heed them. The findings of the study reinforced those posited by Lind and Tyler (1988), who found that a person's sense of fairness of a particular process can depend on whether that

person's comments or questions are ignored or acknowledged. Thus, increased participation could improve the image of the FDA by providing more legitimacy and increased status (Berry et al., 1993), feelings which would transfer to its decisions.

Evidence in the policy literature shows that citizen participation improves the quality of public policies (Wagle, 2000). From a study of public participation in five American cities, Berry et al. (1993) found that the involvement of ordinary citizens leads to policy decisions that promote the public interest; policymakers had more awareness of the issues and opinions that were important to the public in cities with more public participation. The authors also found increased policy responsiveness corresponding to higher levels of participation. In addition, Marinoff (1997) argues that participation yields more effective policies because the public receives power, which encourages people to become part of the solution. Further, Green (1997), in a study of American and Canadian participation processes with respect to pollutants, found that the role of public participation can be crucial in moving policy away from under regulation, can balance the power of industry, and can also be beneficial from an economic perspective. Berry et al. (1993) found that enhanced participation led to a "more equal distribution of influence" (p. 134) between citizens and special interests in the cities they studied.

However, introducing public participation into a process can lead to gridlock and the opening of a Pandora's Box of problems if policy makers are not careful. Public participation requires structure to be successful and meaningful (Berry et al., 1993; Wagle, 2000). Expectations should be clearly outlined and the agency should understand exactly what role the comments will play in its decision. For example, the FDA could specifically announce that it is soliciting value-based, subjective, grassroots level response to an application (Wagle, 2000), thereby limiting the scope of such participation. Of course, the agency receiving the comments needs to have a specific means for incorporating the comments.

In addition, participation should be timely and frequent. The FDA should include the public in multiple phases of the process to ensure democratic policymaking and to improve the quality of the decisions (Wagle, 2000). A single, short public comment period may fail to effectively increase transparency and public input. While a public comment period traditionally occurs at the end of the process, making it reactive in nature (Konisky and Beierle, 2001), the period of public consultation should begin early and occur continually throughout the process (Creighton, 1999). Earlier involvement will allow scientists and the public to posit constructive ideas that can enhance consideration of the application and actually affect the eventual outcome by bringing diverse perspectives and experience into play.

Extended, continual public involvement will also open the door for networking and communication between advocacy groups, citizens, application sponsors, and the

FDA (Creighton, 1999). By becoming informed of application details and working towards a trusting relationship with the FDA, dissenters may be moved away from outright disagreement and towards acceptance of the final decision.

Although public participation should play a role in formulating a decision, the FDA must still be given the power to make the final decision. Effective government requires accountability in addition to participation (Creighton, 1999). Decision making by the FDA will provide a party to be politically and legally responsible for any consequences of the decision.

Even if policy makers create an enlightened plan for public participation under the current framework, statutory protection of trade secrets and the FFDCA would continue to block its implementation. As noted earlier, the required protections of trade secrets, as interpreted by the FDA, result in the virtual elimination of the public comment process as outlined by NEPA. The new regulatory framework therefore needs to allow both for the protection of the applicants' trade secrets and inclusion of the public in the process. The FDA needs to be able to share those portions of the application that would not reveal any trade secrets; the effects of genetic modification could be revealed without the specifics of the modification itself. Furthermore, the publicly accessible application could contain a summary of the data relevant to the genetic makeup of the applicant's species instead of raw data that could be used by a competitor to duplicate the applicant's work.

Trying to find an appropriate balance between protecting trade secrets while opening up the process to public opinion will present political and legal challenges. Yet, the FDA acknowledges the need for more public involvement when evaluating environmental impacts. Regarding the current conflict between the NEPA guidelines and the secrecy provisions in the FFDCA, the FDA "recognizes the difficulty in ensuring a public process for evaluating possible environmental risks associated with any particular transgenic modification to a fish and is considering what options it might have to address this situation" (CEQ/OSTP, 2001). This recognition is an important step in moving towards a more democratic process.

4. Conclusions

Science and technology – including modern transgenic technology – have advanced to a point beyond that which was foreseen when the FFDCA was written. Transgenic fish and the challenges they pose are unique enough to warrant their own regulations in order to keep pace with new developments in science and technology. Any regulations for transgenic fish must address them in a way that fully considers the environmental impacts of their introduction into aquatic ecosystems. We have demonstrated that the current regulatory approach to transgenic fish is unlikely to meet this standard. Further, the secrecy of FDA's approval

process not only fails to meet democratic standards, but its efficacy in creating good policy may be compromised by the lack of input from the public on what constitutes acceptable risks regarding transgenic fish.

Based on our consideration of three alternatives for a new regulatory framework within the FDA, it appears that creating a separate category in which to regulate transgenic fish may be the best option for establishing an approval process that adequately examines environmental risk. By constructing an effective mechanism for public participation to include in this framework, the FDA should find itself making policy choices that better reflect the common interest and therefore enjoy broader acceptance. It was beyond the scope of this paper to consider moving the authority for examining environmental risk out of the FDA's hands and into those of another agency. Although not addressed herein, this question is certainly an appropriate subject for further research.

America's decision regarding the regulation of transgenic fish may influence how other countries or international bodies such as the FAO or World Health Organization approach the issue. As noted earlier, the U.S. is a small player in the world aquaculture market. If other countries follow a U.S. lead in approving transgenic fish for commercial consumption, it is likely that these other countries, such as China (the world leader in aquaculture), will feel the lion's share of the impacts from farming transgenic fish. Given this possibility, the implications of the decision on how to regulate transgenic fish in the U.S. could be felt worldwide.

The problems we identified with the FDA's approval process for transgenic fish are likely not isolated. Scientists in the U.S. and beyond have been and will continue introducing genetic modification technology into society in other forms such as animals, crops and medicines – many other examples will likely follow. Based on the U.S.'s Coordinated Framework, agencies use current laws and regulations to address these organisms, even though they may not accommodate unanticipated biotechnology products. Controversy will accompany the introduction of these technologies, assuming current trends in public opinion continue. As we have seen with transgenic fish, excluding the public from consideration of these technologies and limiting the examination of their effects to samples in a laboratory may risk poor policy choices and irreversible damage to the natural world. Researchers may wish to examine approval processes of these other technologies, not only in the U.S., but in all countries, in a similar manner to this paper to determine if they are capable of taking new risks into account.

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Nathaniel Logar is a graduate student in the Program in Environmental Studies at the University of Colorado at Boulder. Outside of his interest in the regulation processes for transgenic organisms and other biotechnology,

Nat's research interests include policies for public participation in other venues of scientific decision making, such as climate change.

Leslie K. Pollock is a graduate student in the Program in Environmental Studies at the University of Colorado at Boulder. Leslie's research interests include the application of public opinion to natural resources and energy policy.