CITIZEN PETITION BEFORE
THE U.S. FOOD AND DRUG ADMINISTRATION
Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
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Petitioners.

Docket No. _____

CITIZEN PETITION REGARDING AQUABOUNTY TECHNOLOGIES' APPLICATION FOR APPROVAL OF GENETICALLY ENGINEERED SALMON

Earthjustice hereby submits this Citizen Petition on behalf of Ocean Conservancy, Friends of the Earth, Center for Food Safety, Food & Water Watch, Center for International Environmental Law, and Greenpeace (collectively, "Petitioners") pursuant to the Administrative Procedure Act, 5 U.S.C. § 553(e), and Food and Drug Administration ("FDA" or "the Agency") regulations, 21 C.F.R. §§ 10.20, 10.25, 10.30. This Petition requests that the Commissioner of Food and Drugs ("the Commissioner") refrain from taking final action on AquaBounty Technologies' ("ABT's") pending application for the first-ever approval of a genetically engineered ("GE") animal intended for human consumption until FDA has completed a comprehensive environmental impact statement ("EIS") on that application. This EIS must reach far beyond the scope of the narrow environmental assessment ("EA") submitted by ABT in August 2010 and evaluate the full range of threats that stand to confront wild fish populations if ABT's GE AquAdvantage Salmon are released into the natural marine environment. Petitioners also request that FDA amend its existing regulatory framework to create specific provisions that (1) account for the unique environmental risks inherent in the production and distribution of GE food animals, and (2) provide for increased transparency and public involvement as required by the National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4321 *et seq.*

I. ACTION REQUESTED

Petitioners request that the Commissioner (1) refrain from taking final action on ABT's application for approval of AquAdvantage Salmon, a GE animal intended for human consumption, until FDA has completed a comprehensive EIS that fully assesses the potential environmental impacts associated with GE salmon, and (2) amend its regulatory framework to specifically define the Agency's oversight of GE food animals in a manner that provides greater and necessary environmental protection and is consistent with NEPA.

II. STATEMENT OF GROUNDS

Petitioners' request for completion of a comprehensive EIS for the ABT application is fully supported by the law and the facts relevant to FDA's final determination.

By assuming regulatory authority over transgenic food animals FDA is bound to ensure compliance with NEPA's plain mandate to prepare an EIS where—as here—the approval of such animals could significantly affect the environment. Likewise, FDA must amend its existing process for consideration of GE food animal applications in order to comply with NEPA's directive to provide meaningful and consistent opportunities for public involvement in a federal agency's decision-making process.

The need for an EIS is further evinced by the factual record surrounding ABT's application, which, though limited, reveals significant deficiencies in ABT's environmental risk analyses and assurances. Not only has FDA itself acknowledged ABT's failure to adequately address potential risks presented by AquAdvantage Salmon, but several notable transgenic fish experts have expressed serious misgivings regarding GE fish and the myriad questions regarding potential environmental threats that ABT has left unanswered. These concerns are exacerbated in the face of ABT's impending expansion plans and FDA's closed and opaque regulatory review process, which, as discussed below, is not adequately suited for the consideration of GE food animal applications.

For these reasons, and as more fully set forth herein, Petitioners ask that FDA (1) refrain from taking final action on ABT's pending application until the Agency has prepared a full EIS for that application, and (2) amend its overall regulatory authority to create specific requirements for GE food animals that take into account the environmental concerns relevant to the production and commercialization of such animals, and also provide meaningful opportunities for public participation.

A. FDA Must Consider the Full Range of Environmental Impacts Related to GE Salmon.

As a threshold matter, Petitioners emphasize that FDA's reliance on its existing regulatory structure to extend its reach to GE animals produced for human consumption constitutes an improper and unprecedented interpretation of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq*, and the Agency's implementing regulations.[1] The production and distribution of GE food animals like ABT's AquAdvantage Salmon inherently pose unique environmental risks—including those threatening disruption and potential destruction of entire natural ecosystems—that are simply not contemplated by the FFDCA or its regulations. There can be no question that FDA's authority was designed to effectuate the Agency's oversight of traditional pharmaceutical drugs, and that even the new animal drug application ("NADA") process, which the Agency asserts governs applications like ABT's, does not ensure adequate protections for the environment. Indeed, as explained below, the existing framework presents a number of dangerous loopholes that can potentially be exploited by GE food animal applicants to circumvent important and requisite environmental analyses. Even worse, the present NADA process occurs almost entirely behind closed doors, making it nearly impossible for the public to participate meaningfully in an agency decision that could lead to devastating and irreversible ecological harm. In light of the plain unsuitability of the existing framework and the burgeoning GE food animal industry, FDA must promulgate new regulations that set forth specific requirements for GE food animal applicants and integrate relevant environmental considerations in a manner that is consistent with NEPA.[2]

Nonetheless, even under the existing regulatory scheme, FDA is required by NEPA to consider the full range of potential environmental impacts associated with ABT's NADA, including the potential release of AquAdvantage Salmon. 21 C.F.R. § 514.1(b)(14); Guidance

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[1] FDA has asserted authority over GE or transgenic food animals pursuant to its statutory authority to regulate new animal drugs. FDA Guidance for Industry 187, Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs, at 5-6 (January 15, 2009) (hereinafter "FDA Guidance 187" or "2009 Guidance for Industry"); *see also* 21 C.F.R. § 25.10(c); 21 U.S.C. § 355, § 360(b). The FFDCA defines the term "drugs" as including, among other things, "articles (other than food) intended to affect the structure of any function of the body of man or other animals." 21 U.S.C. § 321(g). "New animal drug" is defined, in turn, as any drug that is intended for use in animals and is not generally recognized by "experts qualified by scientific training and experience" as safe and effective for use under the conditions prescribed, recommended, or suggested in the drug's labeling, and has not been used to a material extent or for a material time. 21 U.S.C. § 321(v). FDA has interpreted these definitions to encompass the rDNA construct in a GE animal that is intended to affect the structure or function of the body of the GE animal in order to bring those animals, including ABT's AquAdvantage Salmon, within its regulatory purview. FDA Guidance 187, at 5.

[2] Though applicable to GE food animal applicants, FDA's 2009 Guidance for Industry does not adequately address the regulatory concerns discussed herein.

187, at 10-11. When considering the role of NEPA in FDA's decision-making, FDA must keep in mind that in enacting NEPA, Congress explicitly recognized the profound impact of "new and expanding technological advances" on the natural environment. 42 U.S.C. § 4331(a). In fact, the legislative history of NEPA "reveals an underlying concern with '[a] growing technological power... far outstripping man's capacity to understand and ability to control its impact on the environment.'" *Foundation on Economic Trends v. Heckler*, 756 F.2d 143, 147 (D.C. Cir. 1985) (quoting S. Rep. No. 91-296 (1969)). While realizing the need to stay abreast of the technological tide, NEPA seeks to "insure that environmental information is available to public officials and citizens before decisions are made and before actions are taken." 40 C.F.R. § 1500.1(b). This requires agencies to take environmental considerations into account in their planning and decision-making "to the fullest extent possible." 42 U.S.C. § 4332.

Unless seeking a categorical exclusion, new animal drug applicants are required to submit an EA as part of their NADA in order to comply with NEPA. 21 C.F.R. § 514.1(b)(14); FDA Guidance 187, at 10-11. FDA must thereafter evaluate the EA's accuracy and objectivity and determine whether "the proposed action *may* significantly affect the quality of the human environment." 21 C.F.R. § 25.15(b) (emphasis added). If it identifies the potential for significant effects, FDA must prepare an EIS in accordance with the Administration's regulations and NEPA. *Id.* The EIS must describe:

> (i) the environmental impact of the proposed action,
> (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,
> (iii) alternatives to the proposed action,
> (iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and
> (v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

42 U.S.C. § 4332(C). As articulated in FDA's own regulations, "EIS's are prepared for agency actions when evaluation of data or information in an EA or otherwise available to the agency leads to a finding by the responsible agency official that a proposed action may significantly affect the quality of the human environment." 21 C.F.R. § 25.22(b); 21 C.F.R. § 25.15(b).

In light of the potential for the significant environmental impacts detailed below, it is clear that approval of the ABT application "may significantly affect the quality of the human environment." Therefore, FDA must prepare an EIS. *See, e.g., American Bird Conservancy, Inc. v. Federal Communications Commission*, 516 F.3d 1027, 1033 (D.C. Cir. 2008) ("'if *any* 'significant' environmental impacts might result from the proposed agency action, then an EIS must be prepared *before* the action is taken'") (quoting *Sierra Club v. Peterson*, 717 F.2d 1409, 1415 (D.C. Cir. 1985)) (emphasis in original); *Scientists' Institute for Public Information, Inc. v. Atomic Energy Commission*, 481 F. 2d 1079, 1088 (D.C. Cir. 1973) ("The phrase 'actions significantly affecting the quality of the environment' is intentionally broad, reflecting [NEPA's] attempt to promote an across-the-board adjustment in federal agency decision making so as to make the quality of the environment a concern of every federal agency.").

The need for an EIS in this case is underscored by the Council on Environmental Quality ("CEQ") NEPA regulations, which direct federal agencies to take into account the context and intensity of the potential environmental impacts of the proposed action when determining whether to prepare an EIS. *See* 40 C.F.R. § 1508.27 ("Significantly as used in NEPA requires considerations of both context and intensity."). In connection with ABT's application, these regulations require FDA to consider, among other things:

> (4) The degree to which the effects on the quality of the human environment are likely to be highly controversial;
> (5) The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks; and
> (6) The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.

40 C.F.R. § 1508.27(b). Each of these factors weighs heavily in favor of the preparation of an EIS here. As set forth below, leading transgenic fish experts have stated that GE fish like AquAdvantage Salmon present unique environmental risks that must be studied further before these animals are approved for production and commercialization. Further, the uncertainties associated with ABT's application have generated ongoing controversy among a broad-range of experts, lawmakers, and consumer health and environmental advocates, both within the United States and abroad.[3] And, given that ABT's application is the first to seek commercialization of a GE food animal and thus implicates new risks not previously evaluated by FDA, the approval of this application has the potential to establish a precedent for other transgenic animals intended for human consumption. For these additional reasons, the preparation of an EIS is not only warranted, but required, prior to any final action with respect to the ABT application.

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[3] *See, e.g.*, Letter from Gregory Moyer, Regional Geneticist, US Fish and Wildlife Service ("FWS"), to FDA (September 30, 2010) (US FWS expresses major concerns including lack of risk assessment regarding environmental damage in the event of escape) (Attachment 1); E-mail from Deborah Burger (FWS) to Allan Brown (FWS) and Cynthia Williams (FWS) ("We need to give this... a lot of thought and...the chance of escape is huge") (Attachment 2); Letter from Members of the United States Senate to Commissioner Hamburg (September 28, 2010) (urging Commissioner Hamburg to "discontinue the FDA's approval process of the GE salmon at this time to protect consumers, fishing and coastal communities, and the environment") (Attachment 3); Letter from Members of the U.S. House of Representatives to Commissioner Hamburg (September 29, 2010) (expressing "serious concerns" regarding FDA's process for reviewing and possibly approving ABT's application and urging Commissioner Hamburg to "immediately suspend your approval process until you thoroughly examine and address the very serious flaws with your process including the need for greater public input and independent scientific data") (Attachment 4); Letter from Members of California Legislature to Commissioner Hamburg (September 16, 2010) (requesting FDA to deny ABT's application until "there is ample, publicly available research and a comprehensive national framework to address the full suite of environmental and food safety concerns of genetically modified organisms") (Attachment 5); S. 230, 112th Cong. § 1 (January 31, 2011) (bill to amend FFDCA to prevent approval of transgenic fish) (Attachment 6); H.B. 521, 112th Cong. § 1 (February 8, 2011) (same) (Attachment 7); AB 88 California Assembly (January 6, 2011) (requiring labeling of all transgenic salmon sold or produced in California) (Attachment 8); Canadian House of Commons Motion M-648 (March 1, 2011) (proposing that the government immediately "prevent the introduction into the Canadian food system of genetically modified salmon destined for human consumption until further scientific studies are concluded ...to determine the impact of genetically modified salmon on human health and on the health of marine species, ecosystems and habitats") (Attachment 9).

In addition to preparing an EIS, FDA must go beyond its 2009 Guidance for Industry and amend its existing regulatory framework to create explicit requirements for applications seeking approval of GE food animals like AquAdvantage Salmon. In doing so, FDA must ensure consistency with NEPA's general mandates. 42 U.S.C. §4333[4]; *see also People Against Nuclear Energy v. Nuclear Regulatory Commission*, 678 F.2d 222, 231 (D.C. Cir. 1982) (explaining that CEQ regulations "were expressly designed to establish uniform procedures for implementing NEPA and to eliminate inconsistent agency interpretations"), *reversed on other grounds*, 460 U.S. 766 (1983). In particular, Petitioners request that FDA promulgate new regulations specific to GE food animals that *at least* address the following deficiencies, which render the existing framework wholly unsuitable for effective oversight of ABT's application.

Environmental Safety: FDA's regulations must explicitly require GE food animal applicants to provide the Agency with affirmative proof of environmental safety. Under the current regulations, a sponsor is required to submit evidence establishing that its new animal drug is both safe and effective for the intended use. *See, e.g.*, 21 U.S.C. § 360b(a)(1) (stating that a new animal drug is considered "unsafe" until it is approved). Neither the regulations nor the FFDCA set forth a clear definition of the term "safe," but 21 U.S.C. § 321(u) explains that it "has reference to the health of man or animal." Although the 2009 Guidance for Industry suggests that environmental impacts are part of the FDA's safety analysis, such an interpretation is not codified in the relevant regulations. Accordingly, FDA must provide a precise, formal regulatory definition of the term "safe" to clarify that evaluating whether a new animal drug is "safe" manifestly requires the consideration of environmental impacts, such as risks of escape and subsequent ecological disruption. In this regard, FDA must also promulgate provisions that set forth minimum requirements for demonstrating environmental safety.

Inter-Agency Coordination and Consultation: Given the unique risks and scientific uncertainties associated with transgenic animals, FDA must implement regulations for GE food animal applicants that expressly require interagency coordination and consultation. NEPA demands that FDA "shall consult with and obtain the comments of any Federal agency which has jurisdiction by law or special expertise with respect to any environmental impact involved." 42 U.S.C. §4332(C); 40 C.F.R. §1501.6 (emphasizing agency cooperation "early in the NEPA process"). In the case of GE food animals like AquAdvantage Salmon, these other agencies necessarily include the U.S. Environmental Protection Agency, the Fish and Wildlife Service ("FWS"), the National Marine Fisheries Service ("NMFS"), and the U.S. Department of Agriculture—each of which has experience and expertise relevant to the study and regulation of GE organisms.

Notably, when FDA issued a draft of its 2009 Guidance for Industry for public comment, FWS notified FDA of the Service's "expertise in fish and wildlife biology, ecology and management," and specifically recommended that FDA "consult with the Services when reviewing New Animal Drug Applications (NADA) for genetically engineered aquatic animals

[4] All federal agencies were required to review "present statutory authority, administrative regulations, and current policies and procedures for the purpose of determining whether there are any deficiencies or inconsistencies therein which prohibit full compliance with the purposes and provisions" of NEPA, and "propose to the President not later than July 1, 1971, such measures as may be necessary to bring their authority and policies into conformity with the intent, purposes, and procedures" of NEPA. 42 U.S.C. § 4333.

and determining whether or not to exercise enforcement discretion of the NADA process for genetically engineered aquatic animals." *See* FWS Comments re Guidance 187, November 18, 2008 (Attachment 10). Despite this request it is unclear whether FDA has formally consulted with FWS or any other federal agency in reviewing ABT's application; indeed, evidence made available to the public suggests that it has not. *See supra* note 2, FWS e-mails (Attachments 1-2; 19); 40 C.F.R. § 1501.6 (directing federal agencies to designate agencies possessing "special expertise with respect to any environmental issue" as "cooperating agencies").[5]

Increased Public Participation: FDA's revised regulations for GE food animals must also provide for direct, early, and meaningful opportunities for public participation. As demanded by NEPA's regulations, agencies are to "integrate the NEPA process with other planning at *the earliest possible time* to insure that planning and decisions reflect environmental values, to avoid delays later in the process, and to head off potential conflicts." 40 C.F.R. § 1501.2 (emphasis added). Yet it is evident from FDA's review of ABT's application that the Agency will not provide an opportunity for public input until the very final stages of its decision-making process, thereby creating the precise delays and conflicts NEPA seeks to avoid.

Although FDA has hosted a public hearing on ABT's application and has stated that it will seek public comment on its NEPA document related to this application before publishing a final determination, such opportunities are not presently required by law and therefore may not be afforded each time the Agency is considering approval of a GE food animal application. In fact, the regulations only require FDA to make a NADA EA and associated finding of no significant impact ("FONSI") available for public review before final action is taken "for a limited number of actions." 21 C.F.R. § 25.51(b)(3). Those limited actions include ones that would normally require an EIS or "when the proposed action is one without precedent." *Id.* FDA has already declared that it does not automatically require the preparation of an EIS for any NADA, *see* 21 C.F.R. § 25.22(a); September 20, 2010 Veterinary Medicine Advisory Committee ("VMAC") Meeting Transcript at 54: 7-9, and given that ABT's application is the first of its kind, it is possible that it might serve as a precedent for future applications. Similarly, the regulations state that a completed EIS "will become available only at the time of the approval of the product" and that although public comments can be submitted after the approval, the only relevance of those comments would be to form a basis for the Agency to "consider beginning an action to withdraw the approval" of the application." 21 C.F.R. § 25.52(a)-(b).

Increased Transparency: In developing regulations specific to GE food animals, FDA must reconsider the applicability of the broad trade secret and confidentiality protections that it currently affords to applicants. Those provisions allow FDA to avoid disclosing to the public even the most basic NADA information until the NADA has been formally approved. *See, e.g.*, 21 C.F.R. § 514.11(b)-(c) (stating that FDA will not disclose to the public the existence of a NADA file before approval has been published in the Federal Register, unless it has previously been publicly disclosed or acknowledged); 21 C.F.R. § 25.50(b) (asserting that "unless the existence of applications for...animal drugs...has been made publicly available, the release of the environmental document before approval of...animal drugs...is inconsistent with statutory

[5] To the extent FDA has consulted with other agencies, Petitioners request that the associated documents containing all communications between FDA and any other agencies reflecting that consultation be made publically available as soon as possible and before FDA makes any final decision on ABT's application.

requirements imposed on FDA"). By advancing this interpretation, FDA and GE food animal applicants might argue that they have no obligation to disclose critical information concerning the environmental and human health implications of GE food animal products to the public until these products have been approved for commercialization. However, in the case of GE food animals like AquAdvantage Salmon this interpretation is hardly appropriate because once these animals have been approved for production and distribution it may very well be too late to prevent irreversible ecological damage.

To the extent that trade secret protections are necessary in the context of GE food animal regulation, FDA must attempt to reconcile them with the need to provide the public with the kind of timely access to relevant information of environmental and public health risks that is required by NEPA. In this regard, Courts considering individual agency interpretations of NEPA have made clear that "CEQ guidelines are entitled to substantial deference in interpreting the meaning of NEPA provisions, even when CEQ regulations are in conflict with an interpretation of NEPA adopted by one of the Federal agencies." *Morris County Trust for Historic Preservation v. Pierce*, 714 F.2d 271, 276 (3d Cir. 1983) (citing *Andrus v. Sierra Club*, 442 U.S. 347, 358 (CEQ's interpretation given precedence over contrary interpretation of NEPA adopted by Department of Interior)). For instance, it is unclear why the mere existence of a NADA or an applicant's environmental and public health safety assessment should not be released to the public for review and comment early in the application process and as soon as they are made available to the Agency. At the least, to comply with NEPA and the CEQ regulations, FDA must promulgate minimum disclosure requirements for GE food animal applicants that provide the public with adequate notice of the issues and risks at hand. It is not sufficient in this context for FDA to merely "make diligent effort to involve the public in preparing and implementing NEPA procedures." 21 C.F.R. § 25.52(c).

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At present, FDA's regulatory scheme makes it virtually impossible for citizens, including scientists, advocates, and government representatives, to opine on and raise informed concerns about applications like ABT's before they are approved. Such a result is squarely inconsistent with NEPA's most basic tenets for prioritizing public participation and transparency in federal agency decision-making and must be avoided. *See, e.g.*, 40 C.F.R. §1501.2 (requiring agencies to consider the environmental implications of its actions at the "earliest possible time"); 40 C.F.R. §1500.1(b) (requiring agencies to alert the public of their actions so as to facilitate public participation). As explained by the United States Supreme Court,

> NEPA promotes its sweeping commitment to 'prevent or eliminate damage to the environment and biosphere' by focusing Government and public attention on the environmental effects of proposed agency action. By so focusing agency attention, NEPA ensures that the agency will not act on incomplete information, only to regret its decision after it is too late to correct. Similarly, the broad dissemination of information mandated by NEPA permits the public and other government agencies to react to the effects of a proposed action at a meaningful time.

Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 371 (1989) (internal citations omitted).

Petitioners note that FDA's current regulatory system not only conflicts with the stated goals of NEPA, but also plainly contravenes the Obama Administration's cross-cutting Open Government Directive, which expressly seeks to increase transparency, public participation, and government collaboration.[6] FDA must recognize that these inconsistencies simply cannot be sustained in the course of regulating GE food animals like AquAdvantage Salmon, which, as discussed herein, present serious risks of escape and consequent, potentially irreversible ecological harm. Without making such revisions to its regulations, FDA's application of NEPA is effectively meaningless and thus contrary to the mandate of law.

B. The Facts Surrounding ABT's Application Plainly Support the Preparation of a Comprehensive EIS.

In addition to the legal requirements demonstrated above, there exists a strong factual basis underpinning the position that FDA must prepare an EIS prior to taking final action on ABT's application.

1. ABT's Own Application Admits Serious Environmental Risks.

Both the EA submitted by ABT and FDA's analysis of ABT's application raise serious questions concerning the efficacy of ABT's proposed "containment" measures. These measures, which include a triploidy induction process, are intended to mitigate the risk that AquAdvantage Salmon will escape confinement, become established in the environment, and spread to other areas. ABT maintains that the risks associated with potential escape of AquAdvantage Salmon are dramatically lessened by the triploidy induction process used to sterilize the eggs before they are transported to Panama for grow-out. However, while ABT's data show that its process induced triploidy in 98.9% to 100% of the egg batches treated in its study, information contained in ABT's EA (and FDA's conclusions based on analysis of that information) indicates that up to 5% of the eyed-eggs taken from the ABT facility on Prince Edwards Island to the ABT facility in Panama may not be sterile.

In particular, as confirmed by FDA, "ABT has not submitted any specific data to show whether or not AquAdvantage Salmon are indeed sterile." FDA Briefing Packet, September 20, 2010 at 126. Notably, FDA has stated that ABT's characterization of the AquAdvantage Salmon as "sterile" is "potentially misleading" because "sterility has not been explicitly verified in these fish and up to 5% of the eggs sold for grow-out may be non-triploid and still within release specifications." *Id.* at 115. These findings raise serious questions about the sufficiency and reliability of ABT's plan to mitigate the risks presented by the potential escape of the AquAdvantage Salmon and must be carefully evaluated in an EIS.

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[6] Memorandum for Heads of Executive Departments and Agencies, Open Government Directive (December 8, 2009), available at http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m10-06.pdf.

Furthermore, two important scientific studies have found that in certain circumstances, transgenic fish can out-compete wild fish to the point of total population collapse.[7] These studies underscore the need for a comprehensive EIS. Although these studies do not address the specific risks presented by the release of AquAdvantage Salmon, their findings are relevant considering the limited evidence presented in support of ABT's application and should therefore be considered in this application review process.[8]

2. Transgenic Fish Experts Have Expressed Deep Concern Regarding the Deficient Science Surrounding the ABT Application.

When reviewing this application, FDA must take into account the scientific concerns that notable transgenic fish experts have expressed with regard to ABT's contention that any risks posed by transgenic salmon are adequately addressed in the EA. During the September 20, 2010 VMAC Meeting, Dr. Anne Kapuscinski, a renowned GE fish expert, expressly highlighted deficiencies in the science supporting ABT's application:

> *[T]he Environmental Assessment does not give the full information needed to predict environmental effects of AquAdvantage Salmon.* It stops at estimating that the likelihood of escape is 'extremely small' due to multiple confinement at the two facilities. But this assumes 100 percent achievement of the confinement and even with actual exposure very close to zero, it is necessary to assess ecological consequences and then estimate the overall risk especially given the precedent set by this Environmental Assessment.

September 20, 2010 VMAC Meeting Transcript at 321:12-21 (emphasis added). Dr. Kapuscinski further explained that ABT's EA "*does not adequately address the major questions that should be asked about genetic and ecological risks*," and that "[e]mpirical studies have shown that there is a high scientific uncertainty in predicting overall fitness and ecological effects of growth enhanced transgenic fish because it is extremely challenging to extrapolate to nature from experiments using simulated natural conditions in the laboratory." *Id.* at 321:22-25;

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[7] Howard RD, DeWoody JA, Muir WM (2004) Transgenic male mating advantage provides opportunity for Trojan gene effect in a fish. Proceedings of the National Academy of Sciences 101:2934-2938 (Attachment 11); Devlin RH, D'Andrade MD, Uh M, Biagi CA (2004) Population effects of growth hormone transgenic coho salmon depend on food availability and genotype by environment interactions. Proceedings of the National Academy of Sciences 101: 9303-9308 (Attachment 12).

[8] Although Dr. William Muir has stated that the "Trojan gene effect" will not occur as a result of the release of AquAdvantage Salmon, the theory's relevance should not be dismissed outright. Other studies note that background genetics or behavior can change the likelihood of the Trojan gene effect, and suggest that in-depth risk assessment is crucial to understanding the potential risks of transgenic fish escape events. *See, e.g.*, Ahrens, RNM, Devlin RH, Standing genetic variation and compensatory evolution in transgenic organisms: a growth-enhanced salmon simulation, Transgenic Res. (published online, September 29, 2010) (Attachment 13); Valosaari K-R., Aikio S, Kaitala V (2008) Male mating strategy and the introgression of a growth hormone transgene, Evolutionary Applications 1: 608–619 (Attachment 14). This kind of risk assessment has not yet been undertaken as part of this application, and until it has, FDA should not accept untested assumptions about the AquAdvantage Salmon. *See* Kapuscinski AR, Hayes KR, Li S, Dana G (2007) Environmental risk assessment of genetically modified organisms. Vol 3. Methodologies for transgenic fish. CABI International, Oxfordshire.

322:1-4 (emphasis added). Thus, she stated, it is "very hard to predict how transgenic fish will effect environments where they have not been studied." *Id.* at 322:11-13. Dr. Kapuscinski concluded her statements by expressing concern about the "overly simplistic claims in the documents" for AquAdvantage Salmon "without the scientific evidence" needed to support them. *Id.* at 322: 20-22.

Some of the statements Dr. Kapuscinski made to the VMAC referenced the research of Dr. Robert Devlin, considered among the world's leading experts on transgenic fish, and salmon in particular.[9] Dr. Devlin has been studying transgenic salmon since 1989, and while he has achieved sterility rates between 97 to 99.8 percent (comparable to those attained by ABT), he has concluded that these rates are "not quite high enough for biological containment yet."[10] Dr. Devlin's work has also identified concerns regarding the dearth of information relating to how transgenic salmon will behave in the wild, including how they will interact with native salmon.[11] Dr. Eric Hallerman, one of FDA's presenters at the VMAC Meeting, emphasized these concerns, stating that "development of quantitative risk assessment is presently incomplete...especially regarding the likelihood of harm given exposure to the hazard. We need more studies quantifying net fitness, especially under near-wild, or wild, conditions." September 20, 2010 Meeting Transcript at 86:1-6.[12] As expressed by Dr. Hallerman, "we have a lot to learn about the likelihood of genetic harm being realized due to the interbreeding of wild and transgenic aquacultured fish." *Id.* at 80:8-10. Based on the current state of scientific uncertainty, it is clear that to make a sound safety determination for this application and comply with applicable environmental law requirements, FDA must evaluate the full range of potential outcomes related to the commercial production of AquAdvantage Salmon in an EIS before reaching a final determination on the ABT application. *See, e.g.,* 40 C.F.R. § 1508.27(b)(5) (in an EIS determination, the agency should consider "[t]he degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks"). Indeed, FDA should follow the recommendation of the sole fisheries biology expert included on the VMAC, Dr. Gary Thorgaard, who stated that "considering this issue in a comprehensive way, together with other agencies through an environmental impact statement, would be the best way to proceed." September 20, 2010 Meeting Transcript at 383:19-23.

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[9] Sarah Schmidt, *Canadian scientist's work front and centre in GE fish debate*, Postmedia News, Feb. 23, 2011, http://www.canada.com/technology/Canadian+scientist+work+front+centre+fish+debate/4334542/story.html#ixzz1Fse0GpD5. (Attachment 15).

[10] *Id.*

[11] *Id.* ("Devlin's work has found, among other things, that his growth-enhanced GE coho salmon had ravenous appetites that out-competed and even ate native salmon in a laboratory environment. The genetic engineering process also alters their behaviour, so they are likely to explore novel prey and new areas.").

[12] Dr. Hallerman continued to explain that "[w]e need advances in understanding certain fundamental genetic or ecological issues, for instance, the likelihood of outbreeding depression should transgenic and wild fish interbreed, genotype by environment effects, and ecological interactions in the wild. Regarding risk management, there is the need to demonstrate the effectiveness and economic viability of aquaculture production under confinement conditions." September 20, 2010 Meeting Transcript at 86:7-14.

3. ABT Has Announced Plans to Expand Production of AquaAdvantage Salmon in the U.S. and Abroad.

Despite the weak scientific foundation supporting ABT's application, and notwithstanding the stated concerns of transgenic experts, ABT has announced imminent expansion of its operations, thereby compounding the risks at issue here and the need to prepare an EIS. Over the last several months, ABT's Chief Executive Officer, Dr. Ron Stotish, has publicly expressed ABT's intention to increase production of AquAdvantage Salmon throughout the U.S. and around the world. *See e.g,* September 20, 2010 Meeting Transcript at 114:19-21 ("The kinds of facilities that we are thinking will be constructed in the United States and other locations are perhaps on the order of 2,000 tons...").[13] In fact, recent government correspondence reveals that a former ABT executive has already been in contact with individuals from the Maine Department of Environmental Protection to discuss raising AquAdvantage Salmon in a hatchery, rearing, and processing facility in the State that would discharge final waste waters into the marine environment.[14] ABT's latest financial report confirms the company's plans to increase production within the U.S. and abroad:

> In anticipation of approval, AquaBounty has developed relationships with authorities and producers in several countries that have appropriate production resources and are interested in testing the AAS [AquAdvantage Salmon] product. *The Company has received a number of enquiries from developers, within the USA and elsewhere, that are enthusiastic about the economic prospects of growing AAS. Plans to expand capacity for the production of eggs for sale are in place and will be implemented as soon as approval is granted.*

AquaBounty Technologies Preliminary Results for the year ended 31 December 2010, at 3 (May 3, 2011) (Attachment 18) (emphasis added).

Notwithstanding these stated expansion plans, FDA has indicated that it is reviewing ABT's pending application by strictly limiting its focus to the application itself, and refusing to examine questions triggered by future planned ABT actions. *See, e.g.,* September 20, 2010 Meeting Transcript at 125:15-25 (FDA's Dr. Larisa Rudenco directing VMAC not to consider

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[13] *See also* September 20, 2010 Meeting Transcript at 113:1-23 (referring to the Panama site as "an initial production facility" and explaining that the AquAdvantage Salmon is "not only an economic development opportunity for a lot of countries, including the United States, but that this fish can now be grown closer to those population centers").

[14] *See* October 6, 2010 e-mail from Robert D. Stratton (Maine Department of Environmental Protection) to Joan Trial (Maine Department of Marine Resources), Jeff Murphy (National Oceanic Atmospheric Administration (NOAA)), David Bean (NOAA), Wende Mahaney (FWS), and Fred Seavey (FWS) (explaining that Stratton had spoken with Joe McGonigle, a former ABT Vice President, about bringing GE salmon to Maine and that there is specific interest in the former Great Eastern Mussel property in St. George) (Attachment 16). Notably, ABT's suggested expansion in Maine could be at odds with a prohibition against using transgenic salmonids at existing marine sites of the coast of Maine. *See* 2003 NOAA, National Marine Fisheries Service (NMFS), Endangered Species Act (ESA) Consultation Biological Opinion concerning permits allowing net pens for use of raising finfish off the coast of Maine, at 74- 75 (noting that the prohibition is necessary to "eliminate the potentially adverse disease and ecological risks posted by the use of transgenic salmonids in aquaculture") (Attachment 17). Of course, if ABT were to expand its operations into Maine or other parts of the U.S., consultation with FWS and NMFS would be required under the ESA. *See* 40 C.F.R. §1508.27.

ABT's future business plans). FDA must reassess this improper approach and recognize that because the extent of risks associated with the potential escape of these GE fish has not been fully assessed, the preparation of an EIS that evaluates all known potential scenarios in which the AquAdvantage Salmon may be produced, raised, and released is imperative and required by law. *See, e.g.*, 40 C.F.R. §1508.25(a)(2)-(3) (in determining the scope of an EIS, an agency shall consider "[c]umulative actions, which when viewed with other proposed actions have cumulatively significant impacts," and "[s]imilar actions, which when viewed with other reasonably foreseeable or proposed agency actions, have similarities that provide a basis for evaluating their environmental consequences together...").

Given ABT's future plans, this pending application could arguably represent FDA's last best chance to evaluate closely the wide range of risks posed by GE salmon. Both FDA and ABT have indicated that should the company wish to modify or expand its production and manufacturing operations into the U.S. in the future, then ABT would simply need to submit a supplemental NADA and EA. At the September VMAC meeting, for instance, the director of FDA's Center for Veterinary Medicine, Dr. Bernadette Dunham, confirmed that any "additional requests [to grow AquAdvantage Salmon]. . . would come through as supplementals." September 20, 2010 VMAC Meeting Transcript at 114:1-8. Dr. Ron Stotish recently reiterated this position at BIO's Animal Biotech Briefing, stating that any future expansion would be subject only to a supplemental application and EA and that such a procedure is merely a "technicality" and poses no barrier to raising AquAdvantage Salmon within the United States. Statements made by Dr. Stotish at BIO's Animal Biotech Briefing, Washington, D.C. (March 9, 2011).

If FDA's current supplemental NADA regulations, 21 C.F.R. §514.8, will apply to GE food animal applications as indicated, ABT's application raises even greater concerns than those noted above. Under these regulations, the holder of an approved application has complete discretion to determine whether supplemental FDA approval is required before effecting certain changes in its "drug, production process, quality controls, equipment, or facilities." 21 C.F.R. § 514.8(b). According to the regulations, pre-approval is necessary only where the change has "substantial potential to have an adverse effect on the *identity, strength, quality, purity, or potency* of the drug as these factors may relate to the safety or effectiveness of the drug." 21 C.F.R. §514.8(b)(2) (emphasis added).[15] Because these provisions do not expressly consider the potential for adverse environmental effects, a GE food animal applicant like ABT could attempt to argue that FDA approval is not needed for major alterations to its facilities or containment measures even though such changes could pose significant environmental risks.[16] Any such interpretation would magnify the concerns expressed herein since these regulations do not

[15] Where the applicant predicts that the potential effect of a particular change on these factors is lower—either moderate or minimal—mere notice of the change to the Agency will suffice. 21 C.F.R. §514.8(b)(3) (new animal drugs with moderate changes may be distributed 30 days after FDA has received notice of the change even if it has not yet been approved); 21 C.F.R. §514.8(b)(4) (minor changes in new animal drugs need only be described and submitted in an annual report to FDA).

[16] Again, Petitioners emphasize that any effort by FDA, ABT, or similar GE food animal applicant to interpret these supplemental NADA regulations in a manner that circumvents oversight of changes to production processes, facilities, or containment measures would be unfounded and unlawful since these regulations are plainly not suited to apply to NADAs for the production of transgenic animals like the AquAdvantage Salmon.

expressly require NADA holders or new sponsors of the approved animal drug to prepare a supplemental EA analyzing the environmental effects of their changes.[17]

In practice, these exemptions could be invoked by FDA and the industry in an unlawful effort to create a huge loophole through which ABT could potentially produce AquAdvantage Salmon in new locations within the U.S. and abroad without implementing the same containment measures described in the current application or conducting any analysis of the environmental and ecological risks presented by such changes. This procedure could also potentially allow ABT and future sponsors of AquAdvantage Salmon to simply incorporate data contained in ABT's current application, including its woefully deficient EA, into a supplemental notice of change, without completing additional scientific analyses or assessing cumulative impacts.

Gregory Jaffe, a temporary VMAC member selected by FDA, voiced concerns about this piecemeal regulatory system at the September VMAC Meeting, noting that the current "segmented" process could provide a way for ABT to "get around doing an environmental impact statement about the fact that this salmon could be grown in multiple locations around the world in multiple facilities with different levels of control in them," and that the way it "is being set up may in fact avoid a full environmental impact statement or a full assessment under NEPA as this moves along, if this moves along, as the business plan of the sponsor [ABT] suggests." September 20, 2010 VMAC Meeting Transcript at 382-383. Indeed, applying the established supplemental process to ABT's future expansion proposals could substantially increase the risk that non-sterile fish will escape ABT's facilities and contaminate wild populations of salmon. Accordingly, in addition to the other revisions discussed above, FDA must amend its existing supplemental application regulations, 21 C.F.R. § 514.8, to expressly require GE food animal applicants and sponsors to acquire agency approval for any change to approved production and manufacturing processes, controls, containment measures, equipment, facilities, or batch sizes *before* effecting those changes. Likewise, FDA must require all GE food animal applicants and sponsors to prepare EAs or EISs for any such changes.

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For each of the reasons presented in this Petition, FDA is under a legal obligation to comply with NEPA and prepare a comprehensive EIS that takes into account the full range of possible risks AquAdvantage Salmon may present to wild fish populations before taking final action on ABT's application. FDA must also amend its current regulations as requested herein to create specific provisions for GE food animals that recognize the importance of environmental considerations and demand compliance with all aspects of NEPA, including those requiring increased transparency and agency coordination.

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[17] FDA's Guidance for Industry 82 (October 28, 2002), which includes discussion of supplemental EAs, does not alleviate Petitioners' concerns since it suggests that changes to the manufacturing process for new animal drugs do not require the preparation of a new EA. Moreover, it appears that this Guidance has not been updated to reflect FDA's 2007 revisions to 21 C.F.R. §514.8. To the extent that Guidance for Industry 83 (May 30, 2007) is controlling, Petitioners' concerns are further amplified as this document does not in any way instruct holders of NADAs to consider environmental effects.

III. ENVIRONMENTAL IMPACT

This Petition requests that FDA refrain from taking final action on ABT's pending NADA without first completing an EIS and revising its regulatory framework for GE food animals. The Petition itself does not assert a claim for categorical exclusion under 21 C.F.R. sections 25.30, 25.31, 25.32, 25.33, or 25.34 or an environmental assessment under 21 C.F.R. § 25.40. To the extent that FDA seeks to understand the risk of environmental impacts associated with ABT's application, Petitioners refer the Agency to the discussion above.

IV. CERTIFICATION

Pursuant to 21 C.F.R. § 10.30(b), the undersigned certifies, that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioners which are unfavorable to the Petition.

Respectfully submitted this 25th day of May, 2011.

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