EXHIBIT ONE

(U.S. FWS emails)

Attached are my thoughts. Please let me know what you think.

Thanks-
Wade

Wade D. Wilson
U.S. Fish and Wildlife Service
Dexter National Fish Hatchery and Technology Center
P.O. Box 219
Dexter, NM 88230

Phone: (575) 734-5910 ext. 41
Fax: (575) 734-6130

UPS/FEDEX Delivery:
Dexter National Fish Hatchery and Technology Center
7116 Hatchery Road

Dexter, NM 88230 AquAdvantage Salmon.doc

Yes, nice work Greg, especially pointing out that there is no data to support the claims of low survival in the event of escape, which I agree with you all is a big concern. I also agree with Wade that using triploid fish is not foolproof. Maybe they should watch Jurassic Park :). I am available at either of the times John suggested.

Denise

Denise Hawkins
Regional Geneticist
U.S. Fish & Wildlife Service

Allan Brown/R4/FWS/DOI
10/19/2010 02:33 PM

To Thomas Sinclair/R4/FWS/DOI@FWS
cc
bcc
Subject Fw: Briefing Paper Development - AquAdvantage Salmon

tom,

foia - this was my only comment about the aquadvantage salmon. see my comments in the e-mail string below.

----- Forwarded by Allan Brown/R4/FWS/DOI on 10/19/2010 02:32 PM -----

Linda Kelsey/R4/FWS/DOI
09/30/2010 02:11 PM

To Joe Moran/ARL/R9/FWS/DOI@FWS
cc Bryan Arroyo/ARL/R9/FWS/DOI@FWS, Jeff Underwood/ARL/R9/FWS/DOI@FWS, Stuart Leon/ARL/R9/FWS/DOI@FWS, Thomas_Sinclair@fws.gov, Deborah_Burger@fws.gov, Allan_Brown@fws.gov, Cynthia_Williams@fws.gov
Subject Fw: Briefing Paper Development - AquAdvantage Salmon

Joe: please see comments from folks in R4 on the AquAdvantage salmon. I agree that the escapement issue and it potential impact to native stocks is our greatest concern.
----- Forwarded by Linda Kelsey/R4/FWS/DOI on 09/30/2010 02:09 PM -----

Linda Kelsey/R4/FWS/DOI
09/30/2010 02:06 PM

To Greg Moyer/R4/FWS/DOI
cc Allan Brown/R4/FWS/DOI@FWS, Deborah Burger/R4/FWS/DOI@FWS, Thomas Sinclair/R4/FWS/DOI@FWS, Vincent Mudrak/R4/FWS/DOI@FWS, William Wayman/R4/FWS/DOI@FWS, Cynthia Williams/R4/FWS/DOI@FWS
Subject Re: Fw: Briefing Paper Development - AquAdvantage Salmon

Greg: Thank you for you thoughtful review of this document. I will forward your comments on to DC. I especially like your suggestions that the Service seek input AFS and the NAS. I would also suggest that our Genetics "Community of Practice" group may want to form a recommendation as well.

Cynthia Williams/R4/FWS/DOI

Cynthia Williams/R4/FWS/DOI
09/30/2010 12:08 PM

To Linda Kelsey/R4/FWS/DOI@FWS
cc Thomas Sinclair/R4/FWS/DOI@FWS, Greg Moyer/R4/FWS/DOI@FWS, Vincent Mudrak/R4/FWS/DOI@FWS, William Wayman/R4/FWS/DOI@FWS, Allan Brown/R4/FWS/DOI@FWS, Deborah

****
For list information, and to subscribe or unsubscribe, go to:
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****

I have been asked to comment on the AquAdvantage salmon issue and how it may relate to the Service and its mission (for our ARD). Does anyone have any thoughts? Has anyone else commented on this?

I am still reading the FDA brief, but one concern at this point is environmental risk management. During the creation of triploids via pressure treatment of eggs, it was found that on average 99% were triploid, but the lower bound was 97%. When doing mass production, this could lots of fish that are diploid and possibly viable. They state that there are physical, chemical, and geographic barriers...but in my mind things get around.

Anyway, thought I would ask.

Thanks-
Wade

Wade D. Wilson
U.S. Fish and Wildlife Service
Dexter National Fish Hatchery and Technology Center
P.O. Box 219
Dexter, NM 88230

Phone: (575) 734-5910 ext. 41
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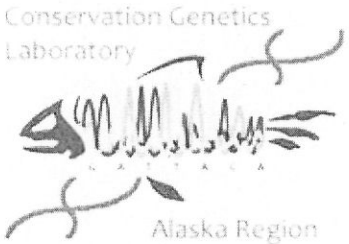
Conservation Genetics Community of Practice Lab Leads List http://www.fws.gov/ConservationGeneticsCOP/
****
****

Hi Everyone,

I have been asked to comment on the AquAdvantage salmon issue and how it may relate to the Service and its mission (for our ARD). Does anyone have any thoughts? Has anyone else commented on this?

John Keim Wenburg
Conservation Genetics Laboratory
U.S. Fish & Wildlife Service
1011 E. Tudor Rd.
Anchorage, AK 99503

office (907) 786-3858
fax (907) 786-3978
john_wenburg@fws.gov



****
Conservation Genetics Community of Practice Lab Leads List http://www.fws.gov/ConservationGeneticsCOP/
****

I agree with Greg that it would be good to have it be a CoP comment. I think Greg did a very nice job on his comments. I am comfortable with everything he says and would happily sign off. In addition, it sounds like Wade had major concerns about the potential for escape, which I echo. Perhaps Wade's comments could be incorporated as well, in addition to any other folks have.

Talk on the phone Friday about this? I can do 1pm EST or after 4pm EST....?

John

Cindy A. Williams
Fisheries Program Supervisor
US Fish and Wildlife Service, Region 4
1875 Century Blvd, Suite 250
Atlanta, GA 30345

404-679-4148

Deborah Burger/R4/FWS/DOI

09/29/2010 08:42 AM

To Allan Brown/R4/FWS/DOI@FWS, Cynthia Williams/R4/FWS/DOI@FWS
cc Greg Moyer/R4/FWS/DOI@FWS, Thomas Sinclair/R4/FWS/DOI@FWS, Vincent Mudrak/R4/FWS/DOI@FWS, William Wayman/R4/FWS/DOI@FWS
Subject Re: Fw: Briefing Paper Development - AquAdvantage SalmonNotes Link

I agree with Allen. We need to give this kind of thing a lot of thought and I do think the chance of escape is huge.

----- Original Message -----
From: Allan Brown
Sent: 09/28/2010 11:43 AM EDT
To: Cynthia Williams
Cc: Deborah Burger; Greg Moyer; Thomas Sinclair; Vincent Mudrak; William Wayman
Subject: Re: Fw: Briefing Paper Development - AquAdvantage Salmon

yeah, a little out of my league. i think the idea of genetically engineering animals that will be consumed is a bad idea anyway but it is done all the time. i think the uncertainty of what will eventually happen to a species if genetically altered animals mix with "native" stocks, is reason enough to oppose this, at least until such times that controlled experimentation can take place. with domesticated animals that are farmed in a very controlled environment i.e. chickens, the chances are these animals getting out and screwing up native "chicken" stocks is probably remote but with fishes, it is very much a different story. not matter what precautions you take, fish escape and once they do, there is no closing that door. so, that being said, i think it is very bad precedent to set but will defer to more learned people than i.

allan

Cindy A. Williams
Fisheries Program Supervisor
US Fish and Wildlife Service, Region 4
1875 Century Blvd, Suite 250
Atlanta, GA 30345

404-679-4148

Deborah Burger/R4/FWS/DOI

09/29/2010 08:42 AM

To Allan Brown/R4/FWS/DOI@FWS, Cynthia Williams/R4/FWS/DOI@FWS
cc Greg Moyer/R4/FWS/DOI@FWS, Thomas Sinclair/R4/FWS/DOI@FWS, Vincent Mudrak/R4/FWS/DOI@FWS, William Wayman/R4/FWS/DOI@FWS
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allan

EXHIBIT TWO

(U.S. FWS emails)

Jeff Adams/R7/FWS/DOI

10/04/2010 12:19 PM

To Richard Hannan/R1/FWS/DOI@FWS, Mike Oetker/RO/R2/FWS/DOI@FWS, Mike Weimer/R3/FWS/DOI@FWS, Linda Kelsey/R4/FWS/DOI@FWS, Steve Klosiewski/R7/FWS/DOI@FWS, Robert Clarke/SAC/R1/FWS/DOI@FWS

cc Jaime Geiger/R5/FWS/DOI@FWS, Bill Archambault/R5/FWS/DOI@FWS, David Perkins/R5/FWS/DOI@FWS, Mike Millard/R5/FWS/DOI@FWS, William Ardren/R5/FWS/DOI@FWS

Subject R5 draft comments on FDA's briefing packet re: genetically engineered Atlantic salmon

I'm on a detail w/ the R5 RO Fish Program, and Jaime asked me to send out these R5 draft comments regarding a Food & Drug Admin. (FDA) briefing packet that describes Aqua Bounty Technologies Inc. (ABT) commercial application to raise genetically engineered Atlantic salmon ("AquAdvantage Salmon") outside the USA and import the processed fish for sale as food in the USA.

ABT proposes to rear triploid females to the eyed stage in a hatchery on Prince Edward Island, Canada. Eyed eggs would be shipped for growout in Panama. At 18 months of age, fish would be harvested and processed in Panama for shipment to the USA for sale. R5 has concerns that approval of the proposal is premature, given the unknowns and uncertainties regarding the possible ecological and environmental effects of these fish. The proposal also presents a situation where FDA, whose jurisdiction is not focused on natural resources, is entrusted with the authority to approve an application which poses such a threat to the country's natural resources.

Contributions from Jaime, William Ardren, and others formed the basis of the attached synthesis by Mike Millard.

Thank you for your attention.

[attachment "Region 5 Fisheries Program Comments on FDA approval AquaBounty DRAFT.docx" deleted by Cynthia Williams/R4/FWS/DOI]

Jeff Adams
Branch Chief
Fisheries and Habitat Restoration
Fairbanks Fish and Wildlife Field Office
US Fish & Wildlife Service
101 12th Ave Room 110
Fairbanks, AK 99701-6237
Phone = (907) 456-0218
FAX = (907) 456-0454

Dear Dan and Bryan:

I thought you both might want to see my written and oral comments submitted in response to the FDA's release of public versions of two documents pertaining to an application for commercial approval of AquAdvantage salmon. My co-author, Dr. Fredrik Sundstrom, has published extensively on his ecological risk assessment experiments with genetically engineered salmon. Our joint comments focused on the environmental risk analysis of this application.

Please note:
The new animal drug regulations do not require FDA to make public future environmental assessments (or Environmental Impact Statements) before approval of such future applications. Yet, the company understandably wants to sell its GM salmon eggs to many other growers, as soon as the FDA approves this first application. (This intent is clear on the company's website, in a posted June 30, 2010 report to its shareholders). I added this point at the start of my verbal comments on Sept 20 because it underscores why the environmental analysis in this first application sets a crucially important precedent.

On a related note, thank you Bryan for speaking at the June 2010 symposium on genetic biocontrol on invasive fish, which I chaired. And Dan, thank you for serving on the steering committee to plan that symposium. We are hard at work on producing a series of peer-reviewed articles from the symposium

Let me know if I can be of any further help. Best regards,

Anne

Anne R. Kapuscinski
Sherman Fairchild Distinguished Professor of Sustainability Science
Environmental Studies Program, Dartmouth College
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Tel. +1-603-646-2668, FAX +1-603-646-1682
Assistant email: Kapuscinski-assistant@mac.Dartmouth.edu


Kapuscinski_Sundstrom_Comments_Sent16Sept10.pdf

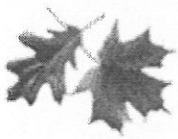

Kapuscinski_Sundstrom_OralComments_20Sept10.pdf

Martin Miller/R5/FWS/DOI
10/06/2010 10:45 AM

To Steve Mierzykowski/R5/FWS/DOI@FWS, Wende Mahaney/R5/FWS/DOI@FWS
cc
bcc
Subject Fw: Kapuscinski comments to FDA on genetically modified salmon application

fyi

Martin Miller, Chief, Div. of Endangered Species, U.S. Fish and Wildlife Service, 300 Westgate Center Dr., Hadley, MA 01035, 413-253-8615, 413-253-8482 (fax)
----- Forwarded by Martin Miller/R5/FWS/DOI on 10/06/2010 10:44 AM -----

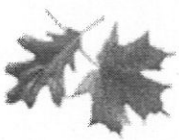


Gary D Frazer/ARL/R9/FWS/DOI
10/06/2010 09:14 AM

To Paul Phifer/R5/FWS/DOI
cc Don_Morgan@fws.gov, John Fay@FWS, Martin Miller/R5/FWS/DOI@FWS, Rick Sayers/ARL/R9/FWS/DOI@FWS, Wendi Weber/R5/FWS/DOI@FWS
Subject Re: Fw: Kapuscinski comments to FDA on genetically modified salmon application

Hazy to me, too. Based on my quick read, Anne's comments focus on potential future risks if these genetically modified salmon are used more broadly. Is it reasonable to view those as indirect effects of the current action in front of FDA, i.e., caused by and reasonably certain to occur? I don't know, but her comment that there's only one bite at this apple does give one pause.

Gary Frazer
Assistant Director for Endangered Species
Phone: (202)208-4646
Fax: (202)208-5618
Email: Gary_Frazer@fws.gov
Paul Phifer/R5/FWS/DOI



Paul Phifer/R5/FWS/DOI
10/06/2010 08:43 AM

To Gary D Frazer/ARL/R9/FWS/DOI@FWS, Martin Miller/R5/FWS/DOI@FWS
cc Don_Morgan@fws.gov, John Fay@FWS, Rick Sayers/ARL/R9/FWS/DOI@FWS, Wendi Weber/R5/FWS/DOI@FWS
Subject Re: Fw: Kapuscinski comments to FDA on genetically modified salmon application

Thanks Gary. I'll talk with Marty to make sure we are doing everything we need to on this issue. It's a little hazy to me how we are supposed to be engaged.

BTW - Anne K. was one of my principal advisors in grad school. Paul

Paul Phifer, PhD
Assistant Regional Director - Ecological Services
R5 - Northeast Region

In light of this precedent-setting action, we are interested in submitting a joint statement by scientists who have studied risk assessment of transgenic fish, potential environmental, economic, and social impacts of commercializing transgenic salmon, and relavent key issues in aquaculture, salmon biology/ecology, and ecological economics. If you would be interested in joining such an effort, and recognizing that we are constrained by a fast-approaching deadline (Sept. 16), we invite you to join a teleconference to frame comments ASAP.

Of course, it would also be very valuable if many of you submit individual written submissions. We are simply suggesting a joint statement in the spirit of combining efforts for maximum impact.

A joint oral statement may be very smart because the FDA is allowing only 1.25 hours for all oral public comments on Sept 20. SEPT 7 is the deadline to sign up to present an oral statement on Sept 20.

Please fill out this doodle calendar poll for availabilities Sept 2, 3, and 6 (a US national holiday but included due to short deadlines):

"Conference Call re: FDA written comments" at: http://www.doodle.com/vchsf4dva23sabkf

Thanks in advance for your consideration of this invitation, and please let us know if you feel we have omitted someone who you would recommend could contribute to this effort.

Sincerely,

Anne R. Kapuscinski, Dartmouth College, and

Kelly Pennington, Sea Grant Legislative Fellow

---

(1) "Genetically Altered Salmon Get Closer to the Table." New York Times, June 25, 2010
(2) "Poised on History's Doorstep: Super Salmon or Frankenfish?" Los Angeles Times, August 9, 2010

----- Forwarded by Mike Millard/R5/FWS/DOI on 09/02/2010 02:53 PM -----

Meredith Bartron/R5/FWS/DOI
09/02/2010 09:45 AM

To Mike Millard/R5/FWS/DOI@FWS
cc
Subject Fw: URGENT INVITATION: pending US approval of transgenic salmon - scientists' conference call

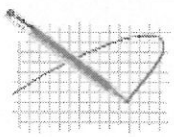
Who should I talk to in the RO that would be able to let me know if it is allowable for me to participate in this? The concern is that my participation would serve as an endorsement of the Service, which I don't would be appropriate. To some degree this is addressed in the aquaculture General Permit (transgenics not allowed).

-Meredith

~~~~~~~~~~~~~~~~~~~~~~

Meredith Bartron
U.S. Fish and Wildlife Service
Northeast Fishery Center
P.O. Box 75, 227 Washington Ave.
Lamar, PA 16848
p: 570.726.4995 x5
f: 570.726.3255

----- Forwarded by Meredith Bartron/R5/FWS/DOI on 09/02/2010 09:43 AM -----



William Ardren/R5/FWS/DOI
09/01/2010 10:00 PM

To Meredith Bartron/R5/FWS/DOI@FWS
cc Dave Tilton/R5/FWS/DOI@FWS, Mike Millard/R5/FWS/DOI@FWS, Bill Archambault/R5/FWS/DOI@FWS
Subject Fw: URGENT INVITATION: pending US approval of transgenic salmon - scientists' conference call

Hi Meredith: I believe you should be involved in this discussion concerning pending FDA approval of transgenic Atlantic salmon. I will send an e-mail to Anne Kapuscinski asking her to put you on the list of scientists discussing this issue in the next couple of days. Please fill out the Doodle poll and participate if you can.

Dave, Mike, Bill: Do you see any issues with Meredith and I participating in a joint statement by scientists to FDA concerning the pending approval of transgenic Atlantic salmon? Please see Anne's e-mail below for more details.

All the best,

Bill
~~~~~~~~~~~~~~~~~~~~~~

EXHIBIT THREE

(U.S. FWS emails)

Jeff Adams/R7/FWS/DOI

10/04/2010 12:19 PM

To Richard Hannan/R1/FWS/DOI@FWS, Mike Oetker/RO/R2/FWS/DOI@FWS, Mike Weimer/R3/FWS/DOI@FWS, Linda Kelsey/R4/FWS/DOI@FWS, Steve Klosiewski/R7/FWS/DOI@FWS, Robert Clarke/SAC/R1/FWS/DOI@FWS

cc Jaime Geiger/R5/FWS/DOI@FWS, Bill Archambault/R5/FWS/DOI@FWS, David Perkins/R5/FWS/DOI@FWS, Mike Millard/R5/FWS/DOI@FWS, William Ardren/R5/FWS/DOI@FWS

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Jeff Adams
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To Steve Mierzykowski/R5/FWS/DOI@FWS, Wende Mahaney/R5/FWS/DOI@FWS
cc
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fyi

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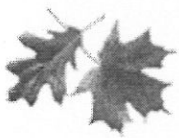

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Phone: (202)208-4646
Fax: (202)208-5618
Email: Gary_Frazer@fws.gov
Paul Phifer/R5/FWS/DOI

Paul Phifer/R5/FWS/DOI
10/06/2010 08:43 AM

To Gary D Frazer/ARL/R9/FWS/DOI@FWS, Martin Miller/R5/FWS/DOI@FWS
cc Don_Morgan@fws.gov, John Fay@FWS, Rick Sayers/ARL/R9/FWS/DOI@FWS, Wendi Weber/R5/FWS/DOI@FWS
Subject Re: Fw: Kapuscinski comments to FDA on genetically modified salmon application

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BTW - Anne K. was one of my principal advisors in grad school. Paul

---

Paul Phifer, PhD
Assistant Regional Director - Ecological Services
R5 - Northeast Region

Martin Miller/R5/FWS/DOI
10/04/2010 03:53 PM

To Wendi Weber/R5/FWS/DOI@FWS
cc "Paul Phifer" <paul_phifer@fws.gov>, Steve Mierzykowski/R5/FWS/DOI@FWS, Wende Mahaney/R5/FWS/DOI@FWS, Glenn S
bcc
Subject Re: Fw: Genetically Modified Atlantic Salmon

We were unaware of the WO's involvement in this, specifically regarding a letter from FDA in September. Here's what we do know/have done:

- We received information about FDA receiving approval of labeling of products made from genetically modified Atlantic salmon. We didn't think an approval of labeling would reach to any effects because there was no specific proposal to produce genetically modified Atlantic salmon, so we did not contact FDA. We had no information about the proposal to grow eggs in Canada and ship them to Panama.

- We received a FOIA on this and have responded to it.

- The BO and subsequent COE permit on aquaculture operations in the Gulf of Maine prohibit use of genetically modified salmon in marine or inland facilities. We have not received any information that any company intends to propose activities that would contradict the BO and COE permit.

Wende M - did I miss anything?

Martin Miller, Chief, Div. of Endangered Species, U.S. Fish and Wildlife Service, 300 Westgate Center Dr., Hadley, MA 01035, 413-253-8615, 413-253-8482 (fax)
Wendi Weber/R5/FWS/DOI

Wendi Weber/R5/FWS/DOI
10/04/2010 03:30 PM

To "Paul Phifer" <paul_phifer@fws.gov>, Martin Miller/R5/FWS/DOI
cc
Subject Fw: Genetically Modified Atlantic Salmon

Wendi Weber
Deputy Regional Director
Department of Interior
U.S. Fish and Wildlife Service
300 Westgate Center Drive
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413/253-8301
413/253-8308fax
413/531-5163cell
wendi_weber@fws.gov

----- Forwarded by Wendi Weber/R5/FWS/DOI on 10/04/2010 03:30 PM -----

Gary D Frazer/ARL/R9/FWS/DOI

To dan_ashe@fws.gov

Dan Ashe/ARL/R9/FWS/DOI

10/04/2010 11:28 AM

To gary_frazer@fws.gov, Marvin Moriarty/R5/FWS/DOI

cc Gloria Bell/ARL/R9/FWS/DOI@FWS, Wendi Weber/R5/FWS/DOI@FWS

Subject Genetically Modified Atlantic Salmon

So, did FDA consult? Should they?

----- Forwarded by Dan Ashe/ARL/R9/FWS/DOI on 10/04/2010 11:26 AM -----

"Elton, Kim" <Kim_Elton@ios.doi.gov>

10/04/2010 10:18 AM

To "Gould, Rowan" <rowan_gould@fws.gov>, "Ashe, Dan" <Dan_Ashe@fws.gov>

cc "Pourchot, Pat" <Pat_Pourchot@ios.doi.gov>

Subject frankenfish

Rowan and Dan—

This email is prompted in part by my sordid past—director of the Alaska Seafood Marketing Institute—and in part by an inquiry from the Alaska governor's office. The FDA is now is actively considering a permit to produce and market genetically modified Atlantic salmon that are super-sized like a McDonald's meal and we have a bit of history with this issue.

Back in October of 2001 the FWS and NOAA sent a letter (attached) to the FDA regarding an early application of Aqua Bounty Farms for a permit to produce and market genetically modified Atlantic salmon. The letter noted:

- The listing of Gulf of Maine Atlantic salmon as an endangered species under the ESA;
- The potential for interactions between farmed and wild salmon;
- That the FDA has a responsibility under the ESA to consult with the agencies to ensure that any action will not jeopardize an endangered species; and
- That the North Atlantic Salmon Conservation Organization is responsible for the implementation for the Conservation of Salmon in the North Atlantic Ocean, an international treaty to which the U.S. is a contracting party, to keep NASCO informed of any proposal to use genetically modified fish within the U.S.

My additional concerns are impacts to the Alaska wild salmon fishery and the fish harvesters and processors who depend upon the integrity of the wild fishery. Hundreds and hundreds of thousands of farmed Atlantics have escaped from marine pens in Washington and British Columbia since the explosion of the farmed industry in the Pacific NW.

This issue is one the State of Alaska has weighed in on very recently. They note that a provision of law inserted by Sens. Stevens and Murkowski into the Food and Drug Administration Amendments Act in 2007 requires the FDA Commissioner to produce a report on any environmental risks associated with genetically engineered seafood products, including the impacts on wild fish stocks, and to consult with NMFS. The state does not think a report has been made or that a consultation with NMFS has occurred.

Also, has the FDA consulted with us and have we informed NASCO? If not, should we, or should we not, get involved?

Kim Elton
Senior Advisor for Alaska Affairs
202-208-4177

[attachment "NMFS-FWS Letter to FDA.pdf" deleted by John Fay/ARL/R9/FWS/DOI]

	General Topic	Specific Topic	Issue(s)	Contact Person(s)	Most Recent Contact (Date)	Status	Action(s) Needed
11	Cormorant Control	Possible study in spring	If study is to take place, needs to be planned ASAP	FWS: Marty Miller, Diane Pence NMFS: Mary Colligan. Will need to involve field stations.	2/23/2004	Marty has looked into ESA issues. Willa discussed with Diane Pence.	Per conference call Feb. 23, NMFS will develop study design for non-lethal control at specific points on Narraguagus. Need to let field know and include in review loop.
12	NMFS hatchery policy		FWS has major concerns re draft	FWS: Willa Nehlsen, Dave Perkins, Marty Miller	3/4/2004	Meeting set up with Dave Allen, Dale Hall, Marv et al.; March 4--postponed	Check with Marv after meeting for any follow-up
13A	Transgenic fish	Potential use in aquaculture	Maine DEP in discharge permits and Corps proposed modifications to existing permits prohibit use of transgenic salmon.	FWS: Wende Mahaney, Dave Perkins, Meredith Bartron	2/23/2004	Services met with FDA in May 2002 to discuss pending application of Aqua Bounty to grow transgenic salmon; no action since then. Permitting would require Sxn 7 consultation with FDA.	Stay tuned.
13B		State concern	NMFS response that transgenic fish have significance according to BO	NMFS: Mary Colligan FWS: Mike Bartlett	2/9/2004	No activity	Need to let state know ASAP if this position changes

Wende Mahaney/R5/FWS/DOI
11/07/2008 08:30 AM

To "David.Bean" <David.Bean@Noaa.gov>
cc Meredith_Bartron@fws.gov, Mike_Millard@fws.gov
bcc
Subject Re: FDA and GEOs

Shortly after the Atlantic salmon was listed as endangered, several of us from USFWS and NMFS spent 2 days down in Maryland meeting with Aqua Bounty and FDA about development of genetically modified salmon and discussion around the need for FDA to engage in Section 7 consultation with the Services. We never heard a peep out of FDA or Aqua Bounty after that.

As Dave notes, there is currently a prohibition on the use of transgenic fish in ocean net pens in Maine (via existing Corps of Engineers permits). I haven't heard anything lately from the aquaculture industry about interest in such critters. But if Aqua Bounty is close to developing something they think is commercially viable and FDA might approve it, then we may have to deal with this issue again.

Oh joy. Wende

>>
Wende S. Mahaney, Fish and Wildlife Biologist
U.S. Fish and Wildlife Service
1168 Main Street
Old Town, ME 04468
Phone: (207) 827-5938, Ext. 20
Fax: (207) 827-6099
Cellular: (207) 944-2991
"David.Bean" <David.Bean@Noaa.gov>

"David.Bean" <David.Bean@Noaa.gov>
10/16/2008 01:27 PM

To Meredith_Bartron@fws.gov
cc Wende_Mahaney@fws.gov, Mike_Millard@fws.gov
Subject Re: FDA and GEOs

Thanks Meredith. It's funny I just spoke with Bill Wolters the other day about GEO's...I wonder if the industry is starting to look into how long it will be before GEO fish are permitted? I guess we'll have to wait and see what comes out of the FDA.
Right now there is a prohibition on stocking transgenic fish.
Dave
Meredith_Bartron@fws.gov wrote:
> Hi,
>
> I ran across this article awhile ago but finally tracked down the
> supporting documents from the FDA for genetically engineered organisms and
> foods. Something to keep in mind since there is a GEO Atlantic salmon that
> has been developed by AquaBounty (referenced in the AP/MSNBC article.)
>
> -Meredith
> (See attached file: guide187_FDA Guidance.pdf)(See attached file: FDA
> ge_animals091808.pdf)(See attached file: FDA GEO press 9182008.pdf)

--

Wende Mahaney/R5/FWS/DOI
10/06/2010 10:58 AM

To "Stratton, Robert D" <Robert.D.Stratton@maine.gov>
cc "David.Bean" <David.Bean@Noaa.gov>, fred_seavey@fws.gov, "Jeff Murphy" <Jeff.Murphy@noaa.gov>, "Trial, Joan"
bcc
Subject Re: transgenic salmon Q

I think you hit the nail on the head. We've been wondering if and when this issue would come up. I've had absolutely no recent involvement with the recent, ongoing FDA business. But I have been told that the FDA is only considering a project currently that would produce eggs in Canada and transport them to Panama for grow-out. Growing these critters in Maine is a whole other "critter". Please keep us posted and encourage an open dialogue between Joe and the Services.

Wende

>>
Wende S. Mahaney, Fish and Wildlife Biologist, CWB
U.S. Fish and Wildlife Service
17 Godfrey Drive, Suite #2
Orono, ME 04473
Phone: (207) 866-3344, Ext. 118
Fax: (207) 866-3351
Cellular: (207) 944-2991
"Stratton, Robert D" <Robert.D.Stratton@maine.gov>

"Stratton, Robert D" <Robert.D.Stratton@maine.gov>
10/06/2010 10:28 AM

To "Trial, Joan" <Joan.Trial@maine.gov>, "Jeff Murphy" <Jeff.Murphy@noaa.gov>, "David.Bean" <David.Bean@Noaa.gov>, <Wende_Mahaney@fws.gov>, <fred_seavey@fws.gov>
cc
Subject transgenic salmon Q

Good morning.

Yesterday I spoke with Joe McGonagle, who will likely be contacting you or someone in your office to discuss raising transgenic salmon in a "land-based" hatchery, rearing, and processing facility in Maine. The facility is proposed to be 80-90% recirculation, with a final wastewater discharge to marine waters. He is looking at the former Great Eastern Mussel property in St. George. Reportedly the eggs, which originate from Aquabounty in PEI, are regulated by USFDA as a new animal drug and facilities that purchase and rear them are regulated like pharmaceutical companies with regular monitoring requirements. Reportedly, these salmon can be reared from egg to marketable size in 16 months, without going to net pens. They would be kept on site during their entire lives and only leave the site after having been butchered for the table market. There will be no broodstock on site and the fish will all be sterile females.

MEPDES Permits for hatcheries and rearing facilities in Maine prohibit transgenic salmon, mirroring requirements in marine aquaculture permits developed in consultation with your agencies several years ago. The current language from the recently renewed UMCCAR facility (Franklin) permit is shown below, with the transgenic paragraph indicated in red. I told Joe that the only way I could envision that we would not continue to prohibit transgenics is if he were to convince your agencies that he had designed an

Wende Mahaney
04/24/2002 03:41 PM

To: Ralph Pisapia/R5/FWS/DOI@FWS, Michael Bartlett/R5/FWS/DOI@FWS, joris_naiman@ios.doi.gov, Gordon Russell/R5/FWS/DOI@FWS
cc:
Subject: Transgenic Atlantic Salmon and Confidential Business Information

At the very bottom of this string of messages are a letter from FDA and the "confidentiality agreement" that FDA says we must sign before we can attend the May 16-17 meeting in Maryland. The agreement is very short and simple, so it scares me!!!! Would anything in this document cause us problems in doing a Section 7 consultation with FDA on the Aqua Bounty application? I'm not sure.....

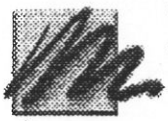
I think I'd feel a little bit better if FDA had mentioned in their invitation letter that they acknowledge their responsibility to consult with the USFWS under the ESA, rather than that they are just requesting our "assistance" in their environmental review. That said, my discussions with John Matheson at FDA left me confident that they understand their obligation to consult with us under the ESA.

Thanks, Wende
----- Forwarded by Wende Mahaney/R5/FWS/DOI on 04/24/2002 03:34 PM -----

Lisa Rossignol
04/24/2002 03:10 PM

To: Gordon Russell/R5/FWS/DOI@FWS, Wende Mahaney/R5/FWS/DOI@FWS
cc:
Subject: Transgenic Atlantic Salmon and Confidential Business Information

----- Forwarded by Lisa Rossignol/R5/FWS/DOI on 04/24/2002 03:09 PM -----

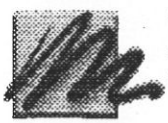


Chris Nolan
04/24/2002 02:36 PM

To: Lisa Rossignol/R5/FWS/DOI@FWS
cc:
Subject: Transgenic Atlantic Salmon and Confidential Business Information

Here is the message...

----- Forwarded by Chris Nolan/R5/FWS/DOI on 04/24/2002 02:36 PM -----



Chris Nolan
04/23/2002 05:25 PM

To: Chris Nolin/ARL/R9/FWS/DOI@FWS
cc:
Subject: Transgenic Atlantic Salmon and Confidential Business Information

----- Forwarded by Chris Nolan/R5/FWS/DOI on 04/23/2002 05:25 PM -----

"Flash, Ki-Cha-May*" <KFlash@CVM.FDA.GOV>
04/23/2002 10:45

To: "'chris_nolan@fws.gov'" <chris_nolan@fws.gov>
cc: "'patrick_leonard@fws.gov'" <patrick_leonard@fws.gov>
Subject: Transgenic Atlantic Salmon and Confidential Business Information

EXHIBIT FOUR

(U.S. FWS emails)

4 February 2008

Aqua Bounty Technologies
("Aqua Bounty" or "the Company")

Aqua Bounty In Trials With Leading Drug Manufacturer

Aqua Bounty Signs Term Sheet For Trialing ProVale™ In Chile

Aqua Bounty Technologies, Inc. (AIM: ABTX), a biotechnology company focused on enhancing productivity in the aquaculture market, announces that it has signed a Term sheet with Stirling Products North America Inc ("Stirling Products NA") for an exclusive option to distribute ProVale™ in the Chilean salmon market. ProVale™ is an environmentally friendly and highly bioactive form of the currently marketed beta glucan product for immune stimulation and disease management in fish. Stirling Products NA is the North American subsidiary to Stirling Products Limited (ASX: STI).

Under the terms of the agreement, Aqua Bounty will manage field trials required for proof of efficacy and market approval of the product. The Company will test ProVale™ as a replacement for antibiotics in the diets of farmed salmon. Subject to regulatory approval, the trials are expected to begin shortly and last for a period of two to three months. During this time, Aqua Bounty will work with Stirling Products NA to finalise an agreement for commercial distribution which management estimates will be decided towards the end of the third quarter.

The strategic partnership will allow Aqua Bounty to target the Chilean salmon market which is the second largest in the world behind Norway. Farmed salmon is valued at over US$4.5 billion of which one third comes from Chile, and this amount is estimated to double in the next six years in direct response to increased world-wide demand. Sales of existing pharmaceuticals and immunostimulants in Chile for the salmon industry totalled close to US$20 million in 2007, and management conservatively estimates the initial market for ProVale™ in Chile to be over US$3 million per year.

ProVale™ is the latest natural bioactive ingredient for immune health and productivity solutions for the agriculture, aquaculture and pet feed industries, produced by patented technology at Stirling's Canadian facility, Progressive Bio Actives Inc (PBI).

The option granted to Aqua Bounty will be exercisable at Aqua Bounty's discretion.

Elliot Entis, Chief Executive Officer of Aqua Bounty commented: "We are delighted to have signed this agreement with Stirling Products NA, who is an excellent strategic partner for us. Provale™ is a natural extension of our approach to limiting disease impacts in aquaculture without compromising environmental or human health and lessening reliance on antibiotics. It fits in well with our focus on building strong relationships with salmon farmers. We look forward to a successful partnership with the company as part of our continued commitment to capitalise on our core market."

Dr Calvin London, Chief Executive Officer and Managing Director of Stirling Products North America commented: "I am sure that Aqua Bounty will prove to be an outstanding partner for this project. The opportunity with Aqua Bounty provides us with an obvious upside in terms of additional revenue potential from sales of ProVale™, but it also provides opportunities for future developments of specialised feeds and disease protection formulations for farmed fish."

-ends-

For further information please contact:

Aqua Bounty
Elliot Entis
Joseph McGonigle
+1 781 899 7755

Bell Pottinger Corporate & Financial
Daniel de Belder
Amy Rajendran
+44 (0) 20 7861 3232

Notes to Editors

About Aqua Bounty

- The Company is headquartered in Waltham, Massachusetts, USA. It has research facilities in San Diego, California and Prince Edward Island, Canada.

- Aqua Bounty has launched health and diagnostic products for the prevention and control of shrimp diseases and is developing new products to increase productivity and profitability in commercial fish farming. The Company's integrated approach to aquatic health management means that Aqua Bounty is well positioned to capitalise on the rapidly growing US$60 billion per annum aquaculture industry.

- The Company's leading product, Shrimp IMS, a stimulant for the shrimp immune system, has shown significant benefit to commercial shrimp farmers through the Company's initial marketing in Mexico and Ecuador. Results have indicated that the use of Shrimp IMS treatments has led to an increase in sales for its Mexican distributor, as well as a return of investment of up to US$2.5 for every dollar spent on the product by the farmers.

- Aqua Bounty intends to increase its sales of Shrimp IMS in Mexico while expanding into Central and South America and then into Asia in 2008. The Company also plans to launch AquAdvantage Viral Blocker in 2009, an effective preventative control against the lethal and widespread White Spot Syndrome Virus ('WSSV'). WSSV can appear suddenly, can kill entire shrimp stocks within 72 hours and has been responsible for significant pre-harvest losses to shrimp stocks in the 1990s, including over US$1 billion of shrimp stock damage in the Americas alone.

- Aqua Bounty is also developing fast growing strains of breeds of fin fish which grow faster than traditional broodstock, known as AquAdvantage™ fish. This AquAdvantage™ fish are capable of reducing growth to maturity time by as much as 50 per cent, resulting in substantial productivity gains for commercial fish farmers. The Company expects commercial launch in 2009.

- Commercial aquaculture, the controlled cultivation and harvest of aquatic plants and animals, is the most rapidly growing segment of the agricultural industry, accounting for more than US$60 billion in sales in 2003. While land-based agriculture is increasing at 2 per cent to 3 per cent per year, aquaculture has been growing at an annual rate of approximately 9 per cent since 1970. (Source: FAO)

- Aqua Bounty's strategy is to focus commercialisation initially within the western hemisphere and launch in Asia after penetrating several markets in the Americas. The Company intends to maximize returns on research and development and resulting intellectual property by supplying its products to the aquaculture industry through existing

Martin Miller/R5/FWS/DOI
10/06/2010 12:11 PM

To Wende Mahaney/R5/FWS/DOI@FWS
cc Mark McCollough/R5/FWS/DOI@FWS, Steve Mierzykowski/R5/FWS/DOI@FWS, John Fay/ARL/R9/FWS/DOI@FWS
bcc
Subject Re: Fw: Genetically Modified Atlantic Salmon

Thanks, Wende.

John - note below the information about a proposal to grow genetically modified salmon in the Gulf of Maine. I asked Wende to call you to coordinate on this.

Marty

Martin Miller, Chief, Div. of Endangered Species, U.S. Fish and Wildlife Service, 300 Westgate Center Dr., Hadley, MA 01035, 413-253-8615, 413-253-8482 (fax)
Wende Mahaney/R5/FWS/DOI

Wende Mahaney/R5/FWS/DOI
10/06/2010 11:08 AM

To Martin Miller/R5/FWS/DOI@FWS
cc Steve Mierzykowski/R5/FWS/DOI@FWS, Mark McCollough/R5/FWS/DOI@FWS
Subject Re: Fw: Genetically Modified Atlantic Salmon

Marty: I'm swamped with a couple of important things at the moment and can't carefully read and respond to the e-mail string below quite yet. **BUT PLEASE BE AWARE** that there has been the first contact in Maine on behalf of someone who wants to grow the AquaBounty genetically modified salmon in a land-based facility on the coast of Maine within the range of the Gulf of Maine DPS for Atlantic salmon. See e-mail excerpt below from a colleague at the Maine Department of Environmental Protection (who would regulate the discharge from the facility), which was sent to me and a couple of staff at NMFS here in Orono. This scenario is obviously very different from what John Fay has supposedly reviewed from FDA which **only** contemplates eggs from Canada being shipped to Panama for grow-out.

Yesterday I spoke with Joe McGonagle, who will likely be contacting you or someone in your office to discuss raising transgenic salmon in a "land-based" hatchery, rearing, and processing facility in Maine. The facility is proposed to be 80-90% recirculation, with a final wastewater discharge to marine waters. He is looking at the former Great Eastern Mussel property in St. George. Reportedly the eggs, which originate from Aquabounty in PEI, are regulated by USFDA as a new animal drug and facilities that purchase and rear them are regulated like pharmaceutical companies with regular monitoring requirements. Reportedly, these salmon can be reared from egg to marketable size in 16 months, without going to net pens. They would be kept on site during their entire lives and only leave the site after having been butchered for the table market. There will be no broodstock on site and the fish will all be sterile females.

MEPDES Permits for hatcheries and rearing facilities in Maine prohibit transgenic salmon, mirroring requirements in marine aquaculture permits developed in consultation with your agencies several years ago. The current language from the recently renewed UMCCAR facility (Franklin) permit is shown below, with the transgenic paragraph indicated in red. I told Joe that the only way I could envision that we would not continue to prohibit transgenics is if he were to convince your agencies that he had

designed an absolutely escape proof facility with zero chance of effects on native fish or habitats. If that were to happen and your agencies sign off on it, then we would look more favorably on it.

This is just a heads-up, please let me know if you know more. Thanks, Bob.

I guess that's all for now. Just wanted you to be aware of this brand-new development. Wende

>>
Wende S. Mahaney, Fish and Wildlife Biologist, CWB
U.S. Fish and Wildlife Service
17 Godfrey Drive, Suite #2
Orono, ME 04473
Phone: (207) 866-3344, Ext. 118
Fax: (207) 866-3351
Cellular: (207) 944-2991
Martin Miller/R5/FWS/DOI

Martin Miller/R5/FWS/DOI
10/04/2010 04:57 PM

To Wende Mahaney/R5/FWS/DOI@FWS, Steve Mierzykowski/R5/FWS/DOI@FWS
cc
Subject Fw: Genetically Modified Atlantic Salmon

here's the letter that was attached

[attachment "NMFS-FWS Letter to FDA.pdf" deleted by Wende Mahaney/R5/FWS/DOI]

Martin Miller, Chief, Div. of Endangered Species, U.S. Fish and Wildlife Service, 300 Westgate Center Dr., Hadley, MA 01035, 413-253-8615, 413-253-8482 (fax)
----- Forwarded by Martin Miller/R5/FWS/DOI on 10/04/2010 04:56 PM -----

Martin Miller/R5/FWS/DOI
10/04/2010 03:53 PM

To Wendi Weber/R5/FWS/DOI
cc "Paul Phifer" <paul_phifer@fws.gov>, Steve Mierzykowski/R5/FWS/DOI@FWS, Wende Mahaney/R5/FWS/DOI@FWS, Glenn S Smith/R5/FWS/DOI@FWS
Subject Re: Fw: Genetically Modified Atlantic Salmon

We were unaware of the WO's involvement in this, specifically regarding a letter from FDA in September. Here's what we do know/have done:

- We received information about FDA receiving approval of labeling of products made from genetically modified Atlantic salmon. We didn't think an approval of labeling would reach to any effects because there was no specific proposal to produce genetically modified Atlantic salmon, so we did not contact FDA. We had no information about the proposal to grow eggs in Canada and ship them to Panama.

- We received a FOIA on this and have responded to it.

Kimballfws@aol.com
05/04/2000 03:20 PM

To Wende_Mahaney@fws.gov
cc
bcc
Subject Re: COE Recommendations-MAJOR CHANGE

No, the COE hasn't heard about this yet. I would hope that we would have an internal conference call as Chris M has suggested previously and that would give us a chance to discuss this.

My limited understanding of the "frankenfish" issue with the industry would suggest this is the best time to set fire to the windmill. There are no established operators that I know of that are planning to use these critters. The only interest seems to come from the new outfit in NJ that apparently has a vested interest in the fish being reared at the R&D facility (actually a veterinary college I believe) in PEI, Canada. The only discussions about these that I have had with industry is with Tom Royal and Joe McGonigle at last year's NASCO meeting in Ireland. They were quite concerned about (scared of) the use of these fish . . . I assume because of the competitive disadvantage to them if a rival had access to them. So, unless things have changed (new deals made?), we may even have support from much of the industry on this issue. If you know someone that has current rapport with McGonigle, they may want to ask, in a general way, what the feeling is about transgenics.

DCK

Dan C. Kimball
Atlantic Salmon Recovery Specialist
US Fish and Wildlife Service
151 Broad Street
Nashua, NH 03060
USA
603-595-0926 (Voice or FAX)
kimballfws@aol.com

EXHIBIT FIVE

(U.S. FWS Moyer letter to U.S. FDA,
September 30, 2010)

United States Department of the Interior

FISH AND WILDLIFE SERVICE
Warm Springs Fish Technology Center
Conservation Genetics Laboratory
5308 Spring Street
Warm Springs, Georgia 31830
Phone: (706) 655-3382 FAX: (706) 655-3389

30 September 2010

This letter briefly outlines several criticisms and concerns regarding the Veterinary Medicine Advisory Committee (VMAC) Briefing Packet for AquAdvantage Salmon. While I feel I can provide a general overview and constructive criticism of this briefing document, more time would allow for a detailed review.

The Briefing Packet provided by VMAC is a detailed synopsis regarding the safety and effectiveness of genetically engineered (GE) Atlantic salmon produced by Aqua Bounty Technologies. The packet provides relevant data to assess the following five critical issues or risks associated with genetically engineered organisms:

1) molecular consequences of the insertion of a gene construct into a lineage of Atlantic salmon;
2) phenotypic effects of the insertion of a gene construct in a lineage of triploid mono-sex Atlantic salmon;
3) genotypic and phenotypic durability of such gene construct;
4) analysis of food feed and safety;
5) environmental consequences

Much of my major concerns are with the environmental risk analysis provided by VMAC and are addressed below. I do not feel comfortable commenting on the analyses of food feed and safety because they are not my areas of expertise. I would also recommend that the American Fisheries Society and National Academy of Sciences review this and other supporting documents as unbiased third party reviewers.

Major criticisms:

The Briefing Packet provides compelling evidence that the risk of escapement by GE AquAdvantage salmon is minimal; however, it falls short of providing an actual risk assessment of putative environmental damages in the event of escapement. The environmental analysis should provide an overview of the general risks associated with escapement or hybridization of GE and wild type individuals. An overview would provide readers with an understanding of the potential harm (and the degree of harm) posed by GE organisms even when the risks of escapement is low. Both of these risks (risk of escapement and degree of harm if escaped) should be more accurately quantified prior to any Environmental Assessment ruling.

I am also concerned with phrases like "are unlikely to survive if exposed to high salinity and low temperature" when no data have been collected on AquAdvantage salmon to evaluate the likelihood of these scenarios. Survival under geographical and geophysical conditions should be evaluated at all life stages in an effort to quantify the likelihood of such escapement scenarios.

Finally, while Aqua Bounty Technologies currently have in place various standard operating procedures to minimize escapement and test for durability of the gene construct, I fail to see any policy in place for monitoring and enforcement of these SOPs by the Food and Drug Administration. The environmental impact of escaped GE salmon is of great concern; therefore, the FDA should carefully monitor each facility and establish/enforce a zero tolerance policy for failure to meet specified containment guidelines.

Minor criticism:

1) Who were the reviewers (including their backgrounds) for this document? I have concerns over whether salmon ecologists and biologist have critiqued the environmental analysis of this document.
2) Scientific names of ocean pout, Chinook, and Atlantic salmon should be reported.
3) page 13 section B.5. A reference should be provided.
4) page 13 section C indicates that supporting data was provided – please reference these data in an appendix.
5) page 14 section A. Again, "data submitted support the Molecular Characterization of . . . ." please reference these data.
6) page 16. section i. "Repeat regions like this are quite variable and nonessential". This needs a citation. While they do not code for anything, repeat regions are probably not non-essential; rather, they serve some purpose.
7) page 43 "AquAdvantage salmon may have reduced tolerance for low DO" – there is much uncertainty in this statement as there is no data to support or reject this. Either a citation is warranted or consider eliminating this statement.
8) page 110 section A the working definition of AquAdvantage salmon. So what are the ones called that are <100 g body weight but are genetically engineered?
9) page111. "The VMAC meeting will be held to solicit comments from the appropriated outside experts (VMAC members)". Do VMAC members really have the expertise to rule on the environmental assessment? I would argue that outside experts such as salmon biologists be considered as a part of this panel.
10) page 123 section a. Again, the conclusion is based on limited data. More studies are necessary to determine containment risks (see major criticisms).
11) page 126. I would argue that a more stringent 98-99% probability of being triploid be invoked. The risk of escapement is too great to be relying on a 95% probability.

Please feel free to contact me regarding further questions or concerns.

Sincerely,

Gregory R. Moyer, PhD

Regional Geneticist

Email: Greg_Moyer@fws.gov

EXHIBIT SIX

(U.S. FWS Conservation Genetics Community of Practice (CoP) letter to U.S. FDA, October 6, 2010)

United States Department of the Interior

FISH AND WILDLIFE SERVICE

06 October 2010,

This letter briefly outlines several concerns that the Conservation Genetics Community of Practice (COP) has raised regarding the Veterinary Medicine Advisory Committee (VMAC) Briefing Packet for AquAdvantage Salmon.

The AquAdvantage Atlantic salmon (*Salmo salar*) is a genetically engineered (GE) salmon that grows at a rapid rate due to the alteration of their growth hormone gene. Specifically, a gene construct is synthesized using a growth hormone gene (GH; derived from the Chinook salmon, *Oncorhynchus tshawytscha*, pituitary gland) that is linked to an anti-freeze protein regulator sequence (opAFP) found in Ocean pout (*Zoarces americanus*). The anti-freeze regulator acts like a switch keeping the GH protein from turning off and allowing for continued growth of the fish. This gene construct (opAFP-GH) is then injected into Atlantic salmon eggs to form an all female broodstock that will produce future product.

The Briefing Packet provided by VMAC is a detailed synopsis regarding the safety and effectiveness of genetically engineered (GE) Atlantic salmon produced by Aqua Bounty Technologies. The packet provides relevant data to assess the following five critical issues or risks associated with genetically engineered organisms:

1) molecular consequences of the insertion of a gene construct into a lineage of Atlantic salmon,
2) phenotypic effects of the insertion of a gene construct in a lineage of triploid mono-sex Atlantic salmon,
3) genotypic and phenotypic durability of such gene construct,
4) analysis of food feed and safety, and
5) environmental consequences.

COP comments are based on concerns that deal with the environmental risk analysis provided by VMAC and the regulatory oversight of such a program. While this document has been reviewed by the COP, we strongly recommend that other genetic communities such as the American Fisheries Society and National Academy of Sciences review this and other supporting documents as unbiased third party reviewers.

Environmental/Ecological Impacts

The Briefing Packet provides compelling evidence that the risk of escapement by GE AquAdvantage salmon is minimal; however, *it falls short of providing an actual risk assessment of putative environmental damages in the event of escapement.*

First, the environmental analysis should provide an historical overview of the general risks associated with escapement or hybridization of GE and wild type individuals. Has escapement of a GE organism ever occurred? What were the environmental consequences of such an escapement? An overview would provide readers with an understanding of the potential harm (and the degree of harm) posed by GE organisms even when the risks of escapement is low. Both of these risks (risk of escapement and degree of harm if escaped) should be more accurately quantified prior to any Environmental Assessment ruling.

Second, the biological containment at either the PEI or Panama facilities along with the possible interaction of AquAdvantage salmon with endangered wild salmon stocks is of great concern to the COP. To this regard, Aqua Bounty Technologies has established several physical and biological containment mechanisms to prevent the escape of AquAdvantage salmon and the Environmental Assessment indicated escapement risk and establishment risks were low. However, history dictates that fish held in aquaculture facilities, either land- or water-based, escape. In addition, the information provided by Aqua Bounty Technologies for the likelihood of establishment relies on the assumption that farmed Atlantic salmon have not established themselves in North America. This assumption is clearly violated because Atlantic salmon juveniles have been found in several streams in the state of Washington as well as British Columbia. While interactions of these fish with native salmon are unknown, any interaction between wild and transgenic salmon must be considered a serious threat. Numerous scientific publications have documented that interactions of wild and introduced fish have led to decreased numbers of wild fish (for ESA listed Atlantic stocks this is of great concern).

As highlighted in the previous paragraph, the Environmental Assessment does not give the full information needed to predict the environmental effects of AquAdvantage salmon. The interpretation of findings could be very misleading because conclusions are based on data for only a few traits that do not span the life-cycle of the organism and are measured under a limited range of environmental conditions and time frames. The COP recommends incorporating the following scientific data in future environmental risk assessments:

- differences in overall fitness between transgenic and non-transgenic fish (e.g., Sundstrom et al 2007);
- shifts in primary prey and utilization of habitat for AquAdvantage salmon (Sundstrom et al 2003).
- assessing how fitness of transgenic fish, when they first escape, translates into environmental risk (Kapuscinski 2007 and Ahrens and Devlin in press)

It is the view of the COP that the Environmental Analysis is overly simplistic and does not adequately capture the actual risk of environmental damages to wild Atlantic salmon or the ecosystem. Additional studies will be necessary to assess this risk and include (but not limited to)

- interbreeding with wild salmon, gene introgression into wild salmon stocks, hybridization with brown trout,
- disturbance of habitat or displacement of wild stocks as a result of competition for resources, predation, or even cross-mating resulting in population impact,

- spread of bacteria, viruses, parasites to wild salmon and other aquatic/estuarine species,
- ecological impacts associated with their degree of fitness, interaction with other organisms, role in ecological processes, and potential for dispersal and persistence.

Regulatory Authority/Oversight comments

Aqua Bounty Technologies currently has various standard operating procedures to minimize escapement and test for durability of the gene construct; however, the COP fails to see any oversight policy in place for assessment, monitoring, and enforcement of these procedures. The current regulatory process is ineffective in handling such a situation. Economics and development take priority over the potential impact to the species or ecosystem. Instead, agencies (FDA, NOAA, USFWS) might benefit from a tiered approach to regulatory authority where such activities are reviewed, evaluated, and if approved, move to the next level for review. The ultimate or final review should lie with the authorities who manage the potentially impacted species (in the case of Atlantic salmon, those public resources are also far beyond just U.S. jurisdiction and include Panama, Canada, the European Union, and Russia). This approach would promote a "first do no harm" strategy designed to protect public resources (i.e., the target species or ecosystem of concern).

Concluding remarks

There are several unknowns and uncertainties regarding possible genetic, ecological, and environmental effects of AquAdvantage salmon that must be elucidated before an environmental risk assessment can be thoroughly evaluated and approved. This, along with a situation where regulatory oversight is adequate at best, suggests that approval of Aqua Bounty Technologies' request for commercial rearing of AquAdvantage salmon is premature.

Sincerely,

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