November 19, 2014

Dr. Margaret A. Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg,

We are writing today to ask the FDA to deny the new animal drug application (NADA) for AquaBounty Technonlogies' AquAdvantage Salmon in light of the disastrous environmental record of AquaBounty. AquaBounty has admitted fault in breaching environmental regulations in Panama and has experienced at least one major security accident involving "lost" salmon. It is also now public record that AquaBounty's production platform in Panama has changed dramatically from the production platform described by AquaBounty and the FDA in the NADA and draft Environmental Assessments (EA), which presents another basis for FDA abandoning AquaBounty's NADA.

As we alerted the FDA two weeks ago, AquaBounty has been fined $9500 for a series of violations of environmental regulations in Panama. The company acknowledged the violations and paid the fine.[1] This letter describes in more detail the nature of those violations and also alerts FDA to the fact that AquaBounty ceded oversight and management of most safety features of the Panamanian facility in 2013 to an independent fish producer, whose death this summer appears to have further compromised the security of the company's operation. This change in management represents a dramatic departure in the terms and conditions outlined in the NADA.

We also include in this letter a brief description of many other security issues at the Panamanian facility that are now a matter of public record. In stark contrast to the assurances that FDA and AquaBounty have provided to the public regarding AquaBounty's highly secure and sophisticated production platform, the public has learned that the Panamanian facility:

- was recently found to have been in breach of a variety of environmental regulations in Panama and subjected to a $9500 fine (close to the maximum allowed).
- has experienced at least one major weather-related accident that led to "lost" AquAdvantage Salmon and tens of thousands of dollars in damages
- has been described by an independent journalist as a "fading" and "rundown shed" in the middle of the Panamanian rainforest
- was at one point managed and operated by an independent grower who apparently also played an advisory role to the Panamanian government on biotechnology issues, presenting a "fox-guarding-the-henhouse" scenario
- is located in a region that routinely experiences extreme weather, including

violent flooding of the region's local aquaculture operations which has prompted the Panamanian government to issue several states of emergency.

The company's security issues, regulatory breaches, accidents and questionable management decisions all strongly indicate that AquaBounty cannot safely contain and produce AquAdvantage Salmon or fulfill the terms and conditions outlined in its NADA. The only responsible course of action for FDA is to deny AquaBounty's NADA.

At a bare minimum, FDA should conduct a new environmental review with a full Environmental Impact Statement (EIS) under the National Environmental Policy Act that reaches far beyond the scope of the narrow EA AquaBounty offered in 2010 or that FDA re-issued, almost verbatim, in 2012. Unlike the narrow EAs, which have failed to apply adequate scrutiny, an EIS would evaluate the full range of environmental risks associated with AquAdvantage Salmon. This call for an EIS has been echoed by members of FDA's own advisory committee, independent scientists, and millions of consumers. Importantly, the public should have an opportunity to review or consider and comment on any new environmental evaluation.

Regulatory Violations in Panama

In November 2013, the Panamanian non-governmental organization Centro de Incidencia Ambiental de Panama (CIAM) filed a legal complaint with environmental regulators in Panama at the Autoridad Nacional del Ambiente (ANAM), which outlined allegations that AquaBounty was not in compliance with environmental law, including failing to secure a variety of legally required permits and inspections. A copy of this legal complaint was submitted to FDA in November 2013 by Food & Water Watch, the Center for Food Safety and Friends of the Earth. AquaBounty publicly denied the allegations as "nonsense," and stated that the company was in "full compliance."[2]

However, a regional office of ANAM, after investigating the alleged environmental breaches, declared in July 2014 that AquaBounty was, in fact, in violation of a series of environmental laws, including those related to environmental safety. A copy of ANAM's ruling was not forwarded to CIAM until late October 2014, at which point it became publicized by groups including Food & Water Watch, the Center for Food Safety and Friends of the Earth. AquaBounty acknowledged the violations and stated that it paid the fine.[3]

ANAM's ruling noted that as far back as March 8, 2012, it was aware that AquaBounty appeared to be out of compliance with a variety of environmental regulations, including missing permits for the introduction and biosecurity of AquAdvantage Salmon, permits for water use, environmental-quality inspections prior to construction, and no evidence of a pathogen control plan, an epidemiological surveillance program or a public health program.[4] It is troubling that FDA issued a draft finding of no significant impact and a second draft EA after ANAM's March 2012 findings, but did not mention the pending questions about AquaBounty's compliance with environmental regulations.[5] This strongly suggests, once again, that FDA was out of touch with the details of

AquaBounty's operations in Panama and highlights how FDA's narrow EA has failed to document and consider crucial details related to the environmental safety of AquaBounty's operations.

The final ANAM ruling, issued in July 2013, found that:[6]

- AquaBounty was out of compliance with requirements to provide reports, documents, modifications and all necessary documents required to execute the approved activity, respecting the deadlines established by ANAM.
- AquaBounty breached environmental law requiring the company to request a water usage permit prior to the start of the project, which was only obtained by the company in 2013, three years after the start of their operations.
- AquaBounty did not secure/arrange its ecological compensation payment until after the start of the project.
- AquaBounty breached article 10 of the Resolution IA-813-2010 in failing to provide evidence for an in site inspection application which was to be submitted to ANAM before the initiation of the construction phase.
- AquaBounty breached article 12 of the Resolution IA-813-2010 in failing to submit an implementation of mitigation measures report every three months during the first year of the project, and this report was provided by the company until 2013.

ANAM ultimately concluded that AquaBounty had breached Panamanian environmental law repeatedly and fined the company $9500, nearly the $10,000 maximum allowed. Though the company had the right to appeal this sanction, imposed July 30, 2014, it apparently chose not to.

AquaBounty's admitted failure to follow environmental laws in Panama indicates the company's inability to produce AquAdvantage Salmon in the highly regulated environment that international regulators have required. As FDA has noted, production of AquAdvantage Salmon requires the implementation and execution of a sophisticated containment plan monitored by a variety of regulators in a variety of jurisdictions, designed to provide a series of checks and balances to ensure, among other things, the prevention of escape or theft of AquAdvantage Salmon. AquaBounty's repeated failure to follow basic environmental regulations, some of which pertain to environmental safety, indicate the company simply does not have the necessary capacity to execute this plan.

Ownership, Operations and Management of Panamanian Facility

The repeated failures of the AquaBounty to comply with legal requirements in Panama reflects on AquaBounty's dangerously evolving management plan at the Panamanian facility. Some or all of the environmental regulations appear to have occurred during the time that AquaBounty had engaged an independent fish producer in Panama to manage most or all aspects of AquAdvantage Salmon production in Panama, including crucial safety elements like the security of the operation and regulatory compliance. The company's grossly irresponsible management decisions, which contradict the terms and conditions laid out in FDA documents, are outlined in regulatory filings that AquaBounty

has submitted to the Securities and Exchange Commission (SEC) in an effort to join the NASDAQ stock exchange.

The SEC filings describe substantial changes to the terms and conditions of the company's production plan that was outlined in its two draft EAs with the FDA and also those details presented to the public by the FDA at the VMAC meeting in September 2010. FDA has long made clear that "any changes to the conditions of use and/or locations of production or grow-out will require further environmental evaluation,.."[7]

AquaBounty made its first regulatory filing to the SEC in April 2014, followed by a succession of "amended" forms to that, among other items, provide details on the company's evolving management structure over its production platform in Panama.[8] AquaBounty states that during its "initial" five-year lease with the landowner in Panama, which commenced October 2008, the company managed the site "remotely," using "local contract workers."[9] When the initial lease expired, AquaBounty entered into a new agreement with Luis Lamastus, the owner of the facility, to take over "all management services and operational expenses" of the facility.[10] AquaBounty included a hefty new "management fee" for Lamastus's taking over responsibility of the facility.[11]

AquaBounty submitted to the SEC a copy of a "lease and management agreement," signed on June 16, 2013, which outlines the responsibilities that Lamastus had over the operation of the Panamanian facility, including all day-to-day operations, regulatory compliance and crucial biosecurity measures.[12]

According to the management agreement, Lamastus's responsibilities included:[13]

2.1 Carry on the daily management of the ABP [AquaBounty Panama] Project;
2.2 Obtain all the permits and authorizations required for the Property and the ABP Project to comply with the regulations of Panama, including, but not limited to import permits and any permit and/or authorization before the National Environmental Authority (ANAM), Ministry of Agricultural Development (MIDA), Aquatic Resources Authority of Panama (ARAP), and the National Biosafety Commission (Comisión Nacional de Bioseguridad- CNB);
2.3 Purchase local and imported feeds;
2.4 Take care of the security within the ABP Project;
2.5 Harvest the product on the dates established to that end by ABP;
2.6 Maintain the necessary stock of food for the salmons, and parts for repairing the facilities within the ABP Project;
2.7 Transfer the AAS from the incubation system to the fry tanks, and from the fry tanks to the growout tanks as indicated and/or established by ABP;
2.8 Maintain the facilities within the ABP Project in good conditions to guarantee the health, safety, and survival of the AAS and the ABP Project;
2.9 Assume the minor legal expenses related to the administration of the ABP Project, and not covered in Article 9.6;

2.10 Pay all the operating expenses of the ABP Project, including but not limited to, all salaries for full time and part time employees, feed, oxygen, gas, supplies, equipment, maintenance, utilities, and costs related to regulatory compliance; and
2.11 Maintain a minimum of 100 AAS alive in the ABP Project.

Of most obvious concern was that AquaBounty entrusted this independent grower with responsibility over the security of the project and maintaining regulatory compliance. It would appear grossly irresponsible for AquaBounty to hand over these sensitive aspects of its experimental, transgenic fish production to this independent grower, who has no established expertise or competence to manage the highly regulated, technically sophisticated production platform that the company and FDA frequently trumpet. That AquaBounty's operation was determined to be out of compliance with environmental laws was a totally predictable outgrowth of AquaBounty's grossly irresponsible management decision.

In an amended SEC form filed in August 2014, AquaBounty revealed that it received notice in July 2014 that Lamastus died, resulting in the termination of the existing lease.[14] It is unclear when Lamastus actually died. The death prompted the company to attempt to negotiate a new lease with the heirs of Lamastus.[15] The results of those negotiations were unknown until September 22, 2014, when AquaBounty submitted yet another amended form with the SEC, stating that the company had successfully negotiated a lease with the heirs of Lamastus on August 24, 2014.[16] AquaBounty stated that this lease terminates August 25, 2014.[17] It is unclear if this is a typo, as this would represent a one-day lease.

It is also unknown how the facility was managed in the weeks between Lamastus's death, in July 2014, and the new lease agreement, on August 24, 2014. Though AquaBounty states that operations continued "unabated," this totally unverified, ad hoc management style is grossly irresponsible and totally inappropriate from a risk-management perspective.[18] This extremely troubling gray area of management does not instill confidence that AquaBounty has the capacity to safely produce AquAdvantage Salmon.

AquaBounty's filings with the SEC have noted several times, including after Lamastus's death, that: "Upon completion of the lease, we expect the landowner to take over the site and thus become a customer for AquAdvantage Salmon eggs."[19] This arrangement suggests that AquaBounty has prematurely handed over operations to a future commercial customer, allowing this company to test-drive commercial production via growing yet-unapproved AquAdvantage salmon. This arrangement represents a radical departure from the production plan described to the VMAC and the public and irresponsibly introduces risk into the production platform.

On September 22, 2014, AquaBounty submitted an amended form with the SEC that included a copy of a new lease agreement with the heirs of Luis Lamastus, dated August 24, 2014.[20] Unlike the previous lease and management agreement with Luis Lamastus from 2013,[21] the 2014 agreement only addresses a lease, not management. The lease states that AquaBounty has the right "to impose its technical and management parameters on the management of the ABP [AquaBounty Panama] Project to guarantee the survival,

performance, and production of the AAS [AquAdvantage Salmon]" and that AquaBounty Panama will manage the water distribution system.[22] It remains unclear which entity took over the management and operational responsibilities from Lamastus.

On October 24, 2014, the company submitted to the SEC yet another amended form, which states that AquaBounty has "re-establish[ed] management control over the operation."[23] It is unclear if this means the company's new arrangement with the heirs of Lamastus re-establishes the previous management arrangement or if some other arrangement has been devised. The SEC submission continues to state that it "expect[s] the landowner to take over the site and become a customer for AquAdvantage Salmon eggs."[24]

At the very least, the SEC documents indicate that under the lease and management agreement in place between June 2013 to July 2014, AquaBounty had very little or no role in the operations of the Panamanian facility and had relinquished control over crucial safety dimensions to an independent grower. This wholly unacceptable arrangement needlessly introduces enormous risk into the company's production platform and contradicts what AquaBounty and the FDA have told the public in Environmental Assessments, as we explain in detail below. This feature alone should constitute grounds for FDA denying AquaBounty's NADA.

SEC Filings Detail Conflicts with Environmental Assessment

AquaBounty's disclosures to the SEC describe a management and operational platform that is strikingly different from what is described in FDA documents. The SEC documents note that AquaBounty, since the opening of the Panamanian facility in 2008, has "managed the site remotely using local contract workers for daily operations."[25] This raises concerns about the level of control that AquaBounty has historically exercised over the Panamanian facility and also about the transparency of AquaBounty and FDA, which have always stressed AquaBounty's "commitment to containment" and "point-to-point control" over the life-cycle of AquAdvantage salmon.[26]

FDA's most recent EA, from 2012, makes no mention of the use of remote management practices or the employment of non-staff, contract workers. Likewise, the FDA has never publicly documented or reviewed AquaBounty's 2013 decision to hand over security, regulatory compliance and day-to-day operations to an independent grower. Quite the opposite, on multiple occasions, FDA describes how the company will have its own "staff" in place at every step in order to successfully implement its complicated and delicate, multinational production platform, including such things as barring entry to the facility and guaranteeing that the shipments of eggs are securely transported to the Panamanian facility from the company's Canadian facility.[27]

Citing the recommendations of Dr. Anne Kapuscinski on effective containment of genetically engineered fish, the FDA's 2012 EA notes that AquaBounty's Panamanian facility has "dedication of permanent staff to maintain continuity."[28] It was partially on the basis of this point that FDA responded favorably to the preliminary risk question:

"What is the likelihood that AquAdvantage Salmon will escape the conditions of confinement?"[29] However, according to SEC documentation, AquaBounty does not now have (and may not have ever had) permanent staff in place. Clearly, the most recent EA is out of touch with the facts on the ground today and, in fact, may never have accurately represented AquaBounty's production platform.

The FDA's regulatory review also notes that "[Containment measures would include…use of experienced, properly-trained staff operating under established plans and procedures."[30] But, as the FDA notes (and as we will explain in detail later), the Panamanian facility does not yet have established plans and procedures in place.[31] And as SEC documentation indicates, AquaBounty has at times contracted management and operations to an independent grower.

At the most sensitive parts of the AquaBounty production plan, such as the transport of eyed eggs from Canada to Panama, AquaBounty and the FDA have told the public that AquaBounty and AquaBounty alone would maintain absolute control: "Product prepared for shipment would be transported by car (or truck) to a local international airport by **ABT staff**….and personally monitor air-freight shipment of the product to Panama (inclusive of permits & customs requirements), where control would be **returned to ABT personnel waiting on the ground [in Panama]."**[32] (Emphasis added).

The FDA's EA also appears out of date in so far as it states that "In the event of approval, commercial rearing and grow-out of eyed-eggs of AquAdvantage Salmon would only occur at one site: the sponsor's land-based, freshwater aquaculture facility in the highlands of Panama."[33] Because this facility is not owned by AquaBounty, and may no longer be managed or operated by AquaBounty, this statement may no longer be accurate—and may never have been accurate.

Certainly, VMAC and members of the public would have provided comments to the FDA on the specifics of this production model had they been presented with the facts. The operations and management of the Panamanian facility were a topic of importance at the 2010 VMAC meeting. Dr. Eric Hallerman, an FDA-invited presenter to the VMAC, stressed the importance of "operations management," which "is sometimes overlooked," but which "is critical. Some of the key aspects include ensuring that culture activities promote confinement, that we are preventing unauthorized human access, that there is regular inspection and maintenance, and that there should be no marketing of live fish, as live sales pose an escape pathway."[34]

Hallerman's comments later sparked a discussion from VMAC members, include Dr. Craig Altier, who noted, "This morning Dr. Hallerman said that operations management is critical in facilities like this and that the unauthorized entry of humans needs to be eliminated…So, what safeguards are being put into place to prevent that? Specifically Panama I think is important…"[35]

VMAC member Greg Jaffe followed up with "a little broader question about the operations management," asking, "What kind of analysis is in the EA or what kind of

analysis has FDA done to ensure those [containment requirements] are maintained?"[36] (The FDA responded, erroneously, that standard operating procedures are "already in place," when, in fact, they were not and apparently still are not in Panama[37]).

Jaffe ultimately concluded that FDA had not adequately reviewed the operations management dimensions of AquaBounty's production plan, stating, "I do not think those are really covered and those are not really assessed in the Environmental Assessment. How good those are in place, how they going to be overseen, how they are going to be monitored, and what happens if—what are the risks associated around those activities. And I think that does need to be included in the Environmental Assessment."[38]

Almost certainly, the new radical changes in the operations and management of the Panamanian facility since the 2010 VMAC meeting would present even greater cause for concern. There is no indication that the FDA is aware of these changes—or that the agency has been responsive to the recommendations of the VMAC. FDA's 2012 EA, released two years after the VMAC meeting, did not include new details on operations management of the Panamanian facility, nor did the FDA give any indication that it had done any additional inspections of the Panamanian facility, despite promises to the public and the VMAC that it would be engaged in "continuous inspections and reassessment."[39]

Operational Protocols

According to the FDA's most recent EA, AquaBounty does not have a "written plan for implementing backup measures in case of failure, including documentation, monitoring, and remediation" for the Panamanian facility.[40] FDA also noted in the EA that AquaBounty would not put in place planning and documentation regarding standard operating procedures until FDA grants regulatory approval, which has not happened.[41]

Similarly, AquaBounty will not produce "a specific written plan addressing responses to loss of operational capacity, breach of security, or catastrophic incidental occurrence" for Panamanian facility until approval.[42] Operational plans that apparently are missing from AquaBounty's Panamanian facility include the following:

- Operational descriptions of systems-supplies for water, electricity, oxygen and security monitoring.
- On-call responsibilities and emergency responses to system-supply failures.
- Priority listings for fish inventory.
- Contact information for service providers.
- Training, certification and emergency response checklists.
- Schematics of systems-supplies.[43]

The fact that these basic elements may not be in place would raise concern under any circumstances, but the concerns would be enormously heightened under the arrangement that AquaBounty put in place in 2013, allowing an unknown entity to take the helm at the Panamanian facility.

Elsewhere in FDA regulatory review materials, the agency notes the critical importance of operations and management, stating: "Any breakdown of these [containment] measures would be highly unlikely because of the….use of experienced, **properly-trained staff operating under established plans and procedures**…'"[44] (Emphasis added.)

Again, such statements may no longer be accurate, if not outright false, given that AquaBounty's Panamanian operation was, and possibly still is, operated by a different entity—at times in a facility over which AquaBounty apparently has no legal lease.

Significance of SEC Revelations to Public Process

That AquaBounty alone is responsible for its production and control of AquAdvantage Salmon has been well established and is clearly a matter of public interest. The specific operations and management of AquaBounty's Panamanian facility has been the subject of inquiries and investigations by the FDA's VMAC, Congress, members of the public and the media.

At a Senate Commerce committee hearing on AquAdvantage salmon in 2011, Senator Mark Begich pressed AquaBounty President Ron Stotish for details about the management and "control mechanism" of the company's several foreign facilities. Ron Stotish was careful to stress that AquaBounty was fully in control of the Panamanian facility:

> "…We created a facility there that contains the redundant biological and physical containment that is characterized in my written testimony, and that site has then been submitted as the initial approved production site for AquAdvantage Salmon…And the control is ours, Senator. I should mention that. We are in control of that facility."[45]

It would appear debatable whether this statement was ever accurate, given that AquaBounty, at best, was *remotely* managing the site at the time the comments were made. The statement would clearly no longer hold true in 2013 when AquaBounty handed over control of the Panamanian facility to an independent fish grower, whose competence, qualifications and abilities were not a matter or public record or independently verified.

Other Problems in Panama

The public knows almost nothing about the independent growers that AquaBounty engaged to run the Panamanian facility, except that they appear to have presided over a dangerously insecure and improperly regulated production facility. It is not at all unreasonable to assume that some or all of the deficiencies we describe below could be a result of AquaBounty's hands-off management practice.

--The Panamanian facility has been described by an independent journalist with the *Guardian* as a "fading" and "rundown shed" in the "Panamanian rainforest."[46] Accompanying video and pictures to the report corroborate this description of Aqua bounty's grow-out operation, clearly showing how rudimentary it is, strongly suggesting a lack of sophistication in its biosecurity.[47] Notably, these are the only independent, detailed descriptions of the facility. In stark contrast to the *Guardian's* description, FDA's description of the facility in the most recent draft EA calls the facility "newly built and well-maintained."[48]

--In August 2008, an "unusually severe storm" caused a tree to fall on part of AquaBounty's salmon operation in Panama, leading to a batch of experimental GE salmon being "lost."[49] The lost generation of GE salmon was a major event, one that the company felt compelled to disclose to its shareholders, noting that the event cost the publicly traded company $50,000 and set its research objectives back by nine months.

The serious nature of this security breach raises questions not just over whether the company is able to safely produce AquAdvantage Salmon but also about the management arrangement that was in place during this biosecurity lapse. In SEC filings, AquaBounty notes that its "initial five-year lease" over the Panamanian facility commenced in October 2008, during which time it remotely managed the Panamanian facility.[50] However, the accident in Panama took place in August 2008.

Though there has never been an independent verification of what happened with the "lost" salmon, AquaBounty staff, when pressed for more details by a journalist, stated the "lost" fish actually all died.[51] The FDA has never acknowledged this major accident, but the agency has described what sounds like a second mishap at the Panamanian facility. In its environmental review of GE salmon, the FDA says that an undated incident in 2008 at the Panamanian facility caused by flooding resulted in minor damage.[52] The FDA is also clear that "the facility itself, however, was not directly affected by flood waters and sustained no serious damage."[53]

The details of the FDA's account differ markedly from the "lost" salmon event in August 2008. Unlike the flood and minor incident described by the FDA, AquaBounty said the August 2008 event involved no flooding, but rather a tree that fell on the facility, which caused major damage – a nine-month delay in production, "lost" salmon, and $50,000 in damages.[54] These differences strongly suggest that the FDA's EA is describing a separate event. This suggests that AquaBounty experienced two major breakdowns in 2008.

This begs many questions about the operational and management competency of AquaBounty, its remote contractors, or whatever entity was at that time in charge of the facility. When that storm hit, who exactly was in charge of the facility? If another severe storm were to hit the facility, as it did in 2008 when salmon went "lost" from AquaBounty's Panamanian facility, who will manage emergency efforts? What procedures will they follow? Does the Panamanian facility, located in a very remote location, have consistent telecommunications and/or internet access that would allow AquaBounty to get in touch? Has it always had access? Does it have sufficient back-up

generators or other power supplies to keep the operations functioning when the next violent storm hits the area? As history shows, these are not merely hypothetical questions.

--AquaBounty's operations in Panama are located in a region of the world prone to extreme weather. The company's production facility is part of the fish farm owned by Lamasur Aquaculture,[55] whose fish operations were forced to close for five days in 2008 because of widespread flooding in the area. The president of Lamasur, Luis Lamastus, reported to local news media that his farm's 21 workers were all employed in an emergency effort to prevent rising waters from flooding the company's trout operations.[56]

During the flood, the area of Bajo Mono, identified as the location of Aqua Bounty's operations in Panama,[57] experienced dramatic devastation because of the flooding. This included the destruction of major roads, which also affected Lamasur's operation.[58] About ten miles away from Lamasur, fish farms were destroyed by the floods, with newspapers reporting that people were collecting hundreds of escaped trout that apparently had been flooded out of these aquaculture operations.[59] One trout producer lost its entire production, valued at $250,000 due to the flooding.[60]

A single storm on August 22, 2010 in Boquete delivered 14 inches of rain.[61] Just a few weeks later, on September 5, an incredible 29 inches of rain fell in a single weather event.[62] In all, 384 inches (975cm) of rain fell in 2010, far exceeding the average cited by the FDA's EA of 570 cm.[63]

Indeed, the threat of another natural disaster seems likely given that the nearby Caldera River is prone to flooding. In November 2008, severe weather caused the Caldera to flood, leading to deaths and the destruction of multiple bridges, and the government issued a state of emergency.[64] In mid-August 2009, the Panamanian government declared the Caldera River a state of emergency, saying that the large amount of debris in the river basin makes the river prone to flooding.[65] It is not clear if the issues were resolved because in 2010, as noted, the river experienced massive flooding, causing major flooding in the town of Boquete, which is adjacent to AquaBounty's operations.

In April 2011, the Panamanian government declared a state of emergency for Boquete based on the heavy rains it was receiving, which caused several bridges to collapse.[66] It appears that this state of emergency was still in effect at least through September 2011.[67] The Panamanian government noted that a state of emergency was still in effect at this time and considered it urgent that the Caldera River basin be cleaned to prevent continued flooding. The Panamanian Ministry of Public Works declared that it did not have the $30 million needed to clean the Rio Caldera river channel.[68] It does not appear that this work has been initiated yet.

Panamanian authorities investigating AquaBounty's grow-out facilities have several times criticized the operation's location, which could facilitate a salmon escape.[69] Aqua Bounty's facilities are near a body of water stocked with rainbow trout, a salmonid species that has similar requirements for water temperature and dissolved oxygen

concentrations as does the GE Atlantic salmon.[70] That naturalized trout population strongly suggests that GE salmon might also survive if released.

Food & Water Watch's efforts to contact relevant regulators over AquaBounty in Panama include correspondence sent to the Panamanian Ministry of Agricultural Development, which asked Luis Lamastus to respond to our questions about the regulatory requirements over AquaBounty in Panama.[71] Lamastus initially identified himself as a consultant on AquaBounty's project, but also as someone working with the Ministry of Agricultural Development. When asked for clarification, Lamastus said he was actually not an employee of either; as a personal friend of the President of Panama, he serves as a pro-bono consultant to Panamanian government on a variety biotech projects, including GE salmon.[72]

Luis Lamastus is also the name of the head of Lamasur Aquaculture, the Panamanian trout company that owns AquaBounty's grow-out facility in Panama, and it would appear they are the same person.[73] AquaBounty contributed more than $346,000 toward its obligation over the term of the first five-year lease.[74] In SEC documents, AquaBounty identifies Luis Lamastus as the landowner of the Panamanian facility and the party overseeing AquaBounty's operations, until his recent death.[75]

On the face of it, this would appear to have been a major conflict of interest. Lamastus's financial relationship with AquaBounty appears to conflict with his position as a national advisor on biotech policies,[76] which may influence the rules and regulations governing AquaBounty's business practices. This 'fox-guarding-the-henhouse' scenario clearly has the potential to needlessly introduce new risks into AquAdvantage salmon production. This troubling revelation should spur FDA action.

Conclusion

AquaBounty and the FDA have asserted that the company's effective operation of the Panamanian facility will mitigate the threat of fish escapes or thefts. The FDA made a point to do a visit to the site in Panama to verify AquaBounty's operation and procedures.[77] Members of the VMAC, the scientific community, the public and the U.S. Senate have all investigated and inquired into the operation and management and operation of AquaBounty's Panamanian facility. Clearly the specific operations of the Panamanian facility are of great interest to stakeholders, as they should be, for an escape of AquAdvantage salmon could have very serious environmental consequences.

It is now a public record that AquaBounty has not abided the terms and conditions of production agreed upon and reviewed by the FDA, VMAC and the public. Moreover, the company's very brief time in Panama has been disastrous from an environmental safety perspective, with AquaBounty experiencing at least one major accident involving "lost" salmon as well as stiff penalties from Panamanian regulators for repeated breaches of environmental law.

News that the company, in 2013, handed over management of safety features to a future customer of AquAdvantage Salmon eggs, also contributes to the increasingly clear portrait of AquaBounty as a decidedly unfit steward and manager of a highly risky production platform for genetically engineered fish. To be sure, the production platform that AquaBounty has put in place in Panama bears very little resemblance to the production platform described in FDA documents, which specifically emphasize the fact that trained AquaBounty staff would be in control of every aspect of production.

The public has a great interest in the FDA's decision on AquAdvantage Salmon, which, if approved, would be the first transgenic animal allowed into the food supply. The public has a right to play a meaningful role in the decision-making process, yet again and again, the public is unable to play a meaningful role because the FDA's regulatory review does not accurately reflect the facts on the ground.

Clearly, the terms and conditions of AquaBounty's production platform have changed in a substantial and meaningful way that requires additional attention from FDA regulators and an opportunity for public review. While FDA's undertaking of an EIS could address many of these issues, given the myriad, grave deficiencies and lapses in the company's operations in recent years, highlighted most recently by the environmental violations in Panama, the only responsible action for FDA to take is to deny AquaBounty's NADA.

We would appreciate a response from FDA about what steps it plans to take to adjust its evaluation process for AquAdvantage salmon. Specifically, we would like to know if FDA plans to:

- Deny AquaBounty's NADA;
- Require a new application from AquaBounty for the production of AquAdvantage Salmon at the Panamanian facility;
- Conduct a full Environmental Impact Statement (EIS), with findings made available to the public with sufficient time for review and comment;
- Conduct a new site visit at the Panamanian facility to verify that the personnel, operating procedures and other relevant aspects of the new facility's operations are adequate and effective at mitigating the risk of escape;
- Investigate the status of AquaBounty's lease in Panama and the operations and management platform.

Thank you for your consideration of this important issue. If you have questions or need more information, please contact Patty Lovera at Food & Water Watch, (202) 683-2500.

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[1] AquaBounty Technologies.“ [Press Release]. AquaBounty responds to misleading claims made by anti-GM organizations.” October 28, 2014.
[2] Watson, Elaine. “GM salmon a step closer to commercialization as Environment Canada says AquaBounty’s AquAdvantage Salmon are not harmful to the environment or human health.” *Food Naviator-USA*. November 25, 2013.
[3] AquaBounty Technologies.“ [Press Release]. AquaBounty responds to misleading
[4] Autoridad Nacional del Ambiente Administracion Regional de Chiriqui. Resolucion ARACH 071-2014. July 30, 2014.
[5] AquaBounty Technologies. Environmental Assessment for AquAdvantage Salmon. May 25, 2012.
[6] Autoridad Nacional del Ambiente Administracion Regional de Chiriqui. Resolucion ARACH 071-2014. July 30, 2014.
[7] Food and Drug Administration. Veterinary Medicine Advisory Committee Briefing Packet: AquAdvantage Salmon. September 20, 2010 at 110
[8] AquaBounty Technologies. SEC Filing. Form 10. April 25, 2014.
[9] AquaBounty Technologies. SEC Filing. Form 10. July 23, 2014 at 29-30.
[10] AquaBounty Technologies. SEC Filing. Form 10. July 23, 2014 at F-9 and Exhibit 10.9.
[11] AquaBounty Technologies. SEC Filing. Form 10. July 23, 2014 at F-9 and Exhibit 10.9.
[12] AquaBounty Technologies. SEC Filing. Form 10. July 23, 2014 at Exhibit 10.9.
[13] AquaBounty Technologies. SEC Filing. Form 10. July 23, 2014 at Exhibit 10.9 at 2,3.
[14] AquaBounty Technologies. SEC Filing. Form 10. August 19, 2014 at 38, F-11.
[15] AquaBounty Technologies. SEC Filing. Form 10. August 19, 2014 at 38.
[16] AquaBounty Technologies. SEC Filing. Form 10. September 22, 2014 at 39.
[17] AquaBounty Technologies. SEC Filing. Form 10. September 22, 2014 at 39.
[18] AquaBounty Technologies. SEC Filing. Form 10. August 19, 2014 at 38, F-11
[19] AquaBounty Technologies. SEC Filing. Form 10. July 23, 2014 at 30; AquaBounty Technologies. SEC Filing. Form 10. September 22, 2014 at 33; AquaBounty Technologies. SEC Filing. Form 10. October 24, 2014 at 35.
[20] AquaBounty Technologies. SEC Filing. Form 10. September 22, 2014. Exhibit 10.17.
[21] AquaBounty Technologies. SEC Filing. Form 10. July 23, 2014 at Exhibit 10.9.
[22] AquaBounty Technologies. SEC Filing. Form 10. September 22, 2014. Exhibit 10.17 at 4, 6.
[23] AquaBounty Technologies. SEC Filing. Form 10. October 24, 2014 at 32.
[24] AquaBounty Technologies. SEC Filing. Form 10. October 24, 2014 at 35.
[25] AquaBounty Technologies. SEC Filing. Form 10. August 19, 2014 at 32.
[26] AquaBounty Technologies. Environmental Assessment for AquAdvantage Salmon. August 25, 2010 at 54-55.
[27] AquaBounty Technologies. Environmental Assessment for AquAdvantage Salmon. May 25, 2012 at 14, 48, 54, 66, 74
[28] AquaBounty Technologies. Environmental Assessment for AquAdvantage Salmon. May 25, 2012 at 75
[29] AquaBounty Technologies. Environmental Assessment for AquAdvantage Salmon. May 25, 2012 at 65.
[30] AquaBounty Technologies. Environmental Assessment for AquAdvantage Salmon. May 25, 2012 at 66.
[31] AquaBounty Technologies. Environmental Assessment for AquAdvantage Salmon. May 25, 2012 at 55, 75.
[32] Food and Drug Administration Center for Veterinary Medicine. “Draft Environmental Assessment for AquAdvantage® Salmon.” May 4, 2012 at 54.
[33] AquaBounty Technlologies, Environmental Assessment for AquaAdvantage® Salmon. May 25, 2012 at 49.

[34] Food and Drug Administration Center for Veterinary Medicine. Transcript of Veterinary Medicine Advisory Committee Meeting on AquAdvantage Salmon. Monday, September 20, 2010 at 87
[35] Food and Drug Administration Center for Veterinary Medicine. Transcript of Veterinary Medicine Advisory Committee Meeting on AquAdvantage Salmon. Monday, September 20, 2010 at 253-254.
[36] Food and Drug Administration Center for Veterinary Medicine. Transcript of Veterinary Medicine Advisory Committee Meeting on AquAdvantage Salmon. Monday, September 20, 2010 at 256
[37] Food and Drug Administration Center for Veterinary Medicine. Transcript of Veterinary Medicine Advisory Committee Meeting on AquAdvantage Salmon. Monday, September 20, 2010 at 257.
[38] Food and Drug Administration Center for Veterinary Medicine. Transcript of Veterinary Medicine Advisory Committee Meeting on AquAdvantage Salmon. Monday, September 20, 2010 at 381-382
[39] Food and Drug Administration Center for Veterinary Medicine. "Draft Environmental Assessment for AquAdvantage® Salmon." May 4, 2012; Food and Drug Administration Center for Veterinary Medicine. Transcript of Veterinary Medicine Advisory Committee Meeting on AquAdvantage Salmon. Monday, September 20, 2010 at 257.
[40] AquaBounty Technologies. Environmental Assessment for AquAdvantage Salmon. May 26, 2012 at 75.
[41] AquaBounty Technologies. Environmental Assessment for AquAdvantage Salmon. May 25, 2012 at 55.
[42] Food and Drug Administration Center for Veterinary Medicine. "Draft Environmental Assessment for AquAdvantage® Salmon." May 4, 2012 at 55.
[43] Food and Drug Administration Center for Veterinary Medicine. "Draft Environmental Assessment for AquAdvantage® Salmon." May 4, 2012 at 55.
[44] Food and Drug Administration Center for Veterinary Medicine. "Draft Environmental Assessment for AquAdvantage® Salmon." May 4, 2012 at 74.
[45] Stotish, Ron. AquaBounty Technologies. "Environmental risks of genetically engineered fish." Testimony before Subcommittee on Oceans, Atmosphere, Fisheries, and Coast Guard of Commerce Committee. U.S. Senate. December 15, 2011.
[46] Goldenberger, Suzanne. "GM salmon global HQ - 1,500m high in the Panamanian rainforest." *The Guardian*. April 24, 2013.
[47] Goldenberger, Suzanne. "GM salmon global HQ - 1,500m high in the Panamanian rainforest." *The Guardian*. April 24, 2013; "See inside a genetically modified salmon farm in Panama." *The Guardian*. April 25, 2013. Available online at http://www.guardian.co.uk/environment/video/2013/apr/25/gm-salmon-panama-video.
[48] Food and Drug Administration Center for Veterinary Medicine. "Draft Environmental Assessment AquAdvantage® Salmon." May 4, 2012 at 142.
[49] AquaBounty Technologies, Inc. Regulatory Filing on London Stock Exchange: Operations update. August 15, 2008; LeVaux, Ari. "The genetically engineered salmon that could soon run wild." *Outside Online*. June 6, 2012.
[50] AquaBounty Technologies. SEC Filing. Form 10. August 19, 2014 at 32
[51] LeVaux, Ari. "The genetically engineered salmon that could soon run wild." *Outside Online*. June 6, 2012.
[52] Food and Drug Administration Center for Veterinary Medicine. "Draft Environmental Assessment for AquAdvantage® Salmon." May 4, 2012 at 71.
[53] Food and Drug Administration Center for Veterinary Medicine. "Draft Environmental Assessment for AquAdvantage® Salmon." May 4, 2012 at 71.
[54] AquaBounty Technologies, Inc. Regulatory Filing on London Stock Exchange: Operations update. August 15, 2008; LeVaux, Ari. "The genetically engineered salmon that could soon run wild." *Outside Online*. June 6, 2012.
[55] Sierra, Luis "Ordenan destruir 'supersamon.'" *La Estrella*. January 1, 2010; "Genetically modified salmon condemned." Fish Information Services. January 11, 2010. Available at http://fis.com/fis/worldnews/worldnews.asp?l=e&ndb=1&id=35111 and on file. Accessed September 14, 2010; "Trout farm back in business." *La Prensa*. November 30, 2008.
[56] *La Prensa*. "Trout farm back in business." November 30, 2008.
[57] Sierra, Luis Alberto. "Piden oportunidad para 'supersalmon.'" *La Estrella*. January 22, 2010.
[58] Pinzon, Milagros Sanchez. "La furia del rio Caldera." *El Chiricano*. November 25, 2010; *La Prensa*. "Trout farm back in business." November 30, 2008.
[59] Rosario, Marcelino. "Aprovechan secuelas de inundacion." *Panama America*. December 5, 2008.

[60] Bocharel, Flor and Sandra Alicai Rivera. "Devastacion en Chiriqui." *La Prensa*. November 24, 2008. NOTE: Distance of 10 mile estimated from a google maps search for Bajo Mano and Bendito.
[61] Weather Underground. Online historical weather database using weather station ICHIRIQU4, based in Boquete, Chiriqui. Available at www.wunderground.com and on file .
[62] Weather Underground. Online historical weather database using weather station ICHIRIQU4, based in Boquete, Chiriqui. Available at www.wunderground.com.
[63] Weather Underground. Online historical weather database using weather station ICHIRIQU4, based in Boquete, Chiriqui. Available at www.wunderground.com and on file; Food and Drug Administration Center for Veterinary Medicine. "Draft Environmental Assessment for AquAdvantage® Salmon." May 4, 2012 at 61.
[64] Rivera, Sandra et al. "Furia de dos rios causa desastres." *La Prensa.* November 23, 2008.
[65] Rivera, Sandra Alicai. "Entregan licitacion a Ceiba." *La Prensa*. August 21, 2009.
[66] Valdes, Yessika. "Sinaproc declara estado de emergencia en zonas afectadas." *Panama America*. April 10, 2011.
[67] Sistema Nacional de Proteccion Civil. "Inspeccionan cauces de rios Director de Sinaproc y Ministro del MOP." September 22, 2011.
[68] Riviera, Sandra. "Boquete espera fondo para canalizar sus rios." *La Prensa*. September 28, 2011.
[69] Sierra, Luis "Ordenan destruir 'supersamon.'" *La Estrella*. January 1, 2010; Sierra, Luis Alberto. "Piden oportunidad para 'supersalmon.'" *La Estrella*. January 22, 2010.
[70]Food and Drug Administration Center for Veterinary Medicine. Veterinary Medicine Advisory Committee. "Briefing Packet: AquAdvantage Salmon." September 20, 2010 at 120-124.
[71] Food & Water Watch email to Manuel Gonzales at MIDA. March 1, 2013.
[72] Food & Water Watch correspondence with Luis Lamastus. March 2013. On file.
[73] Sierra, Luis. "Piden oportunidad para 'supersalmon'" *La Estrella*. January 22, 2010; Goldenberger, Suzanne. "GM salmon global HQ - 1,500m high in the Panamanian rainforest." *The Guardian*. April 24, 2013.
[74] AquaBounty Technologies. "Annual Report and Accounts 2009." 2009 at 20.
[75] AquaBounty Technologies. SEC Filing. Form 10. July 23, 2014 at F-9 and Exhibit 10.9; AquaBounty Technologies. SEC Filing. Form 10. August 19, 2014 at 38, F-11.
[76] Food & Water Watch correspondence with Luis Lamastus. March 2013. On file.
[77] Food and Drug Administration. Veterinary Medicine Advisory Committee Briefing Packet: AquAdvantage Salmon. September 20, 2010 at 117-118.