# FDA AquaBounty Draft Environmental Assessment Summary

Below are the four leaked pages of the April 19, 2012 **FDA AquaBounty Draft Environmental Assessment Summary**. Click on the images to expand them or right-click and open link in new tab to view at their highest resolution.

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use of physical, biological, and geographical/geophysical forms of containment. For the proposed action (i.e., approval of an application for AquAdvantage Salmon), the conditions proposed in the materials submitted by the sponsor in support of an NADA would limit production of eyed-eggs to a single specific facility on PEI, Canada, for delivery to a single specific land-based facility in Panama for grow-out (i.e., rearing to market size), with harvesting and processing (e.g., preparation of fish fillets, steaks, etc.) in Panama prior to retail sale in the United States. The specific proposed limitations on the production and use (grow-out) of AquAdvantage Salmon, including the production of triploid, all-female fish populations, are designed to mitigate potential adverse environmental impacts.

The proposed action is limited to an NADA approval for a specific set of conditions. Any modifications that the sponsor may propose to the conditions of an approval would require the filing and review of a supplemental NADA. Approvals of such supplemental applications would constitute agency actions and trigger environmental analyses under NEPA.

As part of the NADA review process, but separate from the environmental impact analysis itself, CVM has evaluated both the direct and indirect food safety impacts of AquAdvantage Salmon and any potential impacts of the rDNA insertion on target animal safety. With respect to food safety, FDA has concluded that food from AquAdvantage Salmon is as safe as food from conventional Atlantic salmon, and that there is a reasonable certainty of no harm from consumption of food from triploid AquAdvantage Salmon. FDA also determined that triploid AquAdvantage Salmon are not materially different from other Atlantic salmon based on their composition or allergenicity. Further, FDA has concluded that no significant food safety hazards or risks have been identified with respect to the phenotype of the AquAdvantage Salmon (FDA, 2010).

As the proposed action would only allow production and grow-out of AquAdvantage Salmon at facilities outside of the United States, the areas of the local surrounding environments that are most likely to be affected by the action lie largely within the sovereign authority of other countries (i.e., Canada and Panama). Because NEPA does not require an analysis of environmental effects in foreign sovereign countries, effects on the local environments of Canada and Panama have not been considered and evaluated in this draft EA except insofar as it was necessary to do so in order to determine whether there would be significant effects on the environment of the United States due to the origination of exposure pathways from the production and grow-out facilities in Canada and Panama.

In addition, social, economic and cultural effects of the proposed action on the United States have not been analyzed and evaluated because the analysis in this draft EA preliminarily indicates that the proposed action will not significantly affect the physical environment of the United States. Courts have held that under NEPA, social and economic effects must be considered only once it is determined that the proposed agency action significantly affects the physical environment.

FDA's approach in draft this environmental assessment is one based on a characterization of hazards, an evaluation of potential exposure pathways, and the likelihood of any resulting risk. The environmental analysis of consequences in the draft EA incorporates the principles described above by the National Research Council (NRC, 2002) as well as the U.S.

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