U.S. Food and Drug Administration

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VMAC Meeting: September 20, 2010

Chairman's Report

Veterinary Medicine Advisory Committees are intended to provide advice and recommendations to the agency. The questions that were posed to the VMAC served as a framework for discussion among the Committee members, and allowed for open but directed discussion of the four particular issues on which advice was sought.

Given the data and information presented, and the methodology, the Committee members were asked to provide comments regarding the strengths and weaknesses of data presented in the VMAC Briefing Packet and its recommendations on the following:

1. Do the data and information demonstrate that the rDNA construct is safe to AquAdvantage salmon?
2. Do the data and information demonstrate that there is a reasonable certainty of no harm from consumption of foods derived from AquAdvantage salmon?
3. Do the data indicate that AquAdvantage Salmon grow faster than their conventional counterparts?
4. Are any potential environmental impacts from AquAdvantage Salmon production adequately mitigated by AquaBounty Technologies' proposed conditions of use?

1. Do the data and information demonstrate that the rDNA construct is safe to AquAdvantage salmon? (The committee was asked to consider the safety of the rDNA construct to AquAdvantage Salmon in the context of the health of other farmed Atlantic salmon.)

The committee found no evidence in the data to conclude that the introduction of the construct was unsafe to the animal.

Some doubts were expressed with respect to the impact on results of culling procedures used prior to selection of salmon for the comparison studies because the culling described in the VMAC Briefing Packet was not typical of standard production management practices.

From the single study performed there was no evidence to suggest that AquAdvantage Salmon have less resistance to the infectious disease furunculosis. This supports immune adequacy relative to the many immune functions important in the protective response against furunculosis.

Suggestions for further procedures that might be considered to clarify this issue included:

1. Use of culling procedures similar to standard commercial production before animals are randomly entered into the comparison study.
2. An analysis of fluctuating asymmetry could be used to assess differences between AquAdvantage Salmon and Atlantic salmon. This type of analysis compares the number of countable elements (e.g., fin rays) on the left and right side of the fish as a measure of regularity of development.
3. Examination of disease resistance might be explored from a fundamental approach using tests of immunological competence if such tests have been determined to be relevant in fish.
4. Development of a metric for "difference" between GE and non-GE animals.

2. Do the data and information demonstrate that there is a reasonable certainty of no harm from consumption of foods derived from AquAdvantage salmon? (The Committee was asked to consider the safety of food from AquAdvantage Salmon in the context of the safety of food from other Atlantic salmon.)

The committee deemed the studies selected to evaluate this question to be overall appropriate and a large number of test results established similarities and equivalence between AquAdvantage Salmon and Atlantic salmon.

The studies presented confirmed that N-3 PUFA were present in AquAdvantage Salmon at the same levels to be found in farm raised Atlantic salmon. This is an important finding because consumers eat foods to meet specific nutritional needs or goals.

The levels of growth hormone in the meat and skin of AquAdvantage Salmon do not appear to be biologically relevant from a food safety standpoint. First, measured levels were at or below the values found in other commonly eaten animal protein food. Second, humans destroy Salmonid growth hormone in the gastrointestinal tract and, even if absorbed, it is not biologically active.

There is currently lack of consensus in the scientific and medical literature relating the magnitude of increase in endogenous allergens in allergenic food that would present an additional risk to public health. An example of this is the natural variability in levels of the endogenous allergen, parvalbumin, in herring and tuna, which vary by a factor of 100 fold. Given that reliable predictors of risk of allergy when eating allergenic foods are currently elusive, it cannot be concluded from the data submitted that AquAdvantage Salmon would be more or less allergenic than Atlantic Salmon. Data and analysis on the introduced construct did not identify it as likely to produce a novel antigen.

Suggestions for further procedures that might be considered to clarify this issue included:

1. Define the levels at which tested values would have biological importance and interpret data presented against these benchmarks.
2. Conduct the studies as equivalency trials rather than solely relying on the identification of statistically significant differences.
3. If, after concluding that the levels of a component in a food under review are biologically relevant to the consumer, studies to determine statistically significant differences and risk should take power into account when designing the studies so that adequate samples are obtained.
4. While it is sound to draw conclusions from undetectable concentrations of a test result if the limit of sensitivity of the test is below physiologically relevant levels, it would be preferable to use tests of sufficient sensitivity so actual values can be obtained.

3. Do the data indicate that AquAdvantage Salmon grow faster than their conventional counterparts? (The committee was asked to consider whether AquAdvantage Salmon do indeed reach the growth claims set forth in the product definition.)

The committee found evidence in support of this claim.

4. Are any potential environmental impacts from AquAdvantage Salmon production adequately mitigated by AquaBounty Technologies' proposed conditions of use? (The Committee was asked whether there are any environmental risks that the FDA CVM has not considered given the conditions of use described in the application.)

Although the committee recognized that the risk of escape from either facility could never be zero, the multiple barriers to escape at both the PEI and Panama facilities were extensive. Because part of the containment strategy is dependent on management SOP's, the committee felt that rigorous adherence to policy would need to be maintained at both sites to sustain the barriers. Further, it is the committee's understanding that both facilities will be regulated as "drug manufacturing" locations, which carries a high level of FDA scrutiny. Although information was presented to indicate that mitigation for escape risk had been planned, the potential for theft was mentioned as an additional risk.

Because of multiple physical (size) and physiological (DO requirement, slower swim speed) factors associated with AquAdvantage Salmon, the committee could not determine their fitness to survive in the environment and ability to impact native Atlantic salmon populations.

Suggestions for further procedures that might be considered to clarify this issue included:

1. While beyond the specific question directed to the committee, although an EIS may not be required for this particular application, certain committee members raised the need for an EIS if the company proposes additional facilities for growing the salmon. There was concern that cumulative impacts might be missed if each individual facility is looked at only by itself under an environmental assessment (EA).

Respectfully Submitted,

/s/
David Senior
Interim Chair, VMAC
10/14/2010