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Before the
U.S. Fish and Wildlife Service
and
National Marine Fisheries Service

REQUEST PURSUANT TO THE DATA QUALITY ACT FOR CORRECTION OF INFORMATION DISSEMINATED IN:

Final Biological Opinion On The U.S. Environmental Protection Agency's Approval Of State Of Maine's Application To Administer The National Pollution Discharge Elimination System, And Its Effects On Atlantic Salmon

and

Draft Biological Opinion On Existing U.S. Army Corps Of Engineers Section 10 Permits Authorizing Installation And Maintenance Of Fish Pens Within The State Of Maine

Submitted on Behalf of

ATLANTIC SALMON OF MAINE
57 Little River Drive
Belfast, Maine 04915

March 28, 2003

I. Introduction

Pursuant to Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 ("the Data Quality Act" or "DQA")[1], and to Guidelines of the Office of Management and Budget ("OMB"),[2] the Fish and Wildlife Service ("FWS"),[3] and the National Oceanic and Atmospheric Administration ("NOAA")[4] which implement the requirements of the Data Quality Act, Atlantic Salmon of Maine ("ASM") hereby requests correction of information disseminated jointly by FWS and National Marine Fisheries Service ("NMFS") (collectively, "the Services") in support of conditions which are to be imposed as a result of Formal Consultation under the Endangered Species Act ("ESA") for the protection of the Gulf of Maine Distinct Population Segment ("DPS") of Atlantic salmon. Those conditions are reflected in an unsigned, undated draft Biological Opinion which has been prepared by the Services, but has not been issued in final form. Similar conditions are reflected in a final Biological Opinion issued on the U.S. Environmental Protection Agency's approval of the State of Maine's application to administer the National Pollutant Discharge Elimination System permit program.

Under the DQA, which was enacted by Congress in December 2000, federal agencies were required to issue data quality guidelines ensuring and maximizing the quality, objectivity, utility and integrity of information disseminated by the agency. The concept of "objectivity" contemplates information that is accurate, reliable and unbiased and that is presented in an accurate, clear, complete, and unbiased manner. The DQA further requires that agencies provide administrative mechanisms that allow affected persons to seek and obtain timely correction of information that does not comply with agency guidelines.

II. Brief Statement of Correction Requested

The Services, in a draft Biological Opinion ("draft Corps BO") prepared pursuant to Section 7(b) of the ESA, proposed the imposition of conditions upon existing Section 10 permits issued by U.S. Army Corps of Engineers ("Corps") for the installation and maintenance of fish pens on the coast of Maine.[5] The Services rely, in pertinent part, upon a conclusion contained in

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1 Pub. L. No. 106-554 (Appendix C, H.R. 5658), 44 U.S.C. §3516, note.

2 Office of Management and Budget, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 *Fed. Reg.* 8452 (Feb. 22, 2002).

3 U.S. Fish and Wildlife Service, Information Quality Guidelines ("FWS Guidelines"), available at http://irm.fws.gov/infoguidelines/index.htm.

4 National Oceanic and Atmospheric Administration, Information Quality Guidelines (NOAA Guidelines"), available at http://www.noaanews.noaa.gov/stories/iq.htm.

5 Transmitted to the Corps under cover dated September 20, 2002.

a 1999 genetic study conducted by Dr. T. L. King and others.[6] These proposed permit conditions under the draft Corps BO are intended to protect anadromous Atlantic salmon in seven rivers flowing into the Gulf of Maine. The Services have found these Atlantic salmon to be a DPS, based in part upon genetics, and have declared the DPS to be in danger of extinction. 65 *Fed. Reg.* 69459 (Nov. 17, 2000). The King Study was apparently important in the Services' findings, by means of genetic evidence, of the genetic discreteness and significance of the Gulf of Maine DPS.

The Services also cite to three additional studies[7] for the follow-on proposition that "in[ter]breeding among genetically-divergent populations will negatively impact natural populations." *Id.* These three papers essentially argue that it is *impossible* to predict the genetic consequences of interbreeding and, for that reason, a cautious approach should be applied. The intersection of the King Study with these Precautionary Principle Studies is offered as support for the Services' conclusion that "introgression by non-North American stocks presents a substantial threat to the genetic integrity of North American stocks and threatens fitness through outbreeding depression." *Id.*

Prior to the draft Corps BO, on January 12, 2001, the Services had issued a final Biological Opinion ("final EPA BO") relating to the U.S. Environmental Protection Agency's ("EPA's") approval of the State of Maine's application to administer the National Pollutant Discharge Elimination System ("NPDES") permit program under the Clean Water Act. As in the draft Corps BO, the Services relied in this final EPA BO upon the same conclusion contained in the King Study, together with the Precautionary Principle Studies, to specify conditions under which permits will be issued for aquaculture projects engaged in the rearing of salmon and operating in or discharging to Maine waters that are virtually identical to the conditions contained in the draft Corps BO. These conditions were reflected in a Memorandum of Understanding ("MOU") between EPA and the State of Maine and in a Draft General Permit for Finfish Aquaculture on which the Services have filed comments.

Despite repeated attempts by ASM and others to obtain a copy of the primary assignment and scoring data from the King Study, including a Freedom of Information Act request filed by the State of Maine, affected parties have been denied access to the primary data from the King

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6 King, T.L., W.B. Schill, B.A. Lubinski, M.C. Smith, M.S. Eackles, and R. Coleman. 1999. Microsatellite and mitochondrial DNA diversity in Atlantic salmon with emphasis on small coastal drainages of the Downeast and Midcoast of Maine. USGA-BRD-Leetown Science Center, Kearneysville, West Virginia. ("the King Study")

7 (1) Utter, F.M., K. Hindar and N. Ryman. 1993. Genetic effects of aquaculture on natural salmonid populations. Pages 144-165 in K. Heen, R.L. Monahan, and F. Utter, editors. Salmon aquaculture. Fishing News Books, Oxford ("the Utter Study");

(2) Verspoor, E. 1997: Genertic diversity among Atlantic salmon (*Salmo salar* L.) populations. ICES Journal of Marine Science 54: 965-973 ("the Verspoor Study");

(3) Youngson, A.F. and E. Verspoor. 1998 Interactions between wild and introduced Atlantic salmon (*Salmo salar*). Can. J. Fish. Aquat. Sci. 55(supp. 1): 153-160 ("the Youngson Study"). (All three studies hereafter referred to collectively as "the Precautionary Principle Studies")

Study. Only the operative conclusion from the King Study – namely, that "there are significant [genetic] differences between North American and European Atlantic salmon" – has been disseminated by the Services and offered as the basis for permitting restrictions. Under such circumstances, it is impossible for affected parties to undertake their own independent review of that study.

Nevertheless, if ASM does not have the data from the King Study to review, it does have ample evidence to seriously question its accuracy and reliability. A leading fish geneticist of Texas A&M University, who has had opportunity to actually review the King Study, was sharply critical of its approach and conclusions. That critique is attached and is discussed briefly below. Other geneticists have independently attempted to implement Dr. King's Protocol and the results of that effort raised serious questions regarding the quality control/quality assurance practices at Dr. King's laboratory. That analysis is also attached and is described more fully below.

ASM respectfully requests that the Services undertake appropriate corrective action with respect to their reliance on the King Study as a basis for imposing conditions on Corps' permitting of salmon penning operations in Maine waters as well as on other agency actions. This should include, at a minimum, suspension of the issuance of a final Biological Opinion to the Corps, notification to the State of Maine of re-evaluation of a critical premise in the final EPA BO, evaluation of the King Study under DQA standards and the principles espoused by the Services' in their Guidelines, and the solicitation and review of additional scientific study and opinion currently available on the genetic conclusion reached in the King Study and the theory of outbreeding depression. In light of this re-evaluation, ASM requests that the Services also reconsider the applicability of the Precautionary Principle Studies, one of which actually concludes that "there is a strong case to be made for . . . historical introgression between the two continental types in some parts of North America." To the extent that reevaluation of the King Study results in changes to the draft Corps BO, ASM requests that the Services advise EPA and the State of Maine of such changes and their relevance to EPA's delegation of NPDES authority to the State.

III. The Mandate of the Data Quality Act

The DQA amended the Paperwork Reduction Act to require OMB to develop government-wide standards that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information . . . disseminated by Federal agencies." Each federal agency that is subject to the Paperwork Reduction Act was, in turn, required to issue its own data quality guidelines ensuring and maximizing the quality, objectivity, utility and integrity of the agency's information. Final OMB Guidelines were published on February 22, 2002. Guidelines prepared by FWS and NOAA, which adopt the performance standards and basic guidance of the OMB Guidelines, were subsequently reviewed and approved by OMB. The NOAA Guidelines apply to information disseminated by NMFS, which is an agency of NOAA.

A. Disseminated Information

"Information" subject to the quality standards of the DQA and Services' Guidelines includes any communication or representation of knowledge such as facts or data, in any medium or form.[8] It includes, for example, "information from outside parties that is disseminated by the agency in a manner that reasonably suggests that the agency endorses or agrees with the information."[9] Information is "disseminated" when it is distributed to the public – "to a community or audience."[10]

Agency guidelines were to become effective on October 1, 2002. Thus, the guidelines cover information disseminated by the Services on or after October 1, 2002, regardless of whether the information was first disseminated prior to that date. Archived records are exempt. However, "[i]nformation disseminated prior to October 1, 2002, but not archived and still being used in a decision-making process is not exempt from these guidelines."[11]

B. The Standard of Objectivity

The standard of "objectivity" relates to both presentation of the information and the substance of the information. As reflected in the Services' Guidelines, the standard of "objectivity" requires that the agencies ensure that the information they disseminate is "accurate, reliable, and unbiased" and that it is presented "in an accurate, clear, complete, and unbiased manner."[12]

C. Influential Information – A Higher Level of Scrutiny

Each of the Guidelines also provides that "[h]igher levels of scrutiny are [to be] applied to influential scientific . . . or statistical information, which must adhere to a higher standard of quality."[13] "Influential" information is "scientific, financial or statistical information that is expected to have a clear and substantial impact on important public policies or important private sector decisions."[14] FWS has offered examples of influential information disseminated in support of agency decisions or actions. They include substantive notices, policy documents,

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8 FWS Guidelines at 2; *see* NOAA Guidelines at 2.

9 *Id.* As the NOAA Guidelines state, it includes "information that the Agency distributes or releases which reflects, represents, or forms any part of the support of the policies of the Agency." NOAA Guidelines at 2. This includes "interpreted products," such as journal articles, scientific papers, and technical reports. *Id.* at 3.

10 *Id.*

11 FWS Guidelines at 2; NOAA Guidelines at 3, 4.

12 FWS Guidelines at 8; NOAA Guidelines at 6.

13 FWS Guidelines at 4 (emphasis added); *see* NOAA Guidelines at 6.

14 *Id.*

studies, and guidance and "issues that are highly controversial or have cross-agency interest or affect cross-agency policies."[15]

Offices that disseminate influential information must ensure that influential information, "such as analytical results, have a high degree of transparency regarding the source of the information, assumptions employed, analytical methods applied, and statistical procedures employed."[16] Influential information must also be reproducible – that is, "capable of being substantially reproduced, subject to an acceptable degree of imprecision." Information is capable of being substantially reproduced when "independent analysis of the original or supporting data using identical methods would demonstrate whether similar analytic results, subject to an acceptable degree of imprecision or error, could be generated."[17] An agency responsible for disseminating influential information must provide "methods to facilitate the reproducibility of such information by qualified third parties."[18]

IV. Background

ASM has been in the business of breeding Atlantic salmon in the coastal waters of the State of Maine since the late 1980s. The Company's finfish aquaculture operations consist of caged-rearing sites located on the coast of Maine.

Historical records indicate that the majority of subpopulations of Maine salmon were extirpated during the early 1800s. Restoration efforts were undertaken at the turn of the twentieth century using eggs imported from outside the region, including eggs of Canadian and possibly European origin. Certainly DPS segments were not considered in stocking efforts. Nevertheless, for reasons that remain highly speculative, North American populations of Atlantic salmon have continued to decline. It is clear that habitat destruction was once responsible. Historically, factors that adversely affected salmon populations included impassable dams, over-fishing, deforestation and acid rain. Some of these adverse influences may have abated. However, population levels continue to be low. Despite theories that include the impacts of water extraction and obstructions to passage, the reasons for the failure of salmon populations to adequately recover remain largely hypothetical. It is clear, however, that since salmon aquaculture did not begin in the State of Maine until the late 1980's it is not possible for that industry to have had any impact on the decline of the species during the previous 100 years that the species was known to be in decline.

In a continuing effort to stem this decline, a new approach of a river-specific stocking program was initiated by FWS and the State of Maine in 1991. This was contrary to the previous

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15 FWS Guidelines at 4.

16 *Id.*

17 FWS Guidelines at 11; NOAA Guidelines at 3, 6.

18 67 *Fed. Reg.* at 8455.

100 years of stocking efforts by FWS that gave no consideration to river of origin and made use of all available stocks. At the same time, ASM and other aquaculture companies were making efforts to obtain eggs of North American origin from federal hatcheries in the hope of basing the emerging industry on local fish. However, these industry efforts were unsuccessful because of inconsistencies in the quality of the eggs and in the inability of FWS to provide a reliable supply.

For that reason, in the early 1990s, ASM and other aquaculture companies began, under FWS permits, the authorized importation of eggs and milt from elsewhere within the natural range of salmon in the North Atlantic Basin, and ASM began development of a heartier stock that is arguably not very different in origin from the Atlantic salmon subpopulations that are in the Gulf of Maine DPS. Principal sources of European supply were in Norway and Scotland. The official position of NMFS, as stated in 1999, was that Maine's aquaculture industry may continue to use non-North American strains of salmon provided the elimination of escapement was being achieved through implementation of upgraded containment measures.[19] With the full participation of the Services, ASM and other companies developed a Containment Management System ("CMS") based on Hazard Analysis and Critical Control Point ("HACCP") procedures and employing annual independent third-party audits. By January 2003, all Maine salmon farms were operating with final company- and site-specific CMS plans.

A. The Listing Rule

In November 2000, despite a recognition that "it is unlikely that any Atlantic salmon populations in the United States exist in a genetically pure native form," the Services concluded that the Gulf of Maine population segment of Atlantic salmon satisfied the applicable criteria for DPS discreteness and significance and the Services jointly issued a final determination as to the endangered status of that DPS. 65 *Fed. Reg.* 69459 (Nov. 17, 2000). While the Services recognized that past stocking efforts "have likely increased gene flow between populations," they surmised that most stock mixing efforts have been from within the DPS, with genetic effects that are substantially less than from stocks outside the DPS.

The Services expressed their opposition to the use of reproductively viable European strains of Atlantic salmon within North America and the continued importation of European milt. As foundation for this opposition, the Services cited to the King Study, which purportedly demonstrates that there are significant differences between North American and European Atlantic salmon, implying adaptive and aboriginal characteristics. According to one reviewer discussed below, these significant differences amounted, in King's view, to a "deep evolutionary division." The Services concluded, after combining Dr. King's conclusion with the basic approach reflected in the Precautionary Principle Studies, that "[t]he introgression by non-North American Atlantic salmon stocks present a substantial threat of disrupting the genetic integrity of North American stocks and threatens fitness through outbreeding depression." This final listing rule was issued one month prior to enactment of the DQA by Congress.

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19 Letter of the Honorable Terry Garcia, Assistant Secretary for Oceans and Atmosphere, Department of Commerce, to the Honorable Angus King, Governor, State of Maine (July 1999).

B. The Final Biological Opinion Provided to EPA

In January 2001, the Services completed ESA Section 7(a)(2) consultation on, and transmitted to EPA a final Biological Opinion ("final EPA BO") relating to, EPA's proposed approval of the State of Maine's application to administer the NPDES permit program. In this final EPA BO, the Services again expressed their opposition to the use of reproductively-viable European strains of Atlantic salmon within North America, and based that opposition on application of the precautionary principle to the conclusion allegedly developed and supported in the King Study that "there are significant [genetic] differences between North American and European Atlantic salmon." Final EPA BO at 21.

As noted in this final EPA BO, EPA committed by letter to object to any State-issued NPDES permit that does not include conditions recommended by the Services, including the required phasing-out of the use of reproductively-viable non-North American stocks of salmon. Final EPA BO at 8. These conditions were subsequently reflected in an MOU between EPA and the State of Maine, as well as in a Draft General Permit for Finfish Aquaculture which has been proposed by the Maine Department of Environmental Protection and on which the Services have submitted comments.

In commenting on the prohibition on use of non-North American Atlantic salmon stocks, the Services conceded, in response to arguments made by ASM and others, that the original schedule for phasing-out such use was unrealistic and modified the schedule to one which calls for removal of all non-North American salmon by September 15, 2006. Letter of Aug. 23, 2002. As discussed below, this schedule is also reflected in the draft Corps BO, it is also unrealistic, and will cause significant economic hardship in the Maine aquaculture industry. ASM has been actively involved in the proceedings related to delegation of NPDES authority to the State.

C. The Draft Biological Opinion Provided to the Corps

In March 2001, the Services advised the Corps that it should initiate formal Section 7(a)(2) consultation for all existing permits authorizing finfish aquaculture facilities under Section 10 of the Rivers and Harbors Act. The request to the Services for consultation was made by the Corps in August 2001. After a further request from the Services for additional information and for a 60-day extension to complete a Biological Opinion, on September 20, 2002 the Services transmitted to the Corps an unsigned and undated draft Biological Opinion. Despite the fact that the regulations call for involvement of the applicant in the development of a Biological Opinion, neither ASM nor any of the other affected companies received a copy of the draft Corps BO nor were they aware of its issuance until the Maine Aquaculture Association learned of its existence and obtained a copy over a month later. In November 2002, ASM submitted preliminary comments in haste and requested additional time to comment, but neither the Corps nor the Services responded. ASM's request for additional time to submit comments on the underlying science was repeated on February 21, 2003.

D. The Pivotal Importance of the King Study

In the draft Corps BO, the Services repeated their opposition to the use of reproductively-viable European strains of Atlantic salmon within North America and based this opposition on the genetic work reflected in the King Study. Draft Corps BO at 28. While others question the genetic discreteness and significance of the DPS, the King Study apparently found otherwise. The conclusion, again, was that "introgression by non-North American stocks presents a substantial threat to the genetic integrity of North American stocks and threatens fitness through outbreeding depression." Conditions were prescribed for the protection of the Atlantic salmon DPS in the draft Corps BO as in the final EPA BO. These included a prohibition on reproductively-viable non-North American Atlantic salmon at permitted facilities according to a time line that would necessitate destruction of all remaining non-North American strain salmon by September 15, 2006. *Id.* at 17.[20] Conditions also included an unreasonable compressed schedule for the marking of fish. *Id.* at 20.

The pivotal importance of the work of Dr. King is not only reflected in the reliance on the study's conclusion as the basis for the conditions the Services would impose on ASM and others directly and through the delegated State NPDES program, including the prohibition on use of non-North American strain salmon, but also in the Services' proposed protocol for determining which Atlantic salmon may be used for breeding and production by facilities permitted by the Corps and the State. This protocol ("the King Protocol"), which was attached to the draft Corps BO as Attachment 1, "describes a standardized procedure to classify fish as either North American or non-North American and is largely based on the procedures used by King *et al.*"

The primary assignment and scoring data supporting the King Study has not appeared in the public literature. ASM and other Maine aquaculture interests have repeatedly tried to obtain a copy of that primary assignment and scoring data in order to undertake their own scientific review of the inputs, methods, results and conclusions. However, access to the data has been denied. Even a Freedom of Information Act request filed by the State of Maine has failed to produce a copy of the original data. Only "reconstructed" data was provided. As discussed below, other geneticists have independently found the King Study to be seriously flawed and have attempted to implement Dr. King's protocol, but with disappointing results.

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20 Non-North American stock is defined as any Atlantic salmon which possess genetic material derived partially or entirely from Atlantic salmon stocks of non-North American heritage, regardless of the number of generations that have passed since the initial introduction of the non-North American genetic material.

V. The King Study Data Have Not Been Made Available to Affected Parties, But Dissemination of Its Conclusions Is the Basis for Ongoing Regulatory Decision Making

Although the Services have made the conclusions of the King Study publicly available on several occasions, the underlying data have been shared only with a rather select audience. Presumably, the Services have been provided with a copy. Dr. John R. Gold of Texas A&M University had access to sufficient information to enable him to provide public testimony that was sharply critical of the study. This information was provided in the context of a lawsuit which was filed by the State of Maine and which is described more fully below. Dr. Gold's testimony is attached to this Request as Attachment A. However, parties directly affected by the conditions to be imposed under the final EPA BO and the draft Corps BO cannot seem to obtain a copy of the study data.

ASM finds it to be nothing short of incredible that the data allegedly supporting a study of such pivotal importance to regulatory decision making should be withheld from public view without any apparent reason for doing so. The King Study is offered as a critical piece of evidence in support of the imposition of licensing restrictions that could ultimately be devastating to the salmon industry in Maine. Regardless of whether the operative conclusion is ultimately born out, persons directly affected by restrictions imposed as a result of the study are entitled, at the very least, to examine and critique it. As a DQA matter, dissemination of a study's conclusion without providing access to the study runs directly counter to the stated goal of "ensur[ing] and maximiz[ing] the quality, utility, objectivity, and integrity of the information that [agencies] disseminate." The Services Guidelines clearly apply to scientific research, whether conducted by academics or federally-employed scientists, so long as the "agency represents the information as, or uses the information in support of, an official position of the agency." 67 *Fed. Reg.* at 8453.

At the same time, while the King data have been withheld, information developed in the study has been "disseminated." The conclusion of the King Study was made available to the public in the *Federal Register* notices issued in connection with the listing of Atlantic salmon prior to enactment of DQA. It was disseminated in the final EPA BO. It was also disseminated in the draft Corps BO and will undoubtedly appear in the final version of the Corps Biological Opinion unless timely corrected. Moreover, it continues to affect the outcome of licensing and regulatory decisions.

VI. The Conclusion Adopted From the King Study and Disseminated by the Services Does Not Meet the Objectivity Standard of the Services' Guidelines

Under the DQA, federal agencies must ensure and maximize the quality, utility, objectivity and integrity of the information that they disseminate. The standard of "objectivity" has two distinct components – one relating to presentation, the other relating to substance. Under the first, agencies must ensure that "disseminated information is being presented in an accurate, clear, complete and unbiased manner." 67 *Fed. Reg.* at 8459. Under the second, the focus is on ensuring that the information itself is "accurate, reliable and unbiased." *Id.* Neither

of these components of "objectivity" is satisfied in the Services' use of the King Study conclusion. When the information disseminated takes the form of simple statements of conclusion, it is not possible to ensure that its presentation is accurate and unbiased. It certainly cannot be said to be complete. As for the substance of the disseminated information, there is clearly sufficient evidence to question its accuracy and reliability, as the following discussion suggests.

A. An Independent Critique of the King Study Indicates That the Underlying Data and Methodology Are, Themselves, Inaccurate and Unreliable

While ASM does not have a copy of the King Study, it does have the benefit of a very penetrating critique of the study. Attached to this Request as Attachment A is a critique of the King Study which was prepared by Dr. John R. Gold of Texas A&M University. Dr. Gold is Professor of Genetics and Wildlife and Fisheries Sciences at the University. Dr. Gold undertook his review of the King Study in order to "provide scientific/professional review and critique of the genetics work carried out by federal laboratories regarding Atlantic salmon and as that work relates to the listing process." Attachment A at 2. The stated purpose of the King Study was to "allow the most informed planning and implementation of biologically sound management efforts." *Id.* Dr. Gold noted that, as he reviewed the study and related materials, "the importance of the report by King et al. became clear relative to establishing, based on genetics evidence, the concepts of genetic *discreteness* and *significance* of the Gulf of Maine DPS." *Id.* (emphasis in original).

Dr. Gold's conclusions are summarized in his Introduction. Among other things, he is critical of the sampling design. It "could mean that allele frequency differences between year classes, reflective of genetic drift, may have been minimized." He notes that the statistical approach was not up-to-date, that there were problems in the statistical analysis and shortcomings in terms of data analysis and inference. Indeed, there is ample reason to raise serious question about the reliability of the methods employed and the conclusion reached.

Most of the findings and conclusions of the King Study, as Dr. Gold characterizes them, are based on the allelic variations. One central finding is that Atlantic salmon from Europe differ significantly in allele frequency from Atlantic salmon in North America. While there can be little doubt that this is true, the King Study concludes that European and North American fish, thus, represent a "deep evolutionary division" and should be considered different evolutionarily significant units. *Id.* at 11. As Dr. Gold states, "to call the difference between European and North American fish a 'deep evolutionary division' seems a bit of overstated hyperbole." *Id.* at 12. "Not appreciated by the authors," Dr. Gold notes, "is that European fish may represent a valuable resource of adaptively useful alleles that may have been lost in North American fish because of (what appears to be) extensive genetic drift." *Id.* at 3.

The inappropriate statistical approach used by Dr. King and the existence of highly significant genetic instability between yearly samples at the same site within the DPS raise serious questions regarding genetic discreteness and genetic significance. *Id.* at 4. Genetic discreteness may be "illusory." The occurrence of genetic "uniqueness" may "simply reflect chance events precipitated by small effective population size." *Id.* "[T]he supposition that

unique genotypes in Gulf of Maine DPS fish represent an important genetic legacy of aboriginal stocks is," in Dr. Gold's view, "incredibly naïve." *Id.*

Thus, in the view of at least one of the leading experts in the field of fish genetics, there are very serious questions as to the accuracy and reliability of the King Study and the study's conclusion. As Dr. Gold concludes, "the genetics study of King et al. is inadequate relative to assessing the distribution and significance of genetic variation in Atlantic salmon in North America and to risk assessment of management planing [sic] for restoration of the Atlantic salmon resource in Maine." *Id.* at 15.

B. Another Geneticist's Effort to Employ the King Protocol Indicate Serious Weaknesses in the Quality Control/Quality Assurance Practices of Dr. King's Laboratory

Attached to this Request as Attachment B is an analysis provided by Dr. John Patton of his attempt to implement the King Protocol which was offered as an attachment to the draft Corps BO and which will, presumably, become the method for determining which Atlantic salmon can be used for breeding and production stock. This analysis speaks volumes on the reliability of the quality control/quality assurance practices of Dr. King's laboratory.

Briefly, Dr. Patton and his colleagues at Texas A&M University, as well as another independent laboratory contracted by ASM, found that four of the fifteen reference sample animals provided by Dr. King's laboratory were scored incorrectly both through missed alleles and incorrectly sized alleles. Moreover, wide variations were observed in the original DNA concentrations of five of the fifteen test animals which causes artifactual banding patterns that can result in improper genotype determinations. Inasmuch as the approach adopted by the Services for determining North American- and non-North American-origin fish depends on allele frequencies, these can only be viewed as fatal errors, reflecting on the quality assurance/quality control practices of the study laboratory. Once again, the reliability and accuracy of Dr. King's work has been seriously questioned by his peers.

VII. Reliance By the Services on the Conclusion of the King Study Did Not Satisfy the DQA Requirements of Transparency and Reproducibility

Under the DQA and the Services' Guidelines, an agency that is responsible for disseminating "influential" scientific or statistical information must provide a "high degree of transparency" about the data and include, in its guidelines, "methods to facilitate the reproducibility of such information by qualified third parties." 67 *Fed. Reg.* at 8460.

There can be no doubt that the conclusion of the King Study is "influential" scientific information. Dr. King's conclusion that there are risks of outbreeding depression from genetic introgression between North American and European Atlantic salmon provides the basis on which the Services have opposed the use of reproductively viable European strains of Atlantic salmon in North America. *See* 67 *Fed. Reg.* at 69478. This opposition has precipitated the set of conditions reflected in the final EPA BO and the draft Corps BO which will, in turn, directly

impact licensing and regulatory decisions and government policies relating to the use of marine resources in Maine. These decisions will have a clear and substantial impact on the investments which ASM has made in developing a viable aquaculture business and, even more fundamentally, on the ability of ASM to continue to conduct business.

Under the Services' Guidelines, influential information must be subject to a "high degree of transparency." The Services have failed to provide this. Only the study conclusion is presented. The Services are also required to facilitate the "reproducibility" of such information by qualified third parties. The reproducibility standard which is applicable to influential scientific information is intended to ensure that information disseminated by agencies is sufficiently transparent in terms of data and methods of analysis that it would be feasible for a replication to be conducted. To the extent that affected parties are denied access to the study data, it clearly cannot be replicated.

VIII. The Failure of the King Study Conclusion to Meet the DQA Standards for Objectivity, Transparency, and Reproducibility Was Confirmed in the Context of a Request for Injunctive Relief Sought by the State of Maine

In December 1999, the State of Maine filed a Freedom of Information Act request with the U.S. Department of the Interior ("DOI") and its agency, the U.S. Geological Survey ("USGS"), seeking all original genetic data underlying the summary data on which the King Study was based. Dr. King is an employee of the USGS.

In a lawsuit subsequently filed against DOI and its agencies, the State alleged that it had initially receiving computer disks that could not be read, and later received computer disks containing data but without a key computer file needed to interpret the data. DOI informed the State that this key computer file had been modified after the King Study was completed in March 1999. The State filed a lawsuit to obtain, among other things, the key computer file and ultimately received disks which DOI described as containing a key computer file that had been "reconstructed" to its March 1999 format. The State's lawsuit was dismissed, and the State used the information obtained to request the critique of the King Study which was prepared by Dr. Gold and was submitted as part of the State's formal comments on the proposed rule to list Atlantic salmon as endangered. Dr. Gold's critique is discussed above and is attached to this Request as Attachment A.

According to a subsequent lawsuit, the State later received reliable information to the effect that other alterations had been made to the data contained in the file, beyond simply removing the post-March 1999 changes. The State filed a second lawsuit seeking, among other things, an unaltered copy of the key computer file. *State of Maine v. U.S. Department of the Interior, et al.* No. 00-122-B-C (D. Me. June 13, 2000). In its complaint, the State further alleged that DOI acknowledged that "minor errors" were made when they attempted to remove the post-March 1999 modifications.

The controversy with respect to the critical file was ultimately settled under a Consent Judgment entered in the U.S. District Court for the District of Maine on November 6, 2002. A

copy of that Consent Judgment is attached as Attachment C. It confirms that the key computer file used in conjunction with the King Study had been modified such that the version which existed in December 1999 was different from the version that was used in conjunction with the March 1999 King Study. It also confirms that, in March 2000, DOI provided a "reconstructed" version of the file that was used in conjunction with the March 1999 King Study. The parties reserved their rights to make any arguments regarding the effects, if any, of any errors in the reconstructed file.

These efforts by the State of Maine to obtain all of the original genetic data underlying the summary data on which the King Study was based were intended to serve the legitimate and constructive goal of performing an independent evaluation of the King Study. What these efforts demonstrate, however, is that the conclusion of the King Study is not based on data that satisfy the objectivity standard of the Services' Guidelines. No conclusion that is based on files that have been so modified and then reconstructed can be said, with any degree of confidence, to be "accurate" and "reliable." Perhaps more important, the Services' Guidelines apply a "reproducibility" standard to "influential" scientific and statistical information. Qualified third parties should be able to generate similar analytical results using identical methods to independently analyze the original or supporting data, subject to an acceptable degree of imprecision or error. With the filing of the Consent Judgment in U.S. District Court in Maine, DOI and its agencies, including the U.S. Fish and Wildlife Service, conceded that this is not possible.

IX. Perpetuating the Error – The Precautionary Principle Studies.

As noted above, the Services take the King Study conclusion one step further by means of the Precautionary Principle Studies, which are cited for the proposition that interbreeding among genetically-divergent populations will negatively impact natural populations. The proposition is overstated. The Precautionary Principle Studies generally argue that it is not possible to predict the outcomes of introgression. For that reason, caution should be used when empirical data are lacking and until such data accumulate.

The Utter Study, which is now ten years old, expresses the view that it is impossible to predict the genetic consequences of interbreeding between cultured and wild populations because of the near absence of knowledge about mechanisms of genetic adaptation and the fact that nothing is known about the evolutionary histories of the wild populations or of the wild progenitors of cultured populations. "We are largely limited to more or less intelligent guesses and generalizations." Utter Study at 147. The Youngson Study adds that "the adaptive importance of these effects [of interbreeding] and the extent to which the performance of wild populations of salmon [are] likely to be altered by interbreeding with introduced fish is poorly understood." Youngson Study at 155. *Finally, the Verspoor Study offers the revealing conclusion that the level of uncertainty is so high, it could as easily argue for interbreeding. That study states that "there is a strong case to be made for . . . historical introgression between the two continental types in some parts of North America."* Verspoor Study at 968 (emphasis added).

In *Bennet v. Spear*, 520 U.S. 154 (1997), the U.S. Supreme Court found that one of the purposes of the

> requirement [in both Section 4 and Section 7 of ESA] that each agency 'use the best scientific and commercial data available' is to insure that the ESA is not implemented haphazardly, on the basis of speculation or surmise. While this no doubt serves to advance the ESA's overall goal of species preservation, we think it readily apparent that another objective (if not indeed the primary one) is to avoid needless economic dislocation produced by agency officials zealously but unintelligently pursuing their environmental objectives.

520 U.S. at 176-77.

By themselves, these studies do not provide even a preponderance of the evidence in support of the conditions prescribed in both the final EPA BO and the draft Corps BO. They underscore the uncertainties regarding the outcomes of introgression and, at least in one case, suggest that interbreeding could actually be beneficial. Only in combination with the King Study conclusion can the Services arguably transform the "not possible to predict" position reflected in these studies into the "will negatively impact" conclusion in the final EPA BO and the draft Corps BO. As discussed above, in the absence of further analysis, the King Study should not be used to so swing the balance in any risk assessment.

X. ASM is Directly Affected By Conditions Which the Services Have Imposed As a Result of the King Study

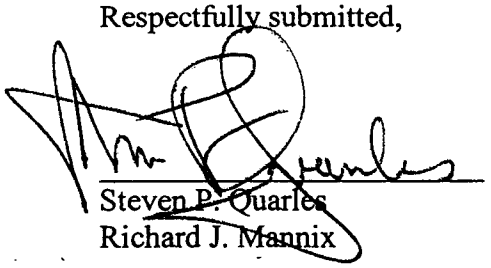
ASM is an affected person entitled, under the DQA and its implementing guidelines, to seek and obtain timely correction of information maintained and disseminated by the Services which does not comply with OMB and Services Guidelines. The unreasonable schedule that the Services included in the draft Corps BO and have asserted that the State should include in NPDES permits as a result of the conclusions of the King Study cannot be met by ASM and other Maine aquaculture companies. The inability of the companies to ensure that North American stocks of salmon are phased-in according the proposed schedule and the required removal of non-North American salmon will almost certainly lead to significant economic disruption in the Maine salmon aquaculture industry. Based on company experience and the stocks they would be allowed to use, cost of production would increase by 30% due to slower growth, early maturation, lower survival and deformities.

XI. The Correction Requested

ASM respectfully requests that the Services undertake appropriate corrective action with respect to their reliance on the King Study as a basis for imposing conditions on Corps' permitting of salmon penning operations in Maine waters as well as on other agency actions. This should include, at a minimum, suspension of the issuance of a final Biological Opinion to

the Corps, notification to the State of Maine of re-evaluation of a critical premise in the final EPA BO, evaluation of the King Study under DQA standards and the principles espoused by the Services' in their Guidelines, and the solicitation and review of additional scientific study and opinion currently available on the genetic conclusion reached in the King Study and the theory of outbreeding depression. In light of this re-evaluation, ASM requests that the Services also reconsider the applicability of the Precautionary Principle Studies, one of which actually concludes that "there is a strong case to be made for . . . historical introgression between the two continental types in some parts of North America." To the extent that reevaluation of the King Study results in changes to the draft Corps BO, ASM requests that the Services advise EPA and the State of Maine of such changes and their relevance to EPA's delegation of NPDES authority to the State.

Respectfully submitted,



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