Possible Changes from the Proposed Rule Based on Public Comment and Internal Review [Updated 6/5/15]

- 1. Revise the term "genetically modified organism" to "genetically engineered animal" and remove the term "transgenic". The term "genetically engineered animal" encompasses both terms "genetically modified organism" and "transgenic" and more accurately describes the use of modern biotechnology. Consistent with this change, the definition for "genetically engineered animal" will be added to § 622.2 and the definitions for "genetically modified organism" and "transgenic animal" will be removed from § 622.2.
- **2.** Also, in § 622.2, the definition for "aquaculture" is being modified slightly based on public comment. In the proposed rule, the definition stated, "aquaculture means all activities, including the operation of an aquaculture facility, involved in the propagation **and** rearing, or attempted propagation **and** rearing, of allowable aquaculture species in the Gulf EEZ." This wording can be interpreted to mean that to engage in "aquaculture," both propagation and rearing need to be conducted. NMFS is revising this definition of by changing the "and" to an "or" in these two places.
- **3.** Consistent with the change to the definition of "aquaculture", the definition of "aquaculture facility" in § 622.2 is being modified based on public comment. In the proposed rule, the definition stated, "Aquaculture facility means an installation or structure, including any aquaculture system(s) (including moorings), hatcheries, equipment, and associated infrastructure used to hold, propagate, **and** rear allowable aquaculture species in the Gulf EEZ under authority of a Gulf aquaculture permit." NMFS is revising "hold, propagate, and rear" to "hold, propagate, or rear."
- 4. A prohibition has been added to § 622.13, which states that it is unlawful to "land allowable aquaculture species cultured in the Gulf at non-U.S. ports, unless first landed at a U.S. port." This prohibition is in the FMP but was not in the proposed rule. However, this prohibition was reasonably foreseeable based on what was included in the proposed rule based on the requirement to have a Gulf aquaculture dealer permit to first receive fish cultured at an aquaculture facility. As proposed, an applicant for a Gulf aquaculture dealer permit "must have a valid state wholesaler's license in the state(s) where the dealer operates, if required by such state(s), and must have a physical facility at a fixed location in such state(s)." The references to a state wholesaler's license and physical facility at fixed location in the state are a clear indication that those authorized to first receive allowable aquaculture species must be located in the U.S. The final rule is clarifying this point by adding a statement to the prohibition section in § 622.13.
- 5. Section 622.101, paragraph (a)(2)(viii) requires the applicant to submit to NMFS a copy of currently valid Federal permits (*e.g.*, ACOE Section 10 permit, and EPA NPDES permit), prior to issuance of a Gulf aquaculture permit. NMFS is moving this provision to paragraph (d)(3) of that section because this documentation is required before issuance of the permit, not as part of the initial application.

- 6. Section 622.101(a)(2)(xiv), requires that permittees certify that all broodstock being used were originally harvested from U.S. waters of the Gulf. NMFS is adding language to this provision to require that permittees also certify that the broodstock, "or progeny of such broodstock were from the same population or subpopulation (based on the best scientific information available) where the facility is located." This language is in the FMP and was discussed in the preamble of the proposed rule; however, it was not in the proposed codified text. Also in the section, NMFS is changing "were originally harvested" to "will be or were originally harvested". This is intended to clarify that the applicant is not required to know the location of broodstock harvest at the time the application is submitted to NMFS but still ensures any broodstock used in the future will be from U.S. waters in the Gulf and from the same population or subpopulation where the facility is located. [ML1]
- 7. In § 622.101(d)(2)(ii)(B), the language regarding grounds for denial of a Gulf aquaculture is being revised. In the proposed rule, grounds for denial of a Gulf aquaculture permit included, "significant risk to the well-being of wild fish stocks..." NMFS is removing the phrase "to the well-being of" to be consistent with the language in the preamble in the proposed rule, which stated that NMFS may deny a permit that would "pose significant risk" to marine resources.
- 8. NMFS is changing "baseline environmental assessment" to "baseline environmental survey." Some public comments indicated that using the term "baseline environmental assessment" is confusing to the public because the term "environmental assessment" is used to refer to a document that may be prepared under the National Environmental Policy Act. NMFS is making this change to make it clear that the "baseline environmental assessment" required by this final rule is not the same as an "environmental assessment" that may be prepared under NEPA. In addition, NMFS is clarifying that permittees are required to submit baseline environmental survey data to NMFS in accordance with procedures specified by NMFS in guidance available on the SERO Web site.
- 9. Language is being added to § 622.102(a)(1)(i)(A) to require permittees to maintain and make available to NMFS or authorized officers upon request, a written or electronic daily record of the number of cultured animals introduced into and the number of pounds and average weight of fish removed from each allowable aquaculture system, including mortalities, for the most recent 3 years. This language is in the FMP and was discussed in the preamble of the proposed rule but was not specifically contained in the codified text in the proposed rule.

- 10. NMFS is adding paragraph (D) to § 622.102(a)(1)(i) to specify that permittees are required to record the date, time, and weight of cultured animals to be harvested and report this information to NMFS at least 72 hours prior to harvesting cultured animals from an aquaculture facility. This harvest notification is intended to aid law enforcement efforts. The notification would alert law enforcement in the case they wish to be present at the time of harvest at an aquaculture facility to verify that permittees are harvesting only cultured species and remain within their production cap. This 72-hour harvest notification is in the FMP and was discussed in the preamble to the proposed rule but was not included in the codified text in the proposed rule.
- 11. NMFS is also adding paragraph (H) to § 622.102(a)(1)(i) to require that the original or copies of purchase invoices for feed must be provided to NMFS or authorized officers upon request, and be maintained for a period of 3 years. This was discussed in the preamble in the proposed rule but was not included in the codified text in the proposed rule because NMFS included the reference to the EPA regulations at 40 CFR 451.21, which NMFS believed covered these feed reporting requirements. After further evaluation, NMFS has determined that the 3-year requirement to maintain the feed purchase invoices is not contained in the EPA regulations.
- 12. In § 622.104(c), the caveat "as authorized by the U.S. Coast Guard" is added to the requirement that "the permittee must mark the restricted access zone with a floating device such as a buoy at each corner of the zone." This is intended to clarify that the floating devices used to mark the restricted access zone must be authorized by U.S. Coast Guard.
- 13. NMFS is replacing the phrase "landed ashore" to the term "offload". The FMP, and the codified text in the proposed rule, stated that species cultured at an aquaculture facility must be "landed ashore" between 6 a.m. and 6 p.m., local time. However, the preamble to the proposed rule stated that permittees participating in the aquaculture program would be allowed to "offload" cultured animals at aquaculture dealers only between 6 a.m. and 6 p.m., local time. NMFS has determined that using the more precise term "offload" in this context is consistent with the objective of the requirement, which is to aid enforcement, while allowing vessels the flexibility to arrive at the dock at any time. By restricting offloading times, law enforcement will be able to ensure that vessels are landing only cultured species (e.g., secure tissue samples to be tested against broodstock DNA). For the purposes of this requirement, NMFS is defining the terms "offload" in to mean to remove cultured animals from a vessel.

14. NMFS imazjs modifying the definition of "significant risk" in section 622.2. When the Council reviewed and deemed this definition in February 2013, it stated: "significant risk means is likely to adversely affect endangered or threatened species or their critical habitat; is likely to seriously injure or kill marine mammals; is likely to result in unmitigated adverse effects on essential fish habitat; is likely to adversely affect wild fish stocks, causing them to become overfished or undergo overfishing; or otherwise may result in harm to public health or safety, as determined by the Regional Administrator." The proposed rule published in the Federal Register contained a modification to this definition with respect to endangered and threatened species, defining significant risk, in part, as "likely to jeopardize the continued existence of endangered or threatened species or adversely modify their critical habitat." The proposed rule also expressly solicited comments on this part of the definition. After considering public comments, and further internal review, NMFS has determined that the definition of "significant risk" as it relates to endangered and threatened species should be modified reflect the text originally deemed by the Council.