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# Genetic Engineering and the Endangered Species Act

Erik C. Baptist, Ann M. Begley, Hume M. Ross
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Genetic engineering and the Endangered Species Act, or ESA, may not, at first glance, appear to have much to do with one another. But a decision from last November by the U.S. District Court for the Northern District of California, Institute for Fisheries Resources v. U.S. Food and Drug Administration, has highlighted the significant relationship between the two.

Companies should be cognizant of this intersection when seeking approval of genetically engineered animals by the FDA, and may even want to consider the case's implications for other FDA decisions. Failure to do so may jeopardize years of investment.

The Institute for Fisheries Resources case directly addresses what ESA analyses FDA must conduct prior to approving any genetically engineered animal. Without doubt, the court's reasoning in holding that FDA failed to comply with the ESA when approving a GE animal increases the burdens on both FDA and the applicant. It also creates a legal precedent that some might seek to invoke to affect other ESA reviews and consultations.

**Statutory Background**

The definition of a "drug" under Section 201(g) of the Federal Food, Drug and Cosmetic Act includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals."

## Authors

Ann M. Begley
Partner
202.719.4585
abegley@wiley.law

Hume M. Ross
Associate
202.719.7296
hross@wiley.law

## Practice Areas

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In light of this definition, the FDA takes the position that it has the authority to regulate the intentional genomic alterations — IGAs — or constructs introduced into GE animals as drugs, because they alter the structure or function of the animal. If the IGA is intended for use in food-producing animals, before granting approval, the FDA confirms the safety of the food produced from the GE animal, as well as the safety and effectiveness of the IGA itself in the target animal.[1]

When the FDA decides whether to permit certain applications of genetic engineering, to confirm the GE animal's safety, it necessarily must determine the conditions under which the GE animals can be raised.[2] As the Institute for Fisheries Resources decision highlights, the FDA's approval of an application to create and raise GE animals arguably is subject to Section 7 of the ESA.

That provision requires every federal decision-making agency to ensure that its actions are not likely to jeopardize the continued existence of any endangered species. To comply with the ESA, the agency taking the action may be required to consult, in advance of its decision, with one or two other agencies.

These agencies are the U.S. Department of Commerce's National Marine Fisheries Service, or NMFS, in the case of potential effects to marine species and some fish that split time between salt and fresh water, and the U.S. Department of Interior's Fish and Wildlife Service, or FWS, in the case of all other species.

But an ESA analysis can quickly become burdensome. Unless the action agency determines that the action will have no effect on endangered species, it must consult with one or both of the services. And consultation can be a time- and resource-intensive process.[3]

In the context of the U.S. Environmental Protection Agency's pesticide registration process, for example, ESA litigation has resulted in massive delays that complicate the statutorily mandated registration review process — under which previously granted registrations are periodically reviewed — and that threaten the viability of a number of new products.[4]

Action agencies and applicants, therefore, have an incentive to reach a "no effect" finding. Even if a no effect finding is reached, opponents of the action may have the opportunity to argue that certain chains of events that the action might set in motion — no matter how improbable — could result in an effect on an endangered species, thus rendering the no effect determination arbitrary and capricious, and warranting consultation with the services.

Even though the FDA may understand its obligations under the ESA, it has far less experience with the statute than other federal agencies. Moreover, the Institute for Fisheries Resources decision calls into question whether the FDA is adequately prepared to handle its ESA obligations by itself. Going forward, companies will likely need to play a substantial role in guiding the FDA's compliance with the ESA.

**The Institute for Fisheries Resources v. FDA Decision**

In Institute for Fisheries Resources, the court needed to decide whether the FDA complied with the ESA when authorizing AquaBounty Technologies Inc. to grow GE salmon in landlocked pens on Prince Edward Island, Canada, and in Panama. The GE salmon, branded AquAdvantage, grow to full size in half to two-thirds the time of wild salmon, thanks to a gene from an eel-like ocean pout fish.

In performing the environmental assessment required of it by the National Environmental Policy Act, or NEPA, the FDA analyzed the likelihood that (1) the fish would escape, and (2) the GE fish might crossbreed, compete for resources or establish a self-sustaining population. The FDA concluded that each of these outcomes was exceedingly unlikely, and therefore concluded that the approval of the applications would have no effect on any endangered species.

But the plaintiffs also raised ESA concerns. And while the court's opinion focused primarily on whether the FDA complied with NEPA, the court separately concluded that the FDA had failed to adequately analyze effects under the ESA.

The court found that the "FDA failed to adequately assess the risk that the salmon would escape and survive in the wild." The court explained that "the FDA was required to consider — and had the authority to act upon — concerns regarding the effect of the AquAdvantage salmon on normal salmon," which are protected under the ESA.

In addition, even though FDA "was not required to formally consider future projects that had not yet been submitted for approval," the court stated that "this does not mean it would be appropriate to conduct its analysis of the proposed action without taking account of the obvious likelihood that future actions would build on it." On remand, FDA was directed to analyze and address "the consequences that would result from the engineered salmon successfully establishing a persistent population outside of captivity."

As is often the case in analogous challenges to action agency decisions, the ESA holding in this case was an outgrowth of the court's NEPA analysis:
Because the FDA did not sufficiently examine whether the engineered salmon would significantly impact wild salmon under NEPA, it follows that the agency cannot defend its conclusion that the engineered salmon would have no effect at all on Gulf of Maine salmon.

On remand, the FDA must determine whether it will adhere to its original no effect determination under the ESA, together with its revised NEPA evaluation, or whether it will reach a "may affect" finding, and then consult with NMFS and FWS.

So now the FDA will need to build a legally defensible record when analyzing both the potential for exposure and the possibility for an effect on wild populations. Consultation, and the consequent complications and delay, can be avoided only if the action agency makes and documents a no effect determination that can withstand judicial scrutiny.

This requires demonstrating that, even if there is the potential that endangered species may be exposed to the action in some way, they will not be affected, as determined by the best available science, and in view of all mitigation measures.[5] But the precise contours of the action agency's discretion are subject to debate and challenge — as the EPA's recent pesticide registration experience has demonstrated.

Depending on the degree of scrutiny imposed by opponents of FDA actions, this may require the FDA to expand on its prior analysis that, even in the unlikely event that the GE salmon escape, they will not have any impact on wild populations. The FDA very well could be required to provide far more details and references to scientific literature to support its conclusion that the GE salmon are, as the FDA characterized them, "reproductively incompetent," or otherwise unable to affect wild populations.

But the FDA and private sector applicants are now on notice that ESA challenges will factor prominently into future regulatory actions concerning GE animals.

**Recommendations**

The district court's decision reflects a changing dynamic that we have observed in recent years across the food, drug and agriculture landscape. When seeking FDA approval of a GE animal, or contemplating seeking approval for other controversial products, companies should make sure that the FDA complies with its obligations under the ESA.

Long gone are the days where an agency can approve a product while avoiding scrutiny from external stakeholders who are looking for any legal vulnerabilities with the decision, including failure to meet the requirements of the ESA. The FDA's review and approval of GE animals — a frequently debated technology — clearly falls within the scope of this increased scrutiny, as likely will other agency decisions.[6]

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*Erik C. Baptist and Ann M. Begley are partners, and Hume M. Ross is an associate, at Wiley Rein LLP.*



[1] Recent actions and statements by the U.S. Department of Agriculture and the U.S. Department of Health and Human Services suggest a significant transfer of GE animal approval authority from FDA to USDA. This proposed transfer is highly contentious among the regulatory authorities and other stakeholders. Thus, with the ushering in of a new administration that is carefully reviewing the prior administration's late game-changing initiatives, we believe this initiative is not likely to be adopted in the short term, if at all.

[2] See Q&A on FDA Regulation of Intentional Genomic Alterations in Animals (last visited 2/8/21); Institute for Fisheries Resources v. FDA at 14.

[3] The potential exists for a slightly more streamlined "informal" consultation; see 50 C.F.R. § 402.13. But this may not be possible in all circumstances. No effect findings are themselves reviewable under the Administrative Procedures Act.

[4] The registration review consultation delays became so severe that the EPA and the NMFS were sued on the theory that the delays themselves constituted a violation of the ESA. Northwest Coalition for Alternatives to Pesticides v. NMFS, No. 07-cv-1791 (W.D. Wash. filed Nov. 5, 2007). A resulting settlement agreement still governs the consultation schedule for many reviews, although the agreement is frequently amended as the schedule slips. For other pesticides, EPA has resorted to issuing interim registration review decisions that acknowledge that ESA consultation remains ongoing.

[5] Nat'l Family Farm Coal. v. U.S. Envtl. Prot. Agency, 966 F.3d 893, 925 (9th Cir. 2020), reh'g denied, 2020 U.S. App. LEXIS 36274 (9th Cir. Nov. 18, 2020) (upholding the EPA's "no effect" determination where the EPA was able to rule out effects on species outside of fields to be treated with pesticide under review, despite potential for exposure).

[6] Opponents of agency actions have a history of success widening the reach of the ESA. See, e.g., Nat'l Wildlife Fed'n v. Fed. Emergency Mgmt. Agency, 345 F. Supp. 2d 1151, 1172–73 (W.D. Wash. 2004) (FEMA required to consult with NMFS because its administration of the National Flood Insurance Program, which included modifying regulations for a program under which communities could become eligible for reduced premiums by implementing conservation measures, could affect Puget Sound chinook salmon). Further expansions are not far-fetched. The FDA cites, for instance, to a paper supporting that only a "negligible" risk exists from flushing certain pharmaceuticals as opposed to participating in a drug take-back program. A litigant may one day challenge the FDA on whether this assertion is sufficient for a no effect determination. Take-back programs would not prevent some releases, however, as some recent studies have even found adverse impacts on fish through the intended use and natural disposal of certain pharmaceuticals.