ORAL ARGUMENT NOT YET SCHEDULED

No. 22-5238(L), 22-5244, 22-5245, 22-5246

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

MAINE LOBSTERMEN'S ASSOCIATION,
Plaintiff-Appellant,

STATE OF MAINE DEPARTMENT OF MARINE RESOURCES; MASSACHUSETTS LOBSTERMEN'S ASSOCIATION; DISTRICT 4 LODGE OF THE INTERNATIONAL ASSOCIATION OF MACHINISTS AND AEROSPACE WORKS; LOCAL LODGE 207,
Intervenors-Appellants,

v.

NATIONAL MARINE FISHERIES SERVICE; GINA RAIMONDO, IN HER OFFICIAL CAPACITY AS SECRETARY OF COMMERCE; JANET COIT, IN HER OFFICIAL CAPACITY AS ASSISTANT ADMINISTRATOR FOR FISHERIES,
Defendants-Appellees,

CONSERVATION LAW FOUNDATION; CENTER FOR BIOLOGICAL DIVERSITY; DEFENDERS OF WILDLIFE,
Intervenors-Appellees.

On Appeal from the United States District Court for the District of Columbia,
No. 1:21-cv-02509-JEB

BRIEF FOR APPELLANT-INTERVENOR MASSACHUSETTS LOBSTERMEN'S ASSOCIATION

SAMUEL P. BLATCHLEY
Counsel of Record
ROBERT T. DUBE JR*
ECKLAND & BLANDO LLP
22 Boston Wharf Road, 7th Floor
Boston, MA 02210
(617) 217-6936
sblatchley@ecklandblando.com
*Supervised by principals of the firm who are members of the MA bar and D.C Circuit bar

November 9, 2022

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rules of Appellate Procedure 26.1(a), the Massachusetts Lobstermen's Association certifies that it does not have a parent corporation and that no publicly held corporation owns more than 10% of its stock.

CERTIFICATE AS TO PARTIES, RULINGS UNDER REVIEW, AND RELATED CASES

Appellant-Intervenor Massachusetts Lobstermen's Association ("MALA") incorporates by reference Appellant Maine Lobstermen's Association's ("MLA") certificate as to parties, rulings under review, and related cases.

JURISDICTIONAL STATEMENT

MALA incorporates by reference MLA's statement of the case.

STATUTES AND REGULATIONS

Relevant statutory and regulatory provisions are set forth in an addendum to this brief.

STATEMENT OF THE ISSUES

MALA incorporates by reference MLA's statement of the case.

STATEMENT OF THE CASE

MALA incorporates by reference MLA's statement of the case.

Page(s)

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

REGULATIONS

RULES

TREATISES AND PUBLICATIONS

GLOSSARY OF ABBREVIATIONS

APA	Administrative Procedure Act
BiOp	References to the 2021 Biological Opinion
Conservation Framework	North Atlantic Right Whale Conservation Framework
ESA	Endangered Species Act
J.A.	References to the joint appendix
M/SI	mortalities and serious injuries
NMFS	National Marine Fisheries Service
right whale	North Atlantic right whale

INTRODUCTION

Massachusetts loves whales and its lobstering heritage, community, and economy, and the law mandates that an appropriate balance be struck to protect both. For example, *infra*, Massachusetts, leading from the front, was the first state to introduce cutting edge harm-reduction techniques for Right Whales, including shuttering its lobster fishery from February 1st to April 30th (usually extended through May 15th) every year to protect the Right Whales during calving season.[1] This is not the lone example of Massachusetts firsts in implementing measures to protect the Right Whales. Indeed, Massachusetts' actions demonstrate that it has struck the balance to preserve its love for both whales and lobstering. On the other hand, NMFS, like a child playing a fantastical game, threatens this balance with modeling based upon clearly incorrect assumptions. But, like children that must eventually put aside toys and experience the real world, NMFS must cast aside its fantastical models, rife with improper bias "in favor of the species" and "worst case scenario" assumptions which NMFS readily admits produce inaccurate results, and, as mandated by the Endangered Species Act ("ESA"), create a Biological Opinion "us[ing] the best scientific and commercial data available." 16 U.S.C. §1536(a)(2).

[1] Indeed, Massachusetts continues its closures even though oceanographic changes have caused right whales and their prey to move northward and away from the Gulf of Maine. *See* JA[BiOp_60661, 18920, 33597, 61537, 25243]. JA refers to the Joint Appendix submitted to the District Court in the proceedings below.

The lower court failed to bring NMFS into reality and put the games to rest. This Court should instead tell NMFS enough with the games. Under the Administrative Procedures Act ("APA") and the ESA, this Court, respectfully, must find the Biological Opinion arbitrary and capricious and require that NMFS promulgate a new Biological Opinion that replaces those "worst case scenario" assumptions and bias "in favor of the species" with "the best scientific and commercial data available."

STATEMENT OF THE FACTS

MALA incorporates by reference MLA's statement of the facts, adding only Massachusetts specific facts, demonstrating *inter alia* Massachusetts has been the first state to aggressively take steps to protect the Right Whale. While Massachusetts has not released official numbers, approximately 1000 commercial lobster permits were issued by the Massachusetts Department of Marine Fisheries, while NMFS has issued 1,601 permits for federal zone 1 (which surrounds Massachusetts' waters) as of 2017.

In 2021, the ex-vessel value of lobster landed in Massachusetts was approximately $120 million. *See* Massachusetts Division of Marine Fisheries, *Massachusetts Seafood Value Reaches an All-Time High in 2021* (Jan. 1, 2022), https://www.mass.gov/news/massachusetts-seafood-value-reaches-an-all-time-high-in-2021. As recently as 2016, Maine and Massachusetts accounted for 94% of

the total American lobster national landings. NOAA, *New England, Mid-Atlantic States Lead Nation in Volume and Value of Several Key Fisheries* (Nov. 1, 2017), https://www.fisheries.noaa.gov/feature-story/new-england-mid-atlantic-states-lead-nation-volume-and-value-several-key-fisheries.

The Massachusetts lobster industry was and has been first in implementing cutting edge harm-reduction techniques for the Right Whale. A few examples follow. Massachusetts was the first to require "year-round use of sinking groundline in all state waters," outlawing floating lines that "can entangle larges whales and other marine life." Massachusetts Division of Marine Fisheries, *Massachusetts Lobster Fishing The Right Way*, https://www.mass.gov/doc/massachusetts-lobster-fishing-the-right-way/download. Further, Massachusetts-licensed lobstermen are already required to use "weak rope," which has a higher tendency to break upon contact with a whale. Massachusetts Division of Marine Fisheries, *New Protected Species Regulations Finalized for Fixed Gear Fisheries and Industry Outreach on Required Gear Modifications* (February 19, 2021), https://www.mass.gov/doc/21921-new-protected-species-regulations-finalized-for-fixed-gear-fisheries-and-industry/download. Most importantly, Massachusetts shuts its fisheries from February 1st to April 30th (and usually extended through May 15th) annually to protect the Right Whale during calving season. *Id*.

Finally, there has not been a single documented incident in Massachusetts or adjacent federal waters of a Right Whale being caught in vertical buoy rope ("VBR") or being struck by a fishing vessel since 2016. *See* JA[Rule_29078.] That Right Whale was released from the rope and has gone on to birth a calf, making it a non-serious incident.[2] *Id*.; *see also* NOAA, *North Atlantic Right Whale Updates*, (August 31, 2022), https://www.fisheries.noaa.gov/national/endangered-species-conservation/north-atlantic-right-whale-updates#sundog-(#3823):-a-newly-entangled-right-whale.

SUMMARY OF ARGUMENT

NMFS's Biological Opinion is arbitrary and capricious because it relies on a fantastical model based on clearly contradictory data and "worst case scenario" outcomes biased "in favor of the species" rather than on "the best scientific and commercial data available" and outcomes reasonably certain or "likely" to occur, in violation of clear U.S. Supreme Court and D.C. Circuit precedent, the APA, and the ESA and its implementing regulations.

[2] NMFS categorizes incidental injuries between fisheries and marine mammals as "serious" or "non-serious" injuries. A "serious injury" is "any injury that will likely result in mortality." 50 C.F.R. § 216.3.

ARGUMENT

I. NMFS's Biological Opinion Is Arbitrary And Capricious And Violative Of The APA Because It Is Founded On A Model Based On Speculative "Worst Case Scenarios" With Bias "In Favor Of The Species" Making It Create Results Not Reasonably Certain To Occur And Contradictory To A Proper Model Based On The "Best Scientific And Commercial Data" As Required By The ESA.

A. Applicable Standard of Appellate Review.

Under the APA, a district court's grant of summary judgment is subject to *de novo* review, and "requires [the Court] to set aside agency action that is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Fogo De Chao (Holdings) Inc. v. DHS*, 769 F.3d 1127, 1135 (D.C. Cir. 2014); *see* 5 U.S.C. § 706(2)(A). An agency's action is not in accordance with law and should be remanded if it is "inconsistent" with applicable law. *Arizona v. Thompson*, 281 F.3d 248, 253 (D.C. Cir. 2002). Agency action is arbitrary and capricious if the agency "fails to 'comply with its own regulations,'" *Nat'l Env't Dev. Ass'ns Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014), or if it has "entirely failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 43 (1983).

B. Thumbing its Nose at the ESA, NMFS Admits that it Did Not Consider What Was Likely to Occur to the Species and Instead Chose to Assume Worst Case Scenarios Never Likely to Occur to the Species by Impermissibly Tipping the Scales in Favor of the Species.

In creating its Biological Opinion, NMFS openly admits that it did not follow the ESA or its implementing regulations. ESA §7(a)(2) mandates that "[e]ach federal agency shall, in consultation with and with the assistance of [NMFS], insure that any action authorized, funded, or carried out by such agency … is not likely to jeopardize the continued existence of any endangered species." 16 U.S.C. §1536(a)(2). "NMFS has interpreted the term 'likely' to have its common meaning (i.e., more likely than not). Indeed, most dictionaries define 'likely' to mean that an event, fact, or outcome is probable." *Alaska Oil & Gas Ass'n v. Pritzker*, 840 F.3d 671, 684 (9th Cir. 2016); *In re Polar Bear Endangered Species Act Listing & Section 4(d) Rule Litig.—MDL No. 1993*, 709 F.3d 1, 14 (D.C. Cir. 2013) ("*In re Polar Bear*"). The ESA's implementing regulations interpret "likely" in the same way. *See* 50 C.F.R. § 402.14(g) (stating, after NMFS identifies the "environmental baseline," it must "evaluate the effects of the action and cumulative effects on the listed species" and then "formulate [an] opinion as to whether the action is likely to jeopardize the continued existence of [the] listed species.")

However, in the Biological Opinion, NMFS admittedly *never* focused on what would "likely" occur to the Right Whale if it continued to authorize lobster fishing.

Rather, NMFS focused on "worst case scenarios" that it repeatedly admitted would "very likely" *never* occur. JA[BiOp_2004, 2149, 2152]:

(1) "[W]e utilized metrics representing the worst case scenario. Consequently, model outputs very likely overestimate the likelihood of a declining population." JA[BiOp_2004];

(2) "[W]e assumed a worst case scenario[.]" JA[BiOp_2005];

(3) "[P]rojections were generated utilizing worst case assumptions for several key variables, so these projections should not be interpreted as an accurate predictor of the actual future right whale population." JA[BiOp_2017];

(4) "[I]t is likely that the projections underestimate the likelihood of an increasing right whale population and that the actual right whale population will likely fare better than the trajectories indicate." JA[BiOp_2015]; and,

(5) "[T]he assumptions may be considered pessimistic but … we need to give the benefit of the doubt to the species." JA[BiOp_1029].

Additionally, rather than focus on what was "likely" to occur, NMFS relied on "worst case scenarios," ignoring the "best scientific and commercial data" and instead tipped the scales "in favor of the species," as NMFS stated:

1) "[T]he uncertainty is resolved in favor of the species." JA[BiOp_1882];

2) "We generally select the value that would lead to higher, rather than lower, risk to endangered or threatened species. This approach provides the 'benefit of the doubt' to threatened and endangered species." JA[BiOp_1882];

3) "This approach provides the benefit of the doubt to the species." JA[BiOp_1892];

4) "[W]e are giving the 'benefit of the doubt' to the species and assuming the interactions were caused by gear used in the federal fisheries in this Opinion." JA[BiOp_1899]; and,

5) "This gives the benefit of the doubt to the species by using years with a low number of births." JA[BiOp_2012].

In sum, NMFS violated the ESA by openly admitting what it cannot – the model used to generate its Biological Opinion, which gives the species "the benefit of the doubt" (i.e., tipping the scales for the Right Whale) and assumes "worst case scenarios" (i.e., the most unlikely scenarios), gives inaccurate data making NMFS's Biological Opinion the quintessential "fruit of the poisonous tree."

C. By Impermissibly Relying Upon "Worst Case Scenarios" Instead of Outcomes "Reasonably Certain To Occur" as Evidenced by the "Best Scientific and Commercial Data," NMFS Was Arbitrary and Capricious.

Rarely does a government agency openly state that it is not complying with the law. And yet that is exactly what happened here, when NMFS repeatedly

represented that it was relying on "worst case scenarios" instead of outcomes "reasonably certain to occur," 50 C.F.R. § 402.02, to develop its Biological Opinion. JA[BiOp_1882, 2004.] Even rarer is for a court to see this open admission of arbitrary noncompliance with the law and allow the agency action to stand. And yet, the lower court made that surprising decision in its summary judgment order, [District Court Dkt. #75,] thereby necessitating this appeal. NMFS's Biological Opinion is arbitrary and capricious because it not only fails to use the best scientific evidence available but also declines to determine outcomes "reasonably certain to occur" in favor of a "worst case scenario" bias that results in drastically more severe outcomes than the actual scientific data shows to be occurring. This Court must correct this clearly arbitrary and capricious decision.

As a preliminary matter, it is well established that agencies are permitted to rely on modeling to forecast results that shape their regulation. *Small Refiner Lead Phase-Down Task Force v. Envtl. Prot. Agency*, 705 F.2d 506, 535 (D.C. Cir. 1983). And indeed, "that a model is limited or imperfect is not, in itself, a reason to remand agency decisions based upon it." *Appalachian Power Co. v. EPA*, 249 F.3d 1032, 1052 (D.C. Cir. 2001); *In re Polar Bear*, 709 F.3d at 13. However, this Court has been clear that "agencies do *not* have free rein to use inaccurate data." *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 56–57 (D.C. Cir. 2015) (emphasis in original). Thus, while the court "must generally be at its most deferential when

examining an agency decision made within its area of special expertise," *Shafer & Freeman Lakes Env't Conservation Corp. v. FERC*, 992 F.3d 1071, 1093 (D.C. Cir. 2021), such deference cannot morph into acquiescence. *Consol. Salmonid Cases*, 713 F. Supp. 2d 1116, 1159 (E.D. Cal. 2010), *supplemented* (June 1, 2010) ("The judicial review process is not one of blind acceptance.") (citing *Esch v. Yeutter*, 876 F.2d 976, 991 (D.C.Cir.1989)).

Here, the lower court undertook that fatal transformation, accepting every erroneous contention of NMFS because of the supposed "reasonableness" of the erroneous assumptions plugged into the model. This Court must not repeat the mistakes of the lower court. Rather, if this Court is to "earn [its] keep" then "judicial deference to the agency's modeling cannot be utterly boundless; [it] must reverse the agency's application of the [subject] model as arbitrary and capricious if there is simply no rational relationship between the model and the known behavior of the [subject] to which it is applied." *Chem. Mfrs. Ass'n v. E.P.A.*, 28 F.3d 1259, 1265 (D.C. Cir. 1994) (citing *Motor Vehicle Mfrs.*, 463 U.S. at 43. Here, there is no rational relationship between the assumptions in the Biological Opinion's underlying model, and the actual behavior (and mortality) of the Right Whale.

To illustrate, let us turn to examples of "the best scientific and commercial data available" that NMFS had in its possession when it created the Biological

Opinion compared to the improper assumptions it arbitrarily and capriciously chose to input into its models:

> (1) the split between Right Whale mortalities in Canadian vs. U.S. waters, based on NMFS's own records, was 80% Canadian / 20% United States from 2010 to 2019, 100%/0% from 2016 to 2019, and 61%/39% from 2012 to 2021; NMFS's model assumes 50%/50%;[3]
>
> (2) Right Whales are not immortal, they die of natural causes; NMFS's model assumes they live forever unless a human-caused event occurs;
>
> (3) the Unusual Mortality Event was just that, unusual; NMFS's model assumes it will continue for 50 years;[4]
>
> (4) Various fisheries contribute to Right Whale entanglement; NMFS's model assumes that trap/pot fisheries cause 100% of entanglements.

Compare NOAA, *2017-2022 North Atlantic Right Whale Unusual Mortality Event,* (Sept. 27, 2022), https://www.fisheries.noaa.gov/national/marine-life-distress/2017-

---

[3] NMFS claims to have chosen a 50/50 split because it was uncertain as to the impacts of Canadian regulations going forward. JA[BiOp_2005]. Apparently, NMFS believes there is something special about its regulations that will achieve benefits for the Right Whale that Canadian regulations, by virtue of being Canadian, will not. Except, NMFS specifically noted that it believed Canada's regulations are now "benefitting right whales." JA[BiOp_1041, 2005, 18920-22, 60679, 60694]. These assumptions and contradictions clearly do not fit within the reasonable certainty test. Either regulations will benefit the Right Whale, and thus Canadian regulations will have an impact, or they will not, in which case NMFS's Biological Opinion is meritless.

[4] Despite NMFS acknowledging it is "likely" that this assumption is wrong. JA[BiOp_2015].

2022-north-atlantic-right-whale-unusual-mortality-event *with* JA[BiOp_1890-92, 1894-95, 1897, 29078].)

As such, the lower court committed clear error is asserting "the agency simply did not have the data that Plaintiffs wish it had, and it accordingly was not required to assume any effects it could not rigorously model," (Dkt. #76 - District Court's Summary Judgment Opinion ("Mem. Op.") at 22.), As is made clear by the facts above, NMFS substituted its own "speculative factual assertion" in favor of actual data, in a "let them eat cake" approach that "ill becomes an administrative agency whose obligation to the public it serves is discharged only if it avoids being arbitrary and capricious." *Chem. Mfrs. Ass'n*, 28 F.3d at 1265 (quoting *Edison Electric Institute v. E.P.A.,* 2 F.3d 438, 446 (D.C. Cir. 1993)); *see also Nat. Res. Def. Council, Inc. v. Rauch*, 244 F. Supp. 3d 66, 96 (D.D.C. 2017) ("Suffice it to say, it is arbitrary and capricious for an agency to base its decision on a factual premise that the record plainly showed to be wrong."). Even the lower court began to acknowledge this discrepancy, noting "indeed, the agency's own peer-review report identifies 'a clear recent shift in the spatial distribution' of the right-whale population towards Canada," before ultimately determining that this clear contradiction in NMFS's assumptions was not arbitrary and capricious. (Mem. Op. at 16.) How then, could the lower court not find NMFS's Biological Opinion to be arbitrary and capricious?

Because it failed to appreciate how the ESA and APA intertwine when conducting an arbitrary and capricious analysis.

The ESA mandates NMFS to "use the best scientific and commercial data available" in formulating its Biological Opinion. 16 U.S.C. § 1536(a)(2). This means that NMFS is forbidden from basing its decision "on speculation or surmise or disregard [of] superior data." *Building Indus. Ass'n of Superior Cal. v. Norton*, 247 F.3d 1241, 1246–1247 (D.C. Cir. 2001). Yet this is exactly what NMFS did. Its model and the assumptions rammed through it flies directly in the face of actual evidence proving its inputs and hypothesis incorrect. See *Tex Tin Corp. v. EPA*, 992 F.2d 353, 354–55 (D.C.Cir.1993) (EPA's reliance upon generic studies in face of conflicting detailed and specific scientific evidence held arbitrary and capricious). What is worse, that conflicting data was data *already held and created by NMFS.* (NOAA, *2017-2022 North Atlantic Right Whale Unusual Mortality Event*, (Sept. 27, 2022).) Further, the ESA imposes an additional burden on NMFS, requiring it to determine "reasonably certain to occur" outcomes. 50 C.F.R. § 402.02. This means that the lower court erred when it determined that "all the [APA] requires" is for NMFS to "reasonably explain how it estimated" and "modeled" the right whale population on "what it assessed was the best available data and submitting its methods for peer review." (Mem. Op. at 2.) What it should have found instead is that NMFS was required to use the "the best scientific and commercial data available,"

i.e., the data it already possessed showing its assumptions about Right Whale mortality to be erroneous, and then apply that data to determine an outcome "reasonably certain to occur," *not* a worst case scenario (which, by definition, is not reasonably certain to occur). 50 C.F.R. § 402.02.

The lower court apparently believed that NMFS did model outcomes "reasonably certain to occur," in that worst case scenarios could indeed happen. (Mem. Op. at 13 (substituting "worst case scenario" with "more species-protective result.").) And, perhaps, the lower court could be forgiven for this mistake, given that there appears to be no case law (or regulatory guidance) interpreting what "reasonably certain to occur" means.[5] If, for instance, "reasonably certain to occur" means "could possibly occur if hypothetical inputs ignoring actual, conflicting data, is applied and then the worst possible outcome from those incorrect, hypothetical inputs is modeled" then yes, NMFS's Biological Opinion could be determined, under an arbitrary and capricious review, to have settled on a reasonably certain to occur outcome regarding Right Whale mortality. But such a definition cannot possibly be what was intended by the regulations, nor can it be what NMFS

[5] The lower court postulated that NMFS's internal Consultation Handbook could be a source of clarification based on the parties' arguments, but ultimately determined that it was unnecessary to conduct an analysis of that Handbook and whether it was entitled to *Chevron* deference due to its conclusory determination that the Biological Opinion complied with the ESA and APA. (Mem. Op. at 13.)

understood the regulations to mean, given its own 2019 preamble to its consultation regulations:

> [T]he "reasonably certain to occur" determination must be based on clear and substantial information, using the best scientific and commercial data available. The information need not be dispositive, free from all uncertainty, or immune from disagreement to meet this standard. By clear and substantial, we mean that there must be a firm basis to support a conclusion that a consequence of an action is reasonably certain to occur. This term is not intended to require a certain numerical amount of data; rather, it is simply to illustrate that the determination of a consequence or activity to be reasonably certain to occur must be based on solid information and should not be based on speculation or conjecture. . . . [W]e do not read the legislative history from the 1979 amendments to section 7 that included the phrase "benefit of the doubt to the species" to require a different outcome.

84 Fed. Reg. 44,976, 44,993 (Sept. 26, 2019); *see also* 50 C.F.R. § 402.17(a)-(b) ("[a] conclusion of reasonably certain to occur must be based on clear and substantial information" not from consequences that are "so remote in time from the action under consultation that it is not reasonably certain to occur" and "only reached through a lengthy causal chain that involves so many steps as to make the consequence not reasonably certain to occur."). If the definition of "reasonably certain to occur" is not clearly defined, it is incumbent upon this Court to supply a definition from which NMFS, the public, and reviewing courts may be guided. *Smith v. United States*, 508 U.S. 223, 228 (1993) ("When a word is not defined by statute, [the court] normally construe[s] it in accord with its ordinary or natural meaning.").

Surely, whatever definition is settled upon will necessarily determine that assuming a worst-case scenario from inaccurate data is not a scenario "reasonably certain to occur" and thus an agency relying on worst-case scenario outcomes is necessarily arbitrary and capricious.

Given the lower court's misapprehension of NMFS's obligations under the APA and ESA, it is unsurprising it found the model not to be arbitrary and capricious. (Mem. Op. at 32.) Nonetheless, this was clearly erroneous considering the conflicting, "best scientific and commercial data available," and therefore must be overturned. *See Chem. Mfrs. Ass'n*, 28 F.3d at 1265 ("The more inflexibly the agency intends to apply the model, however, the more searchingly will the court review the agency's response when an affected party presents specific detailed evidence of a poor fit between the agency's model and that party's reality.").

At the very least, NMFS should have at least considered "significant and viable and obvious alternatives," such as a middle ground between the actual data and the worst case scenario. *Dist. Hosp. Partners, L.P.*, 786 F.3d at 459 (quoting *Nat'l Shooting Sports Found., Inc. v. Jones,* 716 F.3d 200, 215 (D.C. Cir. 2013)); *see also Oceana, Inc. v. Ross*, 275 F. Supp. 3d 270, 288 (D.D.C. 2017), *aff'd*, 920 F.3d 855 (D.C. Cir. 2019) ("[Appellant] is correct that NMFS could not ignore important evidence when it developed the 2015 SBRM."). The lower court contended that NMFS did consider alternatives, waving away NMFS's failure to use actual data by

repeatedly claiming that NMFS's model was "peer reviewed." (Mem. Op. at 2, 15-16, 18, 22-23, 28.) However, it is not sufficient for the lower court to simply note that peer review occurred, rather, the peer review must rationally relate to the final product and the agency must incorporate the feedback of that peer review. Here, NMFS did neither.

For example, the lower court noted the Diagnostic Support Toolwas peer reviewed but ignored that that very peer review "ha[d] a number of concerns over the DST's underlying data, which is coarse (spatially and temporally), stagnant (set years) and does not account for variation in the various data sources." JA[BiOp_75429.] Claiming that this peer review somehow provides support to the Biological Opinion is nonsensical. Simply repeating the phrase "peer review" does not somehow shield NMFS from the consequences of its arbitrary and capricious action. *See Americans for Safe Access v. Drug Enf't Admin.*, 706 F.3d 438, 452 (D.C. Cir. 2013) (citing Charles Jennings, Quality and Value: The True Purpose of Peer Review,Nature.com(2006),http://www.nature.com/nature/peerreview/debate/nature05032.html).("[S]cientists understand that peer review per se provides only a minimal assurance of quality, and that the public conception of peer review as a stamp of authentication is far from the truth."). Patently, if an agency solicits peer review and then ignores that peer review, this perfunctory *ipse dixit* cannot be used

to shield against challenges to that agency action. It was error for the lower court to not so find.

CONCLUSION

The Court should reverse the lower Court and order a remand to NMFS without vacatur[6] to: 1) determine whether authorizing the American lobster fishery would likely jeopardize the right whale without speculating about "worst case scenarios" or tip the scales of justice "in favor of the species," and against the hardworking people of Massachusetts (who were the first to do anything to protect the Right Whale) lobster industry, which is a part of the fabric of Massachusetts's identity, heritage, and economy; and, 2) fashion a Biological Opinion to determine outcomes "reasonably certain to occur" as evidenced by the "best scientific and commercial data."

[6] Vacatur would be unwarranted here because it would likely require the closure of the lobster fisheries as a biological opinion is required to satisfy ESA § 7 requirements. Therefore, vacatur would cause further chaos, which should be avoided. *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002). At a minimum, this Court should remand to the lower court to determine the appropriate remedy.

Dated: November 9, 2022

Respectfully submitted,

ECKLAND & BLANDO LLP

/S/ SAMUEL P. BLATCHLEY

Samuel P. Blatchley BBO# 670237
Robert T. Dube Jr.*
Eckland & Blando LLP
22 Boston Wharf Road, 7th Floor
Boston, MA 02210
(617) 217-6936
sblatchley@ecklandblando.com
*Supervised by principals of the firm who are members of the MA bar and D.C Circuit bar

Counsel for Appellant-Intervenor

CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and Circuit Rule 32(e), as well as this Court's Amended Per Curium Briefing Order, because it contains 4,131 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Circuit Rule 32(a)(1).
2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point font.

Dated: November 9, 2022

/S/ SAMUEL P. BLATCHLEY
Samuel P. Blatchley

CERTIFICATE OF SERVICE

I hereby certify that, on November 9, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/Samuel P. Blatchley
Samuel P. Blatchley

ADDENDUM

50 C.F.R. §402.02 Definitions.

…

Cumulative effects are those effects of future State or private activities, not involving Federal activities, that are reasonably certain to occur within the action area of the Federal action subject to consultation.

…

Effects of the action are all consequences to listed species or critical habitat that are caused by the proposed action, including the consequences of other activities that are caused by the proposed action. A consequence is caused by the proposed action if it would not occur but for the proposed action and it is reasonably certain to occur. Effects of the action may occur later in time and may include consequences occurring outside the immediate area involved in the action. (See § 402.17).

…

Jeopardize the continued existence of means to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species.

…

Reasonable and prudent alternatives refer to alternative actions identified during formal consultation that can be implemented in a manner consistent with the intended purpose of the action, that can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction, that is economically and technologically feasible, and that the Director believes would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat.

Reasonable and prudent measures refer to those actions the Director believes necessary or appropriate to minimize the impacts, *i.e.,* amount or extent, of incidental take.

50 C.F.R. §402.14 Formal consultation.

…

(g) *Service responsibilities.* Service responsibilities during formal consultation are as follows:

(1) Review all relevant information provided by the Federal agency or otherwise available. Such review may include an on-site inspection of the action area with representatives of the Federal agency and the applicant.

(2) Evaluate the current status and environmental baseline of the listed species or critical habitat.

(3) Evaluate the effects of the action and cumulative effects on the listed species or critical habitat.

(4) Add the effects of the action and cumulative effects to the environmental baseline and in light of the status of the species and critical habitat, formulate the Service's opinion as to whether the action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

(5) Discuss with the Federal agency and any applicant the Service's review and evaluation conducted under paragraphs (g)(1) through (3) of this section, the basis for any finding in the biological opinion, and the availability of reasonable and prudent alternatives (if a jeopardy opinion is to be issued) that the agency and the applicant can take to avoid violation of section 7(a)(2). The Service will utilize the expertise of the Federal agency and any applicant in identifying these alternatives. If requested, the Service shall make available to the Federal agency the draft biological opinion for the purpose of analyzing the reasonable and prudent alternatives. The 45-day period in which the biological opinion must be delivered will not be suspended unless the Federal agency secures the written consent of the applicant to an extension to a specific date. The applicant may request a copy of the draft opinion from the Federal agency. All comments on the draft biological opinion must be submitted to the Service through the Federal agency, although the applicant

may send a copy of its comments directly to the Service. The Service will not issue its biological opinion prior to the 45-day or extended deadline while the draft is under review by the Federal agency. However, if the Federal agency submits comments to the Service regarding the draft biological opinion within 10 days of the deadline for issuing the opinion, the Service is entitled to an automatic 10-day extension on the deadline.

(6) Formulate discretionary conservation recommendations, if any, which will assist the Federal agency in reducing or eliminating the impacts that its proposed action may have on listed species or critical habitat.

(7) Formulate a statement concerning incidental take, if such take is reasonably certain to occur.

(8) In formulating its biological opinion, any reasonable and prudent alternatives, and any reasonable and prudent measures, the Service will use the best scientific and commercial data available and will give appropriate consideration to any beneficial actions as proposed or taken by the Federal agency or applicant, including any actions taken prior to the initiation of consultation. Measures included in the proposed action or a reasonable and prudent alternative that are intended to avoid, minimize, or offset the effects of an action are considered like other portions of the action and do not require any additional demonstration of binding plans.

(h) *Biological opinions.* (1) The biological opinion shall include:

(i) summary of the information on which the opinion is based;

(ii) A detailed discussion of the environmental baseline of the listed species and critical habitat;

(iii) detailed discussion of the effects of the action on listed species or critical habitat; and

(iv) The Service's opinion on whether the action is:

(A) Likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "jeopardy" biological opinion); or

(B) Not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "no jeopardy" biological opinion).

(2) A "jeopardy" biological opinion shall include reasonable and prudent alternatives, if any. If the Service is unable to develop such alternatives, the Service will indicate that to the best of its knowledge there are no reasonable and prudent alternatives.

…

(i) *Incidental take.* (1) In those cases where the Service concludes that an action (or the implementation of any reasonable and prudent alternatives) and the resultant incidental take of listed species will not violate section 7(a)(2), and, in the case of marine mammals, where the taking is authorized pursuant to section 101(a)(5) of the Marine Mammal Protection Act of 1972, the Service will provide with the biological opinion a statement concerning incidental take that:

(i) Specifies the impact, *i.e.,* the amount or extent, of such incidental taking on the species (A surrogate (*e.g.,* similarly affected species or habitat or ecological conditions) may be used to express the amount or extent of anticipated take provided that the biological opinion or incidental take statement: Describes the causal link between the surrogate and take of the listed species, explains why it is not practical to express the amount or extent of anticipated take or to monitor take-related impacts in terms of individuals of the listed species, and sets a clear standard for determining when the level ii anticipated take has been exceeded.);

(ii) Specifies those reasonable and prudent measures that the Director considers necessary or appropriate to minimize such impact;

(iii) In the case of marine mammals, specifies those measures that are necessary to comply with section 101(a)(5) of the Marine Mammal Protection Act of 1972 and applicable regulations with regard to such taking;

(iv) Sets forth the terms and conditions (including, but not limited to, reporting requirements) that must be complied with by the Federal agency or

any applicant to implement the measures specified under paragraphs (i)(1)(ii) and (i)(1)(iii) of this section; and

(v) Specifies the procedures to be used to handle or dispose of any individuals of a species actually taken.

(2) Reasonable and prudent measures, along with the terms and conditions that implement them, cannot alter the basic design, location, scope, duration, or timing of the action and may involve only minor changes.

…

5 U.S.C. §706. Scope of Review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2)hold unlawful and set aside agency action, findings, and conclusions found to be—

(A)arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B)contrary to constitutional right, power, privilege, or immunity;

(C)in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D)without observance of procedure required by law;

(E)unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F)unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

16 U.S.C. §1536. Interagency cooperation

(a) Federal agency actions and consultations

…

(2) Each Federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency (hereinafter in this section referred to as an "agency action") is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species which is determined by the Secretary, after consultation as appropriate with affected States, to be critical, unless such agency has been granted an exemption for such action by the Committee pursuant to subsection (h) of this section. In fulfilling the requirements of this paragraph each agency shall use the best scientific and commercial data available.

…

(4) Each Federal agency shall confer with the Secretary on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under section 1533 of this title or result in the destruction or adverse modification of critical habitat proposed to be designated for such species. This paragraph does not require a limitation on the commitment of resources as described in subsection (d).

(b) Opinion of Secretary

…

(3)(A) Promptly after conclusion of consultation under paragraph (2) or (3) of subsection (a), the Secretary shall provide to the Federal agency and the applicant, if any, a written statement setting forth the Secretary's opinion, and a summary of the information on which the opinion is based, detailing how the agency action affects the species or its critical habitat. If jeopardy or adverse modification is found, the Secretary shall suggest those reasonable and prudent alternatives which he believes would not violate subsection (a)(2) and can be taken by the Federal agency or applicant in implementing the agency action.

…

(4) If after consultation under subsection (a)(2), the Secretary concludes that—

(A) the agency action will not violate such subsection, or offers reasonable and prudent alternatives which the Secretary believes would not violate such subsection;

(B) the taking of an endangered species or a threatened species incidental to the agency action will not violate such subsection; and

(C) if an endangered species or threatened species of a marine mammal is involved, the taking is authorized pursuant to section 1371(a)(5) of this title;

the Secretary shall provide the Federal agency and the applicant concerned, if any, with a written statement that—

(i) specifies the impact of such incidental taking on the species,

(ii) specifies those reasonable and prudent measures that the Secretary considers necessary or appropriate to minimize such impact,

(iii) in the case of marine mammals, specifies those measures that are necessary to comply with section 1371(a)(5) of this title with regard to such taking, and

(iv) sets forth the terms and conditions (including, but not limited to, reporting requirements) that must be complied with by the Federal agency or applicant (if any), or both, to implement the measures specified under clauses (ii) and (iii).

…

(e) Endangered Species Committee

(1) There is established a committee to be known as the Endangered Species Committee (hereinafter in this section referred to as the "Committee").

(2) The Committee shall review any application submitted to it pursuant to his section and determine in accordance with subsection (h) of this section whether or

not to grant an exemption from the requirements of subsection (a)(2) of this section for the action set forth in such application.

(3) The Committee shall be composed of seven members as follows:

(A) The Secretary of Agriculture.

(B) The Secretary of the Army.

(C) The Chairman of the Council of Economic Advisors.

(D) The Administrator of the Environmental Protection Agency.

(E) The Secretary of the Interior.

(F) The Administrator of the National Oceanic and Atmospheric Administration.

(G) The President, after consideration of any recommendations received pursuant to subsection (g)(2)(B) shall appoint one individual from each affected State, as determined by the Secretary, to be a member of the Committee for the consideration of the application for exemption for an agency action with respect to which such recommendations are made, not later than 30 days after an application is submitted pursuant to this section.

…

(g) Application for exemption; report to Committee

(1) A Federal agency, the Governor of the State in which an agency action will occur, if any, or a permit or license applicant may apply to the Secretary for an exemption for an agency action of such agency if, after consultation under subsection (a)(2), the Secretary's opinion under subsection (b) indicates that the agency action would violate subsection (a)(2). An application for an exemption shall be considered initially by the Secretary in the manner provided for in this subsection, and shall be considered by the Committee for a final determination under subsection (h) after a report is made pursuant to paragraph (5). The applicant for an exemption shall be referred to as the "exemption applicant" in this section.

(2)(A) An exemption applicant shall submit a written application to the Secretary, in a form prescribed under subsection (f), not later than 90 days after the completion of the consultation process; except that, in the case of any agency action involving a permit or license applicant, such application shall be submitted not later than 90 days after the date on which the Federal agency concerned takes final agency action with respect to the issuance of the permit or license. For purposes of the preceding sentence, the term "final agency action" means (i) a disposition by an agency with respect to the issuance of a permit or license that is subject to administrative review, whether or not such disposition is subject to judicial review; or (ii) if administrative review is sought with respect to such disposition, the decision resulting after such review. Such application shall set forth the reasons why the exemption applicant considers that the agency action meets the requirements for an exemption under this subsection.

(B) Upon receipt of an application for exemption for an agency action under paragraph (1), the Secretary shall promptly (i) notify the Governor of each affected State, if any, as determined by the Secretary, and request the Governors so notified to recommend individuals to be appointed to the Endangered Species Committee for consideration of such application; and (ii) publish notice of receipt of the application in the Federal Register, including a summary of the information contained in the application and a description of the agency action with respect to which the application for exemption has been filed.

(3) The Secretary shall within 20 days after the receipt of an application for exemption, or within such other period of time as is mutually agreeable to the exemption applicant and the Secretary—

(A) determine that the Federal agency concerned and the exemption applicant have—

(i) carried out the consultation responsibilities described in subsection (a) in good faith and made a reasonable and responsible effort to develop and fairly consider modifications or reasonable and prudent alternatives to the proposed agency action which would not violate subsection (a)(2);

(ii) conducted any biological assessment required by subsection (c); and

(iii) to the extent determinable within the time provided herein, refrained from making any irreversible or irretrievable commitment of resources prohibited by subsection (d); or

(B) deny the application for exemption because the Federal agency concerned or the exemption applicant have not met the requirements set forth in subparagraph (A)(i), (ii), and (iii).

The denial of an application under subparagraph (B) shall be considered final agency action for purposes of chapter **7** of title 5.

(4) If the Secretary determines that the Federal agency concerned and the exemption applicant have met the requirements set forth in paragraph (3)(A)(i), (ii), and (iii) he shall, in consultation with the Members of the Committee, hold a hearing on the application for exemption in accordance with sections 554, 555, and 556 (other than subsection (b)(1) and (2) thereof) of title 5 and prepare the report to be submitted pursuant to paragraph (5).

(5) Within 140 days after making the determinations under paragraph (3) or within such other period of time as is mutually agreeable to the exemption applicant and the Secretary, the Secretary shall submit to the Committee a report discussing—

(A) the availability of reasonable and prudent alternatives to the agency action, and the nature and extent of the benefits of the agency action and of alternative courses of action consistent with conserving the species or the critical habitat;

(B) a summary of the evidence concerning whether or not the agency action is in the public interest and is of national or regional significance;

(C) appropriate reasonable mitigation and enhancement measures which should be considered by the Committee; and

(D) whether the Federal agency concerned and the exemption applicant refrained from making any irreversible or irretrievable commitment of resources prohibited by subsection (d).

…

(h) Grant of exemption

(1) The Committee shall make a final determination whether or not to grant an exemption within 30 days after receiving the report of the Secretary pursuant to subsection (g)(5). The Committee shall grant an exemption from the requirements of subsection (a)(2) for an agency action if, by a vote of not less than five of its members voting in person—

(A) it determines on the record, based on the report of the Secretary, the record of the hearing held under subsection (g)(4) and on such other testimony or evidence as it may receive, that—

(i) there are no reasonable and prudent alternatives to the agency action;

(ii) the benefits of such action clearly outweigh the benefits of alternative courses of action consistent with conserving the species or its critical habitat, and such action is in the public interest;

(iii) the action is of regional or national significance; and

(iv) neither the Federal agency concerned nor the exemption applicant made any irreversible or irretrievable commitment of resources prohibited by subsection (d); and

(B) it establishes such reasonable mitigation and enhancement measures, including, but not limited to, live propagation, transplantation, and habitat acquisition and improvement, as are necessary and appropriate to minimize the adverse effects of the agency action upon the endangered species, threatened species, or critical habitat concerned.

Any final determination by the Committee under this subsection shall be considered final agency action for purposes of chapter 7 of title 5.

…

50 C.F.R. § 216.3. Definitions.

In addition to definitions contained in the MMPA, and unless the context otherwise requires, in this part 216:

. . .

Serious injury means any injury that will likely result in mortality.

. . .

50 C.F.R. §402.14 Formal consultation.

…

(g) *Service responsibilities.* Service responsibilities during formal consultation are as follows:

(1) Review all relevant information provided by the Federal agency or otherwise available. Such review may include an on-site inspection of the action area with representatives of the Federal agency and the applicant.

(2) Evaluate the current status and environmental baseline of the listed species or critical habitat.

(3) Evaluate the effects of the action and cumulative effects on the listed species or critical habitat.

(4) Add the effects of the action and cumulative effects to the environmental baseline and in light of the status of the species and critical habitat, formulate the Service's opinion as to whether the action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

(5) Discuss with the Federal agency and any applicant the Service's review and evaluation conducted under paragraphs (g)(1) through (3) of this section, the basis for any finding in the biological opinion, and the availability of reasonable and prudent alternatives (if a jeopardy opinion is to be issued) that the agency and the applicant can take to avoid violation of section 7(a)(2). The Service will utilize the expertise of the Federal agency and any applicant in identifying these alternatives. If requested, the Service shall make available to the Federal agency the draft biological opinion for the purpose of analyzing the reasonable and prudent alternatives. The 45-day period in which the biological opinion must be delivered will not be suspended unless the Federal agency secures the written consent of the applicant to an extension to a specific date. The applicant may request a copy of the draft opinion from the Federal agency. All comments on the draft biological opinion must be submitted to the Service through the Federal agency, although the applicant may send a copy of its comments directly to the Service. The Service will not issue its biological opinion prior to the 45-day or extended deadline while the draft is

under review by the Federal agency. However, if the Federal agency submits comments to the Service regarding the draft biological opinion within 10 days of the deadline for issuing the opinion, the Service is entitled to an automatic 10-day extension on the deadline.

(6) Formulate discretionary conservation recommendations, if any, which will assist the Federal agency in reducing or eliminating the impacts that its proposed action may have on listed species or critical habitat.

(7) Formulate a statement concerning incidental take, if such take is reasonably certain to occur.

(8) In formulating its biological opinion, any reasonable and prudent alternatives, and any reasonable and prudent measures, the Service will use the best scientific and commercial data available and will give appropriate consideration to any beneficial actions as proposed or taken by the Federal agency or applicant, including any actions taken prior to the initiation of consultation. Measures included in the proposed action or a reasonable and prudent alternative that are intended to avoid, minimize, or offset the effects of an action are considered like other portions of the action and do not require any additional demonstration of binding plans.

(h) *Biological opinions.* (1) The biological opinion shall include:

(i) summary of the information on which the opinion is based;

(ii) A detailed discussion of the environmental baseline of the listed species and critical habitat;

(iii) detailed discussion of the effects of the action on listed species or critical habitat; and

(iv) The Service's opinion on whether the action is:

(A) Likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "jeopardy" biological opinion); or

(B) Not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "no jeopardy" biological opinion).

(2) A "jeopardy" biological opinion shall include reasonable and prudent alternatives, if any. If the Service is unable to develop such alternatives, the Service will indicate that to the best of its knowledge there are no reasonable and prudent alternatives.

…

(i) *Incidental take.* (1) In those cases where the Service concludes that an action (or the implementation of any reasonable and prudent alternatives) and the resultant incidental take of listed species will not violate section 7(a)(2), and, in the case of marine mammals, where the taking is authorized pursuant to section 101(a)(5) of the Marine Mammal Protection Act of 1972, the Service will provide with the biological opinion a statement concerning incidental take that:

(i) Specifies the impact, *i.e.,* the amount or extent, of such incidental taking on the species (A surrogate (*e.g.,* similarly affected species or habitat or ecological conditions) may be used to express the amount or extent of anticipated take provided that the biological opinion or incidental take statement: Describes the causal link between the surrogate and take of the listed species, explains why it is not practical to express the amount or extent of anticipated take or to monitor take-related impacts in terms of individuals of the listed species, and sets a clear standard for determining when the level ii anticipated take has been exceeded.);

(ii) Specifies those reasonable and prudent measures that the Director considers necessary or appropriate to minimize such impact;

(iii) In the case of marine mammals, specifies those measures that are necessary to comply with section 101(a)(5) of the Marine Mammal Protection Act of 1972 and applicable regulations with regard to such taking;

(iv) Sets forth the terms and conditions (including, but not limited to, reporting requirements) that must be complied with by the Federal agency or

any applicant to implement the measures specified under paragraphs (i)(1)(ii) and (i)(1)(iii) of this section; and

(v) Specifies the procedures to be used to handle or dispose of any individuals of a species actually taken.

(2) Reasonable and prudent measures, along with the terms and conditions that implement them, cannot alter the basic design, location, scope, duration, or timing of the action and may involve only minor changes.

…

50 C.F.R. §402.17 Other provisions.

(a) *Activities that are reasonably certain to occur.* A conclusion of reasonably certain to occur must be based on clear and substantial information, using the best scientific and commercial data available. Factors to consider when evaluating whether activities caused by the proposed action (but not part of the proposed action) or activities reviewed under cumulative effects are reasonably certain to occur include, but are not limited to:

(1) Past experiences with activities that have resulted from actions that are similar in scope, nature, and magnitude to the proposed action;

(2) Existing plans for the activity; and

(3) Any remaining economic, administrative, and legal requirements necessary for the activity to go forward.

(b) *Consequences caused by the proposed action.* To be considered an effect of a proposed action, a consequence must be caused by the proposed action (*i.e.,* the consequence would not occur but for the proposed action and is reasonably certain to occur). A conclusion of reasonably certain to occur must be based on clear and substantial information, using the best scientific and commercial data available. Considerations for determining that a consequence to the species or critical habitat is not caused by the proposed action include, but are not limited to:

(1) The consequence is so remote in time from the action under consultation that it is not reasonably certain to occur; or

(2) The consequence is so geographically remote from the immediate area involved in the action that it is not reasonably certain to occur; or

(3) The consequence is only reached through a lengthy causal chain that involves so many steps as to make the consequence not reasonably certain to occur.

(c) *Required consideration.* The provisions in paragraphs (a) and (b) of this section must be considered by the action agency and the Services.