

IN RE OCEAN ERA, INC.

NPDES Appeal Nos. 20-08 & 20-09

ORDER REMANDING IN PART AND DENYING REVIEW IN PART

Decided May 6, 2022

Syllabus

This matter involves two petitions for review of a National Pollutant Discharge Elimination System permit that the Environmental Protection Agency, Region 4, issued to Ocean Era, Inc. pursuant to the Clean Water Act. The permit authorizes discharges from a pilot-scale offshore marine aquaculture facility, referred to as the Vellella Epsilon Project, into the Gulf of Mexico.

Taken together, the two petitions argue that the Region's permit decision violates the Clean Water Act, the Endangered Species Act, the National Environmental Policy Act, and the Marine Mammal Protection Act. For all the reasons described, the Environmental Appeals Board denies review in part and remands in part.

Held: The Board remands the permit decision to the Region to clearly state whether the Region determined that the permitted discharge will not cause unreasonable degradation of the marine environment. The Board denies review of all other issues raised. Specific holdings are as follows:

(A) With respect to the Marine Mammal Protection Act and the National Environmental Policy Act, Petitioners have not met their threshold obligations under 40 C.F.R. § 124.19(a) to preserve their arguments for review. As such, the Board denies review of the issues raised under these statutes.

(B) With respect to the Clean Water Act, the implementing regulations require the permitting authority to determine whether a discharge will cause unreasonable degradation of the marine environment based on consideration of ten enumerated factors listed in the regulations applicable to ocean discharges—the Ocean Discharge Criteria. The Region based its unreasonable degradation determination on its consideration of the ten factors, including the potential impacts of the pollutants identified by Petitioners. More specifically, Petitioners did not meet their burden to show that the Region clearly erred in considering: (1) the threat to human health where the Region considered the project's potential contribution to harmful algal blooms and concluded that the discharge of nutrients

from the proposed facility would not pose an environmental threat; (2) the potential impact from antibiotics discharged from the proposed facility where the Region concluded that antibiotics would not likely be used and, if they were, the concentrations of antibiotics outside the immediate proximity of the fish pens would be too low to have any adverse effects; (3) the potential impacts from pathogens and parasites from the facility where the Region considered the impacts and concluded that the permit conditions in place would eliminate the low risk of harm; (4) the possibility of fish escapes as a potential discharge from the permitted facility; and (5) whether copper cages would create an issue for ocean water or marine life where the Region concluded that copper was not expected to occur in measurable levels in the facility's effluent. Additionally, because the Region determined there was sufficient information to make the required determination and issued the permit under 40 C.F.R. § 125.123(a), the Region was not required to include the permit conditions set forth in 40 C.F.R. § 125.123(d).

The Region however, stated two different things in the conclusion of its evaluation with respect to whether the proposed project would cause unreasonable degradation of the marine environment. One sentence indicates that permitted discharges will not cause unreasonable degradation; the other concludes that unreasonable degradation is "not likely" to occur. Under federal regulations, it is the former determination that the Region is required to make when issuing the permit at issue. Consequently, as stated above, the Board remands the permit to the Region to formally clarify its determination.

(C) With respect to the Endangered Species Act, the Board determines that the Region did not clearly err in its consideration of the proposed permit. Based on its review of the record as a whole, the Board determined that the Region considered the issues raised by Petitioners in assessing the potential effects and impacts from the proposed action on listed species and critical habitat and concluded that the proposed action "will have 'no effect' on listed species and critical habitat under the jurisdiction of [FWS]" and the proposed action "'may affect but is not likely to adversely' affect the listed species and critical habitat" under the jurisdiction of NMFS. That determination was reviewed and considered by the Fish and Wildlife Service and the National Marine Fisheries Service—and Petitioners have not provided the Board with a sufficient basis to further question the complex and comprehensive technical and scientific analysis and expertise of these consulting agencies.

Before Environmental Appeals Judges Aaron P. Avila, Mary Kay Lynch, and Kathie A. Stein.

Opinion of the Board by Judge Stein:

I. *STATEMENT OF THE CASE*

The U.S. Environmental Protection Agency ("EPA") Region 4 ("Region") issued a Clean Water Act ("CWA") National Pollutant Discharge Elimination System ("NPDES") permit to Ocean Era, Inc. ("Ocean Era"). The permit

authorizes Ocean Era to discharge from a pilot-scale offshore marine aquaculture facility, referred to as the Vellella Epsilon Project (“Facility”), in the Gulf of Mexico, approximately forty-five miles off the coast of Sarasota, Florida, pursuant to CWA sections 402 and 403, 33 U.S.C. §§ 1342-1343. *See* EPA Region 4, *Ocean Era Inc., NPDES Permit No. FLOA00001* (Sept. 30, 2020) (A.R. B.40) (“Permit”); *see also* Region’s Resp. to CFS Pet. at 1-2.

A consortium of groups consisting of the Center for Food Safety, Friends of the Earth, Recirculating Farms, Tampa Bay Waterkeeper, Suncoast Waterkeeper, Healthy Gulf, Sierra Club Florida, the Center for Biological Diversity, and Food & Water Watch filed a petition for review (“CFS Petition”) of the Region’s permitting decision with the Environmental Appeals Board (“Board”). Friends of Animals also filed a petition for review with the Board (“FoA Petition”). Following briefing and a stay, oral argument was held.

II. ISSUES ON APPEAL

The two petitions present arguments that the Region’s permit decision violates the CWA, 33 U.S.C. §§ 1251-1387, the Endangered Species Act (“ESA”), 16 U.S.C. §§ 1531-1544, the National Environmental Policy Act (“NEPA”), 42 U.S.C. §§ 4321-4370, and the Marine Mammal Protection Act (“MMPA”), 16 U.S.C. §§ 1361-1423h. Based on our review of the briefs filed in this matter as well as the Administrative Record, we consider the following issues on appeal:

- 1) With respect to the MMPA and NEPA, whether Petitioners¹ met their threshold obligations to (a) preserve their arguments for review, (b) state with specificity their arguments on appeal, and (c) address the Region’s responses to comments that were submitted during the public comment period in accordance with 40 C.F.R. section 124.19(a)(4);
- 2) Whether the Region clearly erred in evaluating the proposed project’s discharge under the Ocean Discharge Criteria of the CWA; and
- 3) Whether the Region clearly erred in its consideration of the Permit under the ESA.

¹ Only the CFS petition raises a challenge to the Permit under the MMPA. *See* CFS Pet. at 54; *see generally* FoA Pet.

III. STANDARD OF REVIEW

The Board has discretion to grant or deny review of a permit decision. 40 C.F.R. § 124.19; *see also In re Avenal Power Ctr., LLC*, 15 E.A.D. 384, 394-95 (EAB 2011) (*citing* Consolidated Permit Regulations, 45 Fed. Reg. 33,290, 33,412 (May 19, 1980)), *remanded on other grounds sub nom. Sierra Club v. EPA*, 762 F.3d 971 (9th Cir. 2014). Ordinarily, the Board will deny review of a permit decision and thus not remand it unless the permit decision either is based on a clearly erroneous finding of fact or conclusion of law or involves a matter of policy or exercise of discretion that warrants review. 40 C.F.R. § 124.19(a)(4)(i)(A)-(B); *accord, e.g., In re Prairie State Generating Co.*, 13 E.A.D. 1, 10 (EAB 2006), *aff'd sub nom. Sierra Club v. EPA*, 499 F.3d 653 (7th Cir. 2007); *see also* Revisions to Procedural Rules to Clarify Practices and Procedures Applicable in Permit Appeals Pending Before the EAB, 78 Fed. Reg. 5,281, 5,282, 5,284 (Jan. 25, 2013). In considering whether to grant or deny review of a permit decision, the Board is guided by the preamble to the regulations authorizing appeal under part 124, in which the Agency stated that the Board's power to grant review "should be only sparingly exercised," and that "most permit conditions should be finally determined at the [permit issuer's] level." 45 Fed. Reg. at 33,412.

When evaluating a challenged permit decision for clear error, the Board examines the administrative record that serves as the basis for the permit to determine whether the permit issuer exercised its "considered judgment." *E.g., In re Steel Dynamics, Inc.*, 9 E.A.D. 165, 191, 224-25 (EAB 2000); *In re Ash Grove Cement Co.*, 7 E.A.D. 387, 417-18 (EAB 1997). The permit issuer must articulate with reasonable clarity the reasons supporting its conclusion and the significance of the crucial facts it relied upon when reaching its conclusion. *E.g., In re Shell Offshore, Inc.*, 13 E.A.D. 357, 386 (EAB 2007) (*citing In re Carolina Power & Light Co.*, 1 E.A.D. 448, 451 (Acting Adm'r 1978) (some citations omitted)). As a whole, the record must demonstrate that the permit issuer "duly considered the issues raised in the comments" and ultimately adopted an approach that "is rational in light of all information in the record." *In re D.C. Mun. Separate Storm Sewer Sys.*, 10 E.A.D. 323, 342 (EAB 2002); *accord In re City of Moscow*, 10 E.A.D. 135, 142 (EAB 2001); *In re NE Hub Partners, L.P.*, 7 E.A.D. 561, 567-68 (EAB 1998), *review denied sub nom. Penn Fuel Gas, Inc. v. EPA*, 185 F.3d 862 (3d Cir. 1999).

Similarly, the Board will uphold a permitting authority's reasonable exercise of discretion if that decision is cogently explained and supported in the record. *See, e.g., In re Guam Waterworks Auth.*, 15 E.A.D. 437, 443 n.7 (EAB 2011) (discussing the abuse of discretion standard); *Ash Grove*, 7 E.A.D. at 397 ("[A]cts of discretion must be adequately explained and justified.").

On matters that are fundamentally technical or scientific in nature, the Board will defer to a permit issuer’s technical expertise and experience, as long as the permit issuer adequately explains its rationale and supports its reasoning in the administrative record. *See In re Dominion Energy Brayton Point, LLC, (Formerly USGEN New England, Inc.) Brayton Point Station*, 12 E.A.D. 490, 510, 560-62, 645-47, 668, 670-74 (EAB 2006); *see also, e.g., In re Russell City Energy Ctr.*, 15 E.A.D. 1, 12, 39-42, 60-66 (EAB 2010), *petition denied sub nom. Chabot-Las Positas Cmty. Coll. Dist. v. EPA*, 482 F. App’x 219 (9th Cir. 2012); *NE Hub Partners*, 7 E.A.D. at 570-71.

IV. RELEVANT STATUTORY AND REGULATORY REQUIREMENTS

A. *The Clean Water Act*

Congress enacted the CWA in 1972 “to restore and maintain the chemical, physical, and biological integrity of the Nation’s waters.” CWA § 101(a), 33 U.S.C. § 1251(a). To achieve this objective, the Act prohibits the discharge of pollutants into the waters of the United States, unless authorized by an NPDES permit or other specified CWA provision. *See* CWA §§ 301(a), 402, 502(7), 33 U.S.C. §§ 1311(a), 1342, 1362(7). Section 403 of the CWA, 33 U.S.C. § 1343—entitled Ocean Discharge Criteria—addresses the issuance of NPDES permits for discharges into the territorial sea, the waters of the contiguous zone, or the oceans. In that provision of the CWA, Congress directed EPA to “promulgate guidelines for determining the degradation” of these types of waters.² CWA § 403(c)(1), 33 U.S.C. § 1343(c)(1). EPA promulgated those guidelines, and having done so, the CWA provides that no NPDES permit for a discharge into federal waters shall be issued, except in compliance with the promulgated guidelines. CWA § 403(a), (c), 33 U.S.C. § 1343(a), (c). Thus, while referred to as “guidelines,” they are not simply guidance; they are regulations with which the permit issuer must comply. *Id.*; *see also* Ocean Discharge Criteria, 45 Fed. Reg. 65,942, 65, 944 (Oct. 3, 1980).

Under the regulations (also entitled Ocean Discharge Criteria), EPA must determine “whether a discharge will cause unreasonable degradation of the marine environment.” 40 C.F.R. § 125.122. “If the [permitting authority] on the basis of available information including that supplied by the applicant pursuant to § 125.124 determines prior to permit issuance that the discharge will not cause unreasonable

² Throughout this decision we use the phrase “federal waters” to refer to the territorial sea, the waters of the contiguous zone, or the oceans over which EPA has jurisdiction under the CWA.

degradation of the marine environment after application of any necessary conditions specified in § 125.123(d), [the permitting authority] may issue an NPDES permit containing such conditions.” *Id.* § 125.123(a). “Unreasonable degradation of the marine environment is defined as:

- (1) Significant adverse changes in ecosystem diversity, productivity[,], and stability of the biological community within the area of discharge and surrounding biological communities,
- (2) Threat to human health through direct exposure to pollutants or through consumption of exposed aquatic organisms, or
- (3) Loss of esthetic, recreational, scientific[,], or economic values which is unreasonable in relation to the benefit derived from the discharge.

Id. § 125.121(e). The regulations then provide that the permitting authority “shall determine whether a discharge will cause unreasonable degradation of the marine environment based on consideration of” ten enumerated factors (the “ODC factors”). *Id.* § 125.122(a). Other relevant provisions related to the Ocean Discharge Criteria under the CWA are further discussed in Part VI.B, below.

B. *The Endangered Species Act*

Pursuant to the NPDES regulations, the Region is required to comply with several potentially relevant federal statutes when issuing NPDES permits. *See* 40 C.F.R. § 122.49 (listing federal laws that may apply to NPDES permits and providing that when any of the listed laws is applicable, its procedures “must be followed”); *see also In re Phelps Dodge Corp.*, 10 E.A.D. 460, 464, 522-525 (EAB 2002) (remanding an NPDES permit to the region for further proceedings under the ESA). The NPDES permit regulations specifically refer to the Regional Administrator’s duty under section 7 of the ESA—i.e., “to ensure, in consultation with the Secretary of the Interior or Commerce,³ that any action authorized by EPA

³ The ESA grants authority to two executive departments to implement its major provisions. More specifically, the Secretary of the Interior, whose ESA authority is exercised by the U.S. Fish and Wildlife Service (“FWS”), has jurisdiction over terrestrial and freshwater aquatic species under the ESA. The Secretary of Commerce has jurisdiction over marine species under the ESA, and the National Marine Fisheries Service (“NMFS”) acts on the Secretary of Commerce’s behalf in this regard. *See* ESA §§ 3(15), 4, 16 U.S.C. §§ 1532(15), 1533. Because these agencies—FWS and NMFS—act based on statutory

is not likely to jeopardize the continued existence of any endangered or threatened species or adversely affect its critical habitat.” 40 C.F.R. § 122.49(c); *see also* ESA § 7, 16 U.S.C. § 1536 (and implementing regulations at 50 C.F.R. pt. 402).

The ESA regulations provide a process for federal agencies to fulfill their obligations under section 7. *See generally* 50 C.F.R. § 402. This process requires federal agencies to determine whether a proposed action “may affect” listed⁴ species or designated critical habitat⁵ in a particular geographical area. *Id.* § 402.14(a) (“Each [f]ederal agency shall review its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat.”); *see also Phelps Dodge*, 10 E.A.D. at 485-86. A biological assessment, also referred to as a biological evaluation, evaluates the potential effects of the proposed action and determines whether the action is “likely to adversely affect” any listed species or critical habitat. 50 C.F.R. § 402.12; *see also Phelps Dodge*, 10 E.A.D. at 486. If

authority under the ESA, they are sometimes referred to as the federal “experts” on the ESA.

⁴ A “listed species” is “any species of fish, wildlife, or plant [that] has been determined to be endangered or threatened under section 4 of the [ESA].” 50 C.F.R. § 402.02. Species currently on the endangered and threatened lists are set forth in 50 C.F.R. §§ 17.11-.12. A biological assessment must evaluate the potential effects of the action on both listed species and species proposed to be listed (i.e., proposed in the Federal Register to be listed under section 4 of the ESA). *Id.* §§ 402.02 (defining “proposed species”), 402.12(a) (identifying the purpose of the biological assessment to include the consideration of “proposed species”). For ease of discussion, the term “listed species” used in this opinion in the context of discussing the biological assessment includes both those species listed and those proposed to be listed as endangered or threatened under the ESA.

⁵ The ESA encourages critical habitats be designated concurrently with the listing of a species as endangered or threatened. *See* 16 U.S.C. § 1533(b)(6)(C). A “critical habitat” is any area designated as critical habitat listed in 50 C.F.R. parts 17 or 226. *See* 50 C.F.R. § 424.12 (providing criteria for designating critical habitat). Habitat, “for the purposes of designating critical habitat only, is the abiotic and biotic setting that currently or periodically contains the resources and conditions necessary to support one or more life processes of a species.” *Id.* § 424.02. As is the case with species, a biological assessment must evaluate the potential effects of the action on both designated critical habitat and proposed to be designated critical habitat. *See id.* § 402.12(a). For ease of discussion, the term “critical habitat” used in this opinion in the context of discussing the biological assessment includes designated critical habitats and those proposed to be designated under the ESA.

an agency determines in its biological assessment that its proposed action will have no effect on any listed species or critical habitat in the action area or is “not likely to adversely affect” such species or habitat (sometimes referred to as an “NLAA” determination), the agency seeks the concurrence of the appropriate consulting agencies—i.e., the Fish and Wildlife Service (“FWS”) or National Marine Fisheries Service (“NMFS”)—through “informal” consultation. 50 C.F.R. §§ 402.12(j)-(k), 402.13. If the agency receives written concurrence from the consulting agencies on its determination, then the section 7 process is complete. *Id.* §§ 402.12(k); 402.13(c); 402.14(a)-(b)(1); *see Phelps Dodge*, 10 E.A.D. at 486 n.24.⁶ Relevant portions of the ESA and its implementing regulations are discussed further in Part VI.C, below.

C. *The National Environmental Policy Act*

NEPA requires federal agencies, in proposals for any “major [f]ederal actions significantly affecting the quality of the human environment,” to include a “detailed statement” discussing, among other things, the environmental impacts of, and the alternatives to, the proposed actions. NEPA § 102(C), 42 U.S.C. § 4332(2)(C). This detailed statement is known as an environmental impact statement (“EIS”). 40 C.F.R. § 1502.3. When NEPA is applicable to an agency action, but the agency determines that the action is not likely to have significant effects (or when the significance of the effects is unknown), the agency prepares an “environmental assessment,” or “EA.” *Id.* § 1501.5(a). An environmental assessment provides “evidence and analysis” to determine whether the action has a significant effect and requires an EIS or has no significant effect and warrants a finding of no significant impact (“FONSI”). *See id.* §§ 1501.5(c)(1), 1508.1(h). Because NEPA requires an EIS only when an action significantly affects the quality of the human environment, a FONSI concludes the NEPA process. *See id.* § 1508.1(l).

⁶ Although not relevant in this matter, if the Agency determines that a project “is likely to have an adverse effect” on a listed species or critical habitat, then the Agency must begin “formal” consultation with FWS or NMFS. ESA § 7(a), 16 U.S.C. § 1536(a); 50 C.F.R. § 402.14. This requires, among other things, the submission by the action agency of the “best scientific and commercial data available,” and culminates in the issuance of a “biological opinion” (not to be confused with the “biological assessment” described in the text above) by the consulting agency(ies) as to whether the proposed agency action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat. *See, e.g.*, 50 C.F.R. § 402.14.

That said, actions by EPA under the CWA (with limited exceptions) are exempt from NEPA and NEPA's requirements. CWA § 511(c)(1), 33 U.S.C. § 1371(c)(1) ("Except for the provision of [f]ederal financial assistance for the purpose of assisting the construction of publicly owned treatment works as authorized by section 1281 of [the CWA], and the issuance of a permit under section 1342 * * * for the discharge of any pollutant by a new source as defined in section 1316 * * *, no action of the Administrator taken pursuant to [the CWA] shall be deemed a major [f]ederal action significantly affecting the quality of the human environment within the meaning of the [NEPA] of 1969.")

For purposes of this appeal, the only potentially relevant exception from the CWA exemption from NEPA relates to a permit for the discharge of a pollutant from a "new source," as defined by 33 U.S.C. section 1316. *See id.*; *accord In re Dos Republicas Res. Co.*, 6 E.A.D. 643, 648 (EAB 1996) (explaining that permitting actions under the CWA are generally not regarded as major federal actions under NEPA with an exception for NPDES permits for new sources as mandated by section 511(c)(1) of the CWA). The applicability of NEPA to this permit proceeding is discussed further in Part VI.A.2, below.

D. *The Marine Mammal Protection Act*

The MMPA protects and conserves marine mammals, in part, by prohibiting the "take" of marine mammals without authorization. MMPA § 102, 16 U.S.C. § 1372. The term "take" "means to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal." *Id.* § 1362(13). Under the MMPA, NMFS, as an office within the National Oceanic Atmospheric Administration ("NOAA"), may authorize the incidental "taking" of marine mammals. *See id.* §§ 1371(a)(5)(E), 1374(a). For example, the MMPA requires an owner of a vessel engaging in commercial fishing operations to obtain authorization from NMFS prior to conducting activities that result in any incidental "takes" of marine mammals. *See id.* § 1387(c)(2); 50 C.F.R. § 229.4. The issue concerning the MMPA in this appeal is discussed in Part VI.A.1, below.

V. *PROCEDURAL AND FACTUAL HISTORY*

The Region issues NPDES permits for discharges into the federal waters of the Gulf of Mexico. In October of 2018, Ocean Era submitted a complete application to the Region for an NPDES permit authorizing discharges (including fish food and fecal matter) from a proposed pilot-scale offshore "net-pen"

aquaculture facility—the Vellella Epsilon Facility—into the Gulf of Mexico.⁷ Region’s Resp. to CFS Pet. at 3; Kampachi Farms, LLC, *NPDES Permit Application in Support of the Vellella Epsilon Project* (Oct. 26, 2018) (A.R. A.1-.13). The project proposes to raise a species of fish called Almaco Jack, which is a type of yellow fin native to the Gulf of Mexico, starting with 20,000 fish (sourced from the Gulf) and producing up to 80,000 pounds of harvest fish over a period of 12-18 months. U.S. EPA, Region 4, Water Div., *Final Fact Sheet for NPDES Permit No. FLOA00001*, at 1 (A.R. B.15) (“Fact Sheet”); U.S. EPA, Region 4, Water Div., *Final Ocean Discharge Criteria Evaluation, for Ocean Era, Inc.—Vellella Epsilon, Permit FLOA00001*, at 6 (Sept. 30, 2020) (A.R. B.36) (“ODCE”).

The Facility includes a single submersed and floating cage constructed of mesh net, cylindrical in shape, seventeen meters in diameter across, seven meters high, and made of copper alloy (the “net-pen”). Fact Sheet at 1. The Facility was proposed to be submerged in approximately forty meters of water and anchored to the sea floor by up to three mooring lines using a “multi-anchor swivel” mooring system that allows the net-pen to drift freely in the water. *Id.* The proposal for the Facility also includes a supporting seventy-foot long “tender” vessel that would be tethered to the Facility and another vessel that would be used for harvest and transport of fish. *Id.*; ODCE at 6.

In the course of considering the Ocean Era permit application, the Region prepared an “Ocean Discharge Criteria Evaluation” document (“ODC Evaluation”) to “identify pertinent information relative to the [Ocean Discharge Criteria]” and to address the ten factors for determining unreasonable degradation. ODCE at 4, 5 (tbl.1.1) (identifying where in the document each factor was considered). The ODC Evaluation also includes a discussion of the permit conditions deemed necessary, as well as the Region’s conclusions as to whether the proposed discharge will cause unreasonable degradation of the marine environment. *Id.* at 48. The ODC Evaluation is discussed at length in Part VI.B.

Additionally, the Region (in consultation and coordination with the U.S. Army Corps of Engineers (“USACE”) and NMFS⁸) voluntarily prepared an

⁷ The construction and installation of the net-pen and anchoring system on the sea floor also required a permit from the U.S. Army Corps of Engineers (USACE) under section 10 of the River and Harbors Act, 33 U.S.C. § 403.

⁸ For purposes of NEPA, EPA acted as the lead agency with assistance from cooperating agencies NMFS and USACE. U.S. EPA, USACE, and National Oceanic and

environmental assessment after concluding that a NEPA analysis would be beneficial, even though the Region’s issuance of the NPDES permit for the project was not subject to NEPA’s requirements. U.S. EPA, USACE & NOAA, *DRAFT Environmental Assessment (EA), National Pollutant Discharge Elimination System (NPDES) Permit and Rivers and Harbor Act Section 10 Permit for Kampachi Farms –Velella Epsilon Offshore Aquaculture Project*, at 1 (Apr. 2019) (A.R. A.36) (“Draft EA”). The Draft EA preliminarily found that “the proposed action (issuance of an NPDES permit []) will not cause a significant impact on the environment.” *Id.* at 62.

To fulfill its obligations under section 7 of the ESA, the Region also consulted with NMFS and FWS to ensure that the proposed discharges authorized by the Permit would not be likely to jeopardize listed species or adversely modify critical habitat. Fact Sheet at 8. The Region and USACE⁹ prepared a draft biological assessment¹⁰ and submitted it to NMFS and FWS to initiate informal

Atmospheric Administration of the U.S. Dept. of Commerce (NOAA), *Final Environmental Assessment (EA), NPDES Permit for Ocean Era, Inc. –Velella Epsilon Offshore Aquaculture Project*, at 1 (Sept. 2020) (A.R. B.33) (“Final EA”). In addition to the cooperating agencies, EPA requested that the Bureau of Ocean Energy Management (BOEM), the FWS, the Bureau of Safety and Environmental Enforcement (BSEE), and the U.S. Coast Guard (USCG) contribute to the process as participating agencies. *Id.* at 2. In addition, NOAA completed a Programmatic EIS which broadly considers a range of similar aquaculture projects in the Gulf. Final EA at 6 tbl.4.

⁹ To fulfill their respective consultation and conference responsibilities under section 7 of the ESA, EPA acted as the lead agency and USACE acted as a cooperating co-federal agency. *See* 50 C.F.R. § 402.07; *see also* BE at 3; Resp. to Cmts. at 9. According to the Response to Comments, the ESA consultations were conducted pursuant to the Memorandum of Understanding between EPA, FWS, and NMFS Regarding Enhanced Coordination Under the CWA and the ESA (2001) and the Memorandum of Understanding (MOU) for Permitting Offshore Aquaculture Activities in Federal Waters of the Gulf of Mexico, Bureau of Ocean Energy Management, Bureau of Safety and Environmental Enforcement, NMFS, USACE, U.S. Coast Guard, U.S. EPA, and FWS (Feb. 6, 2017). Resp. to Cmts. at 9, 39, 42; *see also* NMFS Consultation Request at 1; FWS Consultation Request at 1.

¹⁰ The Region’s record document entitled “Biological Evaluation” serves as a biological assessment pursuant to ESA § 7(a)(3), 16 U.S.C. § 1536(a)(3), and 50 C.F.R. § 402.12. The term “Biological Assessment” is used throughout this decision to refer to the Region’s Biological Evaluation.

consultation under the ESA. *See* Letter from Christopher B. Thomas, Permitting and Grants Branch Chief, Water Div., U.S. EPA Region 4, to David Bernhart, Asst.Reg'l Adm'r, Protected Res. Div., Se. Reg'l Office, Nat'l Marine Fisheries Serv., NOAA, re: Informal ESA Section 7 Consultation Request; Kampachi Farms, LLC—Vellella Epsilon Marine Aquaculture Facility 1 (Aug. 12, 2019) (A.R. A.21) (“NMFS Consultation Request”) and attach. 1 (Draft Biological Evaluation, U.S. EPA & USACE (Aug. 5, 2019) (“Draft BE”)); Letter from Christopher B. Thomas, Permitting and Grants Branch Chief, Water Div., U.S. EPA, Region 4, to Roxanne Hinzman, Field Supervisor, S. Fla. Ecological Serv. Field Office, FWS, re: Informal ESA Section 7 Consultation Request; Kampachi Farms, LLC—Vellella Epsilon Marine Aquaculture Facility (Aug. 13, 2019) (A.R. A.22) (“FWS Consultation Request”) and attach. 1 (Draft BE); *see also* Fact Sheet at 8.

The Draft Biological Assessment concluded that “the proposed project’s potential threats * * * to ESA-listed species and critical habitat are highly unlikely to occur or extremely minor in severity,” and as such, “the potential effects to ESA protected species and critical habitats are discountable or insignificant.” Draft BE at 26. Specifically, the Draft Biological Assessment determined that the proposed action “will have ‘no effect’ on listed species and critical habitat under the jurisdiction of [FWS]” and the proposed action “‘may affect but is not likely to adversely’ affect the listed species and critical habitat” under the jurisdiction of NMFS. *Id.*; NMFS Consultation Request at 2; FWS Consultation Request at 2.¹¹

FWS reviewed the Region and USACE’s no effect determination and did not object to issuance of the permit for the proposed project. E-mail from Jeffrey Howe, FWS, S. Fla. Ecological Servs. Off., to Meghan Wahlstrom-Ramler, U.S. EPA Region 4 (Aug. 27, 2019) (A.R. A.23) (“FWS Concurrence”) (explaining that FWS “does not have any additional comments at this time”). NMFS reviewed the Draft Biological Assessment and concurred with the Region and USACE’s “not likely to adversely affect” determination for many of the listed species and designated critical habitat included in the Draft Biological Assessment, but NMFS explained that it concluded “there are no effects” on several of the listed species and critical habitats based on the proposed action and provided supplemental

¹¹ The Region and USACE also jointly prepared an Essential Fish Habitat Assessment pursuant to the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. § 1801, and provided the assessment to NMFS. *See* Region’s Resp. to FoA Pet., att.14. The Region notes that while Petitioners have not alleged a claim under the Magnuson-Stevens Act, the Region assessed the effect of its action on essential fish habitat, and that assessment informed the Region’s decision-making. *Id.* at 4 n.4.

information to supports its conclusions. *See* Letter from David Bernhart, Asst. Reg'l Adm'r, Se. Reg'l Office, Protected Res. Div., Nat'l Marine Fisheries Serv., to Christopher B. Thomas, Permitting and Grants Branch Chief, Water Div., U.S. EPA Region 4, at 4, 7-8 (Sept. 30, 2019) (A.R. B.11) (“NMFS Concurrence”).

On August 30, 2019, the Region published the proposed NPDES permit and associated documents, including a draft Ocean Discharge Criteria Evaluation, a draft EA, and a draft Biological Assessment, and sought public comment. *See*, U.S. EPA, Region 4, Ocean Era Inc., *Draft Permit Public Notice* (Aug. 30, 2019) (A.R. A.58); *see also* Region 4, U.S. EPA Final *Resp. to Significant Cmts., Ocean Era, Inc. –Velella Epsilon, NPDES Permit No. FLOA00001*, at 7 (Sept. 30, 2020) (A.R. B.66) (“Resp. to Cmts.”). The Region received approximately 44,500 comments from various interested individuals and parties—including comments from CFS and FoA—during the public comment period. *Resp. to Cmts.* at 7-8. After the close of the public comment period, which lasted 158 days, the Region issued its “Response to Significant Comments.” *Id.* at 7.

On September 30, 2020, the Region issued the Permit, along with the Region’s responses to public comments, and final versions of the Region’s Ocean Discharge Criteria Evaluation, Biological Assessment, and Environmental Assessment. These petitions for review followed.

VI. ANALYSIS

The two petitions for review in this matter together present issues under four different statutes: the CWA, NEPA, the MMPA, and the ESA. Of these, the arguments made with respect to NEPA and the MMPA raise underlying issues as to whether Petitioners have met the threshold requirements under 40 C.F.R. part 124 for consideration of their arguments on the merits. We resolve these threshold matters first and then turn to the substance of the remaining arguments.

A. *Threshold Matters*

In considering a petition for review of a permit decision filed under 40 C.F.R. section 124.19(a), the Board first evaluates whether the petitioner has met threshold procedural requirements, such as issue preservation and specificity. *In re Indeck-Elwood, LLC*, 13 E.A.D. 126, 143 (EAB 2006). For example, a petitioner must demonstrate that any arguments it raises on appeal have been preserved for Board review, meaning the arguments were “raised during the public comment period.” 40 C.F.R. § 124.19(a)(4)(ii); *see, e.g., In re City of Attleboro, MA Wastewater Treatment Plant*, 14 E.A.D. 398, 405-06, 443-44 (EAB 2009); *City of Moscow*, 10 E.A.D. at 141, 149-50. To satisfy the preservation requirement, the

issues raised on appeal must have been “raised with ‘a reasonable degree of specificity and clarity’ during the public comment period or public hearing.” *In re City of Lowell*, 18 E.A.D. 115, 131 (EAB 2020) (quoting *In re Westborough*, 10 E.A.D. 297, 304 (EAB 2002)); accord *In re Beeland Group, LLC*, 14 E.A.D. 189, 205 (EAB 2008); see also *Attleboro*, 14 E.A.D. at 406 (“[T]o preserve an issue for review, comments made during the comment period must be sufficiently specific.”); *Steel Dynamics.*, 9 E.A.D. at 230 (holding that an issue on appeal was not preserved when it was not presented in comments “with sufficient clarity to enable a meaningful response”). Specific comments “ensure[] that the Region has an opportunity to address potential problems with the draft permit before the permit becomes final.” *In re CertainTeed Corp.*, NPDES Appeal No. 15-01, at 11 (EAB May 7, 2015) (Order Denying Review) (quoting *In re Arecibo & Aguadilla Regional Wastewater Treatment Plants*, 12 E.A.D. 97, 116-17 (EAB 2005)). General comments on a topic are not sufficient to preserve a specific argument on a distinct issue for review. See *In re Footprint Power Salem Harbor Dev., LP*, 16 E.A.D. 546, 574-575 (EAB 2014) (holding that an issue raised on appeal that was not raised during the public comment period with the requisite clarity and specificity was not preserved for Board review; there were fundamental differences between the comment and the issue petitioners raised on appeal); *City of Moscow*, 10 E.A.D. at 149-150 nn.37-39 (denying review of issues that were not specifically raised during the comment period and that were distinct from the issues raised in comments below).

Additionally, in any appeal from a permit under part 124, the petitioner bears the burden of demonstrating that review is warranted. 40 C.F.R. § 124.19(a)(4). More specifically, not only must a petition for review “identify the contested permit condition or other specific challenge to the permit decision,” but it must also “clearly set forth, with legal and factual support, petitioner’s contentions for why the permit decision should be reviewed.” *Id.* § 124.19(a)(4)(i). A “petition must demonstrate that each challenge to the permit decision is based on: []A finding of fact or conclusion of law that is clearly erroneous.” *Id.* § 124.19(a)(4)(i)(A). A “[p]etitioner may not raise new issues or arguments in [a] reply” brief. *Id.* § 124.19(c)(2).

To the extent a petitioner challenges an issue that the permit issuer addressed in its response to comments, the petitioner must explain why the permit issuer’s previous response to that comment is clearly erroneous or otherwise warrants review. 40 C.F.R. § 124.19(a)(4)(ii); see, e.g., *In re Teck Cominco Alaska Inc. (Red Dog Mine)*, 11 E.A.D. 457, 494-95 (EAB 2004); *Westborough*, 10 E.A.D. at 305, 311-12; *In re City of Irving*, 10 E.A.D. 111, 129-30 (EAB 2001), review denied sub nom. *City of Abilene v. EPA*, 325 F.3d 657 (5th Cir. 2003). To meet this

threshold requirement, “the petitioner must address the permit issuer’s responses to relevant comments” and “substantively confront the permit issuer’s subsequent explanations.” *In re Peabody Western Coal Co.*, 12 E.A.D. 22, 33 (EAB 2005). A petitioner’s failure to do so is grounds for denying review.¹² *See, e.g., Lowell*, 18 E.A.D. at 157 (“By failing to grapple with the substance of the [r]egion’s position, [petitioner] leaves the [r]egion’s analysis unrebutted.”); *In re City of Pittsfield*, NPDES Appeal No. 08-19, at 10-12 (EAB Mar. 4, 2009) (Order Denying Review), *aff’d*, 614 F.3d 7 (1st Cir. 2010); *Indeck-Elwood*, 13 E.A.D. at 170 (“[A] petitioner’s failure to address the permit issuer’s response to comments is fatal to its request for review.”); *In re Knauf Fiber Glass, GmbH*, 9 E.A.D. 1, 5 (EAB 2000) (“Petitions for review may not simply repeat objections made during the comment period; instead they must demonstrate why the permitting authority’s response to those objections warrants review.”).

1. *CFS Failed to Properly Preserve for Review Its Arguments Concerning the MMPA*

In two paragraphs of its petition for review, CFS seems to argue that under the MMPA, EPA was required to “complete an accurate assessment of risks posed” to marine mammals and to obtain “proper authorization” from NMFS as a prerequisite to the issuance of the permit. *See* CFS Pet. at 54.¹³ Both statements

¹² Federal circuit courts of appeal have upheld this Board’s denial of review of an issue where a petitioner fails to substantively address the permit issuer’s response to comments on that issue. *City of Pittsfield v. EPA*, 614 F.3d 7, 11-13 (1st Cir. 2010) (holding that the Board’s order denying review was appropriate where petitioner made no effort to engage EPA’s response to comments), *aff’g In re City of Pittsfield*, NPDES Appeal No. 08-19 (EAB Mar. 4, 2009) (Order Denying Review); *Mich. Dep’t of Env’tl. Quality v. EPA*, 318 F.3d 705, 708 (6th Cir. 2003) (“[Petitioner] simply repackag[ing] its comments and the EPA’s response as unmediated appendices to its petition to the Board * * * does not satisfy the burden of showing entitlement to review.”), *aff’g In re Wastewater Treatment Facility of Union Twp.*, NPDES Appeal Nos. 00-26 & 00-28 (EAB Jan. 23, 2001) (Order Denying Review); *LeBlanc v. EPA*, 310 F. App’x 770, 775 (6th Cir. 2009) (concluding that the Board correctly found petitioners to have procedurally defaulted where petitioners merely restated “grievances” without offering reasons why the permit issuer’s responses were clearly erroneous or otherwise warranted review), *aff’g In re Core Energy, LLC*, UIC Appeal No. 07-02 (EAB Dec. 19, 2007) (Order Denying Review).

¹³ CFS also states that the USACE was required to obtain “proper authorization” from NMFS before “authorizing this permit.” CFS Pet. at 54. To be clear, the CFS petition

appear to be based on the argument that the proposed Facility may result in the “take” of marine mammals through vessel strikes, entanglement, and increased ocean noise. *Id.* CFS does not cite any regulatory or statutory provisions within the MMPA or the CWA in support of its argument that EPA must obtain authorization from NMFS prior to EPA issuing an NPDES permit. *Id.* Nor does CFS in any other way articulate the basis for its assertions concerning the MMPA and the NPDES program. *Id.* CFS’s precise argument for how the MMPA should be applied to either USACE or EPA as part of the NPDES permitting program is not discernable from the CFS petition.¹⁴ Thus, CFS has not satisfied the requirement of 40 C.F.R. section 124.19(a)(4)(i) to “clearly set forth, with legal and factual support, [its] contentions for why this issue should be reviewed.”

Additionally, the CFS petition does not identify where in the record this issue was raised during the public comment period below as 40 C.F.R. section 124.19(a)(4)(ii) requires. The only mention of the MMPA in CFS’s comments on the draft permit—that the Board has identified¹⁵—is contained in a single sentence

challenges the EPA’s permit decision. Neither the actions nor inactions of the USACE are before the Board.

¹⁴ CFS’s argument is particularly difficult to discern in light of the MMPA requirement for *the owner or operator of a vessel*—not an NPDES permit issuer—to obtain authorization from NMFS if their activities will result in a “take” of any marine mammal. 16 U.S.C. § 1372(a) (stating it is unlawful for any person, vessel, or other conveyance to take any marine mammal); 50 C.F.R. § 216.11 (stating it is unlawful for any person, vessel, or conveyance to take any marine mammal); 16 U.S.C. § 1387(c); 50 C.F.R. § 229.4 (mandating that the owner or operator of a vessel obtain authorization from NMFS if the vessel is operating within a category I or II commercial fishery). The failure of a vessel owner or operator to obtain proper authorization allows the government to enforce against the violator, i.e., the vessel owner or operator. *See* 16 U.S.C. §§ 1387(h), 1375, 1377; (providing NMFS authority to arrest or penalize any person who commits an unlawful take and/or seize the take). The Region asserts that CFS’s MMPA allegations concern the permittee’s obligations under the MMPA and that CFS’s claim is not cognizable in an NPDES permit appeal. The Board does not disagree.

¹⁵ For purposes of preserving an issue for Board review, the petitioner carries the burden, not the Board, to identify where in the public comment process an issue was raised. *See In re Palmdale Energy, LLC*, 17 E.A.D. 620, 648, n.21 (EAB 2018) (citing *In re Encogen Cogeneration Facility*, 8 E.A.D. 244, 250 n.10 (EAB 1999) (“It is not incumbent upon the Board to scour the record to determine whether an issue was properly raised below: this burden rests with petitioners.”)).

that states, “when the listed species to be taken are marine mammals, the take must first be authorized pursuant to the [MMPA] and the [incidental take statement of the biological opinion issued pursuant to the ESA] must include any additional measures necessary to comply with the MMPA take authorization.” CFS Suppl. Cmts. at 5. This statement however does not argue that EPA is obligated to obtain authorization from NMFS for potential “takes” as part of the NPDES permitting process, let alone provide any legal basis for that assertion. This statement does not contain “a reasonable degree of specificity and clarity,” *Lowell*, 18 E.A.D. at 131, “to enable a meaningful response,” *Steel Dynamics*, 9 E.A.D. at 230. In other words, even if CFS mentioned the MMPA in its comments, the comments were not sufficiently specific to apprise the Region of the argument that CFS attempts to make on appeal. *Attleboro*, 14 E.A.D. at 406 (“[T]o preserve an issue for review, comments made during the comment period must be sufficiently specific.”).

Based on our review of the CFS petition and the administrative record, the Board concludes that CFS has failed to demonstrate that this issue was properly preserved. As such, CFS has failed to satisfy its threshold obligations under 40 C.F.R. § 124.19(a)(4)(ii) with respect to this issue and its request for review of the permit decision based on alleged violations of the MMPA is denied.

2. *CFS and FoA Failed to Properly Preserve for Review Their Arguments with Respect to NEPA’s Applicability to the Permit*

As explained in Part IV.C, above, NEPA requires federal agencies such as EPA to include an EIS in all proposals for “major federal actions” that “significantly affect the quality of the human environment.” NEPA § 102(2)(C); 42 U.S.C. § 4332(2)(C). Section 511(c) of the CWA, however, exempts most NPDES permits from this requirement. CWA § 511(c), 33 U.S.C. § 1371(c) (stating that with two exceptions, “no action of the [EPA] taken pursuant to the [CWA] shall be deemed a major [f]ederal action significantly affecting the quality of the human environment within the meaning of [NEPA]”). The CWA exemption from NEPA does not apply to NPDES permits issued for “a new source as defined in section [306]” of the CWA. *Id.*; *see also* CWA § 306(a)(2), 33 U.S.C. § 1316(a)(2) (defining new source); *accord Dos Republicas*, 6 E.A.D. at 648 (explaining that permitting actions under the CWA are generally not regarded as major federal actions under NEPA with an exception for NPDES permits for new sources as mandated by CWA section 511(c)(1)). “New source” under section 306 of the CWA, in relevant part, includes a newly constructed facility for which a new source performance standard (“NSPS”) has been promulgated. *See* CWA § 306, 33 U.S.C. § 1316. The parties agree that the only NSPS relevant to this Permit is

for Concentrated Aquatic Animal Production (“CAAP”) facilities. Unless EPA specifically designates otherwise, CAAP facilities do not include facilities which produce less than 100,000 pounds of aquatic animals per year. 40 C.F.R. § 122, App. C (b)(2); *see also id.* § 122.24(b)-(c).

Pursuant to EPA policy, permit issuers may voluntarily undertake a NEPA analysis even where they are not legally bound to do so. *See Policy and Procedures for Voluntary Preparation of NEPA Documents*, 63 Fed. Reg. 58,045, 58,046 (Oct. 29, 1998). Under that policy, the Agency has been clear that “[t]he voluntary preparation of these documents in no way legally subjects the Agency to NEPA’s requirements.” *Id.*

In issuing the NPDES Permit in this case the Region determined that the Permit was not subject to NEPA’s requirements. The Region based that determination on the CWA’s exemption from NEPA. The Region concluded that the exception for a “new source” to the CWA’s exemption from NEPA did not apply to this Permit and thus, NEPA was inapplicable. Specifically, the Region explained that the CWA defines a “new source” as “a facility that is subject to an applicable effluent limitation guideline and commenced construction after promulgation of the guideline.” Fact Sheet at 1 n.1. But here, the Region explained, “the appropriate effluent standards for the aquaculture industry (concentrated aquatic animal production facilities) are not directly applicable to the [Facility].” *Id.*; *see also* Resp. to Cmts. at 28 (explaining that the effluent standards for concentrated aquatic animal production facilities “do not apply to facilities producing less than 100,000 pounds of aquatic animals annually” and “the [Facility] will produce approximately 80,000 pounds of aquatic animals per year”); Permit at 1 (authorization to discharge “from an Aquatic Animal Producing Facility producing up to 80,000 pounds/year for one production cycle”).

In this case, the Region conducted an environmental assessment on a voluntary basis, solicited public comment on it, issued a final environmental assessment, and concluded that issuance of the Permit “will not cause a significant environmental impact to water quality or result in any other significant impacts to human health or the natural environment.” U.S. EPA, USACE & NOAA, *Final EA, NPDES Permit for Ocean Era, Inc. –Velella Epsilon Offshore Aquaculture Project*, at 1, 66 (Sept. 2020) (A.R. B.33) (“Final EA”). The Region expressly stated that it had completed an environmental assessment on a voluntary basis and explained numerous times during the permitting process the inapplicability of

NEPA to this Permit.¹⁶ See Draft EA at 1; Final EA at 1; Resp. to Cmts. at 28; Fact Sheet at 1 n.1; U.S. EPA, Region 4, *Finding of No Significant Impact, Ocean Era, Inc. Veleva Epsilon NPDES Permit*, at 1 (Sept. 30, 2020) (A.R. B.34) (“FONSI”). The Region explained that the decision to conduct a voluntary NEPA analysis is consistent with EPA policy. Draft EA at 1 (citing 63 Fed. Reg. at 58,046).

As discussed further below, Petitioners had multiple opportunities to contest the Region’s determination that this Permit was exempt from NEPA under the CWA. Petitioners, however, did not raise concerns about this determination in their comments on the draft permit. Nor did they challenge the Region’s determination in their petitions for review or confront the Region’s explanation for why NEPA is inapplicable to this Permit. On appeal, Petitioners challenge the adequacy of the Region’s NEPA analysis. CFS Pet. at 34-48; FoA Pet. at 35-39. At no point, prior to their reply briefs, did they challenge the Region’s determination that the Permit was exempt from NEPA and its requirements.

During the public comment period, Petitioners challenged only the substance of the Region’s voluntary NEPA analysis. See CFS Cmts. at 6-9 (arguing that the Region’s analysis in the environmental assessment deviated from the NEPA requirements and should have resulted in a finding of significant effects, and therefore, the Region was required to prepare an EIS); FoA Cmts. at 5-18. Petitioners’ comments on the substance of the Region’s NEPA analysis, however, are “distinct from” whether NEPA applies to the Permit in the first instance. *City of Moscow*, 10 E.A.D. at 150 (holding that the issues raised on appeal were distinct from the ones raised in comments and were not preserved for Board review); see also *Indeck-Elwood*, 13 E.A.D. at 168-69 (determining the arguments raised during the public comment period were “distinctly different” from the one raised on appeal and declining to review the issue on appeal because it was not properly preserved). While both concern NEPA, there are “fundamental differences” between the two issues. *Footprint Power*, 16 E.A.D. at 574-575 (holding that an issue was not preserved for Board review when there were fundamental differences between

¹⁶ Because EPA did not make a designation otherwise under 40 C.F.R. § 122.24(c) and this Permit authorizes the Facility to produce approximately 80,000 pounds or less of aquatic animals, the Permit is not for a CAAP facility. The Region correctly determined that the “new source” exception to the CWA’s exemption from NEPA does not apply. See *In re Peabody Western Coal Co.*, 15 E.A.D. 406, 430-31 (EAB 2011) (denying review and concluding that the region correctly determined that the permitted facility was not a new source and that the NPDES permit was not subject to NEPA requirements per the CWA exemption).

petitioners' comments on the draft permit and the issue petitioners raised on appeal). As such, Petitioners have not met their obligation to demonstrate that concern over the applicability of the CWA exemption to the Permit "was raised during the public comment period." See 40 C.F.R. § 124.19(a)(4)(ii). The failure to raise an issue that was "reasonably ascertainable" during the public comment period is grounds for denial of a petition for review.¹⁷ *Id.* § 124.13; see also § 124.19(a)(4)(ii) (mandating that for issues that were not raised during the public period, petitioners explain why such issues were not required to be raised as provided in 40 C.F.R. § 124.13); *In re Tucson Elec. Power*, 17 E.A.D. 675, 689-90 (EAB 2018) (denying review and holding that an argument raised for the first time in a petition "has not been preserved for Board review").

Even if the applicability of the CWA exemption had been raised during the public comment process, which it was not, the Board would deny review based on Petitioners' failure to raise the challenge in their petitions and address the Region's Response to Comments. 40 C.F.R. § 124.19(a)(4)(i)-(ii) (requiring petitioners to the Board to identify and clearly set forth the specific challenges to the permit, where each challenge was raised during public comment, and why the Region's response to each challenge was clearly erroneous or otherwise warrants review, when applicable). In response to substantive comments on the Region's voluntary Draft EA, the Region again explained that the Permit was not subject to NEPA due to the CWA exemption and thus, EPA was not required to prepare any NEPA document for the Permit. Resp. to Cmts. at 28 (further explaining that the project did not qualify as a "new source" under CWA § 306, 33 U.S.C. § 1316). Additionally, in the Final EA that the Region issued with its Response to Comments, the Region explained that it had completed an environmental assessment on a voluntary basis, but that the decision to voluntarily evaluate the Permit did not render the Permit subject to NEPA. Final EA, at 1 (citing *Policy for Voluntary Preparation of NEPA Documents*, 63 Fed. Reg. at 58,046 ("The voluntary preparation of these documents in no way legally subjects the Agency to NEPA's requirements.")). The final permit Fact Sheet and FONSI also explained the inapplicability of NEPA to this Permit. See Fact Sheet at 1 n.1; FONSI at 1

¹⁷ When the Region issued the draft permit for public comment, it explained that this Permit was not subject to NEPA due to an exemption in the CWA and that it was proceeding to conduct an environmental assessment on a voluntary basis. Draft EA, at 1; see also CWA § 511(c)(1), 33 U.S.C. § 1371(c)(1). As such, Petitioners have no grounds to argue that the applicability of NEPA was not reasonably ascertainable during the public comment period.

(concluding that the Permit “is exempt from NEPA compliance under section 511(c) of the CWA and not subject to NEPA analysis requirements”).

Notwithstanding the Region’s many explanations regarding why NEPA and its requirements do not apply to this Permit, the petitions filed in this matter challenge only the *adequacy* of the Region’s NEPA analysis; they do not challenge the Region’s determination that this Permit is exempt from NEPA and its requirements. CFS Pet. at 34-48; FoA Pet. at 35-39. Petitioners do not “clearly set forth, with legal and factual support” any basis for why the Region was required to prepare an EIS under NEPA when the Region had determined the Permit exempt from NEPA. 40 C.F.R. § 124.19(a)(4)(i) (requiring petitioners to the Board to identify the specific challenge to the permit decision in their petitions); *see also Lowell*, 18 E.A.D. at 157 (explaining that failing to grapple with the substance of the permitting authority’s position in the petition leaves the permitting authority’s analysis unrebutted).

Nor do the petitions address the Region’s Response to Comments. *See* Resp. to Cmts. at 28; *see In re Chukchansi Gold Resort and Casino Wastewater Treatment Plant*, 14 E.A.D. 260, 269 (EAB 2009) (denying petition in part based on petitioner’s failure to explain with sufficient specificity why the region’s previous responses to comments were clearly erroneous or an abuse of discretion). In fact, Petitioners “made no effort in [their] petition[s] to the Board to engage the EPA’s [] response” regarding the CWA’s exemption of the Permit from NEPA. *See City of Pittsfield*, 614 F.3d at 13; *accord Native Vill. of Kivalina IRA Council v. EPA*, 687 F.3d 1216, 1221 (9th Cir. 2012) (concluding that the petitioner “simply did not argue or explain why the EPA’s responses were incorrect” and for that reason, affirming the Board’s finding of procedural default), *aff’g In re Teck Cominco Alaska Incorporated (Red Dog Mine)*, NPDES Appeal No. 10-04 (EAB Nov. 18, 2010) 11 E.A.D. 457 (EAB 2004) (Order Denying Review). In their silence, Petitioners have failed to “meaningfully confront the response to comments” on the applicability of the CWA exemption. *See Lowell*, 18 E.A.D. at 166. Petitioners’ failure to address the Region’s Response to Comments is grounds for denial of review. 40 C.F.R. § 124.19(a)(4)(ii); *see, e.g., In re City of Taunton*, 17 E.A.D. 105, 180, 182-83, 189 (EAB 2016) *aff’d*, 895 F.3d 120 (1st Cir. 2018), *cert. denied*, 139 S. Ct. 1240 (2019) (denying review on numerous issues because the petitioner failed to address the Region’s explanation for rejecting its comments).

Not until Petitioners filed their reply briefs in this appeal did they, for the first time, argue that the CWA exemption from NEPA does not apply to the Permit, and that the Region’s voluntary undertaking of an environmental assessment

triggers NEPA requirements regardless of the CWA exemption. FoA Reply Br. at 16-17; CFS Reply Br. at 12-15. Petitioners, however, may not raise new issues in their reply briefs. 40 C.F.R. § 124.19(c)(2). As the Board has explained, “new issues raised at the reply stage of the[] proceedings are equivalent to late filed appeals and must be denied on the basis of timeliness.” *Dominion Energy*, 12 E.A.D. at 595 (quoting *In re Knauf Fiber Glass, GmbH*, 8 E.A.D. 121, 126 n.9 (EAB 1999)). These arguments therefore come too late, and the Board will not consider them.

The Board denies review of Petitioners’ NEPA arguments because Petitioners failed to timely present any argument as to why NEPA is applicable to this Permit, despite the Region’s explanation that it is not. *See* 40 C.F.R. § 124.19(a)(4)(i)-(ii).

We now consider the CWA issues raised in this matter.

B. Review of the Region’s Evaluation of the Permit under the Ocean Discharge Criteria of the Clean Water Act

Petitioners argue that, in issuing the NPDES Permit for this project, the Region failed to comply with the CWA. More specifically, Petitioners maintain that the Region clearly erred in its consideration of the Ocean Discharge Criteria by failing to fully consider the discharge of nutrients (and their potential to contribute to harmful algal blooms, which poses a threat to human health), pharmaceuticals in the form of antibiotics given to the farmed fish (and the consequent threat to human health due to antibiotic resistance), pathogens and parasites (passed from the farmed fish to other marine life), escaped fish, and copper¹⁸ (from the net-pen itself). CFS Pet. at 25-32; FoA Pet. at 11-18. Finally, Petitioners argue that the Region erred by imposing insufficient monitoring provisions and by not including the proper reopener provision in the Permit. FoA Pet. at 12; CFS Pet. at 33-34.

In response to these arguments, the Region maintains that it did consider all of the impacts from the proposed discharge in making its unreasonable degradation determination and that the record as a whole demonstrates that it met its regulatory obligation. Reg. Resp. to CFS Pet. at 14-26; Reg. Resp. to FoA Pet. at 14-25; *see also* Oral Argument Transcript (Dec. 9, 2021) (“Oral Arg. Tr.”) at 73, 90. We begin

¹⁸ Only CFS challenges the Region’s failure to consider copper. *See* CFS Pet. at 31-32; *see generally* FoA Pet.

with a discussion of the Ocean Discharge Criteria requirements under the CWA and the implementing regulations.

1. *The Ocean Discharge Criteria Under the Clean Water Act*

As discussed above, EPA regulations set forth a process for determining whether a discharge will cause an unreasonable degradation of the marine environment. CWA § 403(c)(1), 33 U.S.C. § 1343(c)(1) (requiring EPA to promulgate guidelines that incorporate specific statutory factors); 40 C.F.R. pt. 125 subpt. M (setting forth regulations to implement the statutory requirements). Those regulations further provide that the permit issuer base its “unreasonable degradation” determination on a consideration of ten factors—the ODC factors. 40 C.F.R. § 125.122(a). Those ten factors are:

- 1) The quantities, composition and potential for bioaccumulation or persistence of the pollutants to be discharged;^[19]
- 2) The potential transport of such pollutants by biological, physical[,] or chemical processes;
- 3) The composition and vulnerability of the biological communities which may be exposed to such pollutants, including the presence of unique species or communities of species, the presence of species identified as endangered or threatened pursuant to the [ESA], or the presence of those species critical to the structure or function of the ecosystem, such as those important for the food chain;
- 4) The importance of the receiving water area to the surrounding biological community, including the presence of spawning sites, nursery/forage areas, migratory pathways, or areas necessary for other functions or critical stages in the life cycle of an organism;

¹⁹ The Board observes that in establishing the Effluent Limitations Guidelines and New Source Performance Standards for the Concentrated Aquatic Animal Production facilities (“the CAAP Guidelines”), the Agency identified “pollutants of concern,” and “regulated pollutants” that are discharged from such facilities. *See* 69 Fed. Reg. 51,892, 51,899 (Aug. 23, 2004). The pollutants the Agency identified in the CAAP Guidelines include nutrients, organic compounds such as fish food and fish waste, metals, pathogens, drugs, and pesticides. *Id.* Additionally, the Region applied the CAAP Guidelines to the proposed project authorized by this NPDES Permit. ODCE at 47; *see also* Permit Part III at 9 (incorporating monitoring provisions from the CAAP Guidance into the Permit) and Permit Part IV at 12 (incorporating best management practices from the CAAP Guidance into the Permit); Fact Sheet at 3-4.

- 5) The existence of special aquatic sites including, but not limited to marine sanctuaries and refuges, parks, national and historic monuments, national seashores, wilderness areas and coral reefs;
- 6) The potential impacts on human health through direct and indirect pathways;
- 7) Existing or potential recreational and commercial fishing, including finfishing and shellfishing;
- 8) Any applicable requirements of an approved Coastal Zone Management plan;
- 9) Such other factors relating to the effects of the discharge as may be appropriate;
- 10) Marine water quality criteria developed pursuant to section 304(a)(1).

Id.

If the permit writer “on the basis of available information* * * determines * * * that the discharge will not cause unreasonable degradation of the marine environment after application of any necessary conditions specified in § 125.123(d), [the permit writer] may issue an NPDES permit containing such conditions.” *Id.* § 125.123(a). Subsection (d) conditions include dilution requirements, specification of a monitoring program, location-specific conditions, and a specific clause (the “reopener clause”) that requires the permit issuer to modify or revoke the permit at any time if new data reveals that continued discharges may cause unreasonable degradation of the marine environment. *Id.* § 125.123(d). The permit writer may not issue an NPDES permit if it determines that the ocean discharge “will cause unreasonable degradation of the marine environment.” *Id.* § 125.123(b).

On the other hand, if “insufficient information exists on any proposed discharge to make a reasonable judgment” on any regulatory requirement established under the CWA’s Ocean Discharge Criteria, “no permit shall be issued.” CWA § 403(c)(2), 33 U.S.C. § 1343(c)(2). Under the Ocean Discharge Criteria regulations, when a permit writer “has insufficient information to determine prior to permit issuance that there will be no unreasonable degradation of the marine environment * * *, there shall be no discharge of pollutants into the marine environment unless the [permit writer] on the basis of available information * * *determines that:

- (1) Such discharge will not cause irreparable harm to the marine environment during the period in which monitoring is undertaken, and

(2) There are no reasonable alternatives to the on-site disposal of these materials, and

(3) The discharge will be in compliance with all permit conditions established pursuant to paragraph (d) of this section.

40 C.F.R. § 125.123(c). And if a permit writer issues a permit pursuant to subsection (c), then the permit *must* include the conditions set forth in subsection (d). *Id.* § 125.123(c)-(d).

The preamble to the regulations makes clear that the Ocean Discharge Criteria were intended to “provide flexibility to permit writers to tailor application requirements, effluent limitations, and reporting requirements to the specific circumstances of each discharge situation, while ensuring consistency and certainty by imposing minimum requirements, in situations where the long-term impact of a discharge is not fully understood.” 45 Fed. Reg. at 65,942. The preamble also set forth the standard for evaluating a permit issuer’s determinations on issues under the Ocean Discharge Criteria as one of “reasonable judgment[.]” and explained that a permit issuer’s judgments “will be made on available information compiled in the administrative record of the permit issuance.” *Id.* at 65,947.

2. *Petitioners Have Not Demonstrated the Region Clearly Erred in Its Consideration of the Ocean Discharge Criteria*

As summarized above, Petitioners raise issues with respect to the Region evaluations of: (a) nutrients and harmful algal blooms (“HABs”), (b) pharmaceuticals and antibiotic resistance, (c) pathogens and parasites, (d) escaped fish, and (e) copper. We address each of these issues in turn below.

a. *Nutrients and HABs*

Both Petitioners argue that the Region failed to adequately consider, as required by 40 C.F.R. § 125.122(a)(6), the threat to human health posed by HABs that will result from the Facility’s discharge of nutrients. CFS Pet. at 26-28; FoA Pet. at 15-17. Petitioners’ arguments on this issue rest on the underlying assumption that the discharge of nutrients from this Facility will contribute to the growth of HABs. The Region disagrees with that underlying assumption and argues that there is no basis from which to conclude that nutrients discharged from this Facility will contribute to the growth of HABs. Reg. Resp. to CFS Pet. at 17-20; *id.* at 19 (arguing among other things that “[w]hile acknowledging that, as a general matter, nutrient discharges can contribute to HABs, * * * ‘it is not expected that aquaculture-related pollutants will be measured in the water within 5-10 meters of the project.’”); Reg. Resp. to FoA Pet. at 22-25 (same).

In its ODC Evaluation, the Region identified fish food and fish waste as the major pollutants to be discharged. ODCE at 13, 33. When considering the impacts of the discharge of fish food and fish waste on the marine environment, the Region considered extensively the impact of the nutrients contained in the discharge—including phosphorus and nitrogen. *See, e.g., id.* at 13-14, 33-37, 43-44. As the Region acknowledged, adding nutrients to the Gulf can pose a problem because nutrients are known to contribute to HABs, including *Karenia brevis*, more commonly known as the red tide organism. *Id.* at 34. Notwithstanding the potential that nutrients have to contribute to HABs in general, the Region explained that the concentration of waste nitrogen from net-pens diminishes greatly immediately downstream and that “not enough scientific evidence [i]s available to suggest that macronutrients and micronutrients from fish farming, or the proposed project, can be directly related to the occurrence of red tides.” *Id.* at 35.²⁰

When analyzing the potential transport of pollutants to be discharged from the Facility by biological, physical, and chemical processes, the Region explained that “[f]actors influencing the transport and fate of materials discharged from net-pen facilities include oceanographic characteristics of the receiving water, physical characteristics of the net-pen, water depth below the net-pen, configuration and orientation of the net-pen system in relation to predominant currents, type of food used, fish feeding rates and stock size.” *Id.* at 43. Other oceanographic considerations consist of “tides, wind, stratification, and current velocities and direction.” *Id.*

Environmental modeling analysis was conducted of the proposed project to help determine the fate and effects of solid wastes discharged from the net-pen. *Id.*

²⁰ Petitioners assert that the Region’s statement that “there is not enough evidence * * *” is equivalent to a determination that there was “insufficient information to make a reasonable judgment” as to the Ocean Discharge Criteria. *See* CFS Pet. at 27; FoA Pet. at 16-17. We disagree—the two assertions are not synonymous. While there may not have been enough scientific evidence to link fish farms to HABs as a general matter, that does not mean there was insufficient information to make a reasonable determination that this proposed fish farm will not have negative impacts on human health. Petitioners ignore the other information on which the Region relied in making its determination. As described below, that information included, for example, the environmental modeling for this project, the relatively small fish biomass production, the oceanographic characteristics of the receiving water, the physical characteristics of the net-pen system, the type of food used, and the best management practices in place. *See* ODCE at 43, 45; Resp. to Cmts. at 20, 22-23.

The modeling was conducted using “maximum fish production amounts for the entirety of the simulation period” and several scenarios were used, including one that assumed “a maximum biomass for the entire 5-year term of the NPDES [P]ermit,” even though the Permit allows only one cohort of fish that is expected to be reared over the course of twelve months. *Id.* Based on an analysis of the environmental modeling conducted for the proposed project, the Region explained that “[o]cean currents are expected to flush the cages sufficiently to carry wastes away from cages and dilute and disperse dissolved and solid wastes over a large area.” *Id.* at 45. The Region further explained that “[d]ue to the small scale of the proposed project and because the discharged wastes are largely [made up] of organic and inorganic particulates and dissolved metabolic wastes, there is little potential for biological or chemical transport.” *Id.*

In response to concerns raised during the public comment period regarding HABs and the associated threat to human health, the Region again acknowledged that “[a] small percentage of algae” can produce “powerful toxins that can kill fish, shellfish, mammals, and birds, and may directly or indirectly cause illness in people.” *Resp. to Cmts.* at 22. The Region further explained, however, that “[c]ausal linkages have not been established between fish farming and phytoplankton blooms.” *Id.* at 22-23. The Region added that, as part of its analysis of this permit action, it had considered “water quality impacts related to HABs such as nutrients, organic enrichment impacts to the seafloor sediments and benthic communities, estimated water current magnitude and direction, dilution availability, and solid and dissolved waste impacts.” *Id.* at 23.

The Region also noted that NOAA had concluded that, although there is some evidence that effluent from fish farms may contribute to an occurrence of HABs in the marine environment, “most studies have failed to demonstrate a clear effect.” *Id.* at 23. Further, where effects from nutrients have been found, the Region explained that “hydrological conditions or farm management practices may [have] contribute[d].” *Id.* The Region further observed that “[s]iting farms in deep, well flushed waters will help disperse dissolved nutrients, and siting projects away from areas where effluent will be washed onshore will also help avoid eutrophication.” *Id.* at 23; *see also id.* at 26.

The Region also again pointed out that this Facility is a pilot-scale operation that involves one cage situated “45 miles from shore in a high energy environment and [will be] discharging for approximately one year.” *Id.* at 24. Additionally, the Permit contains non-numeric effluent limitations (in the form of “best management practices”) “to control the discharge of feed and nutrients” and “robust

environmental monitoring requirements up-current, down-current, and at the [F]acility.”²¹ *Id.*; *see also id.* at 20.

After considering the potential impacts of nutrient discharge from the Facility, the Region determined that “[d]ue to the relatively small fish biomass production estimated for this demonstration and the limited discharges other than fish food and fecal matter, the volume and constituents of the discharged material are not considered sufficient to pose a significant environmental threat.” *Id.* at 23.

Petitioners rely heavily on the Region’s general acknowledgement that nutrients can encourage the growth of HABs as a basis for assuming that health effects from HABs must be considered. CFS Pet. at 27; FoA Pet. at 16. Neither petition, however, challenges the Region’s conclusions with respect to the modeling, the siting, the hydrological conditions, or the dispersal of a relatively small amount of nutrients over a large area within a short distance of the Facility. Because the petitions do not address the reasons the Region gave for its determination that the discharged nutrients “are not considered sufficient to pose a significant environmental threat,” Petitioners’ arguments fall short of the threshold they must meet to demonstrate that the permit issuer clearly erred in making its technical determination. *See* Resp. to Cmts. at 23; *see also e.g., Footprint Power*, 16 E.A.D. at 555 (citing *Prairie State*, 13 E.A.D. at 72) (concluding that petitioners failed to provide “a sufficiently compelling rebuttal” of permit issuer’s finding to overcome the deference the Board normally gives to permitting authorities on technical matters).

Based on the foregoing, Petitioners have not carried their burden to demonstrate that the Region clearly erred by not considering the threat to human health from HABs where the Region considered the potential contribution to HABs and concluded that the discharge of nutrients from the Facility would not pose an environmental threat.

²¹ FoA argues that the downstream monitoring required is insufficient because it is not located far enough away from the Facility. FoA Pet. at 12-13. For reasons explained below, FoA’s legal basis for challenging the monitoring is incorrect. Additionally, FoA’s argument with respect to the location of the monitoring does not consider that the Region’s modeling results—which considerably over-estimated levels of discharge by assuming the discharge would be for five years, rather than the approximately twelve months that it will take to rear the permitted one cohort of fish—indicated that even very close to the Facility waste volumes would be extremely low or barely discernable. ODCE at 43-44; Resp. to Cmts. at 23.

b. *Pharmaceuticals & Antibiotic Resistance*

Petitioners next argue that the Region failed to fully consider the potential impacts of antibiotic usage at the Facility and, in particular, the threat to human health in the form of antibiotic resistance. CFS Pet. at 29; *see also* FoA Pet. at 14-15. Petitioners assert the Region's analysis of the scientific data was flawed, and that the Permit should have included terms that limited the use of antibiotics but did not. CFS Pet. at 29; *see also* CFS Reply Br. at 11-12; FoA Reply Br. at 5-6.

On the contrary, the Region evaluated the potential discharge of antibiotics from the Facility over the course of fourteen paragraphs in its ODC Evaluation. ODCE at 40-43. Among other things, the Region explained that “[t]he concentrations of antibiotics outside of the immediate proximity of the fish pens are regarded by most authors as being too low to have adverse effects.” *Id.* at 42. Additionally, the Region distinguished studies done outside of the United States because “federal regulations that apply to the use of antibiotics in fish farming in the United States appear to be much more stringent than those that apply in Japan and Europe * * *.” *Id.* With respect to studies from Japan, the Region noted that even where the use of antibiotics in aquaculture is extensive, the “transfer of drug resistance from fish to human pathogenic bacteria,” has been shown to be “unlikely.” *Id.* at 42-43. The Region also noted that “dosage and duration,” in the studies from Japan “appear[] to exceed both legal and general practices in the United States.” *Id.* at 41.

Ultimately, the Region concluded that the need to use antibiotics would be minimized by strong currents, low fish density, the cage material being used, and the constant movement of the cage. *Id.* at 43. The Region also noted that if antibiotics were used, the Permit requires that the use of any medicinal products including therapeutics, antibiotics, drugs, and other treatments must be reported to EPA. *See* Permit at 6, 9. Additionally, with respect to the fish health management, the Region included a requirement in the Permit that “all stocking of live aquatic organisms, regardless of life stage, must be accompanied by an Official Certificate of Veterinary Inspection signed by a licensed and accredited veterinarian attesting to the health of the organisms” and the Facility must implement best management practices related to fish health management. ODCE at 47-48. The Region also considered the applicant's indication that antibiotics will not likely be used (either within any feed or dosing of the rearing water) during the proposed project. *Id.* at 43; *see also* Resp. to Cmts. at 14. Based on the entirety of the record, the Region did consider the potential impacts of the use of antibiotics at the Facility, including potential impacts on human health. As such, Petitioners have not met their burden to demonstrate that the Region clearly erred by failing to fully consider the potential

impacts of antibiotic usage and, in particular, the threat to human health in the form of antibiotic resistance.

c. *Pathogens & Parasites*

Petitioners also argue the Region did not adequately consider the potential for “pathogens” to be discharged from the Facility. CFS Pet. at 31; FoA Pet. at 14. FoA argues that the Region should have considered the impacts of possible “pathogens” on human health and recreational or commercial fisheries, ODC factors number 6 (relating to consideration of the potential impacts on human health) and 7 (relating to the consideration of existing or potential recreational and commercial fishing), respectively, under the Ocean Discharge Criteria, although FoA does not elaborate on how exactly it believes pathogens relate to those two factors. FoA Pet. at 14 (“EPA erred by not fully considering the possibility of disease and pathogen transfer or conducting new studies aimed specifically at the waters of the Gulf of Mexico. This speaks to at least two of the factors of unreasonable degradation of the marine environment. 40 C.F.R. § 125.122(6), (7).”)

The ODC Evaluation, however, does contain a discussion of pathogens in the context of considering ODC factors number 9—“other factors relating to effects of the discharge.”²² ODCE at 47. In that part of the evaluation, the Region considered the need for permit conditions to ensure that unreasonable degradation to the marine environment will not occur. Again, the Region referred to the permit conditions requiring that all fish stocked “must be accompanied by an Official Certificate of Veterinary Inspection signed by a licensed and accredited veterinarian attesting to the health of the organisms” and the Facility must implement a “best management practices” plan that “include[s] conditions to control or minimize the transfer of pathogens to wild fish.” *Id.* at 47-48.

In the Response to Comments on this issue, the Region agreed that pathogens are a “pollutant” within the meaning of the NPDES permitting program. Resp. to Cmts. at 19. The Region also recognized the possibility of pathogens being transferred from the farmed fish to wild fish as a result of this project. The Region then explained that there is very little information available on the effects of such pathogen transfer, but the information that is available suggests that there is little

²² Although FoA argues in its petition that impacts of possible pathogens “speaks to at least” factors 6 and 7, it makes no argument that the Region erred in considering this as part of factor 9. *See generally* FoA Pet.

risk of harm from the transfer of pathogens to wild stock. *Id.* at 19-20. The Region added that “EPA evaluated the direct and indirect potential impacts from pathogens and parasites in multiple documents when developing effluent limitation guidelines (ELGs) and performance standards for the CAAP industry.” *Id.* at 19. The Region also noted that the permit conditions, which incorporate the CAAP standards, address a number of the concerns raised with respect to pathogens and disease transfer through non-numeric effluent limits in the form of “best management practices.” *Id.* at 20. The Region maintained that these best management practices—e.g., Facility-specific fish health management conditions to minimize pathogen transfer—and the permit condition requiring a certificate of health from a veterinary inspection would be sufficient to address any concerns. *Id.* Based on the record, the Region considered the potential impact of pathogens from this Facility and determined that the permit conditions in place would eliminate the low risk of harm. Petitioners have not carried their burden to demonstrate the Region clearly erred in its consideration, under the Ocean Discharge Criteria, of potential pathogen discharges from this Facility.

d. *Escaped Fish*

Petitioners next argue that the Region failed to fully consider the possibility of “escaped fish” in the ODC Evaluation. CFS Pet. at 32; FoA Pet. at 13-14. Petitioners are correct that the Region did not identify escaped fish as a pollutant to be discharged in the ODC Evaluation. The Region did, however, respond to comments raised during the public comment period regarding escaped fish. Resp. to Cmts. at 17, 19. There, the Region acknowledged that escaped fish are “pollutants” within the meaning of the CWA that fall within the scope of NPDES permitting. Resp. to Cmts. at 19. The Region explained, however, that “the risks that escaped farm fish pose to wild populations are a function of the probability of escape.” *Id.* at 17. And, with respect to this Facility, “[t]he copper mesh cage to be used is impact resistant and designed to survive storm events while being completely submerged,” which results in “a low probability of escape.” *Id.* The Region pointed out that the Permit requires the implementation of a Facility Damage Prevention and Control Requirements plan to mitigate environmental impacts during any disaster and to prevent the release of aquatic animals. *Id.* at 18.²³ The Region also explained that the Facility would be required to adhere to

²³ FoA also argues that the Region did not take into account the increasing frequency and severity of hurricanes in the Gulf of Mexico, particularly given the impacts of climate change. FoA Pet. at 13-14. The Region, however, addressed concerns regarding

a Facility-specific best management practices plan that would ensure the Facility is being operated and maintained to mitigate environmental impacts during any disaster. *Id.*

Notwithstanding the Region's determination that there is a low probability of fish escapes from the Facility, the Region did consider the impacts of escaped fish. *Id.* at 17. The Region observed that the farmed species, Almaco Jack, is native and common to the Gulf and that the fingerlings for the project will be sourced from brood stock that were caught in the Gulf. *Id.* Thus, any environmental impacts from "escaped fish" would be mitigated because, in the event that any fish do escape, there would be no genetic impacts because the fish have the same genetic makeup and would not likely pose a competitive risk to the wild stock. *Id.*

CFS neither acknowledges nor addresses the Region's Response to Comments in its petition. *See* CFS Pet. at 32. Rather, CFS argues that the Region was required to include its analysis in the ODC Evaluation. *Id.* at 32. On the contrary, the Response to Comments document is an appropriate place for the Region to respond to issues raised by comments on the draft permit and to provide its rationale for a final permitting decision. *See City of Taunton*, 17 E.A.D. at 125, 186; *cf. Alaska Eskimo Whaling Comm'n v. EPA*, 791 F.3d 1088, 1092 (9th Cir. 2015) (explaining that the response to comments document, the ocean discharge criteria evaluation, and the environmental justice analysis, taken together, explain the bases for EPA's permitting decision). Indeed, that is precisely the purpose of the Response to Comments document. *See id.*; *see also* 40 C.F.R. § 124.17(a) (requiring the permitting authority to briefly respond to all significant comments on the draft permit).

FoA acknowledges the Region's Response to Comments but argues that the Region should have considered known fish escapes from other fish farm facilities, such as Puget Sound, and asserts that the Region did not explain why the cage has a low probability of escape. FoA Pet. at 13. In describing the comments regarding fish escapes in the Response to Comments document, however, the Region did acknowledge the fish escape that occurred in Puget Sound and explained that the concerns raised about that escape were related to the impacts to the genetic pool of native fish, competition for food and habitat, and the spread of parasites or diseases to wild stocks. Resp. to Cmts. at 17. In responding to that comment and those concerns, the Region also explained why those concerns are not applicable here,

the impact of hurricanes (including a consideration of climate impacts and extreme weather) in the Response to Comments document. Resp. to Cmts. at 18.

namely, as explained above, that the cage has a low probability of escape and the farmed fish proposed for this Facility are genetically identical to the wild fish. *Id.* at 17.

In sum, the Region did consider the possibility of fish escapes as a potential discharge from the permitted Facility. Petitioners' arguments to the contrary do not demonstrate otherwise. Thus, Petitioners have not met their burden to demonstrate the Region clearly erred in its consideration of escaped fish from this Facility.

e. *Copper*

CFS also argues that the Region failed to include copper in its ODC Evaluation. CFS Pet. at 31-32.²⁴ CFS is correct that the Region did not identify copper as a pollutant to be discharged in the ODC Evaluation. This issue was raised during the public comment period and the Region responded with, among other statements, “[c]opper is not expected to be at a measurable concentration in the [F]acility effluent.” Resp. to Cmts. at 15. The Region further explained that, notwithstanding this expectation, and “given the unique nature of this project and the limited water quality data regarding the use of copper in marine aquaculture operations,” the Permit includes a water quality monitoring provision for copper at multiple locations in the water column. *Id.*

On appeal, CFS does not argue that copper will be discharged in the effluent from this Facility, or otherwise confront the Region's determination that copper will not occur in measurable concentrations. *See generally* CFS Pet. at 31-32; *see also* 40 C.F.R. § 124.19(a)(4)(ii) (requiring petitioners to explain why a permit issuer's response to comments is clearly erroneous or otherwise warrants review); *City of Pittsfield*, NPDES Appeal No. 08-19, at 10-12. Instead, CFS relies on the fact that the Permit requires monitoring for copper as the basis for the Region's obligation to consider copper in its ODC Evaluation. CFS Pet. at 31-32. CFS then states without citation or support that “[t]he use of copper net pens can result in heavy metals being released into the environment and subsequent bioaccumulation.” *Id.* at 32.

Under the Ocean Discharge Criteria regulations, the Region is required to consider “[t]he quantities, composition and potential for bioaccumulation or persistence of the pollutants to be discharged.” 40 C.F.R. § 125.122(a)(1) (ODC factors number 1). As stated above, the Region here considered whether copper

²⁴ FoA does not raise this issue in its petition for review.

cages would create an issue for ocean water or marine life and concluded that copper was not expected to occur in measurable levels in the Facility's effluent. Resp. to Cmts. at 15. CFS points to no information to undermine the Region's conclusion, instead relying on the Region's imposition of a monitoring requirement for copper as evidence that the Region believed copper would be discharged. CFS's reliance is misplaced. The fact that the Region conservatively decided to impose a monitoring requirement for copper "given the unique nature of this project and the limited water quality data regarding the use of copper in marine aquaculture operations"—to ensure that copper is not released at a level of concern—does not undermine the Region's conclusion that copper is not expected to occur in measurable levels in the Facility's effluent. CFS has not met its burden to show that the Region clearly erred in its consideration of copper in its evaluation of the Ocean Discharge Criteria.

In sum, based on our review of the record as a whole, the Region based its unreasonable degradation determination on its consideration of the ODC factors, including the potential impacts of the pollutants identified by Petitioners.

3. *The Region Could, But Was Not Required to, Include Certain Permit Conditions Under 40 C.F.R. § 125.123(d).*

Next, FoA argues that the Region was required under 40 C.F.R. § 125.123(d)(2) to include more or different monitoring than the Region required. FoA Pet. at 12. CFS argues that the Region failed to include the reopener provision specified under 40 C.F.R. § 125.123(d)(4), which requires that the permit will be revoked or modified if, on the basis of new data, the permit issuer determines that continued discharges may cause unreasonable degradation of the marine environment.²⁵ CFS Pet. at 33-34. Both Petitioners misconstrue the regulatory requirements. Paragraph (d) of section 125.123 requires that certain provisions be included in "permits which authorize the discharge of pollutants pursuant to paragraph (c)." 40 C.F.R. § 125.123(d). As the Region points out, however, "paragraph (c)" authorizes the Region to issue permits for ocean discharges when it has "insufficient information to determine prior to permit issuance that there will

²⁵ The Permit issued does contain a reopener provision, but that provision is not as broad as the reopener provision in the Ocean Discharge Criteria regulations for permits based on insufficient information, which allows for reopening a permit any time the permit issuer determines, based on new data, that "continued discharges may cause unreasonable degradation of the marine environment." *Compare* 40 C.F.R. § 125.123(d)(4) *with* Permit at 25.

be no unreasonable degradation of the marine environment,” so long as certain other conditions are met. *Id.* § 125.123(c); Region’s Resp. to CFS Pet. at 26. In issuing this Permit, however, the Region did not rely on paragraph (c). *See* ODCE at 47 (relying on 40 C.F.R. § 125.123(a) as the basis for including permit conditions it found “necessary.”); 48 (“Sufficient information currently exists regarding open water marine fish farming activities and expected impacts from activities, coupled with information regarding proposed discharge, to allow the EPA to adequately predict likely environmental outcomes for the Proposed project.”). As such, the permit conditions in 40 C.F.R. § 125.123(d) are not mandatory for this Permit as issued. *See Alaska Eskimo*, 791 F.3d at 1094 (holding that 40 C.F.R. § 125.123(a) and § 125.123(c) represent separate paths to determining that a discharge will not cause unreasonable degradation of the marine environment and rejecting the notion that the permit authority was required to include the provisions of paragraph (d) when the permit was issued under paragraph (a)). Because the Permit in this case was issued pursuant to paragraph (a), the Region was not required to include the provisions of paragraph (d), and the fact that the Region opted to include some of these conditions did not render the other conditions mandatory. *See id.*

4. *The Region Must Correct the Record to Reflect Its Ultimate Conclusion*

As discussed above, the Ocean Discharge Criteria provide that, if the Region determines “on the basis of available information * * * that the discharge will not cause unreasonable degradation of the marine environment” after application of permit conditions, then the Region “may issue an NPDES permit containing such conditions.” 40 C.F.R. § 125.123(a) (emphasis added). In contrast, the Region may not issue an NPDES permit if the Region determines “on the basis of available information * * * that the discharge will cause unreasonable degradation of the marine environment” after application of permit conditions. *Id.* § 125.123(b).

Here, the final two sentences of the Region’s conclusion in the ODC Evaluation are as follows:

EPA finds that * * * [the conditions of the Permit] will ensure that the discharges from the [F]acility *do not cause unreasonable degradation* of the marine environment.

and

The EPA finds that ‘*no unreasonable degradation*’ will likely occur as a result of the discharges from this project based on the available scientific information concerning open ocean fish farming, the results predicted by deposition and dilution modeling, the effluent

limit guidelines for the CAAP industry that are being applied to this [F]acility, and the conditions included within the NPDES [P]ermit as allowed by the [Ocean Discharge Criteria] implementing regulations.

ODCE at 48 (emphases added). Thus, the Region has said two different things in its conclusion in the ODC Evaluation. Finding that the Permit, with its associated conditions, ensures that discharges “do not cause” unreasonable degradation and finding that “‘no-unreasonable degradation’ will likely occur” are not synonymous. The former indicates that permitted discharges will not cause unreasonable degradation; the latter acknowledges that unreasonable degradation may occur as a result of the permitted discharges. It is the former determination that the Region is required to make when issuing the NPDES Permit at issue. See 40 C.F.R. § 125.122(a).

When asked about the inconsistency of language at oral argument and, in particular, about the Region’s use of the phrase that no unreasonable degradation “*will likely occur*” in its final sentence, counsel for the Region referred to the phrasing as “inartful,” and as “just a relic of inartful characterization drafting.” Oral Arg. Tr. at 75. The Ocean Discharge Criteria clearly require the Region make a specific determination before issuing an NPDES permit. As explained above, the unambiguous language of the regulation provides that a permit may be issued authorizing a discharge into federal waters if that discharge will not cause unreasonable degradation of the marine environment. 40 C.F.R. § 125.123(a). That requirement lies at the core of the Ocean Discharge Criteria.

While the use of the phrase “no unreasonable degradation *will likely occur*” may be the result of inartful drafting, given the dichotomous phraseology within the last two sentences of the Region’s conclusion, we remand for the Region to formally clarify its determination. Cf. *In re City of Marlborough*, 12 E.A.D. 235, 250-52 (EAB 2005) (remanding permitting decision that included language inconsistent with determination required by regulation); *In re City of Port St. Joe & Fla. Coast Paper Co.*, 7 E.A.D. 275, 304-05 (EAB 1997) (remanding permit for clarification of the Region’s response to petitioners’ arguments based on the permit authority’s contradictory positions between its response to comments on the draft permit and its statements on appeal).

C. Petitioners Have Not Demonstrated the Region Clearly Erred in its Consideration of the Proposed Permit Under the Endangered Species Act

Finally, CFS and FoA challenge the Region’s Biological Assessment under the ESA on a variety of grounds. We first examine the Region’s obligation to

consider the ESA in the context of an NPDES permit and then consider the specific challenges to the Region's Biological Assessment in the context of the Permit at issue.

The ESA requires that each federal agency ensure, through consultation with the appropriate federal wildlife agency (*e.g.*, FWS or NMFS), that any action it authorizes “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” determined to be critical. ESA § 7, 16 U.S.C. § 1536(a)(2); *see also* ESA § 2, 16 U.S.C. § 1531 (and implementing regulations at 50 C.F.R. part 402). Under the ESA's implementing regulations, an agency is not subject to the formal consultation requirements if it: (1) prepares a biological assessment evaluating the potential effects of the action on listed species; (2) determines in the assessment that the action is “not likely to adversely affect” such species or critical habitat; and (3) receives written concurrence from FWS and/or NMFS, as appropriate, on its determination. *See* 50 C.F.R. §§ 402.12, .13(c), .14(b)(1); *see also Phelps Dodge*, 10 E.A.D. at 486 & n.24 (explaining that if an agency determines that its proposed action is not likely to adversely affect any listed species or critical habitat and receives concurrence from the appropriate federal agency (either NMFS or FWS or both), then no formal consultation is required). A finding of “not likely to adversely affect,” sometimes referred to as an NLAA, is appropriate when all the effects of the action are expected to be discountable, insignificant, or completely beneficial. U.S. EPA, Region 4, & USACE, Jacksonville Dist., *Final Biological Evaluation, Ocean Era, Inc. –Velella Epsilon*, at 21 (Sept. 30, 2020) (A.R. B.10) (“BE”); *see also* FWS & NMFS, *The Endangered Species Consultation Handbook* at xv (Mar. 1998) (A.R. No. C.89) (“ESA Handbook”) (cited in BE at 21). Discountable effects are those extremely unlikely to occur. BE at 21; ESA Handbook at xvi. Insignificant effects relate to the size of the impact and should never reach the scale where a “take” occurs. BE at 21; ESA Handbook at xv-xvi. Beneficial effects are contemporaneous positive effects that have no adverse effects to the listed species or critical habitat. BE at 21; ESA Handbook at xv; *see also Conservation Cong. v. U.S. Forest Serv.*, 720 F.3d 1048, 1052 n.5 (9th Cir. 2013) (quoting the ESA Handbook).

As described above, when listed species may be present in the action area, a permit issuer first conducts a biological assessment to evaluate the potential effects of the action on such species and designated and proposed critical habitat to “determine whether any such species or habitat are likely to be adversely affected by the action.” *See* 50 C.F.R. § 402.12(a). The contents of that biological assessment are determined at the “discretion” of the preparing agency and “depend on the nature of the [f]ederal action.” *Id.* § 402.12(f) (identifying what “may be

considered for inclusion ” in a biological assessment, such as on-site inspections of the affected area, expert views, literature reviews, and analysis of alternate actions, as well as a “consideration of cumulative effects, and the results of any related studies”); *see also Conservation Cong.*, 720 F.3d at 1056 (explaining that the contents of a biological assessment are discretionary and that the relevant inquiry required to be made is “whether any [endangered] species or [critical] habitat are likely to be adversely affected by the action,”) (quoting 50 C.F.R. § 402.12(f)); *Medina Cty. Env’t Action Ass’n v. Surface Transp. Bd.*, 602 F.3d 687, 699 (5th Cir. 2010) (determining a biological assessment was appropriate where it included only those actions associated with proposed action that were reasonably certain to occur); *Water Keeper All. v. U.S. Dep’t of Def.*, 271 F.3d 21, 33 (1st Cir. 2001) (explaining the discretionary content of a biological assessment).

On appeal, the Board reviews for clear error whether a permit issuer has satisfied its obligation under the ESA when issuing an NPDES permit. *See* 40 C.F.R. § 124.19(a)(4); *In re Indeck-Elwood*, 13 E.A.D. 126, 212 n.162 (EAB 2006) (noting the Board’s substantive review of decisions derived from other statutory regimes, such as the ESA, when the applicable legal framework explicitly incorporates the requirements of the other statute by reference, such as in the NPDES permitting regulations); *see also, e.g., Phelps Dodge*, 10 E.A.D. at 489-502. The Board will uphold a permit authority’s reasonable exercise of discretion so long as the permitting authority’s decision is explained and supported in the record. *See, e.g., In re Guam Waterworks Auth.*, 15 E.A.D. 437, 443 n.7 (EAB 2011) (discussing the abuse of discretion standard); *Ash Grove*, 7 E.A.D. at 397 (“[A]cts of discretion must be adequately explained and justified.”).

For this Permit, it is undisputed that the Region and the USACE jointly issued a biological assessment of the proposed action and determined that “the proposed project’s potential threats ([including] disturbance, entanglement, vessel strike[s], and] water quality) to ESA-listed species and critical habitat are highly unlikely to occur or extremely minor in severity” and that “potential effects to ESA protected species and critical habitats are discountable or insignificant.” BE at 28. The Biological Assessment concluded either there was “no effect” on, or the proposed action “may affect, but [is] not likely to adversely affect,” each species considered. *Id.* at 27. Both FWS and NMFS reviewed the Biological Assessment and, as described above, FWS did not object and NMFS concurred with the Region and USACE’s conclusions. *See* Part V, above. Thus, the Region satisfied its procedural obligation under the ESA.

On appeal, Petitioners argue that the Region erred in finding that the proposed action is “not likely to affect” listed species and that, as such, the Region

“failed” to conduct a formal consultation and obtain a Biological Opinion. CFS Pet. at 53; *see also* FoA Pet. at 18. In so arguing, Petitioners essentially challenge the substance (or “content”) of the Region’s Biological Assessment by pointing to potential effects and impacts that the Region allegedly failed to consider. More specifically, CFS asserts that the Region clearly erred by failing to consider the potential effects and impacts to listed species from the release of excess food, light pollution, and fish escapes. CFS Pet. at 49-52. CFS also challenges the Region’s decision to limit its consideration of potential effects to the time period during which the Facility is permitted to operate. *Id.* at 52. FoA asserts that the Region failed to consider possible impacts on listed species with respect to the project’s potential to act as a fish attraction (or aggregating) device (“FAD”), degraded baseline conditions, and the effects of HABs. FoA Pet. at 18-34. As summarized below, we disagree that the Region failed to consider any of the effects and impacts that Petitioners identify.

With respect to excess food, the Region explained that the Permit directs the “efficient feed management and feeding strategies” to “minimize potential discharges of uneaten food.” Region’s Resp. to CFS Pet. at 27-28(citing Permit at 12); *see also* Resp. to Cmts. at 57 (citing Permit parts II and IV.A.1) (discussing feed management restrictions and controls, as well as the appropriate monitoring of feeding activities). Additionally, the Biological Assessment also noted that the risk of entanglements is minimized by the net-pen construction and materials—i.e., rigid and durable cage materials with taut lines reduce entanglements. BE at 21-26. And, as described in more detail below, the Region separately considered vessel strikes as well. Thus, the Region considered and addressed Petitioner’s concern that the release of excess feed could attract endangered species which could, in turn, increase the risk of entanglements and vessel strikes. *See* Pet. at 51; *see also* BE at 19-20 (discussing the required feed monitoring); Resp. to Cmts. at 15, 38 (discussing feed management).

With respect to light pollution, the Region explained in its Response to Comments that “[l]ight disturbance is not expected to be a relevant environmental stressor” because the Facility will not be using lights at night and the navigational lights from the mooring vessel and buoys are expected to be insignificant. Resp. to Cmts. at 38. CFS fails to address the Region’s response in its petition as is required. *See* Part VI.A, above; *see also* 40 C.F.R. § 124.19(a)(4)(ii); *see also* *Peabody*, 12 E.A.D. at 33 (explaining the requirement to “address the permit issuer’s responses to relevant comments” and “substantively confront the permit issuer’s subsequent explanations”).

The Region considered the possibility of fish escapes in the context of the ODC Evaluation and determined that they were unlikely to occur. *See* Part VI.B.2.d, above; *see also* Resp. to Cmts. at 19. The Region also responded to the comments that were raised with respect to listed species. Resp. to Cmts. at 38 (explaining, among other things, that the Facility must implement a “plan to mitigate environmental impacts during any disaster and prevent the release of aquatic animals”). On appeal, CFS has not articulated any basis for concluding that fish escapes are likely to happen or described with any specificity or support the effect that such escapes, if they occur, might have on listed species. *See* CFS Pet. at 51-52.

CFS also argues that the Region should have considered the full length of the five-year Permit term (even though the Permit authorizes operation of the Facility for only twelve to eighteen months during the five-year term), and that the Region should have taken into account the future growth potential of aquaculture and a possible request to renew the Permit. *Id.* at 52. CFS, however, has provided no legal basis in the ESA or elsewhere for requiring the Region to consider activity that is outside the scope of the Permit and the discharges that it authorizes. *See Medina Cty.*, 602 F.3d at 699 (holding that biological assessment was appropriate because it encompassed only those actions associated with proposed action that were reasonably certain to occur, and related development was not dependent on the proposed action such that it would be “interrelated,” “cumulative,” or an “indirect effect” of proposed action and thus was not required to be considered in the biological assessment under the ESA). Again, CFS has not met its burden to demonstrate that the Region clearly erred by failing to consider effects outside of the terms of the Permit.

The Region also considered the Permit’s impacts with respect to the project’s potential to act as a FAD, the degraded baseline conditions, and the effects of HABs. Region’s Resp. to FoA Pet. at 25-31. With respect to the project’s potential to act as a FAD, the Region considered both that potential and the likely impacts if that potential were realized (i.e., vessel strikes, entanglement, and increased fishing). *See, e.g.*, BE at 25 (recognizing and discounting the potential for an increase in fishing in the area due to the project acting as a FAD); *id.* at 24 (analyzing the potential for vessel strikes from both vessels associated with the proposed project, as well as vessels not operated by the Facility); *id.* at 24-25 (recognizing that ESA-listed turtles may be attracted to aquaculture facilities and discounting the potential effects from disturbance, vessel strikes from both Facility-operated vessels and other vessels); *id.* at 17-18 (discussing the rarity of vessel strikes with marine animals); *id.* at 17 (considering the potential for entanglements and discounting those effects based on the design of the Facility); NMFS

Concurrence at 6 (discussing the increase in vessels that would be necessary—around 200—to potentially result in a sea turtle take in any single year and recognizing but discounting potential stress or behavioral effects on ESA-listed fish and sea turtles that may be attracted to aquaculture facilities as potential sources of food, shelter, and/or rest); Resp. to Cmts. at 37-38 (responding to concerns raised, including those resulting from increased traffic, including noise, entanglement, vessel strikes, light pollution, excess food escape, nutrient pollution, and fish escapes, among other concerns); *see also* BE at 27 tbl.4 (listing the species considered, potential impacts and effects, and adverse effect determination).

The Region also considered the degraded baseline conditions of the marine environment, including the impacts associated with the Deepwater Horizon spill. *See, e.g.*, Final EA at 14, 50 (considering the Deepwater Horizon spill, recognizing that the cumulative impacts of that event are still relatively unknown, and determining that the minor incremental impact of the proposed project would have little cumulative impact in the Gulf); Final EA at 50-62 (describing the Region’s cumulative impacts analysis, which considered the incremental impact that the proposed action could have when added to other past, present, and reasonably foreseeable future actions including the Deepwater Horizon oil spill, oil and gas operations, other aquaculture operations, and natural disasters); BE at 8 (discussing the Baseline Environmental Survey which noted that there were no physical, biological, or archaeological features that would preclude siting the project in the proposed area); Resp. to Cmts. at 36 (explaining, in support of its consideration of cumulative effects, that the Biological Assessment broadly concluded that the proposed project is “highly unlikely” to affect listed species and critical habitat and that if effects occur, they would be extremely minor in severity).

With respect to the potential impact of the Permit on listed species through HABS, the Region—as explained in Part VI.B.2.a—considered the potential for discharges from the Facility to contribute to HABS and concluded that the discharge of nutrients from the Facility would not pose an environmental threat. *See* ODCE at 34-35, 43, 45; NMFS Concurrence at 7 (explaining and agreeing with EPA’s analysis and conclusions related to the release of nutrients); Resp. to Cmts. at 22-27 (addressing concerns related to HABS); *id.* at 38 (addressing comments regarding the adequacy of the Biological Assessment and potential water quality impacts on listed species).

Based on our review of the record, the Region considered the issues raised by Petitioners in assessing the potential effects and impacts from the proposed action on listed species and critical habitat. The Region concluded that the proposed action “is not likely to adversely affect” any listed species or critical

habitat. *See* NMFS Consultation Request at 2; FWS Consultation Request at 2. That determination was reviewed and considered by the FWS and NMFS—the federal organizations that are charged with ESA program responsibility and thus serve as federal ESA experts—neither of which disagreed with the Region. In this context, Petitioners have not provided the Board with a sufficient basis to further question the complex and comprehensive technical and scientific analysis and expertise not only of the Region, but of the consulting agencies that reviewed EPA’s evaluation and agreed with the Region’s determination.

Petitioners have not met their burden to show that the Region clearly erred in its consideration of the Permit under the ESA.

VII. *CONCLUSION*

For the reasons stated above, the Board denies review in part and remands in part this NPDES Permit. On remand, the Region must clearly state whether the Region determined that the permitted discharge will not cause unreasonable degradation of the marine environment.