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Guide to Permitting Marine Aquaculture in the United States (2022)



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Overview

This Guide to Permitting Marine Aquaculture in the United States was prepared by the National Oceanic and Atmospheric Administration (NOAA) in consultation with the Subcommittee on Aquaculture (SCA) under the National Science and Technology Council (NSTC). The purpose of this guide is to assist individuals with navigating the federal permitting process for marine aquaculture (finfish, shellfish, invertebrates, seaweed). Section 8 of the E.O. 13921, May 7, 2020 called on the Secretary of Commerce, in consultation with other appropriate Federal and State officials, to prepare and place prominently on an appropriate NOAA web page a single guidance document that describes the federal regulatory requirements and relevant federal and state agencies involved in aquaculture permitting and operations.

This guide is intended primarily for individuals seeking basic information about the federal aquaculture permitting requirements and processes. Depending on where an operation is sited, marine aquaculture is also subject to other municipal and state regulations which are not fully captured in this guide. This guidance document outlines the key requirements necessary to obtain federal permits to conduct commercial aquaculture activities and provides an overview of the federal statutes and regulations governing aquaculture in the United States. This guide is neither exhaustive nor inclusive, but is meant to reflect what a typical applicant for an aquaculture operation would require. We always encourage prospective growers to reach out to their local state or federal aquaculture coordinators for more direct and specific information.

Coordination of Federal Aquaculture-related Programs

The National Aquaculture Act of 1980 provides for an interagency coordinating body to provide leadership and to facilitate the coordination of federal programs associated with development of aquaculture in the United States. The Subcommittee on Aquaculture (SCA)—previously known as the Interagency Working Group on Aquaculture (IWGA) and the Joint Subcommittee on Aquaculture (JSA)—serves as the federal interagency coordinating group to increase the overall effectiveness and productivity of federal aquaculture research, regulation, technology transfer, and assistance programs. The SCA reports to the [National Science and Technology Council](#) (NSTC) and the [Office of Science and Technology Policy](#) (OSTP) in the [Executive Office of the President](#).

Improving Regulatory Transparency for Aquaculture: A Guide for Permitting Marine Aquaculture in the United States

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I. Federal Authorizations

Anyone who would like to establish a marine aquaculture operation must secure the appropriate federal permits, which may include a Clean Water Act National Pollutant Discharge Elimination System (NPDES) permit, a Rivers and Harbors Act Section 10 permit (Section 10) and/or verification, or a Clean Water Act Section 404 permit (Section 404) and/or verification (Table 1).

Additionally, depending on the species proposed for cultivation, it's possible that an operation must secure a permit from the [National Marine Fisheries Service](#) (NMFS) (referred to as NOAA Fisheries) under the [Magnuson-Stevens Fishery Conservation and Management Act](#) (MSA).

Table 1. Primary Federal Permits Required for Aquaculture Operations¹

Permit	Jurisdictional Waters	Agency	Statutes & Authorities	Facilities Required to Obtain Coverage	Application Form(s)
Section 10 Permit or Verification ²	Navigable waters, including outer continental shelf	U.S. Army Corps of Engineers (USACE)	Section 10 of the Rivers and Harbors Act of 1899 and the Outer Continental Shelf Lands Act	Required in navigable waters of the U.S. to protect navigation for commerce	ENG Form 4345
Section 404 Permit or Verification ²	Waters of the United States	U.S. Army Corps of Engineers (USACE)	Section 404 of the Clean Water Act (CWA)	Required for discharges of dredged or fill material into waters of the United States	ENG Form 4345 or ENG 6082 - Nationwide Permit Pre-Construction Notification
NPDES Permit	Federal waters ³ ; state waters in MA, NH, NM; all territorial waters except VI; Tribal waters; DC. State or territorial waters except MA, NH, NM, and VI.	U.S. Environmental Protection Agency (EPA). State/territorial agency authorized to implement the NPDES program.	Sections 402 and 403 of the Clean Water Act (CWA). In addition to CWA requirements, state regulations may apply.	Required for the discharge of pollutants to waters of the U.S. If the operation will add feed, nutrients, pharmaceuticals, antifouling agents, disinfectants, or any other substances or materials directly to, or that will be discharged to waters of the U.S., permit coverage is required.	National Pollutant Discharge Elimination System (NPDES) Permit Application Forms 1 and 2B . If a relevant General Permit is in effect, a Notice of Intent (NOI) form should be used. State programs often have their own application form(s) or NOIs.

Magnuson-Stevens Fishery Conservation and Management Act (MSA)	Federal waters	NOAA Fisheries	Magnuson-Stevens Fishery Conservation and Management Act (MSA)	Activities and operations related to the catching, taking, or harvesting of MSA managed species.	Should be verified with the applicable NOAA Fisheries regional office.
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1. This list is neither exhaustive nor inclusive, but is meant to reflect what a typical applicant for an aquaculture operation in federal waters would require. For example, a permit may be required under the National Marine Sanctuaries Act when an individual wishes to conduct an activity within or into a sanctuary that is otherwise prohibited; however that’s not a typical location to cite an operation.
2. The Corps issues verifications for proposed activities under an established Nationwide Permit.
3. For purposes of federal permitting under the Clean Water Act (CWA), federal waters begin at 3 nautical miles from shore and extend to approximately 200 nautical miles from the coast. Under the Submerged Lands Act title to submerged lands in the Gulf of Mexico has been transferred to Texas and Florida out to 9 nautical miles from shore, but this does not affect CWA jurisdiction. For purposes of permitting under Section 10 of the Rivers and Harbors, USACE issues permits for both state and federal waters, regardless of title under the Submerged Lands Act.

Overview of Primary Federal Permits

A. Section 10 of the Rivers and Harbors Act of 1899 Permits and Section 404 of the Clean Water Act Permits

Agency: U.S. Army Corps of Engineers (USACE)

Summary of Authority:

The USACE—under section 10 of the Rivers and Harbors Act of 1899 [RHA (33 U.S.C. §403)], including the extension of the RHA to the limits of the outer continental shelf by the Outer Continental Shelf Lands Act {OCSLA [43 U.S.C. §1333(a)(1)]}, and section 404 of the Clean Water Act [CWA (33 U.S.C. §1344)]—renders decisions for aquaculture activities affecting navigable waters and resulting in discharges of dredged or fill material into waters of the United States.

Section 10 authority prohibits the unauthorized obstruction or alternation of any navigable water of the U.S. The construction of any structure in or over any navigable water of the U.S., the excavating from or depositing of material in such waters, or the accomplishment of any other work affecting the course, location, condition, or capacity of such waters is unlawful unless the work has been authorized by USACE through Department of the Army permit (33 CFR 320.2(b)). Additionally, the authority of the Secretary of the Army to prevent obstructions to navigation in navigable waters of the United States was extended to artificial islands, installations, and other devices located on the seabed, to the seaward limit of the outer continental shelf, by section 4(f) of the Outer Continental Shelf Lands Act of 1953 as amended (43 U.S.C. 1333(e)). Section 404 of the CWA authorizes the Secretary of the Army, acting through the Chief of Engineers, to issue permits after notice and opportunity for public hearing, for the discharge of dredged or fill material into the Waters of the U.S. at specified disposal sites (33 CFR 320.2(f)).

Types of Permits:

1. **General Permit (GP):** The USACE promotes the use of General Permits (GPs) whenever possible because GPs are intended to streamline the authorization process for defined categories of activities that only result in minimal individual and cumulative adverse effects to the

environment. GPs include Nationwide Permits (NWP), Regional General Permits (RGPs), and Programmatic General Permits (PGPs). GPs are reissued every 5 years and proposed activities are verified if they meet the terms and conditions of the GP; therefore, authorization for activities under an NWP is called a “verification” as opposed to a “permit”. USACE divisions and districts may add regional and project-specific conditions to NWPs, and USACE districts may develop RGPs to address state or regional laws and environmental concerns. Aquaculture activities that do not qualify for a GP may be authorized by an individual permit (IP). While a GP process is typically less cumbersome than an IP process, external agency consultation (e.g., National Marine Fisheries Service, U.S. Fish and Wildlife Service, State Historic Preservation Officer, etc.), and tribal consultations may still be required. In accordance with Executive Order 13921, Promoting American Seafood Competitiveness and Economic Growth, which directed USACE to remove barriers to aquaculture permitting, the two below NWPs were developed and published in the Federal Register on 13 January 2021 and became effective on 15 March 2021:

- a. **NWP 55 - Seaweed Mariculture Activities:** Structures in marine and estuarine waters, including structures anchored to the seabed in waters overlying the outer continental shelf, for seaweed mariculture activities. This NWP also authorizes structures for bivalve shellfish mariculture if shellfish production is a component of an integrated multi-trophic mariculture system (e.g., the production of seaweed and bivalve shellfish on the same structure or a nearby mariculture structure that is part of the single and complete project). This NWP authorizes the installation of buoys, long-lines, floats, anchors, rafts, racks, and other similar structures into navigable waters of the United States.
- b. **NWP 56 - Finfish Mariculture Activities:** Structures in marine and estuarine waters, including structures anchored to the seabed in waters overlying the outer continental shelf, for finfish mariculture activities. This NWP also authorizes structures for bivalve shellfish mariculture and/or seaweed mariculture if the structures for bivalve shellfish and/or seaweed production are a component of an integrated multi-trophic mariculture structure (e.g., the production of bivalve shellfish or seaweed on the structure used for finfish mariculture, or a nearby mariculture structure that is part of the single and complete project). This NWP authorizes the installation of cages, net pens, anchors, floats, buoys, and other similar structures into navigable waters of the United States. This NWP does not authorize the construction of land-based fish hatcheries or other attendant features.

Additionally, the NWP 48 was reissued on 13 January 2021 and became effective on 15 March 2021:

- c. **NWP 48 - Commercial Shellfish Mariculture Activities:** Structures or work in navigable waters of the United States and discharges of dredged or fill material into waters of the United States necessary for new and continuing commercial shellfish mariculture operations (i.e., the cultivation of bivalve mollusks such as oysters, mussels, clams, and scallops) in authorized project areas. For the purposes of this NWP, the project area is the area in which the operator is authorized to conduct commercial shellfish mariculture activities, as identified through a lease or permit issued by an appropriate

state or local government agency, a treaty, or any easement, lease, deed, contract, or other legally binding agreement that establishes an enforceable property interest for the operator. This NWP authorizes the installation of buoys, floats, racks, trays, nets, lines, tubes, containers, and other structures into navigable waters of the United States. This NWP also authorizes discharges of dredged or fill material into waters of the United States necessary for shellfish seeding, rearing, cultivating, transplanting, and harvesting activities.

- 2. Individual Permit (IP):** Individual Permits (IPs) are customized for specific activities that do not qualify for a GP and can be issued for a permit duration longer than 5 years, if appropriate. The IP process may include steps such as reviewing the application, publishing a public notice with comment period, sending agency notification letters, coordinating internal and external agency input for compliance with other federal laws (e.g. Endangered Species Act, National Historic Preservation Act, etc.), consulting with Tribes, documenting decision-making processes including National Environmental Policy Act (NEPA) analysis, 404(b)(1) analysis, a Public Interest Review, and drafting the permit. There are two types of IPs: Letters of Permission (LOP) and Standard Permits (SP). A LOP is a type of IP with an abbreviated process that includes coordination with federal and state fish and wildlife agencies and a Public Interest Review but without the publishing of an individual public notice. Section 10 work that is determined to be minor, would not have significant individual or cumulative impacts on environmental value, and should encounter no appreciable opposition (33 CFR 325.5(b)(2)). For Section 404 activities, an LOP may only be issued after : a) The district engineer, through consultation with federal and state fish and wildlife agencies, the Regional Administrator, Environmental Protection Agency, the state water quality certifying agency, and, if appropriate, the state Coastal Zone Management Agency, develops a list of categories of activities proposed for authorization under LOP procedures; b) The district engineer issues a public notice advertising the proposed list and the LOP procedures, requesting comments and offering an opportunity for public hearing; and c) 401 certification has been issued or waived and, if appropriate, CZMA consistency concurrence is obtained or presumed either on a generic or individual basis. Additionally, LOPs are categorically excluded from NEPA documentation (CFR 225 Appendix B 6(5)). If a project does not qualify for a GP or an LOP, it will be processed as an SP. As described above, SPs require the publishing of an individual public notice and are not categorically excluded from NEPA documentation. Section 10 and Section 404 SPs are processed the same, with the exception that a 404(b)(1) analysis is required for Section 404 activities. The type of authorization issued for aquaculture activities depends on the location and the activity. For example, a fish pen located 10 miles offshore could be processed under an NWP 56, a LOP, or a SP, while an inshore shellfish mariculture operation involving a discharge of fill material could be processed as an NWP-48 or SP.

Resources:

- [USACE. "How to Obtain a Permit."](#)
- [Example of "Nationwide Pre-Construction Notification \(PCN\)," form ENG 6082](#)

B. National Pollutant Discharge Elimination System (NPDES) Permit

Agency: Environmental Protection Agency (EPA) or Authorized State Agency

Summary of Authority:

Section 301(a) of the Clean Water Act prohibits the “discharge of any pollutant” except in compliance with prescribed provisions of the CWA, including section 402. Section 402 of the CWA establishes the National Pollutant Discharge Elimination System (NPDES) and authorizes EPA or authorized states/territories to issue permits for point source discharges of pollutants into waters of the U.S., including the territorial seas. The NPDES implementing regulations are at 40 CFR Parts 122 through 129. In addition, Section 403 of the CWA, Ocean Discharge Criteria, provides that no NPDES permit may be issued for discharges into the territorial sea, the waters of the contiguous zone, or the oceans except in compliance with guidelines for the determination of degradation of those waters, per 40 CFR Part 125, Subpart M. An NPDES permit may be required for off-shore aquaculture operations depending on the production thresholds and the types of culturing systems. Shellfish and macroalgae operations that add no substances or materials to waters of the U.S. at any time during operations, may not be required to obtain NPDES permit coverage; this should be confirmed with the relevant permitting authority. In state waters, discharge regulations in addition to NPDES requirements may apply.

NPDES permits may be individual (tailored to a single facility) or general (tailored to cover multiple operations with similar types of discharges, often within a specified geographic area). For individual permits applicable to federal waters, EPA Form 1 must be submitted by all NPDES applicants; [Concentrated Aquatic Animal Production](#) (CAAP) operations must also submit Form 2B. Where general permits exist applicants will usually request coverage using a specified Notice of Intent (NOI). NPDES-authorized State or Territory programs often have their own application form(s) or NOIs. In federal waters EPA will also request baseline environmental survey information in order to adequately assess for compliance with the Ocean Discharge Criteria. EPA may also request additional information in order to fulfill requirements under the National Environmental Policy Act, the Endangered Species Act and the essential fish habitat requirements of the Magnuson-Stevens Fisheries Conservation and Management Act (see Section IV of this Guide).

Once the permitting authority has drafted the permit it will publish notice of the draft permit for public comment, typically for 30 to 60 days depending on the level of public interest. If requested to do so, the permitting authority may also hold a public hearing on the draft permit. Following the close of the public comment period, the agency will consider all comments received and, as appropriate, finalize the permit. The final permit will be published along with a document explaining how the agency responded to all comments received, including any changes made to the permit as a result of the comments. NPDES permits are issued for a period not to exceed five years. Monitoring results must be regularly reported (the frequency will be identified in the permit), and annual reports may also be required. The agency may also perform compliance inspections at the facility. Permits must be reapplied for every 5 years for as long as the facility continues to discharge.

Resources:

- [NPDES Permitting Program: Application Form 1, General Information](#)

- [NPDES Permitting Program: Application Form 2B, Concentrated Animal Feeding Operations and Concentrated Aquatic Animal Production Facilities](#)
- [Concentrated Aquatic Animal Production Compliance Guide and Reporting Forms](#)
- [EPA NPDES Program Contacts \(Aquaculture\)](#)
- [EPA NPDES Agency Contacts for Permits Issued by Authorized State/Territorial Programs](#)

C. Magnuson-Stevens Fishery and Conservation Management Act (MSA) Permit

Agency: National Marine Fisheries Service (NOAA Fisheries)

Summary of Authority:

NOAA Fisheries, acting under authority delegated from the Secretary of Commerce, is responsible for conserving and managing fisheries from the seaward boundaries of states out to 200 nautical miles. Under the MSA, eight Regional Fishery Management Councils are charged with preparing Fishery Management Plans and amendments (collectively, FMPs) for fisheries under their geographic areas of authority that require conservation and management. Councils also submit proposed implementing regulations that they deem necessary and appropriate. NOAA Fisheries approves or disapproves Council-developed FMPs based on consistency with MSA provisions and other applicable law, and promulgates implementing regulations. Not every Council managed geographic area may have an FMP governing aquaculture. Applicants for aquaculture operations in federal waters should check with their NOAA Fisheries Regional Office if a plan exists and inquire what is required under that plan. NOAA Fisheries directly prepares the FMP for Atlantic Highly Migratory Species and may prepare other FMPs as described in MSA section 304(c). In addition, NOAA Fisheries has general rulemaking authority to implement the Act. For example, NOAA Fisheries may issue an exempted fishing permit (EFP), under 50 CFR 600.745, authorizing the otherwise prohibited harvest of a species managed under an FMP, for various purposes, which may include marine aquaculture activities.

Resources:

- [U.S. Regional Fishery Management Councils](#)
 - [NOAA Fisheries Office of Aquaculture: Regulation and Policy](#)
 - [Example of an Aquaculture EFP \('Special Coral Reef Ecosystem Fishing Permit'\)](#)
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II. Overview of Federal Permitting Process

A. Pre-application Phase

Federal agencies have been setting up regional coordination groups or committees to create a more efficient and streamlined regulatory process. For example, USACE, EPA, NOAA, USFWS, USDA, DOD, BOEM, BSEE, and the Coast Guard established a coordinated process for permitting offshore aquaculture in the Gulf of Mexico. A memorandum of understanding (MOU) and several guidance documents developed by this work group provide a model for other potential regional efforts (for more information, see [Marine Aquaculture in NOAA Fisheries' Southeast Region](#)).

A pre-application phase focuses primarily on siting of the aquaculture operation. Siting is one of the most complicated and expensive parts of the permitting process and has the potential to generate numerous associated conflicts. Thus, having all interests represented up front avoids sending the applicant back to the drawing board because of one or more previously unidentified conflicts. A pre-application process clarifies the expectations of all agencies for the applicant. Pre-application meetings can help ensure a well-documented application is prepared with supporting technical information necessary for thorough permitting and environmental review.

The pre-application coordination provides the applicant with an assessment of the viability of some of the more obvious alternatives available to accomplish the project purpose. The coordination allows the applicant the opportunity to discuss measures for reducing the impacts of the project, and review the factors the permitting agency must consider in its decision-making process. Scoping meetings can help applicants define project purpose and need statements required for permit applications. This helps federal action agencies in consideration of practicable alternatives and in risk assessment for avoidance, minimization, and mitigation of impacts.

In locations where federal and/or state agencies have not established formal interagency cooperative pre-application processes, the permitting agencies may provide, at the request of the applicant, assistance during the pre-application phase. Anyone considering establishing an aquaculture operation is encouraged to contact the permitting authorities prior to submitting permit applications. The permitting authorities can provide clarity on what information should be included in the application, and what the permitting process will entail. This could help ensure that resources are expended only on required information and may also expedite processing of the permits.

B. Permit Application, Development, and Issuance Phase

Applicants must complete and submit separate application forms for the permitting agencies, as appropriate (see Table 1). While preparing permit applications, applicants are encouraged to maintain open communication with the relevant point of contact at each agency. Agencies may also contact applicants if additional information is needed to assist in their review processes and applicants should provide the necessary information in a timely fashion to reduce delays in obtaining permits.

If the applicant is eligible for coverage under an existing General Permit (NPDES or USACE Section 10/404), coverage may potentially be obtained relatively quickly due to some consultations, reviews, and public notice and comment (described later in this document) having been done up-front, assuming all applicable conditions are met and no exceptional circumstances exist. If an individual permit is required, the process will take longer since the agency must conduct all analyses associated with developing the permit, publish a public notice and provide a comment period, conduct public hearings if required, coordinate internal and external agency input, consult with Tribes and other federal agencies, and conduct environmental reviews.

C. Permit Operational Phase

- **Implementing Permit Conditions:** All permits must be issued and in effect before operations may commence, i.e., before structures, plants or animals may be placed in the water. Permits contain a variety of terms and conditions with which the operator must comply, so the operator should read each permit and develop the necessary systems and schedules to ensure that all operational requirements are met, all monitoring is conducted according to methods and schedules, all records are properly kept, and all reports are submitted on time.
- **Compliance:** Periodically, one or more of the agencies may conduct compliance reviews or inspections. A review may be as simple as requesting clarification on an item the applicant has included in a report. However, the agency may also request records for a more thorough review and may also conduct an on-site inspection of the operation. The regulatory authorities for these reviews and inspections are clearly established, and applicants are encouraged to cooperate fully. Each agency has policies to protect Confidential Business Information (CBI); if an applicant believes that certain information required to be included in a report or inspection falls into this category, they must inform the relevant agency(s); each agency will make a determination as to whether the information meets the criteria for CBI.

Permittees are encouraged to contact the permitting or authorizing agency with questions or concerns at any time, preferably as soon as they arise. The agencies generally provide guidance or technical assistance to support compliance with the relevant requirements and are invested in ensuring the success of permittees in meeting those requirements.

When agency compliance efforts identify permit violations, the agency will generally work with the operator to get the facility back into compliance. Operators are encouraged to cooperate fully with these efforts in order to avoid or minimize enforcement consequences.

- **Permit Modification:** If the operator decides to change structural components or operational conditions during the permit term beyond parameters established in the permit, e.g., production thresholds are increased or the anchoring or management

systems are modified, the permittee should contact the applicable permitting agency prior to implementation of these changes. The permit may need to be modified to accommodate these changes. The operator may also consider whether the timing of the changes could be aligned with permit reissuance, at which time the permit can be adapted to the changing conditions.

- **Permit Reissuance:** Appropriate permits must be in effect for the aquaculture operation to remain authorized. The permittee should be aware of expiration dates for all permits, and the deadlines for submitting applications for renewal, which are often well in advance of the expiration dates. Permit reissuance provides an opportunity to refine the permit to more effectively accommodate existing or new conditions in the operation, changes in the local environment, improvements to technology, changes in standards, and other factors.
- **Facility Closure:** If the operator plans to suspend operations or close the facility, the permit likely stipulates specific provisions with which the operator must comply, including notifying the permitting agency in advance of these types of actions.

III. Other Federal Agency Authorizations and Processes

For operations proposed in federal waters, the Bureau of Ocean Energy Management (BOEM) and the Bureau of Safety and Environmental Enforcement (BSEE) must review and provide certain approvals for the activities permitted by the EPA and the USACE, if those activities are co-located with existing oil and gas facilities. These approvals will be incorporated into the federal permitting processes, i.e., no separate authorizations will be issued.

The U.S. Department of Defense's Military Aviation and Installation Assurance Siting Clearinghouse may coordinate with relevant branches of the military to ensure that the aquaculture operation is not sited in a location that would interfere with national security, including military readiness operations that could damage or disrupt the facility.

Once all federal permits have been obtained, or during the permitting stage, applicants must apply to the U.S. Coast Guard (USCG) to receive an authorization to deploy Private Aids to Navigation (PATON), e.g., markers, buoys, at their approved aquaculture operation site. These other types of authorizations are summarized in Tables 2A and 2B below.

Table 2A. Federal Authorizations and Reviews Required for Aquaculture Operations

Agency	Statutes & Authorities	Purpose	Application Process	Form of Authorization
U.S. Coast Guard (USCG)	33 U.S.C. 1221 <i>et seq</i> ; 33 CFR Part 66	Ensure safe navigation; authorize private aids to navigation	Private Aids to Navigation application form CG-2554	Formal authorization from appropriate USCG district
U.S. Department of Agriculture Animal and Plant Health Inspection Service Veterinary Services (USDA APHIS VS)	Animal Health Protection Act (AHPA) (7 USC Sections 8322 and 10401)	Authority over the prevention, detection, control, and eradication of animal diseases, including aquaculture	National Aquaculture Health Plan and Standards	Consultation only
DoD; Military Aviation and Installation Assurance Siting Clearinghouse	32 CFR Part 211	Minimize conflicts with military readiness operations	Initiated through the Clearinghouse website	Consultation only

Table 2B. Additional Authorizations for Aquaculture Operations Co-located with OCS Oil and Gas Facilities

Agencies	Statutes & Authorities	Purpose	Application Process	Form of Authorization
Bureau of Ocean Energy Mgmt. (BOEM)	Outer Continental Shelf Lands Act; Energy Policy Act of 2005; 30 CFR Parts 500-599	Required for any offshore aquaculture operations that utilize or tether to existing oil/gas facilities	Right of Use and Easement (RUE) for Energy and Marine-related Activities Using Existing Outer Continental Shelf (OCS) Facilities	A formal RUE is established using the facility for the purpose of aquaculture.
Bureau of Safety and Environmental Enforcement (BSEE)	Outer Continental Shelf Lands Act; Energy Policy Act of 2005; 30 CFR Parts 500-599	Required for any offshore aquaculture operations that utilize or tether to existing oil/gas facilities	—	Consultation only.

Type of Authorization: Private Aids to Navigation (PATON) Permit

Agency: U.S. Coast Guard

Summary of Authority:

The Coast Guard has authority to control private aids to navigation in waters subject to the jurisdiction of the United States and on the outer continental shelf, and on the high seas when the owner is subject to the jurisdiction of the United States. This includes regulating the establishment, maintenance and discontinuance of private aids to navigation. (14 USC § 542).

The District Commander authorizes private aids to navigation. Private aids may, in some instances, comprise an entire aid system. Private aids may be used to mark navigation obstructions, piers, docks and private navigation channels that may be of use to a private user group. The characteristics of a private aid to navigation shall conform to the U.S. Aids to Navigation System (33 CFR Part 66).

Standard Process:

When the applicant receives the USACE permit approval for the aquaculture project, it is necessary that the applicant directly contact the USCG District Private Aids to Navigation Section via email to request a Coast Guard marking determination for the aquaculture project. At that time, the applicant may ask questions and discuss the necessary Private Aids to Navigation markings. If markings are required, then the applicant shall be required to forward a signed and completed CG-2554 - Private Aids to Navigation application along with a copy of the USACE permit approval for the aquaculture project to the appropriate USCG District Private Aids to Navigation Section via email or USPS mail. CG-2554 Application is required a minimum of 90 days prior to installation of required/proposed Private Aids to Navigation. Applicants should check with their local USCG and Corps of Engineers offices to ensure there are no additional, regionally-specific requirements. For example, offshore projects in California may need to submit a Navigation Hazard Risk Assessment.

Resources:

- [Private Aids to Navigation Application Form 2554](#)

Type of Authorization: Review/Approval

Agency: USDA APHIS Veterinary Services (VS)

Summary of Authority:

The Animal Health Protection Act (AHPA; 7 USC) grants the Secretary of Agriculture authority over the prevention, detection, control, and eradication of animal diseases, including aquaculture, with 'animal' defined as any member of the animal kingdom (excluding humans). Section 8322, (National Aquatic Animal Health Plan) grants the Secretary of Agriculture authority to enter into cooperative agreements for the purpose of detecting, controlling, or eradicating diseases of aquaculture species and promoting species-specific best management practices. Section 10401 provides authority for the Secretary to regulate aquaculture. This includes health certification for export, negotiations of sanitary regulations,

regulation of biologics, World Organization of Animal Health (OIE) representation, regulation of imported aquatic animals and products, diagnostic services, and disease control and eradication.

Standard Process:

Consultation with APHIS VS is requested for any permitted aquaculture operations prior to stocking aquatic animals in marine federal waters to ensure both animal health safety and security. The National Aquaculture Health Plan and Standards (NAHP&S) provides guidance on health inspection and oversight for aquatic animals stocked and harvested from federal marine waters.

Resources:

- [Title 7 CFR 371.4 – Veterinary Services \(VS\)](#): describes the role of APHIS Veterinary Services.
- [Title 9 CFR Part 161 – Requirements and Standards for Accredited Veterinarians and Suspension or Revocation of Such Accreditation](#)
- [Title 9 CFR Part 130 – User Fees](#)
- [Title 9 CFR Part 93.900 et. seq. – Importation of Certain Animals, Birds, Fish, and Poultry, and Certain Animal, Bird, and Poultry Products; Requirements for Means of Conveyance and Shipping Containers](#)
- [Title 9 CFR Part 53 – Foot-and-Mouth Disease, Pleuropneumonia, and Certain Other Communicable Diseases of Livestock or Poultry](#)

Type of Authorization: Informal Review Only

Agency: Department of Defense (DoD); Military Aviation and Installation Assurance Siting Clearinghouse

Summary of Authority:

The Military Aviation and Installation Assurance Siting Clearinghouse works with industry to overcome risks to national security while promoting compatible development. Development outside the installation fence line has the potential to degrade military testing, training and operations. The Department of Defense (DoD) does not have direct authority over offshore development, but does participate in state and federal review processes. The Clearinghouse performs reviews to help developers minimize risk and learn if any compatibility challenges might arise in one of the official processes. While DoD encourages developers to engage this process early, it is entirely voluntary for a private developer.

Standard Process:

When a project proponent provides a proposal to the DoD, the Clearinghouse shares the information with the Army, Air Force, Navy, Marine Corps, Space Force, Joint Staff and Combatant Commands. If a likely impact to military testing, training or operations is identified, the Clearinghouse provides a local point-of-contact to the requestor so that discussions can take place. There is no approval or denial of the project. The process is initiated through the Clearinghouse website. The Department of Defense may require mitigation or other considerations for offshore aquaculture development in operational areas to include Hold Harmless Agreements and Waivers of Liability. Additional information or operational requirements may be required of applicants.

Resources:

- [Military Aviation and Installation Assurance Siting Clearinghouse](#)

Type of Authorization: Right of Use and Easement (RUE) Permit for Alternate Use of Outer Continental Shelf (OCS) Facilities for Energy or Marine-related Purposes

Agency: Bureau of Ocean Energy Management (BOEM)

Summary of Authority:

Information forthcoming.

Standard Process:

Information forthcoming.

Type of Authorization: Review/Approval

Agency: Bureau of Safety and Environmental Enforcement (BSEE)

Summary of Authority:

Information forthcoming.

Standard Process:

Information forthcoming.

IV. Federal Consultation and Review Requirements

Permits issued by EPA and USACE are “federal actions.”⁴ Thus, EPA and the Corps must fulfill a variety of statutory requirements by consulting with other agencies during the permit development process (Table 3). The relevant and applicable provisions of the laws identified below will be applied during the permitting process, and may be reflected in certain permit provisions.

EPA and the Corps are responsible for undertaking these consultations and reviews, not the applicant. However, a non-federal applicant for a federal license or permit may provide a state with a consistency certification if the state has identified the federal license or permit on a list of activities subject to federal consistency review in its federally approved coastal management program. Still, to expedite consultations and reviews, applicants must submit all necessary information in a timely manner.

4. NPDES permits issued by authorized states are not federal actions. Though state programs take many of the same issues into consideration during the permit development process, they are not required to undertake formal federal consultations or reviews.

Table 3. Required Federal Consultations and Reviews

Consultation or Review	Description of the Requirement
Endangered Species Act	Section 7(a)(2) of the Endangered Species Act (ESA) requires federal agencies to consult with, as applicable, the NOAA National Marine Fisheries Service (NOAA Fisheries), the U.S. Fish and Wildlife Service, or both, before taking any action that may affect an endangered or threatened species or designated critical habitat to ensure their actions are not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. Formal and informal consultation is a cooperative process involving the Services and Federal action agencies, as well as applicants, in considering the effects of a proposed action on listed species and/or designated critical habitat and measures to avoid and minimize these effects.
Essential Fish Habitat	The essential fish habitat (EFH) provisions of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) require federal agencies to consult with NOAA Fisheries when activities they authorize, fund, or undertake, or propose to authorize, fund, or undertake, may adversely affect EFH. The consultation process results in NOAA's preparation and transmittal of conservation recommendations, which may be adopted by the permitting agency. The permitting agency is required to provide a written response that describes measures proposed to avoid, mitigate, or offset the impact of activities on EFH and, if applicable, explain reasons why it is not following conservation recommendations.
National Environmental Policy Act	The National Environmental Policy Act (NEPA) requires federal agencies to prepare an Environmental Impact Statement (EIS) for any major federal action significantly affecting the quality of the human environment. An Environmental Assessment (EA) may be prepared to assist the permitting agency in determining whether significant environmental impacts are likely to occur. The EIS or EA requirement does not apply if the permitting agency determines the activity is categorically excluded from NEPA review.
Marine Mammal Protection Act	The Marine Mammal Protection Act (MMPA) prohibits the "taking," which includes harassing, hunting, capturing or killing, of marine mammals or attempting to do so. The MMPA includes several exceptions to the take prohibition, including for incidental (unintentional) take during specific activities. Section 118 of the MMPA addresses incidental take during commercial fishing operations and authorizes incidental take of marine mammals during commercial fishery operations. Fishermen (e.g., including those operating aquaculture facilities) engaging in a Category I or II fishery must obtain a Marine Mammal Authorization Program certificate from NOAA Fisheries; fishermen engaging in a Category I, II, or III fishery must report incidental death or injury of marine mammals that results from commercial fishing operations (including aquaculture) within 48 hours. Fishery categories are published in the annually reviewed and revised MMPA List of Fisheries (LOF), which is available on the NOAA Fisheries website and in the Federal Register.
Fish and Wildlife Coordination Act	The Fish and Wildlife Coordination Act requires any federal agency issuing a permit to consult with the U.S. Fish and Wildlife Service and NOAA Fisheries, as applicable, if the proposed aquaculture activities could potentially harm fish and/or wildlife resources. These consultations may result in project modification and/or the incorporation of measures to reduce these effects.

National Historic Preservation Act	Section 106 of the National Historic Preservation Act (NHPA) requires any federal agency issuing a permit to account for potential effects of the proposed aquaculture activity on historic properties, e.g., shipwrecks, prehistoric sites, and cultural resources. If a proposed aquaculture activity has the potential to affect historic properties, these details must be provided by the applicant as part of the application package. The consultation process may result in an agreement that requires the permitting agency to implement mitigation measures.
Coastal Zone Management Act	The Coastal Zone Management Act of 1972 (CZMA) encourages coastal states to develop and implement coastal zone management plans as a basis for protecting, restoring, and establishing a responsibility in preserving and developing the nation’s coastal communities and resources. Coastal states with an approved coastal zone management program are authorized to review certain federal actions affecting the land or water uses or natural resources of its coastal zone for consistency with its program. The CZMA requires federal agency activities to be consistent to the maximum extent practicable with the enforceable policies of a state’s approved coastal zone management program. Under the CZMA, a state may review activities conducted by, or on behalf of, a federal government agency within or outside the coastal zone that affects any land or water use or natural resource of the coastal zone; or an application for a federal license or permit.
National Aquaculture Health Plan and Standards (NAHP&S)	The NAHP&S establishes guidance for national disease reporting, laboratory and testing standardization, surveillance, response, biosecurity, data management, and education and training, which will benefit and protect the health of the nation's aquaculture operations.
National Marine Sanctuary Resources Act	Section 304(d) of the National Marine Sanctuaries Act (NMSA) requires any federal agency issuing permits to consult with NOAA’s National Marine Sanctuary Program (NMSP) if the proposed aquaculture activity is likely to destroy, cause the loss of, or injure sanctuary resources. As part of the consultation process, the NMSP can recommend reasonable and prudent alternatives. While such recommendations may be voluntary, if they are not followed and sanctuary resources are destroyed, lost, or injured in the course of the action, the NMSA requires the federal action agency(ies) issuing the permit(s) to promptly prevent and mitigate further damage, and restore or replace the damaged resources in a manner approved by NOAA.

A. The Endangered Species Act

The federal government has the responsibility to protect endangered species, threatened species, and designated critical habitat, as directed by the Endangered Species Act of 1973 (ESA), as amended (16 U.S.C. §§ 1531 et seq.), and its implementing regulations (50 CFR Parts 401-453). The National Marine Fisheries Service (NMFS or NOAA Fisheries) and the U.S. Fish and Wildlife Service (USFWS) share responsibility for implementing the ESA. NOAA Fisheries is generally responsible for endangered and threatened marine and anadromous species—from whales and seals to sharks, salmon, and corals. The USFWS is responsible for most terrestrial and freshwater species but also has responsibility over a few marine mammal species (walrus, sea otters, manatees, and polar bears). The Services share jurisdiction over several other species such as sea turtles and Atlantic salmon.

Under Section 7(a)(2) of the Endangered Species Act, federal agencies must consult with NOAA Fisheries and/or USFWS when any project or action they authorize, fund, or carry out (e.g., issuing a permit for aquaculture, providing grant funding for an aquaculture project) may affect an ESA-listed species or designated critical habitat. These interagency consultations help action agencies meet their statutory

obligations that federal actions do not jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. Consultation will conclude informally if the consulting agency concurs with the action agency's determination that the action is not likely to adversely affect any listed species or designated critical habitat. If adverse effects are anticipated, formal consultation is required. Formal consultation results in preparation of a biological opinion that draws conclusions related to jeopardy and adverse modification and provides an exemption for otherwise prohibited take of listed species that is incidental to the proposed action for actions that will not result in jeopardy or damage and adverse modification.

Although consultation is conducted between NOAA Fisheries and/or USFWS and the federal action agency, applicants should be aware of the consultation process as it relates to the overall timeline for obtaining authorizations, be prepared to provide information on the proposed action (e.g., gear configurations and operational plans), and participate as needed in pre-consultation discussions and the consultation process.

Resources:

- [ESA Section 7 Interagency Cooperation Regulations, 50 CFR 402](#)
- ESA Section 7 Interagency Consultations:
 - [NOAA Fisheries. "Consultations."](#)
 - [U.S. Fish and Wildlife Service. "Endangered Species Consultations."](#)

The following links provide more information regarding ESA section 7 consultation procedures in general and in the five NMFS regions:

- [Contact your ESA Section 7 Consultation Coordinator](#)
- [Alaska ESA Consultations](#)
- [New England/Mid-Atlantic ESA Consultations](#)
- [Pacific Islands ESA Consultations](#)
- [Southeast ESA Consultations](#)
- [West Coast ESA Consultations](#)

See also:

- [NOAA Fisheries. "Critical Habitat."](#)

B. Essential Fish Habitat (EFH) Under Magnuson-Stevens Fishery Conservation and Management Act (MSA)

Congress established the Essential Fish Habitat (EFH) provisions in 1996 to improve the nation's main fisheries law—the Magnuson-Stevens Fishery Conservation and Management Act (MSA), highlighting the importance of healthy habitat for commercial and recreational fisheries. Essential fish habitat is identified and described for federally managed fish (including invertebrates and algae) in Fishery Management Plans (FMPs), which would not include species that reside strictly in freshwater. However, non-federally managed species, such as lake trout, might be managed by a state or local authority.

As required by the [provisions for EFH under the MSA](#) (16 U.S.C. § 1855(b)), NOAA Fisheries established guidelines to assist the Regional Fishery Management Councils (Councils) and the Secretary of Commerce (Secretary) in the description and identification of EFH in FMPs, the identification of adverse effects to EFH, and the identification of actions required to conserve and enhance EFH (50 CFR Part 600, Subparts J and K). The regulations also detail procedures the Secretary (acting through NMFS), other federal agencies, and the Councils will use to coordinate, consult, or provide recommendations on federal and state actions that may adversely affect EFH.

When aquaculture operations are assessed for permitting in areas identified as EFH, the permitting agency must determine whether its action may adversely affect that EFH. If the action may adversely affect EFH, the permitting agency must consult with NMFS, who will provide EFH Conservation Recommendations (CRs) to avoid, minimize, or offset any impacts. The permitting agency is required to provide a written response that describes measures proposed to avoid, mitigate, or offset the impact of activities on EFH, and if applicable, explain reasons why it is not following a CR.

Resources:

- [NOAA Fisheries. "Essential Fish Habitat."](#)
- [NOAA Fisheries. "Consultations for Essential Fish Habitat."](#)
- [NOAA Fisheries. "Essential Fish Habitat Mapper."](#)
- [NOAA Fisheries. "EFH Data Inventory."](#)
- [NOAA Fisheries. "Environmental Consultation Organizer \(ECO\)."](#) - national website on EFH
- [NOAA Fisheries. "Habitat Conservation and Restoration Policy Directives."](#) - policies related to EFH

C. National Environmental Policy Act (NEPA)

The National Environmental Policy Act of 1969 (NEPA) and the Council on Environmental Quality's (CEQ's) NEPA implementing regulations (40 CFR Parts 1500-1508) establish a process for review of the environmental impacts of actions taken by the federal government, including related economic, social and cultural effects. This review is intended to ensure that environmental concerns are examined and alternatives considered prior to making the final decision on a project or action. This is accomplished by the preparation of either an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) by the federal agency(s) coordinating and/or administering the permitting processes that describes the environmental impacts of a project and discusses alternative actions and mitigation measures. An EIS can be a lengthy, complex document, requiring substantial time and cost. An applicant may be asked to fund the cost of an EIS. An EA is generally more focused and less complex, costly, and time-consuming. The EIS or EA is meant to inform stakeholders, who are able to offer comments, so that the responsible agency can make an informed decision.

Resources:

- [NOAA's Office of NEPA](#)

D. The Marine Mammal Protection Act

All species of marine mammals are protected under the Marine Mammal Protection Act (MMPA) (16 U.S.C. §§ 1371 et seq.). NOAA's National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (USFWS) share responsibilities for the protection, conservation, and management of marine mammals under the MMPA. NMFS has jurisdiction over whales, dolphins, porpoises, seals, and sea lions, while the USFWS maintains jurisdiction over walrus, manatees, sea otters, and polar bears.

The MMPA prohibits the "taking" of any marine mammal species in U.S. waters where "take" means to hunt, harass, capture, or kill any marine mammal or attempting to do so. It also prohibits, among other things, the import and export of marine mammals and their parts or products.

The MMPA includes several exceptions to the take prohibition including:

- incidental take (e.g., unintentional take) during commercial fishing
- incidental take that may occur during non-fishing activities (e.g., coastal construction, oil and gas exploration, or military readiness training)
- permitted directed take and import for scientific research, enhancement, commercial or educational photography, and public display

Most aquaculture operations are considered commercial fisheries under MMPA section 118 and the List of Fisheries (LOF) nationwide. As such, these fisheries are authorized to incidentally take marine mammals during the course of commercial fishing, provided these fisheries comply with certain provisions (e.g., registration, reporting).

Commercial fisheries are classified on the LOF as Category I, II, or III based on the level of marine mammal death and serious injury that they cause incidentally. If you operate in a Category I or II fishery, you must obtain a marine mammal authorization certificate each year from NOAA Fisheries or its designated agent. You must, regardless of your Category, report every incidental marine mammal death or injury of marine mammals that results from commercial fishing operations. If a fishery is not listed on the LOF, it is automatically classified as a Category II fishery, which confers take coverage and requires the reporting of any marine mammal injuries or deaths within 48 hours.

The List of Fisheries LOF is updated annually and more information on registration and reporting can be found at the following links.

Resources:

- [NOAA Fisheries. "Marine Mammal Authorization Program."](#)
- [NOAA Fisheries. "Marine Mammal Protection Act List of Fisheries."](#) (interactions with marine mammals)

E. Federal Consistency Review Under the Coastal Zone Management Act

The Coastal Zone Management Act of 1972, as amended (16 U.S.C. §§ 1451 et seq.) requires that federal agencies conduct their planning, management, development and regulatory activities in a manner consistent with applicable state Coastal Zone Management Programs (CZMPs). Activities within the Coastal Zone that are federally funded, require a federal permit or license, or are conducted by the federal government and directly impact the Coastal Zone, are subject to review for consistency with the state's CZMP. Aquaculture facilities that require a permit will be sent to the state CZMP for consistency review, as part of the federal permit process. This process does not apply in Alaska. The review process generally involves: Determination by the proponent and applicable federal agency as to whether the activity is consistent with the CZMP; submission of the determination, CZMP forms and related information to the state for review; State concurrence with or objection to the determination; and non-concurrence can be appealed to the Secretary of Commerce. If the state determines the federal permitting action is not consistent with its CZMP, the federal activity cannot go forward unless the U.S. Secretary of Commerce overrides the determination.

Resources:

- [NOAA Office for Coastal Management. "Federal Consistency."](#)
- [NOAA Office for Coastal Management. "State Coastal Management Program Manager and Federal Consistency Contacts \(2021\)."](#)

F. Fish and Wildlife Coordination Act

Whenever a federal agency proposes to impound, divert, channel deepen, or otherwise control or modify waters of any stream or other body of water, or permit or license any public or private agency to undertake such actions, the [Fish and Wildlife Coordination Act](#) (FWCA) (16 U.S.C. §§ 661 et seq.) requires the agency to:

- consult with the U.S. Fish and Wildlife Service (FWS), the NOAA National Marine Fisheries Service (NOAA/NMFS), and their state counterparts
- provide FWS, NOAA/NMFS, and their state counterparts with timely notice of an action
- provide FWS, NOAA/NMFS, and their state counterparts with an opportunity for continuous informal and formal involvement in all stages of planning for an action.

The FWCA requires wildlife conservation to receive equal consideration and be coordinated with other water resource development programs, and establishes fish and wildlife conservation as a coequal purpose or objective of federally funded or permitted water resource development projects or proposals. The purpose of a FWCA consultation is to prevent the loss of and damage to wildlife resources, as well as provide for the development and improvement of those resources. They primarily focus on impact/effects analyses; avoiding, minimizing, rectifying, reducing or eliminating impacts over time; compensating for residual impacts; and enhancement.

A consultation may be appropriate for the following activities:

- Construction and operation of dams, levees, and water diversion
- Construction and operation of navigation features
- Other actions dependent on or resulting in the diversion, control, or modification of a stream or other water body
- Discharges of pollutants
- Army Corps of Engineers (USACE) permits issued pursuant to Section 404 of the Clean Water Act or Section 10 of the Rivers & Harbors Act

Resources:

- [U.S. Fish and Wildlife Service. "Information for Planning and Consultation \(IPAC\)."](#)

G. National Historic Preservation Act

The purpose of Section 106 of the National Historic Preservation Act (NHPA) (54 U.S.C. §306108) is to reduce or avoid damage to historic resources of the U.S. from federal actions. The Act, and its implementing regulations (36 CFR Part 800), require federal agencies to take into account the effects of their decisions on historic properties, and affords the Advisory Council on Historic Preservation (ACHP), an independent federal agency, a reasonable opportunity to review and comment on such actions.

Section 106 applies when two thresholds are met: 1) there is federal or federally licensed action, including grants, licenses and permits; and 2) that action has the potential to affect properties listed, or eligible for listing, in the National Register of Historic Places. This broad applicability means that properties which have not yet been listed and even those not yet discovered can be subject to the Section 106 review requirements. Section 106 requires each federal agency to identify and assess the effects of its actions on historic properties. The responsible federal agency must consult with the applicable State Historic Preservation Officer, federally recognized Indian tribes, Native Hawaiian Organizations, and members of the public and consider their views and concerns about historic preservation issues when making final project decisions. Concerns are resolved by mutual agreement, usually among the affected state's Historic Preservation Officer, the federal agency, and any other involved parties. Resolution of adverse effects to historic properties is resolved through execution of a formal written agreement that sets forth required mitigation measures.

Resources:

- [National Park Service. "Guidance for National Register of Historic Places."](#)

H. USDA APHIS VS National Aquaculture Health Plan & Standards

The National Aquaculture Health Plan & Standards (NAHP&S) establishes guidance for national disease reporting, laboratory and testing standardization, surveillance, response, biosecurity, data management, and education and training, which will benefit the nation's aquaculture health. It also outlines health inspection options to provide consistent and verifiable ways to establish, maintain and certify the health

and safety of aquatic livestock, and lists the actions USDA will take in each of these areas to implement the plan. These actions will support the overall health of the aquaculture industry, which will provide protection and assurance for producers of farm-raised aquatic animals in the United States. Specifically for aquaculture operations licensed in federal marine waters, the NAHP&S presents a health inspection option to ensure animal health prior to stocking in open waters and harvesting animals from these environments.

USDA is taking a lead role in providing guidance for aquatic animal health. USDA is the primary federal entity with oversight over livestock and other agricultural commodities, so it is a natural fit to take the lead in providing oversight for aquatic animal and aquaculture health. USDA will continue to collaborate with the National Oceanic and Atmospheric Association (NOAA) and the United States Fish and Wildlife Service (USFWS), as well as other Federal, State, and Tribal entities to ensure the health of all aquatic animals in the United States. The NAHP&S will be updated every 2 years by USDA in consultation with these partners.

Resources:

- [USDA APHIS. "National Aquaculture Health Plan and Standards, 2021-2023."](#)
-

V. Regulations Applying Directly to Operators of Aquaculture Facilities

Food and Drug Administration (FDA)

The U.S. Food and Drug Administration (FDA), under the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 301 et seq.) protects public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled and that human and veterinary drugs are safe and effective.

- **FDA Food Safety Modernization Act (FSMA):** Enacted in 2011, the act made changes to the FDCA shifting the focus of federal oversight from responding to food contamination and foodborne illnesses to prevention. This approach includes risk-based preventive controls and other regulations that ensure food safety is a shared responsibility throughout the global supply chain. FSMA broadened FDA's authority to regulate human and animal food facilities and established new requirements for those facilities. The FSMA regulations apply to domestic food producers, and producers in other countries who export to the United States, who are required to register with FDA as food facilities. There are also regulations that apply to importers of food. Aquaculture operations that manufacture, process, pack, or hold human or animal food are required to register as food facilities under 21 CFR part 1, subpart H, unless an exemption applies. Animal food facilities that are required to register are subject to the FSMA Preventive Controls for Animal Food (PCAF) regulation (21 CFR part 507), which includes current good manufacturing practice, hazard analysis, and risk-based preventive controls requirements for food for animals, unless an exemption applies. Aquaculture operations that meet the definition of

a farm in 21 CFR 1.227 and are exempt from food facility registration are exempt from the requirements in part 507. Aquaculture operations that import animal food and meet the definition of an importer in 21 CFR 1.500 are subject to the Foreign Supplier Verification Program (FSVP) regulation (21 CFR part 1, subpart L), which includes requirements for importers of food for animals.

- **Other Animal Food and Drug Requirements:** Regardless of whether they are required to register with FDA as food facilities, aquaculture operations that manufacture medicated feed are required to follow the Current Good Manufacturing Practice for Medicated Feed requirements in 21 CFR part 225. Aquaculture operations that manufacture, distribute, or use medicated feed with a veterinary feed directive (VFD) marketing status are also subject to the VFD requirements in 21 CFR 558.6.

Many substances added to animal food are food additives as defined in 21 U.S.C. 321(s) because they are intended to or expected to become a component of animal food. With certain exceptions, these substances must either be covered by a food additive regulation (see 21 U.S.C. 348(a)(2)) or be generally recognized as safe (GRAS) (see 21 CFR 570.30 and 570.35) for an intended use. The Official Publication of the Association of American Feed Control Officials (AAFCO) contains the most complete list of animal food ingredients with their definitions. The Official Publication list includes approved animal food additives as well as substances that are GRAS for an intended use. In addition, many of the ingredients listed are not approved animal food additives and may not meet the criteria needed to be recognized as GRAS for use. Nevertheless, FDA generally does not intend to act against such ingredients defined in the Official Publication and marketed in interstate commerce, provided there are no animal food safety concerns about the ingredient.

Drugs intended for use in food producing animals, including drugs used in animal food, must be approved or conditionally approved by FDA (see 21 U.S.C. 360b and 360ccc). A drug for use in non-food early life stages of food-producing minor species may be added to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species by FDA if the requirements in 21 U.S.C. 360ccc and 21 CFR part 516 are met.⁶

- **FDCA Misbranding and Adulteration Provisions:** As with all other foods, foods from aquaculture operations are subject to the adulteration, misbranding, and prohibited acts provisions of the FDCA in 21 U.S.C. 331, 342, and 343, respectively. Labeling regulations for animal food are located in 21 CFR part 501.
- **Seafood Hazard Analysis and Critical Control Point Regulation:** Processors of fish and fishery products for human food are subject to FDA's Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, commonly known as the Seafood HACCP (Hazard Analysis and Critical Control Point) Regulation, 21 CFR part 123. This regulation requires both domestic and foreign processors of fish and fishery products to understand the food safety hazards associated with their processes and products and, through a system of preventive controls, to keep those hazards from occurring. The processor is responsible for obtaining an assurance from the aquaculture producer that all chemical compounds (food additives,

pesticides, and animal drugs) used during production are applied in accordance with approvals and permits and would not result in unsafe residues in the food product. FDA published the Fish and Fishery Products Hazards and Controls Guide (the Guide) to assist processors in conducting hazard analysis and formulating appropriate control strategies. The Guide is also intended to serve as a tool to be used by federal and state regulatory officials in the evaluation of HACCP plans for fish and fishery products (see [Fish and Fishery Products Hazards and Controls \(FDA.gov\)](#)).

Other regulations may apply to aquaculture operations, depending on the market form of fish products. Additional information, including relevant guidance documents, can be found on the FDA website and state Department of Health websites.

- **Bivalve Molluscan Shellfish:** The aquaculture of bivalve molluscan shellfish is unique in that it is regulated through a Federal/State cooperative program called the National Shellfish Sanitation Program (NSSP). The NSSP is a cooperative program between FDA and other federal agencies (the National Oceanic and Atmospheric Administration (NOAA) and the Environmental Protection Agency (EPA)), state shellfish sanitation programs, academia, tribes, and the shellfish industry for the sanitary control of bivalve molluscan shellfish produced and sold raw (live, fresh or fresh frozen) and/or subjected to post-harvest processing (PHP). The Interstate Shellfish Sanitation Conference (ISSC) is the cooperative body which manages the NSSP and provides a formal structure wherein State shellfish sanitation program regulatory authorities, with FDA concurrence, establish updated guidelines and procedures for the NSSP Guide for the Control of Molluscan Shellfish. Through the NSSP, as recognized by the ISSC and FDA, all aquacultured molluscan shellfish subject to NSSP requirements entering interstate commerce must be grown in and harvested from approved shellfish growing areas, handled by state-certified dealers, be tagged and tracked, and be processed in plants that meet NSSP sanitation requirements. FDA continually reviews State shellfish control programs for their effectiveness in complying with the NSSP requirements. The NSSP is authorized under section 702 of the FDCA (21 U.S.C. 372) and section 311 of the Public Health Service Act (42 U.S.C. 243). The regulatory responsibility for shellfish commercially harvested from federal waters is shared by FDA and NOAA. Under international agreements with FDA, foreign governments also participate in the NSSP through compliance or equivalence arrangements.

General information about the National Shellfish Sanitation Program (NSSP) can be found on the FDA's [NSSP website](#). There is also information on the [Interstate Shellfish Sanitation Conference \(ISSC\) website](#) and in the [NSSP Guide for the Control of Molluscan Shellfish](#). Information regarding FDA's final equivalence determination of European Union shellfish safety requirements as implemented by Spain and Netherlands can be found in the [Federal Register notice \(85 FR 60172\)](#). FDA has also provided info about the program in FR notices (e.g. [83 FR 10487, March 8, 2018](#)).

VI. Summary of Federal Agencies Involved in Aquaculture Permitting and Authorizations

Permitting Agencies

- **U.S. Army Corps of Engineers (USACE)**: has the authority to regulate aquaculture activities pursuant to Section 10 of the Rivers and Harbors Act of 1899 [RHA (33 U.S.C. §403)], including the extension of the RHA to the limits of the outer continental shelf by the Outer Continental Shelf Lands Act [OCSLA [43 U.S.C. §1333(a)(1)]], and section 404 of the Clean Water Act [CWA (33 U.S.C. §1344)]
- **U.S. Environmental Protection Agency (EPA)**: has the authority to permit discharges from aquaculture operations in federal waters pursuant to the Clean Water Act Sections 301, 318, 402, and 403 (see 33 U.S.C § 1251 et seq.), and subject to the regulatory requirements of 40 CFR § 122.24, 40 CFR § 122 Appendix C, 40 CFR Part 451, and 40 CFR Part 125, Subparts B and M.
- **National Marine Fisheries Service (NMFS)**: has adopted regulations governing aquaculture in certain geographic areas of federal waters. Where applicable, these regulations implement Fishery Management Plans developed by the Regional Fishery Management Councils under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. § 1801 et seq.).

Authorizing Agencies

- **Bureau of Ocean Energy Management (BOEM)**: has authority under the Outer Continental Shelf Lands Act (43 U.S.C. §§ 1331 et seq.), and further defined in 30 CFR Parts 500-599. The BOEM reviews and authorizes the Right-of-Use and Easement for offshore aquaculture operations and activities that use an existing federal Outer Continental Shelf facility in federal waters pursuant to 30 CFR Part 585, Subpart J.
- **Bureau of Safety and Environmental Enforcement (BSEE)**: pursuant to the Outer Continental Shelf Lands Act (43 U.S.C. §§ 1331 et seq.), and further defined in 30 CFR Parts 200-299, the BSEE has regulatory responsibility for oil, gas, and sulfur exploration, development, and production operations on the federal Outer Continental Shelf. The BSEE reviews and authorizes proposed activities that utilize an existing Outer Continental Shelf oil and gas facility to convert the existing platform at the current location for a new purpose pursuant to 30 CFR § 250.900.
- **National Marine Fisheries Service (NMFS)**: has the responsibility to ensure that relevant federal actions comply with applicable provisions of the Magnuson-Stevens Fishery Conservation and Management Act, the Fish and Wildlife Coordination Act (16 U.S.C. §§ 661 et seq.), the Endangered Species Act (16 U.S.C. §§ 1531 et seq.), and the Marine Mammal Protection Act (16 U.S.C. §§ 1361 et seq.).

- **U.S. Coast Guard (USCG):** has the regulatory responsibility to protect maritime navigation as it relates to the establishment, maintenance, and operation of lights and other signals on fixed and floating structures in or over waters subject to U.S. jurisdiction and in the high seas for structures owned or operated by persons subject to U.S. jurisdiction (14 U.S.C. § 542).
 - **U.S. Fish and Wildlife Service (USFWS):** has the responsibility to ensure that relevant federal actions comply with applicable provisions of the Fish and Wildlife Act (16 U.S.C. §§ 742a et seq.); the Fish and Wildlife Conservation Act (16 U.S.C. §§ 2901 et seq.), the Fish and Wildlife Coordination Act (16 U.S.C. §§ 661 et seq.), the National Wildlife System Administration Act (16 U.S.C. § 668dd et seq.), the Endangered Species Act (16 U.S.C. §§ 1531 et seq.), the Migratory Bird Treaty Act (16 U.S.C. §§ 703 et seq.), and the Marine Mammal Protection Act (16 U.S.C. §§ 1361 et seq.).
 - **U.S. Food and Drug Administration (FDA):** does have responsibility to review shellfish aquaculturist operations against the National Shellfish Sanitation Program (NSSP) requirements in Federal waters. The NSSP is a cooperative arrangement between FDA, states, and other federal agencies to establish a program for states to follow regarding shellfish sanitation. This is not a federal regulatory program, and there are no specific federal regulations for the NSSP. It is authorized through more general authority under section 702 of the FDCA (21 U.S.C. 372) and section 311 of the PHS Act (42 U.S.C. § 243). Each State Shellfish Authority has specific shellfish aquaculture requirements based on the NSSP as well.
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VII. State-by-state Aquaculture Permitting Information

State Aquaculture Permitting Information

A separate effort by NOAA Fisheries and NOAA Sea Grant to compile local and state information regarding state, regional, and municipal permitting for other mariculture sectors, such as finfish and algae is linked below. These resources are managed separately from this guide. Some of the information in this table directed at shellfish aquaculture permitting may prove useful to proponents interested in other sectors, when combined with consultation with pertinent agency guidance. Communication with agency contacts in your regions is encouraged so that updated information is shared.

- [State-by-state Shellfish Aquaculture Permitting Guide \(2021\)](#)
- [State-by-state Finfish Aquaculture Permitting Guide \(2021\)](#)
- [State-by-state Seaweed Aquaculture Permitting Guide \(2021\)](#)

Other State Aquaculture Permitting Guides

- **Alaska:**
 - [Alaska Aquaculture Interagency Working Group. "Alaska Aquaculture Permitting."](#)

- [NOAA Fisheries. "Alaska Aquaculture Permitting Guide \(2021\)."](#)
- **New England:**
 - [NOAA Fisheries. "Federal Waters Permitting in the Greater Atlantic Region."](#)