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Molluscan Shellfish Aquaculture in Federal Waters of the Exclusive Economic Zone (EEZ): Agencies, Industry, and Academia Working Together on Compliance and Permitting Requirements

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Introduction

Approximately 91% of the seafood products sold in the United States are imported, and roughly half of those imports are produced by aquaculture.⁵ These seafood imports total 2.45 million metric tons, 89,000-90,500 metric tons of which is comprised of molluscan shellfish (e.g. oysters, mussels, clams, and scallops).⁶ These imports have contributed to a significant seafood trade deficit, which ballooned to \$14 billion in 2016.⁷ Increased domestic aquaculture production has

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5. See U.S. Food and Drug Administration, *Aquacultured Seafood* (last accessed December 23, 2018).
6. See U.S. Food and Drug Administration, *Aquaculture Data* (last accessed December 23, 2018). See also NOAA Fisheries Statistics Division, *Commercial Fisheries Statistics* (last accessed December 23, 2018).
7. Sarah E. Lester, Rebecca R. Gentry, Carrie V. Kappel, Crow White & Steven D. Gaines, *Opinion: Offshore aquaculture in the United States: Untapped potential in need of smart policy*, 115(28) PNAS, July 10, 2018, at 7162. See also National Marine Fisheries Service Fisheries Statistics and Economics Division, *NMFS Trade Query* (last visited Dec. 28, 2018).

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the potential to reduce this reliance on seafood imports, which could result in an estimated additional 50,000 full-time and part-time jobs⁸ if United States “offshore” aquaculture production is doubled.⁹ Furthermore, it has been suggested by some as a way to reduce the carbon footprint associated with imported seafood.¹⁰

While the potential for increased domestic molluscan shellfish marine aquaculture production¹¹ has been the subject of high-level discussion at federal and state levels, it is not without policy challenges. Development of commercial marine aquaculture in federal waters of the Exclusive Economic Zone (EEZ)¹² has been constrained for decades by an unclear regulatory process and

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8. The value of an additional 50,000 jobs is specific to marine aquaculture and includes the following activities: “offshore aquaculture, coastal shellfish farming, on-shore production methods, and hatcheries to produce stock for private fish and shellfish farms and for marine enhancement purposes.” Rubino, Michael (editor). 2008. *Offshore Aquaculture in the United States: Economic Considerations, Implications & Opportunities*. U.S. Department of Commerce; Silver Spring, MD; USA. NOAA Technical Memorandum NMFS F/SPO-103. 263 pages.
 9. Hauke Kite-Powell, Michael C. Rubino & Bruce Morehead, *The Future of US Seafood Supply*, 17(3) *AQUACULTURE ECONOMICS AND MANAGEMENT* 228 (2013). See also <https://spo.nmfs.noaa.gov/sites/default/files/tm103.pdf>. According to the sources cited in this paper, “offshore aquaculture” is defined as aquaculture in exposed ocean waters and is not limited to production in waters under the jurisdiction of the federal government.
 10. The carbon footprint of any species is inclusive of more than simply the “food miles”, or the distance the product traveled from where it was caught to where it will be consumed, it is also dependent on factors such as the method in which it was caught (e.g. long-line vs. purse seine), how it was transported (e.g. by air or by sea), and if the product was preserved by canning or frozen. For this reason, it is necessary to measure a product’s carbon footprint using a method such as a life cycle assessment, which shows the net carbon contribution of something from “cradle to grave”. Anna K. Farmery, Caleb Gardner, Bridget S. Green, Sarah Jennings & Reg A. Watson, *Domestic or imported? An assessment of carbon footprints and sustainability of seafood consumed in Australia*, 54 *ENVIRONMENTAL SCIENCE & POLICY* 35(2015). See also Elizabeth M.P. Madin & Peter I. Macreadie, *Incorporating carbon footprints into seafood sustainability certification and eco-labels*, 57 *MARINE POLICY* 178 (2015).
 11. Marine aquaculture refers to the rearing, breeding, and harvesting of aquatic plants and animals in the ocean or on land in tanks or ponds and typically includes production of oysters, clams, mussels, shrimp, salmon, and other marine fish. See NOAA Fisheries, *Understanding Marine Aquaculture* (last visited Dec. 28, 2018).
 12. Lines of legal authority for maritime zones in the United States are based on a mix of domestic and international laws and include the territorial sea (0-12 nautical miles), contiguous zone (12-24 nm), and the EEZ (12-200 nm). In addition, within the territorial sea, coastal states have jurisdiction from either 0-3 or 0-9 nm seaward from the baseline of their coast. Most coastal states have jurisdiction only to 3 nm out, but the jurisdiction of Texas, the west coast of Florida, and Puerto Rico extends out 9 nm. For a map of maritime legal boundaries in the United States, as well as other maritime zone facts, see NOAA Office of Coast Survey, *Maritime Zones of the United States* (last visited Dec. 28, 2018). The difference between the territorial sea and the EEZ is that under international law, a coastal nation has sovereign rights in the EEZ to explore, exploit, conserve, and manage living and nonliving resources and over artificial islands or other structures with economic purpose. See *Exclusive Economic Zone of the United States of America*, Proclamation 5030, 48 Fed. Reg. 10605 (Mar. 14, 1983). Whereas, under international law, jurisdiction of the territorial sea means sovereignty over the air space, water column, seabed, and subsoil of this area, subject to certain rights of innocent passage for foreign vessels and sometimes also for foreign aircraft. This case study focuses only on shellfish aquaculture operations in the parts of the territorial sea under federal jurisdiction and in the EEZ (i.e., 3-200 or 9-200 nm). Shellfish aquaculture operations in coastal waters under state jurisdiction are not included in this case study.

by the technical challenges of operating in an offshore environment.¹³ These uncertainties have resulted in limited commercial investment, which federal and state regulatory agencies, academia, and the industry have partnered to address. An additional challenge faced by the aquaculture industry is the potential for user conflict in the growing area, such as competition for space between aquaculture facilities and commercial and recreational fishing,¹⁴ which can arise both during the permitting and operations phases of shellfish aquaculture production. Though a common problem in both state and federal waters, user conflicts are often more pronounced in state waters due to the host of recreational (e.g., SCUBA diving and boating) and commercial uses (e.g., fishing and shipping) that are more prevalent.¹⁵ Despite these challenges, the aquaculture industry continues to explore the option of operating facilities in the federal waters of the EEZ. One example is Catalina Sea Ranch (CSR), a farm based in Southern California, that currently farms mussels in the federal waters of the EEZ.

While CSR has received all necessary permits from the U.S. Army Corps of Engineers (USACE) to construct and operate its farm in federal waters of the EEZ, there are separate National Shellfish Sanitation Program (NSSP) requirements that the company must meet as well, in order to harvest and sell their product for human consumption in interstate commerce. The NSSP is a federal-state cooperative program tasked with ensuring the safety of molluscan shellfish for human consumption. The issues CSR faced while obtaining their regulatory permits and in order to comply with the NSSP are complex and have implications for the future of shellfish aquaculture in federal waters of the EEZ. While this case study will reference CSR as an example, the focus will be on the broader requirements for growing and harvesting molluscan shellfish in federal waters and the potential value in introducing a long-term permitting process for aquaculture in federal waters of the EEZ.

The goal of this case study is to provide background information on the permitting process and to highlight an important aspect of operations – compliance – to shellfish growers and investors

13. For example, aquaculture facilities offshore are more exposed to wind and waves, in addition to the engineering needs to appropriately anchor and operate in an open ocean environment. See FAO Technical Workshop, *Expanding mariculture farther offshore: Technical, environmental, spatial, and governance challenges* (Alessandro Lovatelli, José Aguilar-Manjarrez & Doris Soto eds., 2010) (last visited Dec. 28, 2018).

14. See, e.g., California Sea Grant, *Impediments and Opportunities for Coordinating Use of California's Coastal Ocean: Adding Aquaculture to the Mix* (last visited Dec. 28, 2018).

15. See NOAA Fisheries Greater Atlantic Region, *First federally permitted offshore mussel aquaculture project on east coast soon to get underway* (last visited Dec. 28, 2018).

considering operating in federal waters of the EEZ. Therefore, it is important to note that this case study is limited in scope to focus on the permitting process and NSSP compliance, and that all information is current as of November 2018. Section I will set the stage for the case study by providing background on CSR and a summary of the current regulatory process to obtain permits to operate a shellfish aquaculture facility in federal waters of the EEZ. Section II will describe the potential for a nationwide permitting process through S. 3138. Section III will provide a description and an analysis of the NSSP. Section IV will describe California's implementation of NSSP requirements, followed by a discussion of the challenge of obtaining NSSP compliance for shellfish grown in federal waters of the EEZ in Section V. Section VI will conclude the case study with an analysis of current NSSP compliance requirements to grow and harvest molluscan shellfish in federal waters of the EEZ and the steps federal and state agencies, as well as growers, have implemented in order to comply with the NSSP.

Section I: Current Permitting Process for Aquaculture in the EEZ

CSR, the first aquaculture facility in federal waters off the West Coast of the United States, is located approximately six miles off Huntington Beach, California. Currently, CSR only farms Mediterranean mussels (*Mytilus galloprovincialis*), however, they are considering farming scallops, oysters, and seaweed (kelp) in the future. Because shellfish are filter feeders, they do not require external feed and are also able to filter a large volume of water each day¹⁶ with one adult mussel able to filter up to 15 gallons of water per day.¹⁷ It is for these reasons that CSR considers molluscan shellfish as ideal crops, since the company's goal is for their aquaculture activities to "show no measurable [environmental] impact on the surrounding ocean."¹⁸

Given aquaculture production in federal waters of the EEZ is a developing practice in the United States, an overview of the permitting process a shellfish aquaculture business must follow in order to operate in federal waters of the EEZ provides helpful context for the case study.¹⁹

16. See Andrea Bennett, The Environmental Protection Agency, "[Our Friends the Freshwater Mussels](#)", EPA BLOG (July 17, 2014) (last visited December 28, 2018).

17. For context, in one presentation to the California Water Boards CSR reported that in one year their facility could produce 2 million pounds of mussels, which in turn can filter around 13,607,787,270 gallons of water, or 41,760 acre feet of water which is a little more than a third the amount of water in Lake Tahoe, CA. See the California State Water Resource Control Board, [Catalina Sea Ranch](#) (last visited Dec. 28, 2018).

18. See Louisa Burwood Taylor, [Catalina Sea Ranch Raises \\$2M for Innovative Offshore Aquaculture Project](#), AG FUNDER NEWS (Jan. 25, 2017) (last visited Dec. 28, 2018).

19. Kelly B. Boden & Karen A. Mignone, [The aquaculture permitting process in federal waters](#), Trends May/June 2014, ABA Section of Environment, Energy and Resources.

The current federal permitting requirements are outlined below, using CSR as an example. For CSR, the two major federal laws that apply to shellfish aquaculture facilities in federal waters of the EEZ off California’s coast are the Rivers and Harbors Act (RHA) and the Clean Water Act (CWA), with the U.S. Army Corps of Engineers (USACE) acting as the main permitting authority for the placement and construction of the farm.

Rivers and Harbors Act (RHA)

In order to construct a commercial shellfish aquaculture facility in state or federal waters, it is highly likely the operator will need a Section 10 Rivers and Harbors Act (RHA) permit from the USACE, which CSR did through the USACE’s Los Angeles District.²⁰ The USACE’s authority to regulate obstructions to “the navigable capacity of any of the waters of the United States” originates under the RHA.²¹ Under the RHA, a Section 10 permit is needed for any “construction of structures in, over, or under, excavating from or depositing material into, and any other work affecting the course location, condition, or capacity of navigable waters.”²² Permits under the RHA are issued, issued with special conditions, or denied.

Before the USACE grants a Section 10 permit, the agency must consider the effects that the activity will have under other federal laws, listed under regulation 33 C.F.R. 320.3. These laws include any applicable treaty rights, Section 106 of the National Historic Preservation Act,²³ Marine Mammal Protection Act,²⁴ and Section 304(d) of the National Marine Sanctuaries Act.²⁵ In addition, the USACE must consult with NOAA Fisheries (also known as the National Marine Fisheries Service, or NMFS) to determine compliance, as necessary under 33 C.F.R. 320.3, with endangered species regulations under the Endangered Species Act (ESA) and essential fish habitat regulations under the Magnuson-Stevens Fishery Conservation and Management Act.²⁶

The USACE, in consultation with NOAA Fisheries, in 2012 issued a Section 10 permit to CSR conditioned upon the “completion of review of the permit for consistency with state law”

20. READ PORTER & REBECCA KIHSLINGER, ENVIRONMENTAL LAW INSTITUTE, U.S. ARMY CORPS OF ENGINEERS REGULATION OF OFFSHORE AQUACULTURE (2015).

21. See 33 U.S.C. 403.

22. See 33 C.F.R. 322.

23. See 16 U.S.C. 470f.

24. See 16 U.S.C. 1361 et seq.

25. See 16 U.S.C. 1434.

26. See Boden & Mignone, *supra* note 21.

pursuant to the Coastal Zone Management Act (CZMA).²⁷ Under the consistency provision of the CZMA,²⁸ coastal and Great Lakes states may review the USACE's decision to grant a Section 10 permit if the project will have reasonably foreseeable effects on any coastal land or water use or natural resource in that state's coastal zone. If a state denies CZMA consistency, then the federal permit applicant may appeal the denial to the Secretary of Commerce or choose to either withdraw its permit application or submit a new permit application with changes. The major policy goal of the CZMA, which is administered by NOAA, is to help achieve a balance between the wise use of land and water resources in the nation's coastal zone and compatible economic development.²⁹ This policy goal is achieved in part through: (1) funding assistance³⁰ and technical assistance³¹ provided by NOAA to coastal and Great Lakes states;³² and (2) the act's federal consistency provision.³³

During the Section 10 permitting process for CSR's facility, the California Coastal Commission (CCC) received authorization from NOAA's Office for Coastal Management (OCM) to ensure that CSR's proposed plan was consistent with the enforceable policies of California's Coastal Management Program (CMP). After an independent review by the CCC and a public comment period, the CCC concurred with the Section 10 permit subject to 13 conditions, such as environmental impact monitoring during and after the construction process (see Figure 1 for a complete list of the conditions).³⁴ While at first glance these conditions may seem to be simple requests, closer examination reveals some conditions to be resource-intensive. For example, condition number one calls for CSR to establish an adaptively managed "offshore mariculture monitoring program" which is comprised of 14 provisions, including information such as the methodology used for analysis and reporting of results, and records of the type and amount of commercial and recreational fishing that occurs around the facility.³⁵

27. See PORTER & KIHSLINGER, *supra* note 22.

28. See 50 C.F.R. 930.

29. See 16 U.S.C. 1451 et seq.

30. 16 U.S.C. 1456(a).

31. 16 U.S.C. 1456(c).

32. Participation in the CZMA is voluntary. Coastal and Great Lakes states are only eligible for this funding and technical assistance if they have a NOAA-approved state coastal management plan. See 16 U.S.C. 1455 and 1456(c).

33. See 16 U.S.C. 1456 ("Each Federal agency activity within or outside the coastal zone that affects any land or water use or natural resource of the coastal zone shall be carried out in a manner which is consistent to the maximum extent practicable with the enforceable policies of approved State management programs.").

34. PORTER & KIHSLINGER, *supra* note 22.

35. CALIFORNIA COASTAL COMMISSION, *STAFF REPORT FOR CONSISTENCY CERTIFICATION* CC-035-12 (2013).

CSR is required to submit annual reports for five years to the Executive Director of the CCC, which must include the following:

- Data from all sampling and monitoring activities;
- Narrative summary of sampling and monitoring activities that were carried out and the techniques, methodologies, and equipment used to support them;
- Analysis of sampling and monitoring results; and
- Discussion of preliminary or final results and conclusions.³⁶

If it is determined that CSR is not carrying out their monitoring plan in a way that is consistent with California’s Coastal Management Program, then the CCC can re-open the consistency review and either require project modifications or object to the facility’s continued operation.³⁷

- Conditions for Concurrence with Catalina Sea Ranch Permit**
1. Offshore mariculture monitoring program
 2. Marine wildlife entanglement
 3. Lighting and operation at night
 4. Construction monitor
 5. Notice to mariners
 6. Spill prevention and control plan
 7. Lost/damaged fishing gear compensation program
 8. Update NOAA charts
 9. Letter of credit
 10. Facility removal
 11. Discharge of biological materials
 12. Marine debris
 13. Invasive species

Figure1: List of the CCC’s conditions for CZMA concurrence for CSR permit³⁸

36. *Id.*

37. *Cal-Span, California Coastal Commission Hearing* at 3:40:00 (Jan. 1, 2014).

38. PORTER & KIHSLINGER, *supra* note 22.

Although CSR questioned the need for all 13 of the CCC's conditions,³⁹ which are unique to CSR's facility, the company ultimately accepted them, after which the USACE issued the Section 10 permit in 2014.⁴⁰ CSR's permit allows the facility to grow mussels to a depth of 150 feet and across 100 acres of water,⁴¹ but the company hopes to expand its operations to 1,000 acres.⁴² In addition, CSR consulted with the U.S. Coast Guard (USCG) to select the location and depth of their lines in order to minimize potential space-use conflicts with existing shipping lanes, oil platforms, and oil pipelines.⁴³ Since receiving their federal permit, CSR has successfully farmed mussels and had their first harvest in July 2018. However, in order to harvest and sell their product for human consumption, CSR also must meet the NSSP requirements, which are explored in more detail in Section III.

Clean Water Act

The Clean Water Act (CWA) gives the federal government the authority to regulate the discharge of dredged or fill material into waters of the United States, if the facility is located in "navigable waters."⁴⁴ CWA sections that may apply to shellfish aquaculture operations in federal waters of the EEZ include Section 404 (discharge of dredged or fill material) and Section 401 (water quality certification of discharge of pollutants). Federal jurisdiction under Section 404 is shared between the USACE and the Environmental Protection Agency (EPA). Permits for activities that have the potential to have significant environmental impacts are reviewed by the USACE under a public interest review and 404(b)(1) Guidelines established by the EPA.⁴⁵ Since navigable waters or "waters of the United States" extend out to the EEZ,⁴⁶ the CWA is likely to apply to a shellfish aquaculture facility located within 200 nautical miles of the coast. In addition, a Section 404 permit may be required under the CWA if the aquaculture facility will discharge dredge or fill material into navigable waters.⁴⁷ This permit, which must be renewed five years after the date of issuance, may be required if the aquaculture gear or related activities "substantially disrupts" ocean sediment, resulting in a discharge of dredged material.⁴⁸

39. Telephone Interview with Phil Cruver, Founder and CEO of Catalina Sea Ranch (May 17, 2018).

40. *Id.*

41. Abbie Fentress Swanson, *Growing millions of mussels beneath the Pacific Ocean waves*, KCRW (June 30, 2017).

42. Catalina Sea Ranch, "The Ranch" (last visited Dec. 30, 2018).

43. Porter & Kihlslinger, *supra* note 22.

44. *See* 33 U.S.C. 1344.

45. *See* 40 C.F.R. 230 et seq.

46. *See* 33 U.S.C. 1362(10).

47. 33 U.S.C. 1344(a).

48. 33 U.S.C. 1344(e)(2).

Section 401 requires that any person applying for a federal permit or license for an activity that may result in the discharge of pollutants into waters of the United States apply for a water quality certification that any discharge will comply with all water quality standards.⁴⁹ Federal permits or licenses subject to Section 401 include Section 10 and Section 404 permits and potentially could apply to shellfish aquaculture facilities in federal waters of the EEZ, depending on the scope and design of their operations with respect to landing their product. Section 401 authorizes the EPA to delegate water quality certification to the states, since discharge of pollutants typically occurs within the borders of a state. If a water quality certification is required for a shellfish aquaculture facility in federal waters of the EEZ, that certification would come from the state where discharges may occur to ensure the facility operates under water quality standards relevant to that state.

Private Aid to Navigation (PATON) Permit

In order to avoid conflicts with navigation, a shellfish aquaculture facility in federal waters of the EEZ likely will require a U.S. Coast Guard (USCG) Private Aid to Navigation (PATON) permit.⁵⁰ Aquaculture activities require a PATON to properly mark hazards to navigation.⁵¹ The purpose of this permit is to assess the safety of the PATON object and determine if the object should be lighted, placed on nautical charts, or both.⁵²

Section II: The Potential for a Nationwide Permitting Process

The National Aquaculture Act was passed into law in 1980 and established a national policy to support the development of aquaculture broadly and noted the need to address the regulatory restraints on aquaculture.⁵³ However, there is still not a comprehensive and nationwide permitting process in place for marine aquaculture in federal waters of the EEZ that also provides for long-term permits to promote regulatory certainty and security of tenure needed for long-term business and investment decisions.

49. 33 U.S.C. 1341.

50. 33 U.S.C. 1221 et seq.

51. *Id.*

52. *Id.*

53. 16 U.S.C. 2801-2810.

In June 2018, S. 3138 – entitled the “Advancing the Quality and Understanding of American Aquaculture Act” – was introduced in the Senate by Senator Roger Wicker to: promote the sustainable development of marine aquaculture in the United States; support research and technology development; and provide new jobs and support existing jobs within the seafood industry (including jobs for the traditional fishing industry).⁵⁴ Although the bill in its current form does not address seafood safety or NSSP compliance, if passed into law, the act would designate NOAA as the lead federal agency and charge NOAA with developing a comprehensive permitting process and regulatory procedures for aquaculture operations in the EEZ.

In addition, the bill would authorize NOAA to issue long-term permits (25 years, renewable) for aquaculture in federal waters of the EEZ. This could provide shellfish (and finfish and seaweed) growers with greater security of tenure for projects in the EEZ because federal permits for aquaculture under current law (i.e., Section 10 RHA) are typically much shorter in duration, generally for five years.⁵⁵ Since the bill was introduced on June 26, 2018, it has been referred to the Committee on Commerce, Science, and Transportation.

Section III: National Shellfish Sanitation Program

The National Shellfish Sanitation Program (NSSP) was created by the U.S. Food and Drug Administration (FDA) and adopted by the Interstate Shellfish Sanitation Conference (ISSC)⁵⁶ to promote a uniform standard of sanitation in the harvesting, transporting, and processing of molluscan shellfish. The NSSP operates as a federal-state cooperative to ensure “the safety of shellfish for human consumption by preventing harvest from contaminated growing waters.”⁵⁷ This program offers guidance to states through a Model Ordinance, where “states have agreed to enforce... the requirements which are minimally necessary for the sanitary control of molluscan shellfish.”⁵⁸ The NSSP is a comprehensive program that focuses on an assessment of pollution sources, water quality standards for the classification of growing areas, laboratory requirements, patrol of growing areas, plan processing facilities, and the shipping and handling of molluscan shellfish through the Model Ordinance.

54. [AQUAA Act, S. 3138](#), 115th Cong. (2018) (last visited Dec. 30, 2018).

55. See 33 U.S.C. 1344(e)(2).

56. The ISSC is a cooperative group that includes industry, academic, federal government, and state government representatives that foster and promote the safe harvest of shellfish nationwide. See <http://www.issc.org/home> for more information.

57. [NATIONAL SHELLFISH SANITATION PROGRAM, GUIDE FOR THE CONTROL OF MOLLUSCAN SHELLFISH](#) (2009) (last visited Dec. 31, 2018).

58. *Id.*

Water Quality Standards

Molluscan shellfish are filter feeders, and are susceptible to accumulating high concentrations of harmful pathogens, marine biotoxins, and contaminants in their tissues.⁵⁹ These dangerous concentrations have been linked to shellfish-borne infectious diseases that affect humans and also may harm marine species, such as birds, fish, and marine mammals.⁶⁰ Some of these naturally occur in the ocean, such as *Vibrio parahaemolyticus* – one of several species of pathogenic bacteria naturally present in many marine ecosystems (collectively known as *Vibrio*) – which causes around 32,000 human illnesses each year in the United States when raw or undercooked shellfish are consumed.⁶¹ Other harmful pathogens, however, do not naturally occur in the ocean. For instance, norovirus particles can accumulate in shellfish found in waters that have been contaminated by sewage, which when harvested and consumed, either when raw or inadequately cooked, can inflict the consumer with symptoms similar to food poisoning or the stomach flu.⁶²

To prevent shellfish from being grown in, and harvested from, water that doesn't meet water quality standards, the NSSP Model Ordinance requires that states conduct sanitation surveys.⁶³ A sanitation survey includes an:

1. Identification and evaluation of the pollution sources that may affect the growing areas;
2. Evaluation of the meteorological factors;
3. Evaluation of hydrographic factors that may affect distribution of pollutants throughout the area; and
4. Assessment of water quality.⁶⁴

59. NATIONAL SHELLFISH SANITATION PROGRAM, *GUIDE FOR THE CONTROL OF MOLLUSCAN SHELLFISH* (2017) (last visited Dec. 31, 2018).

60. *Id.*

61. Elaine Scallan, Robert M. Hoekstra, Frederick J. Angulo, Robert V. Tauxe, Marc-Alain Widdowson, Sharon L. Roy, Jeffery L. Jones & Patricia M. Griffin, *Foodborne Illness Acquired in the United States--Major Pathogens*, 17(1) EMERG. INFECT. DIS. 7 (2011).

62. Martha Iwamoto, Tracy Ayers, Barbara E. Mahon & David L. Swerdlow, *Epidemiology of Seafood - Associated Infections in the United States*, 23(2) CLINICAL MICROBIOLOGY REVIEWS 399 (2010).

63. NATIONAL SHELLFISH SANITATION PROGRAM (2017), *supra* note 61.

64. *Id.*

Based on the results of the sanitary survey, growing areas are classified into one of five different water quality classifications:⁶⁵ (1) approved, (2) conditionally approved, (3) restricted, (4) conditionally restricted, or (5) prohibited.⁶⁶ Each of the classifications have different implications for harvesters attempting to use the growing area, as it determines how the “shellstock” can be used following the harvest.⁶⁷ An area is given an “approved” classification when it is free from “unacceptable concentrations” of harmful substances.⁶⁸ These areas are also considered open to harvesting, unless an emergency situation temporarily closes an area.⁶⁹ While the water body classification of an area may be “approved”, meaning that shellfish may be harvested directly without any depuration, other NSSP Model Ordinance requirements such as biotoxin control and management must still be met before shellfish are harvested.⁷⁰

Conversely, an area is classified as “restricted” when a “limited degree of pollution” is detected in water quality.⁷¹ This classification is often placed on areas that are subject to unpredictable water pollution.⁷² With unpredictable pollution, shellfish taken from these areas are often required to go through depuration before being deemed safe for human consumption.⁶¹ This category requires additional monitoring by the state to ensure that the harmful effects from these areas are avoided.⁷⁴ In between these categories are “conditionally approved” and “conditionally restricted” areas – optional classifications available to the state which exist to classify areas that are subject to predictable “intermittent microbiological pollution.”⁷⁵ These classifications offer a more flexible approach for the state to restrict access to areas without creating a year-round overly burdensome classification.⁷⁶ While these more flexible designations hold true for facilities located in state waters, those in federal waters are classified as “approved” for shellfish harvesting unless such areas are known to be polluted⁷⁷ and involve commercial shellfish resources.⁷⁸

65. *Id.*

66. *Id.*

67. *Id.*

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.*

72. *Id.*

73. *Id.*

74. *Id.*

75. *Id.*

76. *Id.*

77. This information comes to the FDA from federal agencies and State Shellfish Control Authorities. Telephone Interview with James “Quentin” Forrest, National Shellfish Growing Area Expert, Division of Seafood Safety, U.S. Food and Drug Administration (November 9, 2018).

78. NATIONAL SHELLFISH SANITATION PROGRAM (2017), *supra* note 61.

The FDA is responsible for both the sanitary survey as well as the classification of growing area in federal waters. The sanitary survey is conducted in accordance with Chapter IV @.01 “as applicable”, which provides a mechanism for the FDA to conduct a sanitary survey in accordance with the potential pollution source and health risk which may be a different process than what might be required for state waters.⁷⁹ On occasion, federal waters may be classified as “conditionally approved” or “conditionally restricted”; however, this is uncommon.⁸⁰

The last area of classification is for “prohibited” areas.⁸¹ Prohibited areas are closed to harvesting and are classified as such for one or more of these reasons:

1. The sanitary survey findings show excessive concentrations of harmful substances in the water;⁸²
2. The state fails to adequately update survey requirements on a timely basis (without updated information, the Model Ordinance requires the area to be classified as prohibited, and is closed until further surveys are completed);⁸³ or
3. The area is located adjacent to a sewage treatment plant or other waste discharge of public health significance.⁸⁴

Biotoxin Testing

While there is a pathway for NSSP compliance for molluscan shellfish grown in federal waters through ISSC proposal 17-116, an outstanding issue is testing the cultured shellfish for biotoxins. Per NSSP, the FDA will conduct sanitary surveys and classify growing areas in federal waters, while the NOAA Seafood Inspection Program (NOAA SI) will work as agents of the FDA, with the growers, to ensure their facilities meet NSSP requirements. However, it is the responsibility of the growers to develop an operational plan that must include a description of a marine biotoxin management and contingency plan that addresses sampling and product segregation. If a shellfish grower lands their product in a state that does not extend testing to shellfish grown in federal waters of the EEZ, such as California, what options would be available to the grower?

79. *Id.*

80. James “Quentin” Forrest, *supra* note 79.

81. NATIONAL SHELLFISH SANITATION PROGRAM (2017), *supra* note 61.

82. *Id.*

83. *Id.*

84. *Id.*

In CSR's case, outside of those operated by NOAA SI, the only lab on the West Coast of the United States at the time of this publication that is certified to test for biotoxins is located in Washington State. Outside of the Washington lab, the only other certified testing facility is located in Maine.⁸⁵ Due to the cost of sending samples to Washington or Maine for testing, CSR is weighing the option of building its own lab for long-term testing.⁸⁶ However, the lab would still need to meet NSSP requirements before it could be used to test CSR's cultured mussels for biotoxins.⁸⁷ Other growers considering this are encouraged to work with the FDA and NOAA SI on the requirements for building a testing facility.

Shipping and Handling

The NSSP also establishes specific regulations regarding the shipping and handling of molluscan shellfish. These regulations are aimed at preventing the contamination that occurs during the harvesting, processing, distributing, or shipping of shellfish. While the document provides too many detailed provisions to adequately describe here, some of the more important provisions are described below.

First, the regulations provide specific transportation requirements, including detailed guidance for the proper use of storage bins and the temperature at which shellfish can be transported. In accordance with these provisions, when transported, shellfish should not be kept with any other type of cargo. Second, the NSSP provides detailed sanitation requirements for dealers. A dealer is defined as "a person to whom certification is issued for the activities of shellstock shipper, shucker-packer, re-packer, re-shipper, or depuration processor."⁸⁸ The general requirements for dealers include ensuring the cleanliness of surfaces and water that contact shellfish and properly labeling and storing shellfish to prevent any contamination. However, the regulations also provide specific sanitation requirements for each stage in the process of preparing shellfish for sale. These requirements include detailed instructions for maintaining sanitation during shucking and packing, repacking of shucked shellfish, shellstock shipping, reshipping, and depuration. In federal waters, there are only NSSP requirements for the harvester. Once the product is harvested and sold to either a dealer or a shipper in the landing state, the state shellfish control authority is responsible for the relevant NSSP compliance.

85. Phil Cruver, *supra* note 41.

86. *Id.*

87. *Id.*

88. *Id.*

The necessary requirements and protocols to be followed are specific to where the shellstock is coming from as well as where it is going, and how it is getting there. These requirements can be found in “Section III Public Health Reasons and Explanations – Chapters XI., XII., XIII., and XIV. Shellfish Processing and Handling”.⁸⁹

Section IV: California’s Implementation of the Requirements Under the NSSP

As discussed above, under the NSSP Model Ordinance, each state shellfish control authority is tasked with implementing the minimum requirements set forth in the ordinance for shellfish harvested in state waters and involved in interstate commerce. In California, the state agency in charge of ensuring that minimum requirements under the NSSP are met within state waters is the California Department of Public Health’s (CDPH) Shellfish Program, which is managed by the Environmental Management Branch (EMB) and the Food and Drug Branch (FDB) under the Center for Environmental Health.⁹⁰ To ensure shellfish sanitation, California distinguishes between pre-harvest and post-harvest duties. While the EMB manages all pre-harvest duties as well as California’s Marine Biotoxin Monitoring Program,⁹¹ the FDB ensures the safety of post-harvested molluscan shellfish and the regulation of manufacturers and distributors of seafood products.⁹² In the past the CDPH has been able to cover some of the costs associated with preharvest commercial shellfish activities, as well as for classification of commercial growing areas within state waters.⁹³

Section V: Obtaining NSSP Compliance for Shellfish Grown in Federal Waters of the EEZ

While CSR is permitted to grow mussels,⁹⁴ the company experienced some challenges obtaining NSSP compliance for its product, even though there is a clear pathway outlined involving NOAA SI and the FDA.⁹⁵ As noted above, commercial shellfish farms harvest and sell their

89. NATIONAL SHELLFISH SANITATION PROGRAM (2017), *supra* note 61.

90. See California Department of Public Health, “[Shellfish Program](#)” (last visited Dec. 31, 2018).

91. *Id.*

92. *Id.*

93. Notably, this cost-sharing mechanism is not a formal policy, and is dependent on the types of testing that need to be done as well as the funding that the CDPH has available. Telephone Interview with Eric Trevena, Chief, Environmental Health Services Section, California Department of Public Health (Sept. 10, 2018).

94. “Federal waters” are defined by the ISSC as “waters that fall outside of State and local jurisdiction but within U.S. sovereignty (typically 3-200 nautical miles offshore). Federal waters include the territorial sea and exclusive economic zone. See [INTERSTATE SHELLFISH SANITATION CONFERENCE, TASK FORCE I REPORT](#) (2017) (last visited Dec. 31, 2018).

95. Phil Cruver, *supra* note 41.

product for human consumption through compliance with NSSP requirements.⁹⁶ However, this national program is typically implemented at the state agency level rather than by a federal agency – in California’s case, by CDPH. As the 2017 NSSP Guide states, “state laws or regulations must provide an adequate legal basis for sanitary control of all phases of handling shellfish.”⁹⁷

However, according to Diane Windham, Southwest Regional Aquaculture Coordinator for NOAA Fisheries, state agencies may certify shellfish for sanitation in federal waters, as long as there is a memorandum of understanding between the relevant state shellfish control authorities, the FDA, and NOAA.⁹⁸ However, if faced with overburdened and understaffed agencies, a state might decline to take on sanitation of shellfish grown in federal waters of the EEZ. California is one such state that has elected not to test outside state waters at this time. If a state declines to certify product grown in federal waters, the grower should work directly with the FDA and NOAA SI, who will be able to provide additional guidance. Because of this, CSR worked directly with the federal government in order to get their product in compliance with NSSP requirements.

While NOAA SI and the FDA are working directly with CSR, the two agencies are focused on addressing the issue more broadly to provide shellfish growers operating in federal waters of the EEZ with a pathway towards NSSP compliance. The FDA and NOAA SI have entered into a private contract with CSR to perform the required water quality and safety tests to obtain certification. However, there is important context as to why CSR needed to enter into a private contract with FDA and NOAA SI and why a more permanent and broadly applicable solution is needed. Currently, there is no permanent pathway because historically there was not as much interest in shellfish operations in federal waters in the EEZ as there is today. However, due to increasing industry interest in siting facilities offshore, the ISSC understood the need for a federal pathway and established a Federal Waters Committee to propose a protocol.⁹⁹

96. NATIONAL SHELLFISH SANITATION PROGRAM (2017), *supra* note 61.

97. NATIONAL SHELLFISH SANITATION PROGRAM (2017), *supra* note 61.

98. Telephone Interview with Diane Windham, NOAA Southwest Regional Aquaculture Coordinator for NOAA Fisheries (Feb. 5, 2018).

99. The FDA encourages the correct terminology be used when talking about aquaculture in federal waters. Therefore, “protocol” should be used not to represent the already established framework developed by the ISSC, but to represent the requirements that were developed by the FDA and NOAA Seafood Inspection to bring CSR and other federal growers into compliance with sanitation.

The FDA submitted a proposal for compliance with NSSP requirements in federal waters, which was approved in 2017 by the ISSC as a four-year interim program, and established a Federal Waters Committee to evaluate the process and re-visit it at the end of the four-year period.¹⁰⁰ This interim program allows the FDA to conduct sanitary surveys in federal waters, in compliance with Chapter IV @.01 in the Model Ordinance as well as growing area classifications, in compliance with Chapter IV @.03.^{101, 102} CSR initially declined the option provided by NOAA SI and the FDA, perhaps due to the burden of costs associated with beginning operations and adhering to California's permitting regulations. CSR originally had hoped to continue to work with the CDPH on an avenue for the agency to test in federal waters (unconfirmed by CDPH); however, they have since decided to utilize the federal pathway which allowed them to have their first harvest on July 30, 2018.¹⁰³

Section VI: Moving Forward

Shellfish aquaculture in the EEZ comes with the technical and logistical challenges that are part and parcel with operating in an offshore environment, but current and prospective marine aquaculturists should be aware of the regulatory and compliance nuances as the U.S. aquaculture industry contemplates further expansion into federal waters of the EEZ. In order for development on a broader scale to occur to meaningfully address our nation's seafood deficit and contribute to the local economies along the coast, the NSSP compliance issue needs a formal resolution because it can prevent harvest. In addition, a federal permitting process that includes long-term authorization of aquaculture activities in the EEZ would provide the regulatory certainty and security of tenure needed for greater investment. CSR is an ideal case study for these issues not because regulations and compliance requirements became roadblocks, but because CSR was able to successfully navigate both processes to construct and operate their facility and harvest their product for sale.

The FDA and NOAA SI continue to work closely with the ISSC to implement the federal compliance pathway interim program (ISSC 17-116). Utilization of the interim program ISSC 17-166 for NSSP compliance in federal waters would provide the FDA, NOAA SI, and the ISSC with important feedback in order to help them move forward with a permanent solution.

100. See INTERSTATE SHELLFISH SANITATION CONFERENCE, ISSC TASK FORCE I PROPOSALS, [ISSC Task Force I Proposals Proposal 17-116](#) (last visited Dec. 31, 2018).

101. *Id.*

102. See INTERSTATE SHELLFISH SANITATION CONFERENCE, *supra* note 96.

103. Phil Cruver, *supra* note 41.

For state-level agencies responsible for NSSP compliance in states that currently do not extend biotoxin testing to EEZ waters but want to consider moving in this direction, broader discussions through the ISSC could be hosted with their counterparts in other state agencies and with federal agencies (those which have authority over NSSP compliance). Such discussions could help these agencies identify resources needed to extend testing to shellfish grown in federal waters of the EEZ. For current and prospective shellfish growers interested in ventures in EEZ waters, understanding NSSP requirements in the context of operating in federal waters of the EEZ and how federal agencies and the ISSC are working with industry to meet them is as important as understanding how to navigate the permitting process. Hopefully, this case study has provided information on these requirements so shellfish growers can understand them from the beginning, and that the transition from permitting to construction and operations to harvest can happen smoothly.