

Woods Hole Case Study



As one of the first teams in the United States pioneering a product to control harmful algal blooms (HABs) in marine environments, there was no easy way for the Anderson Lab to learn about all the necessary governmental approvals that would be required before field testing their products in a marine environment. There wasn't an instruction manual, let alone a success story or compilation of best practices for the lab to follow. As demonstrated in this case study, the lab faced many twists and turns while charting a path through the complex regulatory landscape to field test their products.

The Technology

The Anderson Lab at the Woods Hole Oceanographic Institution in Massachusetts studies the species of toxic algae that are responsible for disrupting human and ecosystem health. This work includes analyzing factors that drive HAB events and the ecosystem impacts that result from a harmful bloom. Part of their research is supported by NOAA's US HAB-CTI program. The US HAB-CTI grant was awarded to the team to assess the effectiveness and environmental impacts of dispersing modified clay minerals to control red tide blooms in marine environments. Over the years, the lab has tested various mineral constituents and polymers in their facilities.

To control red tide, the modified clay would be sprayed on the surface of the water during an algal bloom. The clay particles flocculate or combine with other particles in the water, including the red tide cells. As these aggregations grow, they sink to the bottom of the water.

While the use of modified clay may control the bloom, it does not necessarily prevent the release of harmful brevetoxins that harm marine life. In some cases, the flocculation and sinking process can destroy the algal cell, releasing brevetoxins.



In deeper water, darkness, prolonged contact with the clay, and eventual burial in sediments on the seafloor can also kill the algae cells and release toxins, although, the impacts of toxins released on the sea floor may be more localized than toxins at the water's surface. Additionally, a one-time release of toxins during treatment may be preferable to the long-term release that would result from an untreated bloom where the red tide cells continue to proliferate, allowing the bloom to persist and spread for weeks, months, or even years.

2015 NOAA Programmatic Environmental Assessment

Concurrent with their work under the US HAB-CTI grant, the lab was conducting this research under the National Centers for Coastal Science's (NCCOS) Prevention, Control, and Mitigation of Harmful Algal Blooms (PCMHAB) Program. In February 2015, NOAA staff completed a high-level review under the National Environmental Policy Act (NEPA), called a Programmatic Environmental Assessment (PEA), to assess potential environmental effects associated with projects within the PCMHAB Program, including flocculation. The PEA determined that the proposed actions would not significantly impact the quality of the human environment but noted that environmental assessments examining individual projects may be required in the future.

2019 FDEP Environmental Resource Permit

By the start of 2019, the lab was getting ready to field test products and had identified study sites, but uncertainty remained regarding what permits or approvals were needed to run a field test. They reached out to the MOTE Marine Laboratory & Aquarium (MOTE) in Florida who was also interested in testing products to control HABs in the ocean and who had already run one study using ozone in a small Florida canal. MOTE advised the lab to get in touch with the Florida Department of Environmental Protection (FDEP) to get approval to field test modified clay to control red tide blooms. FDEP is Florida's lead agency for environmental management and stewardship. They are responsible for overseeing permitting and compliance activities that protect air and water quality. In January 2019, the lab contacted FDEP to request verification of exemption from Environmental Resource Permit (ERP) requirements. FDEP is one of the agencies that runs the state's ERP Program, which regulates activities involving the alteration of surface water flows in Florida. FDEP staff advised the lab to reach out to the U.S. Army Corps of Engineers (USACE) west Tampa permit section to be able to field test in tidal waters along the Florida coast.

2019 USACE CWA Section 404 and RHA Approvals

The USACE is responsible for protecting many of the nation's aquatic environments including oceans, rivers, lakes, and wetlands. The Corps regulates activities impacting U.S. waters under laws including the Rivers and Harbors Act of 1899 (RHA) and Section 404 of the Clean Water Act (CWA). The lab reached out to the USACE, who in February 2019, determined that the proposed flocculation activities did not require a Department of the Army permit under the RHA or CWA Section 404. The proposed activities would not affect the course or capacity of a navigable water and would not constitute the discharge of dredged or fill material into waters of the U.S. The lab thought that confirmation from the USACE was the last of the approvals that they would need to run their field test. However, in their determination letter, the Corps suggested the team reach out to the local U.S. Fish and Wildlife Service (USFWS) office to determine if species protected by the Endangered Species Act (ESA) are present at the project site.

NCCOS Staff Stepped in as the Action Agency

After mentioning the next steps of conducting a field study in a presentation, the lab team spoke with USFWS staff who described how statutes such as the ESA and Magnuson-Stevens Act

might require consultations between NOAA, the agency funding the lab's work, and USFWS and National Marine Fisheries Service (NMFS). Section 7 of the ESA requires each federal agency, in consultation with the USFWS and NMFS, to ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the adverse modification of designated critical habitat. Additionally, under the Magnuson-Stevens Act, federal agencies are required to consult with NMFS on all actions they authorize, fund, or undertake that may adversely affect essential fish habitat. The lab was essentially told, "You aren't the one we should be talking to about this project. It should be the agency that is funding you." At this point, a NOAA NCCOS staff member got involved who could represent the funding agency in these consultations. The lab delayed prospective field trials with the hopes that the consultations would produce the final required approvals.



2021-2022 NOAA Special Award Condition

In June 2021, NOAA placed a Special Award Condition on the lab's PCMHAB award funding the proposed field experiments in Florida. This prohibited initiating field trials until NOAA conducted environmental review actions to ensure compliance with federal statutes imposed for the protection of the environment, including the ESA, the Magnuson-Stevens Act, NEPA, the Marine Mammal Protection Act, Coastal Zone Management Act, and the National Historic Preservation Act. Over the next year, the NCCOS staff member took the necessary actions and participated in the required consultations to meet the conditions for project approval.

In September 2022, USFWS determined that the project was not likely to adversely affect any federally listed species or designated critical habitat protected by the ESA. In late September, NOAA then released the Special Award Condition on the field demonstration trials for flocculation.

2023 Additional State and Federal Approvals

In spring 2023, the lab received more state and federal approvals for the clay flocculation field testing project. In March 2023, FDEP determined that the lab's updated proposed project was exempt from the need to obtain an Environmental Resource Permit because it was expected to have minimal adverse impacts on water resources. With approvals or exemptions from FDEP, NOAA, NMFS, USACE, and USFWS, the lab was looking forward to beginning their field trial the next time a harmful algal bloom occurred at one of their preapproved sites along the Florida coast. Unfortunately for the team, they were soon to discover a major oversight in the permitting discussions—the U.S. Environmental Protection Agency (EPA).

2023-2024 FIFRA and the FFDCA

The lab was not aware that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), administered by the US EPA, might be relevant to the substances they were testing. However, after hearing a consultant mention that FIFRA might apply to products to control HABs, MOTE staff reached out to EPA's Office of Pesticides Program (OPP) to see how EPA viewed the use of modified clay to control and mitigate HABs. The lab's senior scientist, Dr. Donald Anderson, presented in early January 2024 on the use of clay and modified versions for HAB control and mitigation.

After the presentation, OPP determined that the modified clay is a pesticide subject to regulation under FIFRA. OPP reviewed the lab's testing plan and in May 2024, wrote a letter stating that the field trial would not require a Federal experimental use permit (EUP) under FIFRA. However, OPP also mentioned that because the lab's pesticide applications will come into contact with fish that could be caught and consumed, EPA must establish a tolerance level for the lab's pesticides or an exemption from the requirement of a tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA). To navigate requirements under FIFRA and the FFDCA, the lab hired a pesticide regulatory affairs consultant. The consultant advised them on how difficult the regulatory process under FIFRA would be for different compounds, which informed the lab of which versions of modified clay they should continue trying to get approvals to field test.

Shifting OPP Guidance

In September 2024, OPP told the lab's consultant that if there was information that fish will not accumulate these substances or not enter interstate commerce, then FFDCA would not be triggered. However, this guidance changed in November 2024, when a different OPP staff member wrote that the field testing would require an EUP for each ingredient that is not currently covered under an existing tolerance. This is because the testing would be conducted in waters which contain or affect fish, shellfish, plants, or animals taken for recreational or commercial purposes and used for food or feed. Finally, OPP noted that if testing were to occur without an EPA-issued EUP, then a National Pollution Discharge Elimination System (NPDES) permit under the CWA Section 402 will be required for application to water.

Focusing on Ingredients with Tolerances or Tolerance Exemptions

The team concluded from these interactions with OPP that the EPA would prohibit field testing in areas where fishing for food could occur unless the ingredients in the test material have tolerances or tolerance exemptions or a nonfood determination that it is not likely to result in residues on food. After discovering the high costs associated with conduct studies to establish tolerances or tolerance exemptions or support nonfood determinations, the lab decided to limit the products they planned to test to only products with existing tolerances or tolerance exemptions.

Later in November 2024, the lab's consultant emailed OPP that the lab proposed to test product formulations made up of ingredients with appropriate tolerances or exemptions, on no more than 1 surface acre of water for the control of *Karenia brevis* in marine waters which may affect fish taken for recreational or commercial purposes and used in food or feed. The email requested a confirmation letter from OPP that an EUP is not required for their planned field efficacy testing.

On February 28, 2025, OPP replied to the lab, confirming that the products they planned to test all had appropriate tolerances or tolerance exemptions. Although the content of EPA's letter seemed to confirm that the lab's testing could occur without an EUP, the letter ambiguously stated that the lab's proposed testing may take place with an EPA-issued EUP. OPP also wrote that if testing were to occur without an EPA-issued EUP, then an NPDES permit would be required. The lab's consultant replied asking OPP to clarify what their next steps should be. OPP directed any questions about the CWA to EPA's Office of Water.

2025 Finalizing State Permits

On March 3, 2025, the lab's consultant emailed the Florida Department of Agriculture and Consumer Services (FDACS) to share OPP's letter. FDACS is responsible for regulating pesticides in Florida, including testing, registration, licensing, and use. FDACS responded that the lab would need to contact FDEP for an NPDES permit under the CWA. In an email response to the lab's consultant, FDEP confirmed the proposed testing would not require additional approval from them.

In July 2025, FDACS emailed the lab the requirements for an exemption from a Florida EUP and noted that no notification is required if the cumulative area treated per site, per crop, per experimental compound is less than one surface aquatic acre per year, which the lab's testing would comply with. Finally, six years after requesting verification of their first permit exemption from FDEP, the lab had received all of the permits and approvals they would need to field test a product. As of September 2025, the lab is permitted to field test their product in six sites on the Florida coast and is waiting for a red tide bloom to commence testing.

Parting Thoughts

As one of the first teams to work their way through the permitting process to field test products to control HABs in a marine environment, the lab faced significant challenges. In describing their experience, they emphasized there was no easy way to learn about all of the steps involved to get necessary approvals to field test their products. The regulatory environment was obscure with misdirection and resulted in delays as they waited months for feedback. Usually, a science principal investigator isn't going to put a regulatory affairs consultant on the project, but the lab found it necessary and beneficial in this case. Hopefully, sharing what the lab went through will help demystify the complex regulatory landscape for future similar projects.

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