
DinoSHIELD Case Study



This case study recounts the obstacles navigated by a research team as they took on permitting a novel harmful algal bloom (HAB) control technology called DinoSHIELD. DinoSHIELD was developed by the University of Delaware in partnership with the National Centers for Coastal Ocean Science (NCCOS), which is part of the National Oceanic and Atmospheric Administration (NOAA) and develops ecosystem science solutions and tools for sustainable stewardship of ocean and coastal resources. This case study was derived from interviews with the DinoSHIELD team members about their complicated experience.

The Technology

DinoSHIELD is a biological harmful algal bloom (HAB) control technology created by extracting an algicidal compound, IRI-160AA, from a naturally occurring bacteria species called *Shewanella* sp. IRI-160. This algicide targets and disrupts the growth of harmful algae without harming the surrounding ecosystem. When deployed, DinoSHIELD could help limit the impact of red tide on coastal communities and economically important industries such as shellfisheries and tourism. Following years of study from laboratory and mesocosm experiments, researchers were nearing readiness to field test the algicide in the water using food grade hydrogel beads in 2020. The DinoSHIELD team soon encountered significant challenges when trying to get their new technology approved for field testing under existing permitting processes.

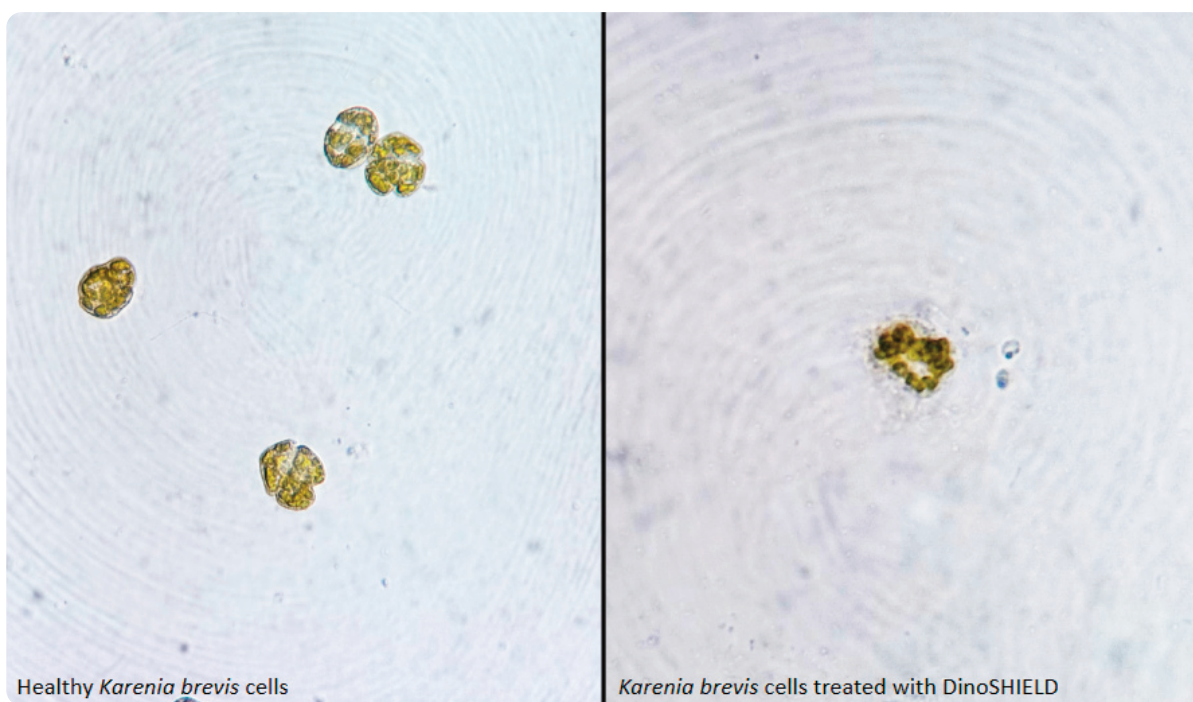


The original concept for DinoSHIELD was funded in 2010 by NCCOS's Prevention, Control, and Mitigation of Harmful Algal Blooms (PCMHAB) program. Years later, NCCOS's United States Harmful Algal Bloom Control Technology Incubator (U.S. HAB-CTI) provided funding for novel technologies intended to control HABs in marine environments, like DinoSHIELD, to push toward field testing and implementation.

Searching for a Starting Point

The DinoSHIELD team first reached out to a contact at the U.S. Environmental Protection Agency (EPA) about permitting field trials in 2021, who suggested that the team could be exempt from certain federal regulations, but they didn't hear back after requesting clarification. They learned through a different research team working under the same NCCOS grant program, that the Federal Food, Drug, and Cosmetic Act (FFDCA) might apply to their work. The FFDCA requires established tolerances or tolerance exemptions for every ingredient in a pesticide product used on food use sites, which might end up with residue on food or feed. Field testing in waters that could impact fish that are then caught and consumed, likely implicates the FFDCA. The DinoSHIELD team reached out again to EPA, the agency that regulates pesticide tolerances under the FFDCA and regulates pesticide registration and use under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). However, they found it very challenging to get in touch with the right EPA staff to answer their questions.

While still figuring out the permitting process in August 2024, the DinoSHIELD team hosted six workshops across southwest Florida that built community trust in the technology. The team was able to inform Florida communities about their product and incorporate their feedback into research and development. After the workshops, they finalized a product; next, it was just a matter of getting through federal and local permitting for small-scale field demonstrations.



Pre-Submission Meeting Request Form

Starting in April 2023, the team tried contacting different EPA staff about necessary permits to field test DinoSHIELD and in some of those cases ended up being forwarded to someone else. In October 2024, NCCOS staff reached out to the EPA Office of Pesticide Programs (OPP). In response, Biopesticides and Pollution Prevention Division (BPPD) staff within OPP sent a pre-submission meeting request form along with general information about experimental use permits and links to guidelines to get started. A pre-submission meeting is an opportunity for EPA's OPP staff to provide guidance on completing pesticides applications under the FFDCA and FIFRA for EPA review. The BPPD staff member also suggested the team would need to submit a tolerance exemption under PRIA B610 to comply with FFDCA requirements. PRIA B610 is a category under the Pesticide Registration Improvement Act (PRIA) that covers the administrative process and fee for applications including temporary tolerance exemptions. EPA may establish a temporary tolerance under FFDCA section 408(r) to permit the experimental use of a non-registered pesticide.

The DinoSHIELD team had questions about the pre-submission meeting request form's directions and which permitting pathway to pursue. Applicants must classify their product as either a biopesticide, antimicrobial pesticide, or conventional pesticide. The team submitted information about DinoSHIELD to EPA's Biochemical Classification Committee, a group of scientists responsible for determining whether a proposed pesticide is eligible to be evaluated as a biochemical pesticide, which EPA lists as one of three major classes of biopesticides. The committee agreed with a biochemical classification in this instance. After the classification was complete, the DinoSHIELD team provided EPA with additional data as required by PRIA. After about two months of work, the DinoSHIELD team submitted their pre-submission meeting request form on December 20, 2024.

On January 2, 2025, an EPA BPPD staff member responded to the pre-submission form asking the DinoSHIELD team to modify the form with separate product information for the bacterium and algicide in their product. At this point, the team decided to only pursue algicide rather than apply for any permits to approve field testing the bacterium. While the algicide without the bacterium is likely easier to get permitted, it would result in changes to DinoSHIELD such as losing the bacterium's continuous algicide production. The DinoSHIELD team worked on updating the form and solicited feedback on testing ideas from their collaborators. They submitted the updated form on March 25, 2025. On April 28, 2025, the DinoSHIELD team received an update from EPA that indicated the staff had determined which regulations seemed most appropriate for permitting DinoSHIELD to field test but were still reviewing possible alternatives.

Possible Regulatory Routes Under the FFDCA

On May 19, 2025, BPPD staff provided information on possible regulatory routes under the FFDCA to permit field testing DinoSHIELD, such as petitioning for a tolerance exemption or submitting data to support a nonfood determination and included links to the requirements of each option. Since then, the team has been reviewing the required testing guidelines for each possible route.

EPA's requirements include a very long list of tests, some of which the DinoSHIELD team didn't know how to conduct, or thought were unnecessary given their product's anticipated use in aquatic environments rather than terrestrial application. The DinoSHIELD team had already conducted ecological tests, but they weren't all the same tests that EPA requires.

As previously mentioned, the FFDCA requires tolerances or tolerance exemptions for every ingredient in a pesticide product intended for use in a food use site. Because fish in the coastal marine waters where testing would occur could be caught and eaten, the DinoSHIELD team would be testing in a food use site. However, it would be extremely difficult to isolate every ingredient in DinoSHIELD for separate testing.

If the team pursues a tolerance exemption, required tests would include oral toxicity and testing on mammals. This route is challenging because the length of some of the required tests is 90 days, which would further delay their project. An alternative to the tolerance requirement is submitting data to receive a nonfood determination, where the ingredients are not likely to result in residues in or on food. To pursue a nonfood determination, the testing is more chemistry focused, analyzing residue of the algicide on different plants and species. A number of these tests include environmental fate testing, some of which appear to be for terrestrial application even though this product would have aquatic use.

The testing requirements for their permitting options do not seem tailored for a product like DinoSHIELD and are so numerous and expensive that the team thinks it is unlikely a lab without significant funding and connections could get a similar product approved for use. As NCCOS staff, the DinoSHIELD team is able to use their vast network of partners to complete testing requirements and move forward with trying to get tolerance exemptions while still weighing the alternative of pursuing a nonfood determination. They decided to start with petitioning for a tolerance exemption and submitting the algicide as the active ingredient and the hydrogel as the inactive ingredient.

In May 2026, the DinoSHIELD team was able to meet with EPA Biochemical Pesticides Branch staff. The team confirmed that they can pursue a small-scale field test that meets the standards for exemption from experimental use permit requirements per regulation 40 CFR 172.3(c)(2). The DinoSHIELD team is still working on a path forward to meet FFDCA requirements, either by pursuing a tolerance exemption or establishment, or a nonfood determination for product residues and nontarget organisms. The team is still working on identifying the active chemical compound for the algicide and developing nontarget tests for other species. As of June 2026, the DinoSHIELD team still has a lot of questions they need answered before making significant progress on getting approved for field testing. They are compiling additional data to discuss next steps with EPA.

Other Federal Statutes with Applicable Requirements

The DinoSHIELD team learned about the FFDCA requirements in 2024 but were aware of other federal statutes with relevant requirements years earlier. Algicide as a HAB control method was evaluated in 2015 as part of a high-level environmental impacts review under the National Environmental Policy Act (NEPA), called a programmatic environmental assessment (PEA), conducted by NOAA. The PEA concluded that the proposed actions, including use of a product like DinoSHIELD, will not significantly impact the quality of the human environment. The PEA also informed the DinoSHIELD team of other federal statutes with requirements that may be relevant including the Clean Water Act, Coastal Zone Management Act, Endangered Species Act, Magnuson-Stevens Fishery Conservation and Management Act, National Historic Preservation Act, National Marine Sanctuaries Act, Rivers and Harbors Act, Marine Mammal Protection Act, and the Wilderness Act. To test in ocean waters, a research permit under the Marine Protection, Research, and Sanctuaries Act may also be needed.

In 2024, NOAA reaffirmed that the PEA covers the scope of environmental impacts of DinoSHIELD pending consultations and approvals of compliance under the other federal statutes listed by the PEA. One of these consultations under the Endangered Species Act (ESA) has been completed. NOAA determined that DinoSHIELD's proposed field testing will have "no effect" on listed species and critical habitat within its purview. As the team plans to field test in Florida, the US Fish and Wildlife Service concurred with NOAA's determination that small-scale algicide deployment may affect, but is not likely to adversely affect, the West Indian Manatees, listed as threatened under the ESA. This determination would mean that the effects of DinoSHIELD's testing on manatees would be beneficial, insignificant, or discountable. The team also received a letter from the U.S. Army Corps of Engineers Tampa Permits Section stating that no Department of the Army permit pursuant to Section 404 of the Clean Water Act is required for their planned field testing. The DinoSHIELD team continues to work to ensure compliance with all relevant federal statutes.

State Approvals

At the state level, the DinoSHIELD team will work with agencies like the Florida Department of Environmental Protection and the Florida Department of Agriculture and Consumer Services to obtain required permits and approvals. The DinoSHIELD team conducted site surveys to identify possible field test locations and will seek local permission to deploy when they are able to confirm ideal test sites.

Conclusion

Getting in touch with the right EPA staff was a major challenge for the DinoSHIELD team as they sought permitting guidance. Furthermore, the task of seeking approvals for product ingredients without existing tolerances or tolerance exemptions under the FFDCA and the difficulty of isolating every ingredient in DinoSHIELD created additional barriers to obtain permits for field testing. The DinoSHIELD team is concurrently working on a paper to document the regulatory challenges they are experiencing and their recommendations to improve the permitting process for field testing HAB control products in marine environments. Nonetheless, the DinoSHIELD team continues to persevere with permitting their new technology through demanding data requirements and a complicated regulatory landscape. Hopefully they will help clear a path for similar safe and effective technologies to come.

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