

Stephanie Otts: Good afternoon everyone. My name is Stephanie Otts. I'm the director of the National Sea Grant Law Center. Thanks everyone for joining us here today for the fifth shellfish aquaculture webinar series that we've done this summer. We've had a lot of great presentations and I'm really looking forward to the one we have planned for you today, which is Certification of Growing Waters in the Exclusive Economic Zone and our presenter is Catherine Courtier from California Sea Grant. But before she gets started I just wanted to give a little bit of background of the project. Also, if you have questions throughout the webinar, please feel free to use the chat box function. We have everyone on mute to eliminate and reduce background noise so you can use the chat function to ask your questions and we'll be answering questions following the end of the presentation.

Stephanie Otts: This webinar series is the kind of the outreach phase of a larger project that was funded by the National Sea Grant College program in 2017 entitled Overcoming Impediments to Shellfish Aquaculture. And the project involved a multi-institutional team of researchers from across the country looking at legal challenges and barriers to shellfish aquaculture. And so we have partners from Rhode Island Sea Grant, Carl Vinson Institute of Government, California Sea Grant and William and Mary School of Law that has a partnership with Virginia Sea Grant.

Stephanie Otts: If you're interested in the project, we do have a project webpage where you can find the final report as well as the eight case studies that were produced through the project and they are all available on our project website. Feel free to access the case studies at this link or to Google the National Sea Grant Law Center and you can get to the page through our projects. That's just a little bit of background on the overall project. And now I'd like to turn it over to Catherine to provide an overview of her case study and the work that they did in California.

Catherine C.: All right. Hi everyone. Let's see if I can pick the right screen to share. Awesome. Thank you to everyone who has joined us today. I know this webinar was originally scheduled for an earlier date and we had to move it. Really great to see that a bunch of you are tuning in for this.

Catherine C.: Today I'll be talking about a case study that I worked on with Lisa Schiavinato who used to be with California Sea Grant but is currently with San Diego River Park Conservancy and then Shana Jones and Danielle Goshen with the University of Georgia.

Catherine C.: This is a really particularly exciting project for me because it was the first project that I started on when I came to Sea Grant almost two years ago, and it was also the first project that I had worked on involving aquaculture. It was definitely very exciting, very steep learning curve with all of the different regulations of aquaculture, but it was really a great opportunity to kind of get my feet wet in this. That being said, I am not an aquaculture specialist so I wanted to take a

minute just to feature the members of our extension team here at California Sea Grant, do work on aquaculture. For those of you who might have some more targeted questions, these are great people to reach out to.

Catherine C.: We have Carolynn Culver who is located at the University of California at Santa Barbara and she's working on a bunch of really cool projects on rock scallops and brown box crabs and she also does some space use planning for aquaculture. Luke Gardner is our extension specialist with Moss Landing Marine Labs. He's working on some projects looking at issues limiting aquaculture growth and he's also recently started a project on alternative fish free feeds. His project right now is looking at different types of algae as a fuel source, also for cultivating algae as a fuel source for cattle. Theresa Talley is located right here at Scripps Institution of Oceanography in San Diego. She has a fishing and aquaculture apprenticeship program. And then we have Carrie Pomeroy who is located at the University of California Santa Cruz and works on a space use planning project with Carrie Culver. If anybody is interested in of these projects, feel free to contact me. I have my email address at the end of this presentation and they'd be more than happy to chat with you about what you work on.

Catherine C.: The focal point of our case study is on a farm called Catalina Sea Ranch and Catalina Sea Ranch is currently farming Mediterranean mussels on about a 100 acres of water where their facilities stand six miles away from the shores Huntington Beach, California, off the San Pedro shelf. And their facilities support research and development, use of technology to aid in the existing monitoring efforts. And they're also, we're working on looking at partnerships to expand their research and development capacity. And so this has been, I think this is the third or fourth time that my group and I have presented on this and it's been very interesting to kind of see how this project has evolved since we started almost two years ago.

Catherine C.: It's definitely in a very different place. I don't know if any of you have listened a previous presentation, but I think this will be very different. And while it has been really interesting to be involved in such a dynamic project, it's also been a challenge because this is a farm that is currently going through some regulatory challenges. And so, working on things in real time has been very interesting. But I'll kind of cover that a little more later.

Catherine C.: Just taking a minute to talk about the legal framework of this. There are, for aquaculture and federal waters of the EEZ, there are multiple agencies involved with permitting, both for fin fish, salt, shellfish, and then seaweed. Know fisheries currently has no legislative authority at this time to issue permits. The permitting process for aquaculture currently falls to the Army Corps of Engineers and then the Environmental Protection Agency. And then in California we also have the Coastal Commission. In state, for state we have specific state aquaculture laws and regulations and then submerged lands leasing requirements. And so here in California the agencies that deal with us are the California Department of Fish and Wildlife and they deal with aquaculture

registration. And also if product is landed and sold in the state, and then also the state Land Commission, which deals with issues of bottom leases in state waters. And then finally California Coastal Commission. In federal waters, farms need to comply with the California Coastal Act as it may affect, their farms can affect marine resources in state waters such as involved in transporting harvest.

Catherine C.: Here is, okay, so I guess why federal waters is a big question that people have asked. And that is because in state waters there is generally higher degree of user conflicts. While you do have this in federal waters, it's oftentimes more pronounced in state waters. And this is due to the fact that there's lots of recreational activities going on such as snorkeling, scuba diving, recreational boating, and then also commercial use. You have fishing and shipping. And so these are more prevalent in the state waters. And so this competition for space is as what has led people to look to federal waters to expand their facilities.

Catherine C.: I had mentioned in a previous slide a little bit about all the different state and federal agencies and this is by no means all of them. I've missed a couple but these are all the ones that I could fit onto one slide. And so this is just to give you kind of an idea of all of the parties who are involved in this. And we were very lucky to speak with, I think almost one individual from almost all of these. And I have them listed at the end, just a huge thank you. This was a very complicating project. And so as you can see here from this whole list.

Catherine C.: See, so I had mentioned briefly that our case study focus has really evolved since the time we started this. Two years ago when we decided to do case study on Catalina Sea Ranch, putting their aquaculture farm in federal waters, we really thought the big issue we were going to focus on for our case study would be kind of the legal issues of the permitting phase. And so this was getting their permits from relevant agencies. And so for those of you who were on a previous webinar, we had kind of thought that the California Coastal Commission had given them these 13 things that they had to follow through with, such as monitoring requirements in order to receive their permits.

Catherine C.: And so this is at the time what we really thought was kind of their issue of how to move forward. But after further discussion, not only with Catalina Sea Ranch, but also with some of the state and federal entities, we realized that it wasn't so much the issues of permitting phase, but operational issues. There is kind of a lack of clarity regarding regulatory permitting processes in federal waters, which has since been addressed. And then there was also this really big issue of biotoxin testing because as you can imagine if you're growing shellfish, you are really want to make sure that what you are growing and then selling is safe to consume.

Catherine C.: At the time this case study was written and concluded, which was I think back in March or actually November, there was no formal pathway for shellfish producers to sell product harvested in the EEZ. And so this is currently not the

case as there is an interim pathway and I will go over that later on in this presentation.

Catherine C.: I just wanted to talk about the National Shellfish Sanitation Program that has a lot to do with the case study. The NSSP was created by the US Food and Drug Administration and then adopted by the Interstate Shellfish Sanitation Conference. And this was done really to promote uniform standard of sanitation in the harvesting, transporting and then also the processing of molluscan shellfish. And so the Interstate Shellfish Sanitation Conference really was designed to promote cooperation and trust among shellfish control agencies, the shellfish industry, and overall to really ensure the safety shellfish products consumed in the United States.

Catherine C.: And so the NSSP really functions as a federal state cooperative that, as I said, kind of ensures the safety of shellfish for human consumption. And it does this by preventing harvest from contaminated growing waters. The NSSP offers guidance to states through a model ordinance. And in this model ordinance states have agreed to enforce the requirements which are minimally necessary for the sanitary of molluscan shellfish. And so this is a comprehensive program that focuses on assessment of pollution sources, water quality standards for the classification of growing areas, laboratory requirements, patrol of growing areas, planned processing facilities, and the shipping and handling of molluscan shellfish. This model ordinance is quite comprehensive.

Catherine C.: Part of the model ordinance has to do with water quality standards. And so the model ordinance is the compliance pathway that is overseen by the FDA, which is the Food and Drug Administration with NOAA seafood inspection acting as an agent of the FDA in the field. And so the model ordinance requirements are going to be the same whether a grower is in state or federal waters. The difference lies in who's able to conduct the sanitation tests. And so for the water quality standards, are conducted to ensure that the growing area does not contain contaminants that will be consumed by the shellfish and then passed onto the consumer. Within this sanitation, within the water quality standards, there is the requirements for a sanitary survey, which involves identification and evaluation of pollution sources that may affect the growing areas, an evaluation of the meteorological factors, an evaluation of the hydrographic factors that might affect distribution of pollutants throughout the area, and then an assessment of water quality.

Catherine C.: And so for the water quality classification, the results of the sanitary survey then place a water body into five classifications, being approved, conditionally approved, restricted, conditionally restricted or prohibited. And so each of these five classifications has different implications for harvesters because it determines how their shell stock can be used following the harvest. And so just to give you an example, an area that has given an improved classification is free from what they call acceptable concentrations of harmful substances. While it is classified as approved, this means the shellfish may be harvested directly

without any depuration, additional NSSP model ordinance requirement such as biotoxin control and management must still be met before the shellfish are harvested. There's really this emphasis on biotoxin testing.

Catherine C.: Facilities in federal waters are classified as approved for shellfish harvesting, unless such areas are known to be polluted and involve commercial shellfish resources. On occasion, federal waters can actually be classified as conditionally approved or conditionally restricted. And this flexible classification system is available for areas that are subject to kind of this predictable intermittence microbiological pollution. And so this prevents the creation of a year round, overly burdensome classification system. This is kind of more uncommon.

Catherine C.: In the model ordinance it also talks about biotoxin testing. And so there is currently a pathway for NSSP compliance for molluscan shellfish grown in federal waters and this is through a four year interim program. And so the FDA submitted a proposal for compliance with these NSSP requirements in federal waters and so that in 2017 the ISSC approved a four year interim program and established federal waters committee which would evaluate the process of this program and then revisit it at the end of that four year period. And this interim program allows the FDA to conduct sanitary surveys in federal waters in compliance with the model ordinance as well as growing area classifications. And so the FDA will conduct these sanitary surveys and also classify growing areas in federal waters and then NOAA seafood inspection program will work as agents of the FDA with the growers to ensure their facilities are meeting the NSSP requirements.

Catherine C.: However, it is important to note that it is still the responsibility of the growers to develop an operational plan. And this includes such things as a description of marine biotoxin management and also contingency plan that addresses sampling and product segregation. And so California does not currently extend testing via the state's California Department of Public Health who does the biotoxin testing for facilities in state waters. They don't currently extend this testing into federal waters. At the time this case study was written, the paths available to Catalina Sea Ranch were really to use a lab operated by NOAA's seafood inspection for their testing or to test using a lab certified by the FDA. And there are labs located in Washington, and Maine and California, but at the time when CSR was looking for testing facilities, the only one of these three labs that was in compliance with the FDA was in Maine. Since then, Washington's lab is in compliance and I'm pretty sure that California's lab is working towards being in compliance.

Catherine C.: Within the model ordinance, there's also rules on shipping and handling. And so the NSSP established shipping and handling regulations aimed to prevent contamination of shellfish during the harvesting, processing, distribution, and shipping. But for shellfish grown in federal waters, there are only really requirements for harvester. And 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.

Catherine C.: At the time this case study was written, Catalina Sea Ranch was permitted to grow their mussels, that they were were experiencing some challenges with the NSSP compliance. Even though there was this pathway that I had mentioned earlier that involves NOAA seafood inspection and the FDA. Since that time things have been remedied, and they entered into a contract with the FDA and NOAA seafood inspection. State agencies are also able, so in California for us, that would be the California Department of Public Health. They are able to certify shellfish for sanitation in federal waters but there needs to be a memorandum of understanding between the relevant state shellfish control authorities, the FDA and NOAA. But oftentimes, and I know this can be the case in other areas as well, when an agency is overburdened and understaffed, states might decide not to take on looking at sanitation of shellfish grown in federal waters of the EEZ. And this seems to be one, the decision that California has decided at this time.

Catherine C.: The FDA submitted a proposal for compliance with NSSP requirements in federal waters and so this was the interim pathway that I had mentioned earlier and so it was approved for a four year interim program and established as federal waters committee to evaluate this process and then revisit it at the end of these four years. And so Catalina Sea Ranch utilized this pathway and it allowed them to have their first harvest on July 30th, 2018. The interim pathway process is by design to provide a compliance pathway while it's in potentially other pathways may that may be proposed or considered. And so it is still an interim process until it is formally adopted by the ISSC and that will be addressed at the biannual meeting which is coming up in October. The FDA and ISSC evaluate the interim pathway and they may decide to adopt it or they can consider other proposals such as a different interim pathway. Although to my knowledge, I am not sure if there are any alternate proposals at this time.

Catherine C.: It is important to convey that, these NSSP requirements are basically the same in state or federal waters. Although it is oftentimes more data to work with in state waters. And also just to reiterate that if there is not a body like a state public health agency such as the California Department of Public Health here and there's no MOU with the FDA, the FDA, the reason the FDA developed this interim compliance pathway. It's available to any grower in federal waters and it will remain so until a final adoption decision is made by the ISSC. I'm looking forward to hopefully come October, seeing what their decision is.

Catherine C.: Moving forward, what is next for Catalina Sea Ranch? As I had mentioned before, the ISSC will meet in October and then we'll just kind of have to monitor development thereafter. And so I guess take away here is Catalina Sea Ranch is able to grow, harvest and land product with the interim compliance pathway and anything after that we'll just have to stay tuned for. I think one of the interesting parts about this case study was getting to hear about things both

from Catalina Sea Ranch and from the state and federal agencies that we spoke with kind of in real time as it was happening. That also made it a little challenging because it meant that a lot of what we discussed was kind of not set in stone and so I'm really looking forward to even revisiting this case study in a couple of years when we can really look back on it and see kind of the fuller picture.

Catherine C.: That's it for me. It's a little bit of a shorter presentation but I just wanted to give a special thanks to everybody that helped on the project with me and then everyone on the project team and also everyone from the state, federal and municipal agencies that we spoke with.

Catherine C.: I don't know if there are any questions at this time. I will do my best to answer them but if I cannot answer them then I will definitely reach out to our aquaculture extension specialists and hopefully be able to provide you guys with better answers at that time.

Stephanie Otts: Great. Thank you so much Catherine. Yeah, so if participants have questions as I mentioned, you can go ahead and type them into the chat box and we'll just give folks a minute or two to think of them or type them in and in the meantime while we're waiting on that, I just wanted to thank everyone who has participated in the webinar series. I've seen some return folks over the course of the last couple of months which has been great. And we are recording these webinars. We have been recording them and they are available on the National Sea Grant Law Center's website for future viewing. And we will have the recording of this webinar up on our website as soon as we can.

Stephanie Otts: I don't see any questions at this time, which is not unusual for webinars, but we have, feel free to reach out to Catherine if you think of questions later or if you have questions about the general project or of the other case studies that we've done feel to reach out to us here at the National Sea Grant Law Center as well.

Stephanie Otts: Oh, we do Catherine, we do have one question coming in. Could you clarify the role of the seafood inspection service?

Catherine C.: Yeah. Am I, can you hear me? Or did I mute myself?

Stephanie Otts: No, I can hear you.

Catherine C.: Okay. I guess the best way to discuss this would be in the context of how they were used with Catalina Sea Ranch. And so they were really used as an agent of the FDA. And so what that means is when Catalina Sea Ranch would harvest their mussels from their farm for biotoxin testing, NOAA seafood inspection was kind of present for the process. They we're responsible for observing the process and making sure that everything was done in accordance with regulations and then also helping to certify that chain of custody. They are present from the time the Catalina Sea Ranch staff went out to the farm to

collect mussels, through the shucking of it, to the packaging, to having it getting sent off to a biotoxin testing facility.

Stephanie Otts: Great. And Catherine, there was a follow-up. Who paid for that service? Is that on the company?

Catherine C.: For NOAA seafood inspection?

Stephanie Otts: Yes.

Catherine C.: Yes, yes. It is agreed upon. It's an MOU with the individual farm, and so that fee is agreed upon and paid for by the farm.

Stephanie Otts: Good. Thanks. Well, I think that's it on the questions. And again, I thank everyone for joining us and I hope everyone has a great rest of their day.