



STATE OF DELAWARE
**DEPARTMENT OF NATURAL RESOURCES AND
ENVIRONMENTAL CONTROL**

RICHARDSON & ROBBINS BUILDING
89 KINGS HIGHWAY
DOVER, DELAWARE 19901

OFFICE OF THE
SECRETARY

PHONE
(302) 739-9000

Secretary's Order No.: 2021-WS-0031

RE: Approving Final Regulation Amendments to 7 DE Admin. Code 7402, *Shellfish Sanitation Regulations*, Subsection 3.2.1: Shellfish Growing Area Water Quality and Classification

Date of Issuance: December 13, 2021

Effective Date of the Amendment: January 11, 2022

Under the authority vested in the Secretary of the Department of Natural Resources and Environmental Control (“Department” or “DNREC”), pursuant to 7 *Del.C.* §§6006 and 6010, and all other relevant statutory authority, the following findings of fact based on the record, reasons and conclusions are entered as an Order of the Secretary in the above-referenced promulgation.

Background, Procedural History and Findings of Fact

This Order relates to the Department’s proposed regulatory amendments to 7 DE Admin. Code 7402, *Shellfish Sanitation Regulations*, Subsection 3.2.1: Shellfish Growing Area Water Quality and Classification (“Amendments”). The Department’s objective of this proposed regulatory action is to adopt a bacteriological standard for the classification of shellfish growing areas approved by the National Shellfish Sanitation Program and U.S. Food and Drug Administration for shellfish growing areas classifications.

Specifically, this action proposes to add the membrane-Thermotolerant *Escherichia coli* (“mTEC”) method as an approved bacteriological standard for the classification of shellfish growing areas, while maintaining current approved methods found in the regulation. The Department has the statutory basis and legal authority to promulgate these proposed Amendments, pursuant to 7 *Del.C.* Ch. 19, *Shellfish*, and 7 *Del.C.* Ch. 60, *Environmental Control*.

The Department’s *Shellfish Sanitation Regulations*, last updated in 2019, regulate the harvest, sale and transport of bi-valve molluscan shellfish within Delaware and in interstate commerce. In drafting this proposal, Department staff considered input from the Delaware Shellfish Advisory Council, the Delaware Aquaculture Association, and Delaware Shellfish Dealers.

Currently, the Department’s *Shellfish Sanitation Regulations* do not list the membrane filter mTEC as an approved bacteriological standard for the classification of shellfish growing areas. This method is an approved method under the National Shellfish Sanitation Program and is used by many states to classify the bacteriological water quality of shellfish harvesting areas because of its accuracy and significant cost savings for states due to the speed and simplicity of the test. This promulgation will add the mTEC method as an approved method that can be used to classify shellfish growing areas, as noted above, while maintaining the current approved methods found in the regulation.

It should be noted that the Department conducted a side-by-side analysis for over three (3) years, and the results have shown that no changes in shellfish classifications would be required at this time, should the mTEC method be adopted. Further, the proposed adoption of the mTEC method, as described above, has also been presented to the commercial shellfish industry throughout that three (3) year assessment period, to ensure this regulatory promulgation was fully vetted to the regulated community.

Currently, there are no anticipated impacts to the public associated with this regulatory promulgation, due to no significant shellfish growing area classification changes being required. Additionally, no anticipated costs are associated with the proposed Amendments, and there are minimal to no impacts anticipated to commercial or recreational bi-valve shellfish harvesters.

The proposed adoption of the mTEC method will allow the State of Delaware to increase the speed with which laboratory results are available, increase the ability of the Department to monitor additional geographic areas, as needed, to ensure shellfish safety as the industry continues to grow, and continue to protect the State of Delaware's shellfish resources and public health of shellfish consumers.

The Department published the proposed Amendments in the September 1, 2021, *Delaware Register of Regulations*. Thereafter, the virtual public hearing regarding this matter was held on October 5, 2021. No members of the public attended the public hearing, nor were any comments received by the Department in this matter. It should be noted that all notification and noticing requirements concerning this matter were met by the Department. Proper notice of the hearing was provided as required by law.

Following the close of the public comment period on October 20, 2021, Hearing Officer Vest prepared her Hearing Officer's Report, dated December 6, 2021 ("Report"). The Report documents the proper completion of the required regulatory development process, establishes the Record, and recommends the adoption of the Department's proposed Amendments, as attached to the Report as Appendix "A."

Reasons and Conclusions

As set forth above, the Department proposes to adopt the mTEC method as an approved bacteriological standard for the classification of shellfish growing areas approved by the National Shellfish Sanitation Program and U.S. Food and Drug Administration for shellfish growing areas classifications, while maintaining current approved methods found in the regulation.

Based on the Record developed by the Department's experts and established by the Hearing Officer's Report, I find and conclude that the Department has provided appropriate reasoning regarding the need for the proposed Amendments to 7 DE Admin. Code 7402, *Shellfish Sanitation Regulations*, Subsection 3.2.1: Shellfish Growing Area Water Quality and Classification. I further find that the proposed Amendments will enable the Department to add the mTEC method as an approved method to be used to classify shellfish growing areas while maintaining the current approved methodology.

Moreover, I find that the adoption of the proposed Amendments will enable the State of Delaware to increase the speed with which laboratory results are available, increase the ability of the Department to monitor additional geographic areas, as needed, to ensure shellfish safety as the industry continues to grow, and continue to protect the State of Delaware's shellfish resources and public health of shellfish consumers.

Thus, for the reasons stated above, the recommendations of the Hearing Officer are hereby adopted, and I direct that the proposed Amendments to 7 DE Admin. Code 7402, *Shellfish Sanitation Regulations*, Subsection 3.2.1: Shellfish Growing Area Water Quality and Classification be promulgated as final.

In conclusion, the following reasons and conclusions are hereby entered:

1. The Department has the statutory basis and legal authority to act with regard to the proposed Amendments to 7 DE Admin. Code 7402, *Shellfish Sanitation Regulations*, specifically, Subsection 3.2.1: Shellfish Growing Area Water Quality and Classification, pursuant to 7 *Del.C.* Ch.19 and 7 *Del.C.* Ch. 60, which authorize the Department to adopt rules to protect the State of Delaware's shellfish resources and public health of shellfish consumers;

2. The Department has jurisdiction under its statutory authority to issue an Order adopting the proposed Amendments as final;

3. The Department provided adequate public notice of the proposed Amendments and all proceedings in a manner required by the law and regulations. The Department also provided the public with an adequate opportunity to comment on the proposed Amendments subsequent to the time of the public hearing (through October 20, 2021), in order to consider all public comment on the same before making any final decision, however, no comment was received by the Department concerning this promulgation;

4. Promulgation of the proposed Amendments, as set forth herein, will enable the State of Delaware to increase the speed with which laboratory results are available, increase the ability of the Department to monitor additional geographic areas, as needed, to ensure shellfish safety as the industry continues to grow, and continue to protect the State of Delaware's shellfish resources and public health of shellfish consumers;

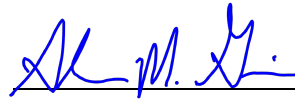
5. The Department has reviewed the proposed Amendments in the light of the Regulatory Flexibility Act, consistent with 29 *Del.C.* Ch. 104, and believes the same to be lawful, feasible, and desirable, that it will not establish reporting requirements or substantive additional costs for individuals or small businesses, and that the recommendations as proposed should be applicable to all Delaware individuals or small businesses equally;

6. The Department's proposed Amendments, as published in the September 1, 2021, *Delaware Register of Regulations*, are adequately supported, are not arbitrary or capricious, and are consistent with the applicable laws and regulations. Consequently, the proposed Amendments should be approved as final Amendments, which shall go into effect ten days after publication in the next available issue of the *Delaware Register of Regulations*;

7. The Hearing Officer's Report, including its established Record and the recommended proposed Amendments, as set forth therein in Appendix "A," are hereby adopted to provide additional reasons and findings for this Order;

8. The Department has an adequate Record for its decision, and no further public hearing is appropriate or necessary; and

9. The Department shall submit this Order approving as final the proposed Amendments to the *Delaware Register of Regulations* for publication in its next available issue and provide such other notice as the law and regulation require, as the Department determines is appropriate.


Shawn M. Garvin
Secretary