

6 NYCRR Part 42 -Shellfish Control - Regulatory Impact Statement

1. Statutory authority:

Environmental Conservation Law (ECL) section 13-0319 authorizes the Department of Environmental Conservation (DEC) to adopt regulations concerning; processing, buying, selling, receiving or otherwise trafficking in bivalve shellfish (clams, oysters, mussels, scallops); labeling or tagging of shellfish; keeping of records of shellfish received, transported and distributed; construction, operation and maintenance of all shellfish handling and, processing and distribution establishments, including facilities, equipment; and the cleaning and water storage of shellfish. Shellfish sanitation regulations must provide adequate sanitary control over shellfish offered for sale and distribution in the state and must not be less restrictive than the minimum requirements of any federal agency regulating the inter-state shipment of shellfish.

2. Legislative objectives:

It is the objective of ECL § 13-0319 that DEC regulates the harvest, processing, handling, shipping and storage of shellfish, and the recordkeeping at shellfish handling facilities to provide adequate protection of public health for the shellfish consumer and the people of New York State. DEC must also ensure that New York State regulations remain compliant with the federal guidelines for shellfish handling and recordkeeping contained in the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish 2019 Revision.

3. Needs and benefits:

This rule making is necessary to bring New York State shellfish regulations into compliance with the NSSP. NSSP guidance is intended to ensure that shellfish harvesters and shellfish shippers and processors (collectively referred to as shellfish dealers) use proper sanitary techniques during and after the harvest of shellfish to reduce the risk of illness from the consumption of raw or

undercooked shellfish. The U.S. Food and Drug Administration (FDA) uses this guidance to routinely evaluate New York State's compliance with established rules for shellfish harvest and handling. If the FDA determines that the State's shellfish program does not provide adequate public health protection, the FDA may prohibit the shipping and sale of New York State harvested shellfish out of New York.

Currently, New York State shellfish sanitation regulations (6 NYCRR Part 42) are not in compliance with the NSSP. This proposed rule will bring 6 NYCRR Part 42 into compliance with the NSSP to provide adequate protection of public health for shellfish consumers.

The new provisions added to Part 42 in this proposed rule will: (1) Require more stringent shellfish identification and tagging requirements; (2) improve the clarity of shellfish harvest area descriptions to clearly identify areas implicated in shellfish illness outbreaks; (3) define requirements for shellfish harvesters and shellfish dealer education, 'Vibrio' Control Plan(s), maintenance of shellfish Hazard Analysis Critical Control Point (HACCP) Plans, and shellfish transaction records; (4) describe procedures that dealers must follow when it has been determined that certain shellfish might be hazardous for use as food for human consumption; and (5) include language to make it easier for shellfish harvesters and shellfish dealers to understand the regulatory requirements under this Part.

The proposed rule will also eliminate the need to include supplemental permit conditions in each individual shellfish harvester and shellfish dealer permit. The proposed rule will also enable DEC to apply or modify special permit conditions when necessary.

4. Costs:

There are no new costs associated with this rule. This rule would codify into state regulation, requirements that have been implemented since 2014 as supplemental conditions on digger and shipper permits. This rule will not impose any new costs for regulated parties or state and local

governments. If the FDA determines that the State's shellfish program does not provide adequate public health protection, the FDA may prohibit the shipping and sale of New York State harvested shellfish out of New York, causing significant losses in revenue for the state's shellfish industry.

5. Local government mandates:

This regulation will not impose any program, service, duty or responsibility upon any county, city, town, village, or municipality.

6. Paperwork:

No additional paperwork is being required for those regulated under this rule.

7. Duplication:

The amendment does not duplicate any state or federal requirement.

8. Alternatives:

No action alternative: Under this alternative, DEC would not adopt this proposed regulation. New York State regulations would remain non-compliant with the NSSP guidelines. The FDA could determine that the State's shellfish program does not provide adequate public health protection and may prohibit the shipping and sale of New York State harvested shellfish outside of New York. Such a determination would have an adverse economic effect on New York State shellfish harvesters, dealers, and shippers. This alternative was rejected because it would fail to provide adequate public health protection for the shellfish consumer and would cause economic hardship to State shellfish harvesters, dealers, and shippers.

9. Federal standards:

This amendment to 6 NYCRR Part 42 complies with the NSSP guidance for the inter-state shipment of shellfish.

10. Compliance schedule:

This rule will be adopted following a sixty-day public comment period after publication in the State Register. Regulated parties must comply immediately and will be notified of the changes to the regulations through appropriate news releases, by mail, and through DEC's website.