

New York 2020 *Vibrio parahaemolyticus* Control Plan (VpCP)

The *Vibrio parahaemolyticus* (Vp) Control Plan (VpCP) for 2020 includes the same postharvest handling and time to temperature controls for harvesters and shippers that have been implemented since 2017. These controls are intended to reduce the potential for postharvest growth of Vp in hard clams and oysters and risk of Vp illness from consumption of raw or partially cooked hard clams and oysters harvested in New York State. The number of Vp illnesses linked to New York shellfish have continued to decline with the implementation of these postharvest handling and time to temperature control measures. The 2020 VpCP provides *Vibrio* control measures that have been effective at reducing Vp illnesses and ensuring protection of public health for shellfish consumers.

The following shellfish harvest areas are included in New York State's VpCP for 2020: all of the normally certified areas of NS1, NS2, NS3 and that portion of LS1 lying west of Eatons Neck Point (Town of Huntington). The VpCP applies to commercial harvest of hard clams and oysters for food consumption in the designated harvest areas. The Plan also applies control measures for all oyster harvest in New York State.

Regulations in 6 NYCRR, Part 42 "Sanitary Control of Shellfish" allow the Department to attach conditions to any permit issued pursuant to article 13 of the ECL.

§42.5 Conditions of a permit (a) *Any permit issued pursuant to article 13 of the Environmental Conservation Law or this Part may be issued with conditions. Conditions may be attached as may be necessary to assure that the public health, safety and welfare of the people of the State of New York are protected and that the intent and purposes of this Part will be carried out. Facilities, buildings, structures, equipment and conveyances used for activities described in this Part shall be in compliance with the applicable provisions of this Part and shall be approved by the department prior to the issuance of a permit.*

The authority to establish conditions for New York shellfish digger and shipper permits has been incorporated into the 2020 VpCP.

- I. Permit Requirements for 2020 Shellfish Harvesters (Diggers) for Reducing *Vibrio* in Shellfish:
 - A. All 2020 Shellfish Digger Permit applicants were provided with a supplemental application that identifies the following conditions for shellfish harvesting, identification and handling requirements that will apply to all Shellfish Digger Permits issued in 2020. Each digger is required to sign the acknowledgement that they have read the conditions and they understand that these conditions are requirements of their 2020 permits prior to the permit being issued.
 1. The permittee shall be in compliance with the applicable shellfish handling, storage, transportation, tagging or labeling, record keeping and other requirements for the shellfish activity or activities for which this permit is issued.
 2. Shellfish harvester tags must include the **time of harvest** for all shellfish taken (*time of harvest* begins on each day when the first shellstock is taken from the water and prior to the start of cooling through icing, mechanical

refrigeration or other cooling method approved by the Department). ***Time of harvest*** must be written in indelible ink on each tag and the tag must be affixed to the container **prior** to the placement of any shellfish into the container.

3. Once a container has been completely filled as intended, a new ***time of harvest*** begins when the next lot of shellfish is removed from the water. **All shellfish tags must be completed prior to leaving the area of harvest.**
4. Shellfish shall not be placed or held in containers that are not self-draining. Under no circumstances shall shellfish be allowed to sit in standing or stagnant water. This provision does not apply to placement of shellfish in an ice slurry for rapid cooling of shellfish when the water temperature of the ice slurry is less than or equal to 45°F (7.2°C). Water used for the production of an ice slurry must be obtained from the same certified shellfish harvest area where the shellfish were taken (harvested). Any ice used must be drinking water quality (potable water) or from an approved source.
5. From **May 1 through October 31**, both dates inclusive, shellfish harvested from New York waters must be **shaded** from direct sunlight at all times, from the ***time of harvest*** while onboard the vessel and during transport in any boat, vehicle or other means of conveyance from the harvest area to the original dealer.
6. **All oysters** harvested from certified shellfish lands for food consumption between the dates of **May 1 through September 30, both dates inclusive**, must be immediately culled and placed under temperature control through icing, mechanical refrigeration maintained at 33°F (0.6°C) to 45°F (7.2°C) or other cooling method approved by the Department **upon commencement of the *time of harvest***. For this condition, ***time of harvest*** begins when each lot of **oysters** is taken from the water and no longer submerged. ***Time of harvest*** must be written in indelible ink on each tag and the tag must be affixed to the container prior to the placement of any oysters into the container.
7. All oysters subject to immediately culling as specified under Condition 6 shall be maintained under temperature control (cooling) throughout the harvest day once the ***time of harvest*** (start of harvest) begins. Once a container has been completely filled as intended, a new ***time of harvest*** begins when the next lot of shellfish is removed from the water. ***Time of harvest must be identified on your shellfish harvester tags and harvest log.*** All shellfish tags must be fully completed prior to leaving the area of harvest.
8. All harvesters shall maintain a log book that indicates the common name of shellfish harvested, quantities (net weights, numerical counts or standard measures) of shellfish harvested, the harvest date, an identification of the areas from which shellfish were harvested, time of harvest and the names and permit numbers of all receivers of shellstock (identify disposition of shellfish). The log book must be completed prior to landing shellfish on a

daily basis and must be made immediately available to the Department or an enforcement officer upon request.

9. **When the Department has determined that a *Vibrio parahaemolyticus* (Vp) Control Plan (VpCP) is required for particular harvest areas, for the protection of public health, the following requirements must also be met by all shellfish harvesters working in the affected areas. These requirements shall apply from May 1 through September 30, both dates inclusive:**
- a. Shellfish harvesters working in shellfish lands specified in a VpCP must adhere to all harvesting and handling requirements included in the VpCP.
 - b. Hard clams and oysters harvested for food consumption from any certified areas under the VpCP (**NS1, NS2, NS3 and LS1, west of Eatons Neck Point**) must be immediately culled and placed under temperature control through icing, mechanical refrigeration maintained at 33°F (0.6°C) to 45°F (7.2°C) or other cooling method approved by the Department immediately upon commencement of the ***time of harvest***. For this condition, ***time of harvest*** begins when each lot of hard clams or oysters is taken from the water and are no longer submerged. ***Time of harvest*** must be written in indelible ink on each tag and the tag must be affixed to the container prior to the placement of any hard clams and/or oysters into the container.
 - c. All oysters and/or hard clams shall be immediately culled and placed under temperature control (cooling) throughout the harvest day once the ***time of harvest*** (start of harvest) begins. Once a container has been completely filled as intended, a new ***time of harvest*** begins when the next lot of shellfish is removed from the water.
 - d. Any ice used must be of drinking water quality (potable water) or from an approved source. Saltwater used in an ice slurry shall only be from the certified harvest area where the lot of clams or oysters was harvested.
 - e. The requirements specified in Condition No. 9 shall apply to all commercial harvesters when they take hard clams and oysters from the following shellfish lands (harvest areas) which are subject to a Vp Control Plan: New York State harvest areas identified as **NS1, NS2, NS3 and that portion of LS1, lying west of Eatons Neck Point (Town of Huntington)**. Other areas will be added as necessary if they are the source of shellfish linked to Vp illnesses in 2020.
 - f. All hard clams and oysters harvested from LS1 west of Eatons Neck Point shall be tagged or labeled LS1 West; all hard clams and oysters harvested from LS1 east of Eatons Neck Point shall be tagged or labeled LS1 East. Hard clams and oysters harvested from

these conditions are requirements of their 2020 permits prior to the permit being issued.

1. The permittee shall be in compliance with the applicable shellfish handling, storage, transportation, tagging or labeling, record keeping and requirements for the shellfish activity or activities for which this permit is issued.
2. All shellfish received from harvesters must include the **time of harvest** on harvester tags and must be kept as part of your shellfish receiving records.
3. Shellstock shall not be shrink-wrapped prior to it reaching the temperature of 50°F (10°C) or below.
4. When the Department has determined that a *Vibrio parahaemolyticus* (*Vp*) Control Plan is required for particular harvest areas for the protection of public health, the following requirements must be met by all original shellfish dealers authorized to receive shellfish directly from harvesters working in the affected areas. **These requirements shall apply from May 1 through September 30, both dates inclusive:**
 - a. All hard clams and oysters received from harvesters from New York State harvest areas in the affected areas, including **NS1, NS2, NS3** or that portion of **LS1 west of Eatons Neck Point** (Town of Huntington), will be rejected if the shellstock temperature at receiving is greater than 60°F (15.6°C) or if the shellfish harvester tag does not include the **time of harvest**. A record of the internal temperature (center of a lot/container of the shellstock) at time of receipt and time received is also required.
 - b. All hard clams and oysters received from harvesters from New York State harvest areas in the affected areas, including **NS1, NS2, NS3** or that portion of **LS1 west of Eatons Neck Point** (Town of Huntington), must be cooled to a temperature of 50°F (10°C) or below within 10 hours or less of **time of receipt** and prior to being shipped.
 - c. All hard clams and oysters received from harvesters that were harvested from New York State harvest area **LS1 west of Eatons Neck Point shall be tagged or labeled LS1 West, NY**; all hard clams and oysters received from harvesters that have been harvested from New York State harvest area LS1 east of Eatons Neck Point shall be tagged or labeled LS1 East, NY. Hard clams and oysters harvested from LS1 West **shall not be comingled** with hard clams or oysters harvested from LS1 East.
 - d. Other harvest areas may be added during 2020 if it is determined that the source of shellfish has been linked to *Vp* illnesses.
5. The Department shall have the right to inspect any facility, building, structure, property or conveyance used for any activity undertaken pursuant to this permit as described in 6 NYCRR Part 42.

6. The Department shall have the right to take samples, without payment, of any shellfish, water, chemicals, food ingredients and other substances for examinations as required under this permit and pursuant to 6 NYCRR Part 42.
7. The Department shall have the right to inspect and/or copy any hazard analysis and hazard control plans, hazard control plan records, sanitation records, tags, labels, shipping or receiving invoices, bills of lading or other records required to be kept pursuant to 6 NYCRR Part 42.
8. The violation of any conditions of the shellfish shipper's permit or provision of 6 NYCRR Part 42 may result in permit modification, suspension, or revocation and/or seizure of any lot, quantity or shipment of shellfish and/or related materials associated with such violation.
9. The shellfish shipper's permit shall be made available for inspection by the Department at all times from the date of issue through the date of expiration and during conducting of any related activity described in 6 NYCRR Part 42 and any applicable sections of the Environmental Conservation Law.
10. Shellstock must be cooled to an internal temperature of 50°F (10°C) prior to distribution and must be accompanied by a shipping document indicating one of the following:
 - a. Shipped adequately iced, the date and time shipped and the initials of the shipper (shipping time must not exceed four hours for this option).
 - b. Shipped in a conveyance pre-chilled and maintained at or below 45°F (7.2°C), the date and time shipped and the initials of the shipper.
 - c. For shellstock picked up by the receiver at the dealer's facility: shipped adequately iced or the temperature of the storage area from where the shellfish were removed, the date and time removed, and the initials of the shipper.
11. All shellstock received must be received with a document from the shipper indicating one of the following:
 - a. Shipped adequately iced and the time shipped.
 - b. Shipped in a conveyance pre-chilled and maintained at or below 45°F (7.2°C) and the time shipped.
 - c. For shellstock received from a shellfish dealer located outside of New York prior to being cooled to an internal temperature of 50°F (10°C) – A time/temperature recording device shall accompany the shellstock indicating continuous cooling; the document must indicate that the product was shipped prior to achieving an internal temperature of 50°F (10°C) and indicate the presence of a time/temperature recording device.

Shellfish received without a proper shipping document must be rejected.

12. Shellfish receiving records (a HACCP record) must include date, time and shellstock temperature (center of a lot/container of the shellstock) when received.

D. All 2020 Shellfish Shipper Wet Storage Permits issued includes an additional condition to the wet storage permit that requires that, “for the period May 1 through September 30, oysters and hard clams harvested from NS1, NS2, NS3 or LS1 West (west of Eaton’s Neck Point) shall not be held in the approved water storage facilities unless the storage water temperature is equal to or less than 45°F (7.2°C) pursuant to Condition No. 5 of the shellfish dealer permit conditions and the water storage permit.”

II. NYSDEC will provide harvesters and shippers with information about the 2019 shellfish-related *Vp* illnesses and advise them about the permit requirements for post-harvest handling and time-temperature controls to reduce *Vp* in shellfish that will be required for 2020 through email communications, information on DEC’s website and at NYS Shellfish Advisory Committee meetings in 2019 and 2020.

III. The NYSDEC shall initiate rulemaking to update applicable regulations of Title 6 of the New York Codes, Rules and Regulations (6 NYCRR) including:

1. § 42.5 “*Conditions of a permit*” to provide for modification of shellfish digger, shipper and processor permits when necessary for the protection of public health or to require compliance with the control measures and requirements of any *Vp* Control Plan implemented by NYSDEC.
2. § 42.7 “*Record Keeping Requirements*” to require harvesters to include the time of the start of harvest in their daily ledger or other approved daily record-keeping for each lot of shellfish harvested.
3. § 42.13 “*Shellfish harvesting, identification and handling by harvesters*”
 - a. 42.13(a)(5) to require harvesters to provide the time of the **start of harvest** (*time of harvest*) on all container tags.
 - b. 42.13(a)(12) to require harvesters engaged in the harvest, transport and sale of oysters or hard clams from any area identified in New York’s *Vp* Control Plan to have all oysters or hard clams harvested from the affected areas to the original dealer and/or under temperature control (icing, mechanical refrigeration or other approved cooling method) upon commencement of the *time of harvest* during the period of May 1 through September 30.
4. § 42.12 “*Storage of Shellfish*” to ensure that:
 - a. All oysters or hard clams purchased from May 1 through September 30 and harvested from any area specified in New York’s *Vp* Control Plan shall be cooled to an internal temperature of 50°F (10°C) or below within 10 hours or less at time of receipt and shall not be shipped prior to reaching 50°F (10°C) to reduce the risk of *Vibrio parahaemolyticus* illness.

- b. The shipper's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters or hard clams purchased from May 1 through September 30 and harvested from any area specified in New York's *Vp* Control Plan has reached 50°F (10°C) or below within 10 hours or less of time of receipt and shall not be shipped prior to reaching 50°F (10°C).
- c. Plastic shrink wrap shall not be applied to containers of shellstock before the product reaches an internal temperature of 50°F (10°C) or below during the period of May 1 through September 30.

5. § 42.2 to include definitions applicable to the updated regulations.

IV. Enforcement:

- A. The Division of Marine Resources Shellfisheries Bureau shall advise the NYSDEC Division of Law Enforcement about the conditions that have been added to Shellfish Diggers and Shellfish Shippers permits for 2020.
- B. Representatives of the NYSDEC Division of Law Enforcement shall conduct periodic unannounced inspections at harvest sites, common landing sites and wholesale dealer facilities to determine compliance with digger and shipper permit conditions.
- C. Representatives of the NYSDEC Division of Marine Resources, Shellfish Inspection Unit, shall conduct periodic unannounced inspections at common landing sites and wholesale dealer and processor facilities to determine compliance with digger and shipper permit conditions.
- D. All shellfish harvested under this plan shall be subject to embargo and/or disposal if found to be significantly time/temperature abused and non-compliant with permit requirements, HACCP Plans or any other requirements of 6 NYCRR Part 42, "*Sanitary Control of Shellfish.*"
- E. Failure of shippers and processors to maintain compliance with permit requirements, HACCP Plans and any other requirements of 6 NYCRR Part 42, "*Sanitary Control of Shellfish*" may result in enforcement action up to and including revocation of permits in accordance with 6 NYCRR §175.5.

V. Response to Outbreaks of Shellfish Related Illness:

- A. In the event that oysters and/or hard clams are epidemiologically linked to a food borne illness outbreak caused by *Vibrio parahaemolyticus*, NYSDEC shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area and the span of time for the illnesses. NYSDEC shall take appropriate action to protect public health consistent with the requirements of the 2017 NSSP Model Ordinance and State regulations as follows:
 - 1. If it is determined that a closure of the harvest area is required, the NYSDEC shall designate the implicated area as uncertified for the harvest of oysters and/or hard clams, as appropriate, under the emergency authority of 6 NYCRR sections 42.17 and 47.4.

2. The NYSDEC Shellfish Inspection Unit will notify all receiving states and the FDA that a potential health risk is associated with shellfish from the implicated harvest area as required under the NSSP's Model Ordinance.
 3. As soon as it has been accurately determined, the NYSDEC Shellfish Inspection Unit shall advise the FDA and receiving states which dealers have shipped shellfish from the implicated area during the 21 days prior to the outbreak.
 4. If deemed necessary, the NYSDEC Inspection Unit shall promptly recall any shellfish from the implicated area remaining in the distribution system using the recall procedure of the NYSDEC Shellfish Inspection Unit.
- B. If a harvest area closure is necessary, the implicated area shall remain closed for periods consistent with the 2017 NSSP Model Ordinance.
- C. If the number of confirmed *Vp* cases exceed ten (10) illnesses in thirty (30) days or four (4) cases from a single harvest date from the implicated area, the following requirements must be met prior to reopening the area to harvest:
1. Until monitoring of replicate shellfish samples from indicator stations in the implicated area show total *Vp* levels are <1,000 MPN/g or equivalent of <1,000 CFU/g, and *tdh+* *Vp* and *trh+* *Vp* levels are <10MPN/g, or 1. No *tdh+*/*trh+* colonies on both replicate plates (<10, <10 *Vp* CFU/g); or 2. One *tdh+*/*trh+* on one replicate plate, with the second replicate plate having no *tdh+*/*trh+* colonies (10, <10 *Vp* CFU/g) in three (3) consecutive samples consistent with protocol for previous *Vp* monitoring; or
 2. Until environmental conditions (air and water temperatures) in the harvest area are no longer conducive to unsafe levels of *Vp* in shellfish.

Definitions

Adequately Iced means that the amount and application of the ice is sufficient to ensure that immediate cooling begins and continues for all shellfish. To accomplish this oysters and clams shall be placed in appropriate containers that allow drainage of standing water, and

- Adequate icing requires that bags or shellfish are completely surrounded by ice. If shellfish are in bags, the bags shall be mesh or other breathable material.
- If ice slurry is used and the shellfish are submerged, then the presence of ice in the slurry indicates adequate icing when the temperature of the ice slurry is less than or equal to 45°F (7.2°C). Only water from approved (certified) waters where shellfish were taken (harvested) may be used to constitute the slurry.
- All ice used to cool shellfish must originate from approved sources of potable water, as established under the NSSP.

Shaded means that measures are taken to prevent oysters and hard clams from direct exposure to sunlight that might cause a significant increase in post-harvest growth of *Vibrio* bacteria due to an increase in temperature.

Internal Temperature means the external temperature of the shell of the animal, at the center of a packaged mass of shellstock (box, sack, bag, etc.).

Time of Harvest (Start of Harvest) begins when the first shellstock in a lot is taken from the water or, in the case of intertidal harvest, the time of first exposure; a.m. or p.m. must be noted. Once a container is completely filled as intended, a new **time of harvest** begins when the next lot of shellstock is removed from the water.

Lot of Shellstock means a single type of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area gathered by one or more harvesters. A lot may also be used by a harvester to segregate the harvest and cooling times and intended uses of shellstock for the purposes of complying with time to temperature requirements.

Trip Records means a form of written documentation that includes the harvest area, harvester permit number and the date and time of each lot of shellfish harvested. The digger's tag satisfies these requirements provided that all information as required is included on the tag.

The NYSDEC Division of Marine Resources, Shellfisheries Bureau will review this Plan on an annual basis and revise it as needed to maintain compliance with the National Shellfish Sanitation Program's Model Ordinance.