APPENDIX III

ENFORCEMENT POLICY FOR MOLLUSCS EXCEEDING ESTABLISHED BACTERIOLOGICAL LEVELS

1. Domestic molluscan shellfish (except scallop adductor muscles) or raw products derived therefrom, whether fresh or frozen, are considered satisfactory when they are harvested from an approved or conditionally approved area and the E. coli (for end-of-line product) or faecal coliform (product prior to processing) counts conform to the current DFO Bacteriological Guidelines for Fish and Fish Products. The following policy (step 2) is graphically represented in the attached flow diagram (***in the diagram, all QMP steps are italicized and bold***).

2. a) Should a shellfish sample taken at the plant fail the bacteriological guideline, a QMP review will occur to:

   i) verify that the processor ensures that all shellfish which are accepted are harvested from open areas*;

   ***NOTE**: Should the suspect product originate from another federally registered plant a QMP review should also occur at the originating plant.

   ii) verify that the operation complies with Schedule II, section 14.1 (records for bivalve molluscs (except scallop adductor muscles)); and

   iii) in the case of failure of end-of-line products - verify that all plant records, monitoring and corrective actions have been properly recorded and implemented.

   b) If, after a product failure, a review of the plant's QMP indicates that the plant appears in control of its operation, ten (10) sample units will be taken by DFO at the implicated harvest area for faecal coliform analysis*.

   ***NOTE**: If there is reason to believe that the harvest area classification of the implicated site is not current, the area may be closed without on-site sampling.

   i) Should results from sample units collected from the implicated harvest area be bacteriologically acceptable, no QMP enforcement action shall be implemented*; however, product from the suspect area should be targeted for bacteriological sampling during

the next QMP inspection;

***NOTE**: If the on-site sample confirms approved area status, and the plant has 2 or more rejects out of the five most recent QMP samples, the "incoming product" CCP will be rated as not in control and the plant corrective action(s) taken considered ineffective.

ii) If following the harvest area sampling greater than 10% of the samples exceed 230 (or one sample exceeds 2300) faecal coliforms, the area shall be closed.

The area may be re-sampled* by DFO (10 sample units) after a minimum of 7 days and if results are acceptable the area shall be re-opened.

***NOTE**: This additional sampling is at the discretion of DFO and does not have to be carried out. The area may be kept closed and DOE requested to re-evaluate the area as survey schedules permit.

c) If, after a product failure, a detailed review of the plant's QMP indicates that the plant appears to not be in control of its operation the appropriate QMP action will be implemented (see most recent QMP Enforcement Policy).

3. **Imported** bivalve molluscan shellfish (except scallop adductor muscles) must comply with Section 6.(1)(b) of the Fish Inspection Regulations, i.e. they must originate from a source approved by the Minister. Satisfactory compliance with this requirement, for imported product, shall be in accordance with the Fish Products Inspection Manual (FPIM) Chapter 3, Subject 1.

DFO must receive proper notification of all imported shellfish. This information must be entered into the Inspection Import Management System (INIM) as per the FPIM Chapter 3, Subject 1. If the product is inspected, then all inspection results must also be entered into INIM.

Where an imported lot meets the above requirements but is found to exceed the current DFO Bacteriological Guidelines for Fish and Fish Products:

a) the licensed importer shall immediately be notified in writing of the high count using the Fish Inspection Report. The product will then be listed on the Mandatory Inspection List (MIL) until such time as **four** (4) consecutive shipments are satisfactory;

b) NHQ must be informed immediately of the details; and

c) appropriate regulatory officials in the source country shall be informed, by NHQ, of the counts, shipment details and subsequent action proposed.

4. Product detained for exceeding the *E. coli* count may be **reconditioned** by canning if counts do not exceed 4000 *E. coli*/100 grams, or may be disposed of, under DFO supervision, for other than human food purposes.

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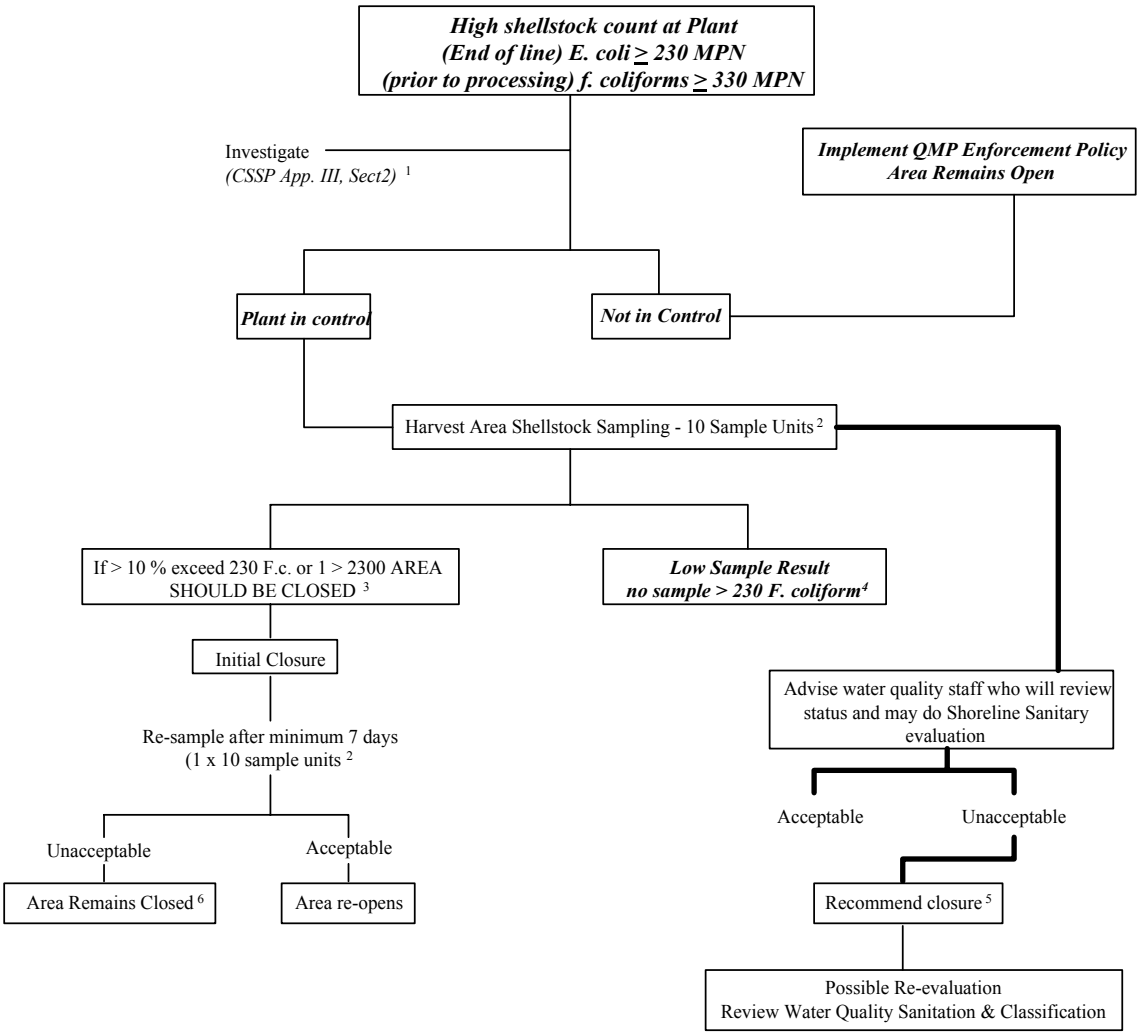

[1] This includes investigation of originating federally registered plant if that is the source of implicated product.

[2] Samples are to be taken from separate, randomly selected sites in the implicated area.

[3] Where area exceeds faecal coliform bacteriological guideline take no plant action.

[4] When there is no apparent contamination problem at the beach, efforts should be made to target product from the suspect area for bacteriological analysis during the next QMP inspection. If the on-site sample confirms approved area stuatus and the plant has 2 or more rejects out of the five most recent QMP samples, the "incoming product" CCP will be rated as not in control and the corrective action taken considered ineffective.

[5] If water quality staff recommend closure, additional Harvest Area Shellstock Samples need not be taken.

[6] Local Inspection staff need not re-sample area indefinitely. The area may be kept closed and DOE requested to re-evaluate the area as survey schedules permit.