

Canadian Shellfish Sanitation Program - Manual of Operations

CHAPTER 10

POLICY AND PROCEDURES FOR CONTROLLED RELAYING AND DEPURATION

Relay systems (natural or in containers) and land-based depuration establishments are efficient methods of achieving microbiologically safe bivalve molluscs that are harvested from areas as restricted for conditionally restricted in the open status. This chapter outlines the requirements for the operation of these types of activities in Canada.

Section 4(2) of the *Management of Contaminated Fisheries Regulations* allows for a license to fish for food purposes in an area that is contaminated, following approval of a decontamination plan. Under the Canadian Shellfish Sanitation Program (CSSP) Memorandum of Understanding (MOU) between the Canadian Food Inspection Agency (CFIA), Fisheries and Oceans Canada (DFO) and Environment Canada (EC), CFIA advises on these decontamination plans. This is done under the authority of the *Fish Inspection Regulations* (FIR) which also contain the requirements for the processing (i.e., depuration), transportation and holding of shellfish.

Anyone proposing to relay or develop a depuration facility must be able to meet these requirements before a license for harvesting can be issued. This is in addition to any commercial shellfish license required regionally.

10.1 Procedures for Approval of a Depuration Facility or Relay Operation

When an interest is expressed by someone wishing to set up a depuration facility or relay operation, the following procedures apply:

- a) The applicant is to submit a proposal to the local CFIA office. The proposal must include the following:
 - i) a description of where any facility is to be located and the proposed timetable for construction;
 - ii) if applicable, in consultation with DFO, the planned shellfish areas, and expected harvest

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- quantity;
- iii) the proposed shellfish area;
 - iv) the process water source for any depuration facility, or when applicable, the relay site;
 - v) the depuration facility and equipment design (section 10.2.2) including provisions for laboratory facilities;
 - vi) the planned utilisation of any product during the evaluation period; and
 - vii) a detailed description of the controls that will ensure that labelling, harvesting, transport, operational and pre- and post-depuration storage requirements are met.
- b) The proposal is to be forwarded by CFIA to the applicable DFO and EC offices for evaluation. The responsibilities for evaluating the proposals are as follows:
- i) EC: responsible for the classification of the shellfish area and the relay site;
 - ii) DFO: responsible for the control of harvest in contaminated areas and the issuance of harvest licenses pursuant to the *Management of Contaminated Fisheries Regulations*.
 - iii) CFIA: responsible for evaluating the proposal against the criteria defined in the depuration or relay protocols described in sub-sections 10.2, 10.3, and 10.4.

A maximum of four weeks is recommended for the return of comments.

- c) After the proposal has been reviewed, CFIA will advise the applicant that:
- i) the proposal is accepted as a basis for continuation of the project; or
 - ii) changes to the proposal are necessary.

A meeting may be arranged with the applicant to

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explain the process and to clarify specific requirements.

d) Project Approval

Once the project proposal is accepted, and the applicant is prepared to commence operations, the following steps must be completed:

- i) any building and storage facility must be inspected and the processing water approved;
- ii) any facility design and operation must conform to protocol and must meet *Fish Inspection Regulation* (FIR) requirements; and
- iii) as applicable, a Memorandum of Agreement (Annex 10D), an approved operational protocol, and/or the License (Annex 10C) are signed.

Each registered facility that depurates or relays shellfish must consider, and where applicable, incorporate the following components (10.2 - 10.4) in the development and implementation of their Quality Management Program.

10.2 Depuration Facility Protocol

All companies planning to develop a depuration system or presently engaged in depuration must conform to the requirements of the QMP and the criteria contained in the following sections.

10.2.1 Harvest Areas

Overlay waters must have median or geometric mean faecal coliform counts not exceeding 88 MPN/100 mL, not more than 10% of samples exceeding 260 MPN/100 mL, based on Environment Canada surveys and recommendations (see Chapter 2).

10.2.2 Processing Water and Facility Requirements

The following are intended as guidelines. Any deviations from the following may be made only after discussion with CFIA and when their efficacy has been proven through verification.

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a) Water

Processing water is required to meet or exceed the following minimum requirements:

- i) the water must be from a source approved by CFIA.
- ii) Water from sources vulnerable to contamination must undergo bactericidal treatment resulting in an absence of total coliforms/100 mL (defined as <2 total coliforms/100 mL). Protected sources, i.e., drilled wells, that consistently meet the standard need not be treated;
- iii) the oxygen* content shall be at least 5 ppm or 50% saturation;
- iv) the salinity* shall be $\pm 20\%$ of the median salinity regime of the area where the bivalve molluscs are harvested, unless salinities outside this range are established as a result of the scheduled depuration process evaluation;
- v) the turbidity* shall be less than 20 Jackson Turbidity Units (or equivalent Nephelometric turbidity units);
- vi) the temperature* shall be adequate to permit normal metabolic activity of bivalve molluscs, the limits to be determined by process evaluation;
- vii) for closed or recirculating systems, the ammonia level of process water must remain below 0.9 ppm;
- viii) there shall be no undesirable chemicals or other substances which may affect pumping of bivalve molluscs; and
- ix) Shellfish depuration facilities will be required to:
 - a) cease using a water supply that is sourced from an area affected by a biotoxin closure or
 - b) filter the water supply to remove any toxic phytoplankton (using a validated system).

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Shellfish in depuration systems affected by biotoxin closures will be assessed using the same criteria found in chapter 11, section 11.6.

<http://www.inspection.gc.ca/english/fssa/fispoi/man/cssppc/csm/chap11e.shtml>

Note: **The criteria marked * may be naturally variable at different locations.**

b) Facility

All facilities must meet the following minimum requirements:

- i) all buildings (including storage) must conform to sections of the Fish Inspection Regulations (FIR) including, but not limited to, sections 6(1), 14(1), 15(1), 16, 20 - 23 and Schedules I and II;
- ii) storage facilities must be designed to maintain physical separation between shellstock to be depurated and other shellstock (depurated and approved area harvests); and
- iii) adequate washing and culling facilities must be present.

c) Off-site Storage

Note: Prior to depuration, pre-process shellstock may be held in wet storage (in near-shore intertidal/subtidal areas). Such wet storage helps provide sufficient inventory for the depuration facility and also allows the shellfish to acclimate to the local seawater conditions in which they will be depurated.

If wet storage of pre-process shellstock is carried out off site (separate location from the main registered establishment), the operators must ensure that:

- i) control and oversight is maintained over such storage locations, that all potential hazards associated with storage are considered, and that these are incorporated into the QMP of a

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registered establishment;

- ii) Vehicles and equipment used to transport shellfish from the storage facility to the main establishment meet the requirements of Schedule III and Schedule V of the FIR;
- iii) Restricted access to stored shellfish is maintained; and
- iv) Records are maintained at the registered establishment which permit CFIA officials to identify lots at the storage area.

Refer to sections 10.2.5 ©) and (d) for further storage considerations.

d) Tanks

Tanks shall be:

- i) constructed of corrosion resistant, non-toxic, non-absorbent, and easily cleaned material;
- ii) self-draining to facilitate cleaning;
- iii) easily accessible for cleaning and inspection;
- iv) maintained in good repair;
- v) able to maintain a minimum flow rate of 107 litres per minute per cubic metre of shellstock. The above criteria are equivalent to 1 U.S. gallon per minute per U.S. bushel (1.24 cubic feet);
- vi) constructed so as to provide adequate water flow throughout the tank (so that shellstock has adequate access to incoming clean water);
- vii) constructed to ensure they contain water and shellstock at a minimum volume ratio of 4:1 (equivalent to 142 litres of water per 35.24 litres shellstock, or 5 cubic feet of water per U.S. bushel) for soft clam, and water and shellstock at a minimum volume ratio of 6.4:1 (equivalent to 227 litres of water per 35.24 litres shellstock, or 8 cubic feet per U.S. bushel) for hard clams (Manila and littleneck) and oysters. Limits for other species would be

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determined with CFIA during scheduled process evaluation); and

viii) constructed such that there is sufficient volume to permit a minimum of 7.6 centimetres (3 inches) of water clearance around each container. This spacing is necessary to provide for uniform water flow through and around processing containers.

e) Processing containers

Processing containers shall be:

- i) constructed of corrosion resistant, non-toxic, non-absorbent, easily cleanable material; and
- ii) of a suitable size and shape to permit:
 - 1) a mid-cycle washing of shellfish;
 - 2) an adequate flow of water to all shellfish;
 - 3) a maximum depth of Manila and littleneck clams of 10 cm (4 inches);
 - 4) a maximum depth of soft-shelled clams in containers of 20 cm (8 inches); and
 - 5) a maximum depth of 30 cm (12 inches) in Pacific oysters, 10 cm (4 inches) in Atlantic oysters and hard-shelled clams.

The loading criteria for other species would have to be determined by experimentation.

Note: **Deviations from these criteria may be allowed only if process verification studies (see 10.2.7) show that the depuration process consistently yields bacteriologically acceptable product.**

f) Water treatment

A water system is installed to provide an adequate quantity and quality of water for the controlled purification process. Any treatment must not leave residues that may interfere with the process. The quality of the incoming water prior to any disinfection shall meet or exceed the requirements specified in section 10.2.1 above. In North America an ultraviolet light (UV) system is the most common method of marine water treatment. Other methods may

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include chlorination/dechlorination or ozonation/deozonation.

Ultraviolet tubes must be regularly checked for intensity and must be replaced as prescribed by the manufacturer.

If, prior to UV treatment, water turbidity exceeds limits [see 10.2.2 a)v)], sand filters or the equivalent may be used as a pre-treatment. The requirements of the UV system for pre-treatment must be checked at the time of installation. The manufacturer of sand filters should be consulted for proper maintenance and the turbidity checked regularly (validation data are required). An automatic shut off is required (which may be connected to a UV sensor to ensure light efficiency) before or after the ultraviolet system or other means to ensure that untreated water does not enter the tanks in the event of power or ultraviolet system failure. If the shut down was significant and/or the water level drops below the level of any shellstock in the tank, in a self-draining system, then the cycle must restart at the beginning of that 24-hour cycle. The time for a shut down to be significant is determined on a system-by-system basis and must be documented in an establishment's QMP.

(WARNING: It is dangerous to look directly at ultraviolet bulbs without eye protection. Signs stating this danger should be prominently displayed.)

Biological filters are also common equipment in recirculating systems. They are needed to reduce ammonia to acceptable levels and to remove waste metabolites. The manufacturer of biofilters should be consulted for proper maintenance.

10.2.3 Shellstock Separation Requirements

The handling and wet storage of approved area bivalve molluscs is permitted at a depuration facility if the control for separation in time and space of depurated and approved area bivalve molluscs is documented and controlled so that there is no chance of mixing.

10.2.4 Laboratory

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Any laboratory used to perform the necessary analyses is required to be approved by a Lab Evaluation Officer.

The requirements that microbiology and bioassay laboratories must meet are described in checklists found in Appendix I (Annex I - CSSP Microbiology laboratory evaluation checklist; Annex II - CSSP Bioassay laboratory evaluation checklist [to be issued at a later date]).

10.2.5 Operational Controls

a) Harvesting Controls

- i) Shellfish areas will be designated and/or assigned by the appropriate DFO office.
- ii) A harvesting plan must be submitted to the appropriate DFO office and approved prior to the harvest. It shall contain:
 - 1) the names of all harvesters;
 - 2) the exact location in which they will be digging; and
 - 3) the exact date of each harvest.
- iii) Each lot of shellfish must be identified and maintained physically separate.
- iv) At the time of harvesting, all containers of shellfish in a lot must be properly identified and the records shall show:
 - 1) the date of harvest;
 - 2) the area of harvest;
 - 3) the harvester's name;
 - 4) the quantity harvested by each harvester; and
 - 5) the harvest license number

These records must be maintained and available for review.

- v) A designated "Master Harvester" will be responsible for supervising the harvesting and maintaining the identity of the lot to the storage facility or depurator.

b) Transport

The shellfish must be transported from the shellfish

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area to the storage area and/or to the depuration facility in a manner approved by CFIA and meet the requirements of Schedule V of the *Fish Inspection Regulations* (FIR). At no time shall product destined for depuration or relay be transported with product from Approved areas.

c) Dry Storage at a Registered Facility

- i) It is recommended that as short a time as possible elapse between the time of harvesting and the onset of depuration. In no case shall pre-process dry storage of shellfish exceed three days from the date and time of harvest to the date and time of the start of the depuration process. Water spray or mist over shellstock in dry storage is permitted. The system must be designed to prevent contamination to the shellstock.
- ii) Storage temperature of bivalve molluscs prior to depuration shall not be:
 - 1) greater than the temperature of the process water; and/or
 - 2) more than 3 degree C below the process water temperature.
- iii) Post-process storage temperature shall not exceed 4 degree C.

d) Wet Storage Off-Site

Bivalve molluscs may be held for up to 21 days in wet storage prior to depuration, providing:

- i) the storage area meets the shellfish area classification for depuration (10.2.1);
- ii) the location is designated in the harvest license and is under constant supervision to prevent theft; and
- iii) the system is not in the verification phase.

e) Handling

- i) Shellfish shall be washed and culled prior to

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deuration. During this procedure, shellfish shall not be mishandled or subjected to thermal shock. The quantity of culled shellfish and the method of disposal shall be recorded.

- ii) A tank shall not contain more than one harvest lot of bivalve molluscs.

f) Container Sanitation

- i) Between deuration cycles, containers and deuration tanks shall be scrubbed clean, disinfected (with approved disinfectant), and rinsed to ensure no residue remains.
- ii) Tanks of bivalve molluscs shall be thoroughly hosed down at the end of each 18-24 hour period in the deuration cycle, in a manner which will not contaminate the shellstock.

10.2.6 Records

Up-to-date QMP records must be maintained at all times and must be available for QMP Compliance Verification. A listing of record types may be found in Annex 10A.

All forms used to record data must be included in the deuration protocol for approval before being used (examples of some forms are included in Annex 10B).

10.2.7 Process Verification

The facility must prove with a minimum of 20 lots that the deuration process is consistently cleansing the shellfish. In this assessment, each lot used must have 0 hr. results \geq a geometric mean of 230 faecal coliform/100 g, with no sample $<$ 100. The number and location of samples to be drawn at zero, twenty-four, and forty-eight hours will be approved by CFIA. These samples may be taken over a number of tanks if these tanks are identical in all characteristics such as flow and dimensions. The services of an independent statistician may be used. The intent of these samples is to determine that all locations in the tank facilitate deuration.

The maximum zero hour limit for deuration of not less than 48 hours will be 2,300 faecal coliforms/100 g. If the system can consistently cleanse shellfish with higher zero

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hour faecal coliform counts, an approved Modified Schedule of not less than 72 hours may be used. CFIA will establish a depuration cycle time and maximum faecal coliform level for each individual system, based on facility performance. Sampling plans to adjust these parameters post-process verification must be approved by CFIA.

The depuration system will be considered to be working satisfactorily under defined processing parameters when faecal coliform analyses of samples of depurated bivalve molluscs meet the criteria as listed in Table 10.1. All sample locations in the tank must be shown to be equally effective in depurating shellstock.

Table 10.1 End Product Standards For Overall Depuration Facility Performance Evaluation (Faecal coliforms/100 g)

SHELLFISH SPECIES	GEOMETRIC MEAN	UPPER 10% VALUE*
Soft Clam (<i>Mya arenaria</i>)	50	130
Hard Clam (<i>Mercenaria mercenaria</i> , <i>Protothaca staminea</i> , <i>Venerupis phillippinarum</i>)	20	70
Blue Mussel (<i>Mytilus edulis</i>)	20	70
Oyster (<i>Crassostrea virginica</i> , <i>Crassostrea gigas</i>)	20	70

* Upper 10 percent level is where no more than 10 percent of the samples' results used in the evaluation may exceed the value established as the upper 10 percent level for each species.

During the evaluation period the product may be released, by CFIA, to the market upon receipt of acceptable final hour bacteriological results as indicated in Table 10.2. Product that underwent a Modified Schedule will not be released to market during the evaluation phase, and may be relayed to a restricted or conditionally restricted area. All shellstock must be clearly identified as a depurated

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product at all stages of marketing. It is the processor's responsibility to ensure that buyers are aware of conditions for marketing depurated products (labelling and repacking restrictions).

Any final hour failures during the verification phase should be examined for cause and any proposed changes to the process or protocol as corrective action must be reviewed with CFIA. Product must be disposed of as per 10.2.10.

Changes to existing depuration facilities or the defined process parameters may require a complete re-evaluation of the system (examples are changed water flow, tank size, and density loading). The addition of identical tanks and systems in existing facilities with an approved process do not require re-evaluation on approval from CFIA.

A written report with all data and parameters from the verification must be prepared and a copy sent to CFIA. An additional copy shall be retained by the establishment.

10.2.8 Routine QMP Monitoring (Post-Verification) - Requirements

The processor must meet the following requirements:

- a) Shellstock samples for bacteriological analysis must be taken from every lot at zero hour and at the final hour of depuration. Lots must meet the zero hour requirement (≤ 2300 faecal coliform/100 g or more for a modified schedule as validated at 10.2.7) and final hour limits stated in Table 10.2.
- b) The minimum number of samples to be analysed from each lot at 0 hours and 48 hours (or at completion of depuration) can be determined by the history of the performance of the depuration process, size of the lots depurated, the variation of the shellfish area or areas, whether spatial or seasonal, and the initial levels of contamination.

A depuration facility which has high overall depuration performance and beaches with consistently low zero hour results, and is processing relatively small lots may, with CFIA approval have the number of zero and/or final (48-hour) samples reduced to 1. If such a facility were to find higher levels of initial faecal coliforms, experience deviations in final product results, or receive product from a new area, 5 zero hour samples would be required.

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A facility which consistently shows initial faecal coliform counts of ≥ 1000 , receives product from diverse shellfish areas, receives product from areas which experience wide fluctuations in contamination over time, would be required to analyse five (5) 48-hour samples.

If a modified schedule (72 hours) is used, five (5) final hour samples must be analysed.

Table 10.2 End Product Standards for Each Process Batch of Shellfish (Faecal coliforms/100 g)

NUMBER OF SAMPLES	SHELLFISH SPECIES	GEOMETRIC MEAN NOT TO EXCEED	ONE SAMPLE MAY EXCEED	NO SAMPLE SHALL EXCEED
1	Soft clam	No value	No value	170
	Oyster, hard clam, mussel	No value	No value	100
2	Soft clam	125	No value	170
	Oyster, hard clam, mussel	75	No value	100
3	Soft clam	110	No value	170
	Oyster, hard clam, mussel	45	No value	100
5	Soft clam	50	100	170
	Oyster, hard clam, mussel	20	45	100
10	Soft clam	50	130	170
	Oyster, hard clam, mussel	20	70	100

c) Samples of depuration water for bacteriological

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analysis must be taken at a frequency of at least one per day.

The depuration facility must keep records of all bacteriological results.

10.2.9 Process Deviations

Any process batch which shows a final hour faecal coliform count greater than 170/100 g for softshell clams or 100/100 g for all other shellfish will be considered as a BATCH DEVIATION. If two consecutive process batches have counts greater than 130/100 g for softshell clams or 70/100 g for all other shellfish, this will indicate a PROCESS DEVIATION. In either case, all information pertaining to the deviation shall be placed in a deviation file. The establishment must notify the CFIA Inspection Office immediately upon discovery of the deviation, and must initiate investigative action to determine the cause(s).

For lots that do not meet the zero hour requirement (≤ 2300 faecal coliforms/100 g or as approved during process verification) or final hour limits (Table 10.2), the following options are available:

- a) depurate using an approved Modified Schedule:
 - i) Lots with any zero hour result > 2300 may be purified using an approved Modified Schedule of not less than 72 hours. The lot shall be detained until the results of bacteriological analysis are complete. The lot will be released if the final hour results do not exceed the species limits in Table 10.2. If results exceed the species limit, the lot may be re-depurated using an approved Modified Schedule.
 - ii) Lots with final hour results which exceed limits in Table 10.2 may be purified by using an approved Modified Schedule of not less than 72 hours in addition to the original depuration cycle. The lot shall be detained until the results of bacteriological analysis are complete. The lot will be released if the final hour results do not exceed the species limits in Table 10.2. If results exceed the species limits, the lot will not be re-depurated, unless it is first returned to restricted or

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conditionally restricted area for at least 14 days;

- b) heat process (e.g., canning) the bivalve molluscs if the faecal coliforms are < 4000/100 g;
- c) return to an area meeting the requirements of section 10.2.1. Product may not be re-harvested for depuration for at least 14 days;
- d) have shellstock disposed of for other than human consumption.

Establishments are required to include overall depuration facility performance as evaluated using Table 10.1 in their Quality Management Plan self-verification.

Note: The end products of depuration operations must meet the guidelines as listed in Appendix II.

10.2.10 Product Release

Product that meets the final hour limits in Table 10.2 may be released to market. Product shall remain under the control of the establishment until released. During process verification, the product may be released, by CFIA, to the market upon receipt of acceptable final hour bacteriological results as indicated in Table 10.2. Product that underwent a Modified Schedule will not be released to market during the process verification, and should be returned to a restricted or conditionally restricted area.

10.3 Short Term Container Relay Protocols

All companies planning to carry out short term container relay (less than fourteen days), must undergo a process verification with the CFIA (see Sections 10.1 and 10.2 for criteria).

10.3.1 Harvest Areas

Shellfish areas must meet the requirements identified in Section 10.2.1.

10.3.2 Storage and Container Requirements

As in 10.2.2e) i) and 10.2.2e) ii) 2) -5).

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10.3.3 Shellstock Separation Requirements

Defined lots of relayed shellstock are separated by at least 10 metres from other shellstock on the lease during decontamination to avoid potential cross contamination.

10.3.4 Laboratory

As in 10.2.4.

10.3.5 Operational Controls

As in Section 10.2.5, a) through d), where applicable. In the case of aquaculture leases, the criteria outlined in Chapter 12 must also be met.

10.3.6 Records

Up-to-date QMP records must be maintained at all times and be available for Compliance Verification purposes. Examples of records may be found in Annex 10A.

10.3.7 Process Verification for Short Term Container Relaying

The facility must prove with a minimum of 20 lots that the relay process is consistently cleansing the shellfish. In this assessment, each lot used must have zero hour results greater than or equal to a geometric mean of 230 faecal coliform/100 g., with no sample < 100. The number and location of samples to be drawn at zero, mid-cycle, and final hours will be approved by CFIA. The services of an independent statistician may be used. The intent of these samples is to determine that all locations in the lot facilitate decontamination.

The maximum zero hour limit will be 2,300 faecal coliforms/100 g meat. If any zero hour sample exceeds this limit, the lot shall be relayed for a minimum of 14 days.

CFIA will establish a minimum relay time of not less than 6 days and a maximum coliform level for each individual system.

10.3.8 Routine Container Relay Monitoring

One sample from every lot must be analysed for faecal coliforms at the final hour of decontamination.

- a) Processor/grower records and bacteriological analysis results must be made available on request for QMP

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Compliance Verification purposes.

- b) An annual review of the data will be required before the licence issued under the MCFR will be renewed.
- c) Any laboratory used to perform the necessary analyses is required to be approved by a CSSP Approved Laboratory.

10.3.9 Process Deviations

If the lot exceeds the species limit in Table 10.2, the following options are available:

- a) use an approved modified schedule of not less than 14 days;
- b) heat process the product if faecal coliforms are less than 4000;
- c) relay to another area classified as approved; or
- d) have shellstock disposed of for other than human consumption.

10.3.10 Release

Product that meets the final hour limits in Table 10.2 may be released to market. Product shall remain under the control of the establishment until released. During process verification, the product may be released to the market, by CFIA, upon receipt of acceptable final hour bacteriological results as indicated in Table 10.2.

10.4 Natural and Extended Container Relay Protocols

All companies engaged in a natural or extended container relay operation (greater than or equal to 14 days) must conform to the following criteria:

10.4.1 Shellfish Areas

Harvesting may occur in any area not classified as prohibited and in the opens status of its classification.

10.4.2 Storage Facilities

As in 10.2.2 c).

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10.4.3 Shellstock Separation Requirements

Defined lots of relayed shellfish are separated by at least 10 metres to avoid cross contamination with other shellfish and to maintain the identity of relayed lots.

10.4.4 Laboratory

As in 10.2.4.

10.4.5 Operational Controls

See 10.2.5 a) and b) where applicable. Shellfish shall not be mishandled or subjected to thermal shock.

Lots of shellfish destined for natural/extended container relay must remain in water for a minimum of 14 days.

Shellfish for relay must be placed in or on a shellfish lease and in an area that is clearly marked off to identify the relay site.

10.4.6 Records

As in Section 10.2.6 (see Annex 10A). Any federally registered facility processing this product must verify as part of their Critical Control Point (CCP) for incoming product that appropriate procedures have been followed.

10.4.7 Routine Natural/Extended Container Relay Monitoring

Lots of shellfish relayed from 14 to 21 days must be analysed for faecal coliforms with a minimum of 1 sample. Lots of shellfish that are relayed in excess of 21 days may be exempt from the testing requirement, at the discretion of CFIA.

Processor/grower records and bacteriological analysis results must be made available upon request.

a) An annual review of the data will be required before the licence issued under the MCFR will be renewed.

b) All analyses are to be performed by a CSSP approved laboratory (See Appendix 1)

10.4.8 Process Deviations

A lot is acceptable if no sample has a faecal coliform count greater than 230/100 g (after the minimum 14-day

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relay period). All deviations must be immediately reported to CFIA for product disposition.

If the lot exceeds this limit, the following options may be provided:

- a) continue relaying for an extended period;
- b) heat process the product if faecal coliform levels are less than 4,000;
- c) relay to another area classified as approved; or
- d) have shellstock disposed of for other than human consumption.

10.4.9 Release

Product that meets the final hour limits referenced in Section 10.4.8 may be released to market. Product shall remain under the control of the establishment until released.

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ANNEX 10A

RECORDS

The following records must be kept, when applicable, and must be available for CFIA Compliance Verification purposes.

10A.1 Per lot:

- date of harvest
- area of harvest
- harvesters' names
- quantity of shellfish harvested
- time and date received at storage*
- time and date removed from storage*
- pre-process storage temperature
- amount of culls, time and place of disposal
- time and date of arrival at facility
- lot number
- time and date of start of depuration
- time and date of removal from depuration system
- zero hour bacteriological results
- final hour bacteriological results
- destination of lot

* If storage facility location is separate from cleansing facility

10A.2 Daily Facility Records:

- a) Depuration Water
 - oxygen content
 - salinity
 - temperature
 - turbidity
 - coliform count

- b) Plant Equipment
 - tank number
 - tank flow rate (measured twice daily and after adjustments are made to any tank)
 - time (in depuration hours) that tanks and shellfish hosed down
 - time of back flush
 - temperature of dry storage
 - ultraviolet lights (hours of use, % efficiency, date replaced)
 - water flow chart

10A.3 Other

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Harvesting Site - salinity and water temperature of overlay
water

NOTE: All records must be acknowledged by the
responsible operator (by initialling records)
and by a management check.

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ANNEX 10B

SELECTED EXAMPLES OF TAGS AND RECORD FORMS

A. Lot Identity At Dig Site

SHELLFISH AREA AND SUB-AREA AND AREA # _____

DATE OF HARVEST _____

NAME(S) OF HARVESTERS _____

PERMIT # _____

QUANTITY OF CLAMS _____

LOT # _____

PROCESSING CO. NAME, ADDRESS & REGISTRATION # _____

B. Lot Identity At Interim Storage Facility

LOT # _____ STORAGE TEMPERATURE _____ DATE RECEIVED _____

SHELLFISH AREA AND NUMBER _____

QUANTITY RECEIVED _____

QUANTITY CULLED _____

DISPOSAL METHOD _____

DISPOSAL DATE _____

QUANTITY SHIPPED _____

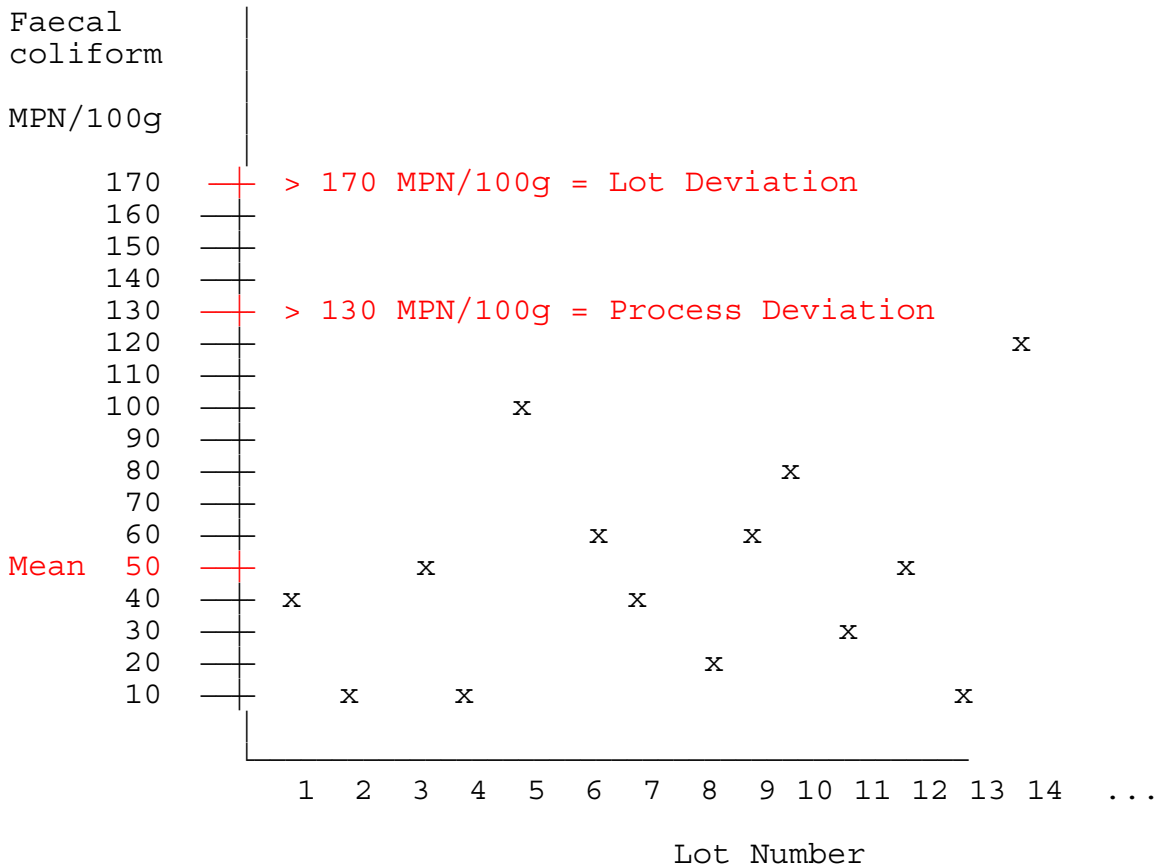
DATE SHIPPED _____

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C. Depuration Cycle

CLEANSING (DEPURATION) CYCLE _____	LOT # _____
DATE (TIME) IN: _____	QUANTITY _____
CONTAINER (TANK) NUMBER _____	
CONTAINER POSITION _____	
TIME OF WASH DOWN _____	
DATE (TIME) OUT _____	QUANTITY _____
DISPOSAL OF CULLS _____	

D. Graph of results per lot (example - soft shell clam)



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ANNEX 10C

EXAMPLE OF LICENCE ISSUED UNDER MCFR

Licence No. _____

Pursuant to Section 4 of the *Management of Contaminated Fisheries Regulations*, permission is hereby granted to (name of company and responsible officer) and persons working under his/her supervision, to remove soft shelled clams from the following areas:

Those portions of the _____ as designated by the DFO Office, _____ (area) _____ for controlled purification or depuration.

- 1 - All operations will be carried out in compliance with the attached Memorandum of Agreement between (name of company) and DFO for the harvesting of soft shelled clams from restricted areas;
- 2 - A copy of the licence will be carried by those working on the harvesting of the clams and is to be available for inspection by a fisheries officer;
- 3 - That _____, Fisheries Manager, _____ (area) _____, (phone number), be kept advised of the details of the clam fishery;
- 4 - The method of harvesting shall conform with existing policies and applicable Regulations;
- 5 - Non-compliance with any condition of the attached agreement or this licence may result in the cancellation of the licence;
- 6 - DFO reserves the right to cancel all or part of this licence at any time; and
- 7 - The harvesting would be permitted from _____ to _____
(Maximum 1 Year)

Issued at _____ (location, date) _____.

(Name)
Director-General

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ANNEX 10D

MEMORANDUM OF AGREEMENT

BETWEEN

(Company)

AND

FISHERIES AND OCEANS CANADA

FOR THE

HARVESTING AND PROCESSING OF SOFTSHELL CLAMS

FROM AREAS CLASSIFIED AS RESTRICTED OR CONDITIONALLY RESTRICTED

This agreement to be in effect from (date) to (date) .

The conditions of the agreement are detailed in Section 1, Harvesting, Transport and Storage, and Section 2, Processing.

Fisheries and Oceans Canada reserves the right to amend the agreement during the effective period.

Signatures

Company Representative

Fisheries and Oceans Canada

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SECTION 1. HARVESTING, TRANSPORT AND STORAGE

1.1 Designation of Closed Areas

Fisheries and Oceans Canada, in consultation with Environment Canada, will designate areas or portions of areas from which bivalve molluscs may be harvested for controlled cleansing. Overlay waters from these areas must have a median faecal coliform count of less than 88 MPN/100 mL, with less than 10% of samples greater than 260 MPN/100 mL.

1.2 Harvesting Licence

A license issued under the authority of the *Management of Contaminated Fishery Regulations* will be required to harvest bivalve molluscs from restricted or conditionally restricted areas for controlled cleansing. The licence holder must comply with all requirements outlined in this agreement and the conditions specified in the licence.

1.3 Method of Harvesting (applies to mechanical harvesters if permitted)

The licence holder must conform to all pertinent regulations with respect to mechanical harvesters and the mechanical harvester must be licensed under the authority of the applicable fishery regulations and the licence must be carried during the harvesting operations.

1.4 Notification of Intent to Harvest

The licence holder must provide the Conservation and Protection Office in the area of operation with at least one week's advance notice of the weekly harvesting plan. This plan will indicate what areas or portions of areas are to be harvested, when and by whom.

DFO reserves the right to restrict the number of areas being harvested and the number of harvesters operating at any one time.

1.5 Designation and Responsibilities of Harvesters

The licence holder must provide to DFO a list of digger representatives ("Master Harvesers") and diggers working under each representative. A written update of this list must be provided for any change of personnel. Each digger representative must be present during the entire harvesting operation and is responsible for designating the dig site

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using stakes or markers. The site must be no larger than that area which is in view of the representative at all times. During the harvesting operation each digger must carry a copy of the licence issued under MCFR to the depuration facility. The digger representative must also ensure that all clams harvested are placed in containers before they leave the dig site.

1.6 Identification of Shellstock

Harvested shellstock must be transported to their destination (storage facility or cleansing plant), in a sealed vehicle meeting the requirements of Schedule V of the *Fish Inspection Regulations*, in containers which are tagged to identify shellfish area, harvesting crew and amount harvested. The licence holder must ensure that records of lot identity are maintained.

1.7 Storage Facilities (Interim Storage Facilities - to Be Used When Cleansing Plant is Located Distant from Shellfish Area)

The storage facility must be approved by CFIA Inspection Services prior to the start of harvesting operations. The facility must have adequate security to prevent free access to shellstock and shall be large enough to allow the identity of the lots to be maintained.

In order to prevent thermal shock or an increase in bacterial levels, shellstock shall not be subjected to temperature fluctuations while in storage. Shellstock shall be maintained at a temperature not greater than the temperature of the process water and not more than 3°C lower than the process water.

Shellstock shall not be stored longer than three days including day of digging and day of transport to depuration plant.

1.8 Transportation of Shellfish

Containers of shellstock shall be transported directly to their destination (cleansing plant or storage facility) by the most direct route and immediately after harvesting.

SECTION 2 - PROCESSING

2.1 Temperature Control

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Shellstock held prior to processing shall be stored at a temperature not greater than that of the process water and not more than 3°C lower than the process water.

2.2 Culling and Washing

Shellstock shall be washed with approved water (less than 2 coliform/100 mL) to remove foreign matter and culled to remove all broken shelled, dead or gaping shellfish prior to the cleansing process.

2.3 Length of Cleansing

Shall be established on process evaluation data.

2.4 Equipment Cleaning

All equipment used to transport, hold or process shellfish must be maintained in good order and washed and sanitised after every use. The requirements of the *Fish Inspection Regulations* must be met.

2.5 Records

Records shall be maintained for the following:

- 1) daily harvesting activities including date of harvesting, shellfish area, and volume harvested;
- 2) placement of lot (one tides digging from one area) into tanks or cages, tank or cage identity and date and time of loading and unloading;
- 3) bacteriological analyses of water samples before and after bactericidal treatment;
- 4) bacteriological analyses of each lot showing basket or tank sampled and zero hour and final hour results. These results must be graphed as well as tabulated (Faecal Coliform vs. Lot#); and
- 5) water temperature, salinity, rainfall data, oxygen content, turbidity, pH, waterflow and ultraviolet lights on a daily basis, as listed in Annex 10A.

Records must be kept up to date and must be available for audit by CFIA.

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2.6 Sampling and Laboratory Analysis (Depuration Operations)

The company will be required to analyse zero hour and final hour samples of each lot of shellstock for faecal coliform levels using approved methods.

The laboratory will be subject to periodic audits by the Canadian Food Inspection Agency (policy on periodic audits and check sample program under revision). The laboratory must participate in the split sample program operated by CFIA and should participate in the check sample program.

2.7 Cleansing Process - Bacteriological Performance Criteria

The cleansing process will be considered satisfactory if faecal coliform analyses of samples of cleansed clams result in a MPN geometric mean value of 50/100 grams (g) or less and not more than 10% of the samples exceed a faecal coliform MPN of 130/100 g.

A lot will be considered acceptable if it has a faecal coliform MPN of 170/100 g or less.

CFIA will establish, based on demonstrated plant performance, a zero hour faecal coliform limit and a minimum depuration cycle time. If any zero hour sample has faecal coliform levels greater than the established maximum, the lot shall be:

- 1) purified using an approved modified schedule (not less than 72 hours for land-based depuration units) and detained by Industry until the results of bacteriological analyses are complete; or
- 2) detained and sampled by Industry. If final hour results are less than 170 faecal coliforms/100 g, the lot will be released; if greater than 170/100 g, the lot will remain detained, with the plant having the option to re-depurate using a modified schedule, or heat-process (e.g., can) the clams; or
- 3) disposed of for other than human consumption; or
- 4) relayed to a restricted or conditionally restricted area.

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2.8 Deviation File

If any depurated lot has a final hour faecal coliform count greater than 170/100 g or if two consecutive lots have counts greater than 130 faecal coliforms/100 g, all information pertaining to the lot, including dig site information, storage time, water quality and bacteriological data must be placed in a deviation file. The establishment must notify the CFIA Inspection Office immediately upon discovery of the deviation as well as initiate investigative action to determine the cause. CFIA will take appropriate action with regard to the lot of clams.