	Harvest	Loading	Transport to Federally Registered Processor	Shellfish Processing	
				CFIA: verify processors have controls to ensure acceptability of incoming shellfish (e.g. <i>Vibrio parahaemolyticus</i>)	
Routine role/process	DFO: shellfish aquaculture site licensing and communication with all licenced leaseholders. FLNRO: BC government shellfish tenure licensing to generate land-file (lease holder) numbers EC: water classification for shellfish harvest area	DFO : Pacific Aquaculture Regulations. See detail below. No shellfish shall remain untagged during transport to market (condition of licence).		CFIA: responsible for auditing each processor, at minimum, 1 time/year Responsible for reviewing QMP plans to ensure they are implemented an reducing risk. (per Facilities Inspection Manual, Ch 3, Subject 3)(a). QM should have Vp control requirements, that include control for harvest, transport to plant, processing, storage. See App. H and K in QMP guidelines. Shellfish processor: must notify CFIA if 5 sample lot testing does not mee standard. One, but not more than one, sample of >100 MPN/g is allowed in th sub-units. Any single sample exceeding 10,000 MPN/g renders the lounacceptable. (HC: Apr 2008)	
Ä				FOOD METHOD OR EQUIVALENT GUIDELINE NATURE OF CONCERN (Health Risk (HR)) n c m M	
nal regulatory role/process	DFO: communicated to license holders and shellfish industry on outbreak, sent notifications using the Fishery Notification System, posted information to website. Provide information to Outbreak Investigation Coordinating Committee (OICC) on volumes of oysters harvested, water temperature and other harvest practices for specific lease areas.			CFIA: Communication with processors on human illness and HC interim guidance and Aug 18 recall. Worked with processors to implement HC interim guidance. Would take action on unsatisfactory results for products still in the marketplac (would require a health risk assessment). Shellfish processor: Must test each lot (finished product) and ensure all subsamples are <100 MPN/g. All results must be shared with CFIA. HC interim guideline: must notify CFIA of all results. No sub-samples may exceed 100 MPN/g of Vp. Each lot must be tested, held, and shown to meet the	
outbreak additio				standard prior to release to market.(b) Bacteriological guideline (end-product) for Vp Test Organism Product Type Sample Units Product Type Sample Units Acceptance Number (c) Number of Number (c) Number of Number (c) Number of Number (c) Number of Number of Number (c) Number of Number (c) Number of Number (c) Number of Number (c) Number of	
2015	DFO: Pacific Aquaculture Regulations condition of licence Prior to leaving the licensed area, all containers holding for market sale shall be marked with a visible tag identifyii (i) Licence Holder Name; (ii) Species; (iii) Pacific Fishery M	shellfish that are destined ng the following:	DFO: Pacific Aquaculture Regulations. Condition of licence, the licence holder shall land all harvested bivalves at a federally registered processing plant prior	identified in the Vp RRS, where the water or oyster temperatures ha consistently demonstrated to be below 15°C and environmental Vp levels a shown to be <3 MPN/g for at least two consecutive weeks. CSSP 7.3: A durable, waterproof tag must be affixed to each container (packed destined for sale. For non-retail packages: date of processing, site, registration number of proce and name and address of responsible party for distribution, type and quantit	
ess	File Number; (v) Date of Harvest; and (vi) Facility Reference Number. The licence holder shall record, within 24 hours, the importation or transfer of shellfish to the licensed area, the transfer of shellfish from the licensed area and harvest for market sale. Records shall include shellfish wet stored at the licensed area(s) from other locations prior to market sale. The licence holder shall record: (a) Aquaculture Licence Number(s), Facility Reference Numbers, or groups of Aquaculture Licence or Facility Reference Numbers associated with the licence holder for sites in the same Pacific Fishery Management Area; (b) Activity date; (c) Species common name; (d) The nature of the activity (i.e. Activity Code (IP - Importation) (TS - Transfer) (H -		to sale for human consumption. CSSP 4.2. Water used for washing shellstock shall be obtained from an approved shellfish area, or from other safe sources approved by the CFIA CSSP 4.6. "Temperature shall be controlled during transport when ambient air temp and time of travel are such that unacceptable bacterial growth or deterioration may occur"	shellstock, depuration and relay info as applicable. For retail packages for sale in Canada: date of processing, best before date harvest date and the statement "keep refrigerated", harvest site, registra number of processor and name and address of responsible party for distribut type and quantity of shellstock, depuration and relay information. CSSP 7.2. Shellstock in storage must be held between -1 and 4°C CFIA: Federal Fish Inspection Regulations. FIR 15.1 processors are registered	
Regulation covering process	Harvest for Market Sale)); (e) Number of containers; (f) Container type; (g) Average container weight, OR total estimated weight individuals; (h) Source of shellfish arriving at the site (source licence Destination of shellfish leaving the site (destination site	OR, estimated number of number, or other); and (i)	CFIA: Federal Fish Inspection Regulations. FIR Sch II 16.1 Fish must be kept iced or chilled before processing at an establishment. BC Ministry of Agriculture: Provincial Fish (Apply to harvest and through to processor	FIR 15.8 processors are compliant with CSSP FIR ar II, 26.1.f Containers must be marked to indicate the date of processing and the location from which they were harvested	
egulation c	buyer, or market sale processor). The CSSP isn't a regulation – it consolidates regulatory information and outlines policy. Shellfish processors must implement requirements in the CSSP (FIR 15 (8)) CSSP 4.4. Label must include harvester's name, harvest location, date of harvest,		ļ ·	BC Min. of Agriculture: FIR 12.3, 14.d and FIR 54.2.b.i	
Ä	shellfish processors are provincially licenced and all bivalves must first pass through a federally registered establishment prior to being sold. CFIA: Federal Fish Inspection Regulations. Temperature control during harvest, transportation and at processing: Schedule II. 16. (1) Fish shall be kept iced or chilled and protected from contamination before processing in the establishment and, if the type of process operation conducted so requires, shall be washed before processing, (2) Cold storages shall maintain the temperature of fish at -18°C or colder, and (3) Coolers shall maintain fish at a temperature from 4°C to -1°C. Schedule III. 8. Fish, while on board a vessel used for fishing or transporting fish, shall be (a) preserved by the use of finely divided ice sufficient to reduce and hold the temperature at 4°C or lower, and such ice shall be made from water from a source approved by a fish inspection laboratory Schedule V. 5. (1) Fish held prior to being transported shall be iced or chilled after unloading from a vessel and be protected from the sun and weather and from contamination, and (2) Fish shall be iced or chilled we being transported. CFIA: Federal Fish Inspection Regulations. QMP plans and Appendix H The federal Fish Inspection Regulations require a QMP plan be developed and implemented (FIR 15 (6) c). The QMP Reference Standard and Compliance Guidelines, Appendix H requires that establishments identify hazards, including those that are present at steps not under their direct control (e.g., Vp risks at the harvest, site) (Facilities Inspection Manual, Ch 3, Subj 4). "Appendix H outlines that levels of naturally occurring microbiological pathogens (such as Vp) must meet identified standards in the final product. Critical limits to address the level of microbiological pathogens at time of harvest, and time/temperature exposure from harvest to final product shipping must be established during the warmer months when shellfish are destined for raw consumption.				
SS	Shellfish farm: Indicator sampling: a single pre-harvest oyster meat sample is tested for Vp, either prior to harvest, or simultaneously with harvest (more sub-samples may be tested).	Temp control methods: Ice totes may be brought to harvest site by some leaseholders, product is layered in ice for transport to the dock.	Trucking companies: Some trucks have temperature dataloggers &/or drivers who monitor temperature during delivery HACCP certification of trucking	Shellfish processor: follow FIR, FIM, QMP reference standard & CSSP. 1. Oysters are checked they are from an open and approved harvest site 2. Sensory assessment is performed. 3. Oysters may be washed 4. Oysters are tagged for identification 5. Oysters are refrigerated	
Industry process	Harvest: from raft (oysters suspended on long-lines); from beach; from raft to beach (hardening of oyster shell). Deep-water submersion before harvesting is one method; cold tank storage with deep line water occurs with one farm.	Previous CFIA control guidance may be followed: Water temp>15°C, 1 hr to place product under temp	companies (e.g., Cold Star Freight)	 (note: processing of oysters is done is small batches, oysters are maintained unrefrigeration. 6. Subunits (n=5) of 10 to 12 oysters (per subunit) per harvest day lot samples taken for verification testing. For Vp, processors additionally: 	
	Washing: at harvest/beach area, or with approved water at registered facility (CSSP 4.2)	place product under temp control. Water temp<15°C, 4 hr to place product under temp control.		7. Evaluate Vp levels at harvest are low enough 8. Evaluate harvest & transportation conditions met time/temp controls 9. Implement time/temp controls for Vp 10. Implement interim Vp guidelines Other processes not described here: wet storage (up to 60 days) (CSSP 5); shuce	

Transport to Distribution Chain		Shellfish Distributors	Retail / Restaurant	Human exposure & Illness Reports
Routine regulatory role/process	CFIA: reviews processor QMP for loading at appropriate temperature.	BC Min. of Agriculture: If a distributor is provincially licensed as a processor, the facility is subject to constructional and operational inspections. For e.g., inspect shellfish holding, verify water quality, species held, source of shellfish from federally registered establishments. Local HA: During complaint investigations, review &/or inspect distributors temperature logs and control.	Local HA: Inspection of all facilities identified during illness investigations with focus on food safety and temp controls. Annual inspections occur based on risk, at least once/yr and usually 3X/year. Evaluation of food safety and sanitation plans, observations during inspection. Posting of risk rating and inspection results on public web-site.	Local HA responsible for case investigation and sending forms/tags to BCCDC and CFIA BCCDC: Responsible for reviewing submitted forms for cluster or common associations in time/place CFIA: responsible for traceback for every tag provided by local HA and follow up with processors identified.
2015 outbreak additional regulatory role/ process			Local HA: Distribution of education materials re: temp control. Distribution of warning to avoid consumption of raw BC oysters to restaurants/retailers. Implementation of order in VCH to ban sales of raw oysters	BCCDC: Review of available tag information, coordinate provincial response, national OICC liaison, engage BCSGA to share data
Regulation covering process	cssp 7.2. no specific time/temp requirements in Canada. "Shellstock shall be transported in adequately refrigerated vehicles when the shellstock have been previously refrigerated or when ambient temperatures are such that unacceptable bacterial growth or deterioration may occur." Shipments destined for US; is shipping time is >4hr, mechanically refrigerated vehicles maintaining <7.2°C must be used; a time temp recording device must accompany shipment. If shipping time is <4 hr, icing is acceptable. Conveyances used to transport shellstock shall be constructed, maintained and cleaned in accordance with the requirements of Schedule V of the Fish Inspection Regulations (FIR).	CSSP 7.2. shellstock in storage shall be protected from contamination and maintained at temperatures between -1°C and 4°C (applies to distributors who are also federally registered fish processing establishments) CSSP 8.3 e. Repackaged shellstock shall be labelled in the same manner as shellstock was initially packaged. BC Ministry of Agriculture: FIR 14 (d) shellfish distributors who meet the definition of processing require a processing licence. FIR S. 53. Condition of oysters and clams Oysters and clams in the shell shall be alive, undamaged and free from mussels, limpets, stones, excess mud and other extraneous material.	BC Food Premises Regulations: S. 14. PHF food is stored at<4°C S. 23/24 requirement for food safety and sanitation plan National Food Retail and Food Services Code 3.2.2.2 Invoices, receipts, and lot coding information should be retained, to allow tracking of unlabelled products (such as carcasses, produce or bakery products) or split lots. Seafood tags shoul dbe retained for a minimum of 90 days after use. BCCDC educational documents for restaurants and retailers	FRFSC: retain tags for 90 days (per previous box) BCCDC: recommendation in educational notices is to retain tags for 3 months
Industry process	Trucking companies: Some trucks have temperature dataloggers &/or drivers who monitor temperature during delivery HACCP certification of trucking companies (e.g., Cold Star Freight)	Distributor (Processor): Verify farms are SQA via inspections 1-2X/yr (in person or 3 rd party audit) Establish cold chain of custody for transport from farm to processor/distributor Provide potable ice/ ice packs for delivery to retail/restaurant Maintain premise interior below 4°C Delivery trucks have data logger and records Maintain temp control logs	Retail/restaurant: Keep all PHF foods ≤4°C Keep shellfish tags/invoices for a minimum of 90 days Maintain temp control logs for refrigerated equipment Follow food safety plan for oysters for raw consumption In VCH: warnings on either menus or tables	Retail/restaurant: Track and report illnesses to Health Authority for follow-up