Exhibit (C)

Supplemental Revised Agenda Item Summary

Agenda Item Summary

BACKGROUND

Oregon and the West Coast have experienced several years of crab fishery disruptions and delays due to domoic acid, a naturally occurring biotoxin that poses a significant health risk to human consumers of domoic acid laden crab. Domoic acid events have periodically occurred in Oregon over the last few decades, however, the strength and frequency of these events is increasing and is correlated with changing ocean conditions, ocean acidification, and climate change. In response to recent events, the Oregon Department of Agriculture (ODA) and the Oregon Department of Fish and Wildlife (Department) initiated an evaluation of testing procedures and management actions which included convening the 2017 Dungeness Crab and Biotoxins Rules Advisory Committee (RAC). RAC members emphasized the industry's strong desire to be able to harvest crab during times when biotoxins are present, as long as human health is protected first and foremost. Because domoic acid accumulates at higher concentrations in crab viscera (guts) than in crab meat, this can often be effectively accomplished by removing the viscera (evisceration).

The RAC developed multiple recommendations (Attachment 4) to support the use of evisceration and to do so in a timely, efficient, and effective manner. Specifically, the RAC recommended additional record keeping requirements for the sale and purchase of commercially-harvested Dungeness crab to improve traceability of crab in the seafood market chain. Traceability supports the State in allowing continued harvest with evisceration because it is critical for conducting rapid and effective recalls, should biotoxins be detected.

The Oregon Department of Agriculture (ODA) has recently established improvements in rule (Attachment 5); the rules proposed here augment the existing records keeping requirements for Dungeness crab under the Commission's authorities, and complement ODA's new rule. In combination, these actions strengthen the State's ability to protect public health from consumption of biotoxins, while maintaining commercial harvest of crab to sustain the economic viability of the fishery.

PUBLIC INVOLVEMENT

The RAC was co-convened by ODA and the Department, and was comprised of 11 industry members, including crab buyers, processors and harvesters from each of Oregon's 6 primary crab ports. Oregon State Police Fish and Wildlife officers also participated. For more details on that process and additional recommendations, see: http://www.dfw.state.or.us/MRP/shellfish/commercial/crab/domoic_acid.asp.

The Department implemented RAC recommendations in temporary rule for the season start, December 1, 2017. In preparation, Department staff sent an industry notice to all Dungeness crab permit holders, Department licensed fish dealers of all types, and all ODA licensed meat retailers on November 7, 2017 (Attachment 6), describing the intent and substance of the temporary rules. Since then, Department staff has answered numerous calls, emails, and other communications regarding the temporary rules and have considered input received in developing these recommendations for permanent rule amendments.

On March 14, 2018, the Department mailed or emailed notification to all Dungeness crab permit holders, Department licensed fish dealers of all types, and all ODA licensed meat retailers that amendment of these rules would be considered by the Commission at this meeting (Attachment 7). The notice included information on potential modifications of the temporary rule, which is identical to the rule language submitted for this exhibit (Attachment 3).

ISSUE 1

RECORD KEEPING REQUIREMENTS FOR COMMERCIAL DUNGENESS CRAB SALES TO IMPROVE TRACEABILITY

ANALYSIS

Biotoxin events can impact public health through consumption of seafood:
Biotoxins are produced from Harmful Algal Blooms (HABs), which typically occur during the summer and fall months on the West Coast. Crabs, as well as other marine species, accumulate these biotoxins in tissues by foraging behaviors. Accumulated biotoxins in seafood can cause physiological distress, illness, and death in humans who consume it. The amnesiac shellfish poisoning agent domoic acid is one of the prevalent biotoxins on the West Coast and is seasonally produced by the HAB species Pseudo-nitzchia. When domoic acid events occur, monitoring of sampled clam and crab tissues help resource managers determine when it is safe to prosecute fisheries on those species.

Evisceration mitigates public health risk:
Both the federal and state governments have mechanisms in place that define danger levels for toxins present in seafood. The federal Food and Drug Administration (FDA) sets the food safety threshold for domoic acid in parts per million (ppm) for crab viscera (≥30 ppm) and crab meat (≥20 ppm). The ODA implements these federal standards. A sample of a single crab above either threshold from an area triggers a management response,

and ODA must take action to protect public health. When Dungeness crab viscera tests above the FDA threshold but meat tests below, commercial processors certified by the FDA and ODA can remove the viscera to allow the continued harvest and consumption of crab. Evisceration of recalled live or whole-cooked crab is also possible in many circumstances. Evisceration (or gutting), is an effective solution because domoic acid accumulates in crab viscera at much higher concentrations than in the crab meat. In contrast, when domoic acid is elevated in the meat, the only management solution is to prohibit harvest in the affected areas and destroy affected crab product that has already been harvested.

Oregon has a monitoring plan in place for sampling biotoxins in shellfish and Dungeness crab. The ODA analyzes samples gathered from the waters of this state and the Pacific Ocean off Oregon, and recommends a management response for fisheries based on those results. The Department participates in sampling, formulating recommended management response, and takes action to close and re-open the crab fishery. In addition, the Department has records requirements that can be used to inform recalls and traceability audits.

2017 in-season domoic acid event:
In 2015, 2016 and 2017, large HABs were observed in the summer and fall, and biotoxins were subsequently detected in clams and crabs, delaying the Dungeness crab season by about month each year. In January 2017, one month into the delayed 2016-2017 season, one sampled crab had elevated domoic acid in the viscera, requiring a management response. This detection event was the ***first in-season biotoxin detection*** for the commercial Dungeness crab fishery in Oregon and heralds management challenges for future seasons.

This event highlighted the need for strengthening the available management tools, coordination between the State and the industry, and communications throughout each season. ODA's investigation of the market chain during this event allowed the fishery to remain open under evisceration requirements, however, the transition from unrestricted fishing to an evisceration order was disruptive. ODA's investigation also revealed the limitations of the system for conducting the recall and auditing compliance with evisceration requirements during in-season events. These limitations undermine the agencies' confidence in effectively using evisceration to protect public health; by resolving the limitations, evisceration becomes a viable management tool to maintain economic vitality for the seafood industry while protecting public health.

2017 RAC recommendations to improve management response and tools:
In response to the 2017 event and management challenges, the RAC identified 3 key objectives for an improved management response:
(1) minimize management response time to biotoxin detection events;

(2) expand communications tools to improve industry's ability to plan for markets, manage risk, trace product and participate effectively in crab recalls; and
(3) strengthen the regulatory framework – particularly records keeping requirements and ODA records inspection authority – to maximize traceability of crab product and facilitate appropriate management of that product during biotoxin events.

A number of the non-regulatory recommendations (supporting objectives 1 and 2, above) have been implemented, while the third objective – strengthening the regulatory framework to maximize traceability – is in progress and is the subject of this decision-making process.

One of the most important outcomes of the RAC process was adoption of a new ODA rule (635-025-0410, Attachment 5) which, for the first time, set down in rule the procedures for testing crab for biotoxins and management options when either viscera or meat are found to above the FDA-established thresholds. Part of that rule (section 5) lays out ODA considerations for deciding whether to recommend evisceration or closure in response to a particular event. One of the key considerations is to what extent crab are traceable throughout the market chain, with the implication that a certain level of traceability is required in order for ODA to recommend evisceration as the appropriate management response. Because ODA can only require records of ODA-licensed processors (which does not include unprocessed, live crab), the Department's records (which include requirements for all crab buyers and sellers) are the State's most comprehensive source of information in the seafood market chain.

Augmenting records keeping requirements to improve traceability of crab:
To improve traceability of Dungeness crab, the Department recommends establishing records requirements that specify the Area of Harvest, and the Date of Landing, so that any crab in the market chain can be identified as containing adulterated product. These proposed rules:

1. Establish in permanent rule 12 Harvest Areas for the State of Oregon for Dungeness crab harvest (Attachment 8), so that the Biotoxin Management Zones (BMZs) are transparent to industry and are increased in number to allow more fine-scale management.
2. Require additional records of the seafood industry that follow the crab throughout the market chain:
    a. Add a "one-forward" requirement (sales) to existing ODFW records keeping requirements, so that anyone in possession of commercially-harvested crab must keep records of sales of crab, that include Harvest Area and Date of Landing. The new sales requirement does not extend to the ultimate consumer.
    b. Add a Harvest Area and Date of Landing requirement to existing "one-back" (purchases) records keeping requirements, so that anyone in possession of commercially-harvested crab

will keep and maintain records of where and when crab were harvested.

The traceability benefit of smaller Harvest Areas and Date of Landing (strategic implementation of BMZs):
The proposed rules improve traceability by creating a fine-scale resolution map of Oregon, to which every crab may be classified and assigned (Attachment 8). Any crab that were harvested from an area (before, during or after a biotoxin detection event occurs) are classified as being harvested from that area from the time it enters the seafood market chain. Because the Harvest Area tracking is in place throughout the season, the information can be used to rapidly conduct recalls and implement evisceration orders in response to biotoxin events. Smaller Harvest Areas, if carefully tracked in crab sales, allow more strategic and targeted management actions with potentially reduced economic impact. In this way, the agencies can continue to allow unrestricted harvest in areas where biotoxins have not been detected, and minimize the amount of crab product already in the market that is affected by a recall.

Date of Landing is also needed to constrain the period of time when crab harvested in that area are considered adulterated and must be eviscerated.

In practice, when elevated biotoxins are detected in a Harvest Area, ODA will establish a BMZ. The BMZ includes the Harvest Area where crab were detected as well as the adjacent Harvest Areas to the north and south; the same management action will apply to the entire BMZ. The time period for the BMZ will be defined by the Date of Landing of the adulterated crab sample until the Date of Landing of the qualifying clear sample that demonstrates that biotoxins have dropped below thresholds.

The traceability benefit of 1-forward, 1-back records requirements (rapid response, auditing efficiency):
During a recall event, public health protection is increased as the rate of identification of adulterated product is increased. With a stronger traceability framework, the State can act more rapidly to prevent illnesses and the State is more efficient and accurate in evisceration effectiveness auditing.

More specifically, by requiring that 1-back records (purchases; existing requirement) include harvest area and date of landing and are maintained on site for each entity in the market chain, the agencies can ensure that employees at the site are able to retrieve this information and act accordingly. This allows the quickest response by eliminating the need to communicate with centralized distribution centers or suppliers, as is the case with centralized systems or when essential records are only kept by one entity in the market chain (e.g., a first receiver).

By requiring 1-forward records (sales; new requirement), and requiring that they include harvest area and date of landing, the agencies ensure that sellers of crab can quickly determine which buyers may have adulterated

crab that needs to be recalled and eviscerated or destroyed. This requirement also increases the efficiency and accuracy of ODA effectiveness audits, as they are able to more easily determine which entities possessed adulterated crab and how much adulterated crab may have reached consumers prior to or despite a recall. The audit results inform future management decisions during biotoxin events, and so positive audit results are essential to retaining evisceration as a management option.

Recommended changes from the temporary rule:

- Since the new Harvest Areas and record keeping requirements were initially implemented through temporary rule in November 2017 in order to meet the season start date, the industry and agencies were able to "test drive" the traceability framework and identify potential unintended problems. Based on that experience, the Department is recommending a few modifications to the temporary rule requirements to provide clarity and ensure that the rules meet the intent of area-specific traceability throughout the market chain. However, these harvest area-specificity provisions are recommended to be applied to uneviscerated crab only, which is the product form that presents the greatest public health risk.Add Washington and California Harvest Areas to the Harvest Area map to clarify that the requirement applies to uneviscerated crab landed or imported from out-of-state.
- Clarify that using a state-wide Harvest Area designation for Oregon will not comply with Harvest Area tracking requirements for uneviscerated crab; tracking uneviscerated crab as "Oregon" is not consistent with the traceability intent.
- Clarify requirements for combining uneviscerated crab from multiple Harvest Areas. Listing multiple Harvest Areas would be allowed only if crab from multiple areas were combined. For the first point of sale (first receiver), it would be **prohibited to list any Harvest Areas that were not harvested from** (i.e. the Harvest Areas could be reported as a range only if the uneviscerated crab came from ALL Harvest Areas within that range). The initial list of areas could then be carried forward without modification to records of subsequent wholesalers or retailers purchasing that crab.

Summary:

The recommended rules strengthen the regulatory framework for traceability in Oregon, and meet ODA needs for allowing evisceration in lieu of harvest closures. Having this framework in place allows the agencies to make management decisions quickly (i.e., same day test results are available), ensures industry can respond to management decisions with equal rapidity, and protects public health while minimizing fishery disruptions and economic impacts.

OPTIONS	1. Adopt staff recommendations on records keeping requirements as described in Supplemental Attachment 3 (rule language), and in Supplemental Attachment 8 (Harvest Areas). 2. Make modifications to staff recommendations. 3. Status quo.
STAFF RECOMMENDATION	Options 1

DRAFT MOTION	I move to adopt the staff recommendations for modification of Dungeness crab records keeping requirement as described in option 1.
EFFECTIVE DATE	Upon filing