Proposal Subject: Addition to the Requirements for the Authority During a Suspected Oyster Related Outbreak of *Norovirus*

Specific NSSP Guide Reference: NSSP Guide Section II. Model Ordinance
Chapter II Risk Assessment and Risk Management
@.01 Outbreaks of Shellfish-Related Illness

Text of Proposal/ Requested Action

A. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one or more persons in the case of paralytic shellfish poisoning [PSP]) the Authority shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing:

(1) Each consumer's food history;
(2) Shellfish handling practices by the consumer and/or retailer;
(3) Whether the disease has the potential or is known to be transmitted by shellfish; and
(4) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent.

NOTE: For additional guidance refer to the International Association of Milk, Food, and Environmental Sanitarians' *Procedures to Investigate Food Borne Illness*.

B. When the Authority has determined an epidemiological association between an illness outbreak and shellfish consumption, the Authority shall conduct an investigation of the illness outbreak within 24 hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling. **In the case of a suspected *Norovirus* outbreak, the investigation shall begin when an epidemiological association between illnesses and the consumption of shellfish is confirmed through sampling; or, if an epidemiological association is determined by linking illnesses from more than one location with the consumption of shellfish.**

Public Health Significance: The basis for this addition is to allow the authority time to determine if the suspected oyster-related *Norovirus* outbreak is due to growing area problems or problems associated with the location where the oysters were served. Due to the nature of *Norovirus*, it would be expected that if the suspected outbreak were growing area related, illnesses would be seen at more than one location. With the known prevalence of *Norovirus* throughout society and the ease with which it can be spread by human to human and human to food contact, it is difficult to determine the actual cause within 24 hours when faced with illness reported from a single location.

The Centers for Disease Control and Prevention (CDC) estimates that *Norovirus* causes 23 million cases of acute gastroenteritis annually, making *Norovirus* the leading cause of gastroenteritis in the United States (CDC, 2006; Fankhauser, et al., 2002, Mead, et al., 1999).

Of viruses, only the common cold is reported more often than viral gastroenteritis (***Norovirus***) (Benson & Merano, 1998).

According to the CDC:

Food and drinks can very easily become contaminated with *Norovirus* because the virus is so small and because it probably takes fewer than 100 *Norovirus* particles to make a person sick. Food can be contaminated either by direct contact with contaminated hands or work surfaces that are contaminated with stool or vomit, or by tiny droplets from nearby vomit that can travel through air to land on food. Although the virus cannot multiply outside of human bodies, once on food or in water, it can cause illness.

People working with food who are sick with *Norovirus* gastroenteritis are a particular risk to others, because they handle the food and drink many other people will consume. Since the virus is so small, a sick food handler can easily – without meaning to – contaminate the food he or she is handling. Many of those eating the contaminated food may become ill, causing an outbreak.

Outbreaks of *Norovirus* gastroenteritis have taken place in restaurants, cruise ships, nursing homes, hospitals, schools, banquet halls, summer camps, and family dinners – in other words, places where often people have consumed water and/or food prepared or handled by others. It is estimated that as many as half of all food-related outbreaks of illness may be caused by *Norovirus*. In many of these cases, sick food handlers were thought to be implicated.

Cost Information (if available): Not Available.

Action by 2009 Task Force II: Recommended adoption of Proposal 09-205 as amended.

B. When the Authority has determined an epidemiological association between an illness outbreak and shellfish consumption, the Authority shall conduct an investigation of the illness outbreak within 24 hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling. ~~In the case of a suspected N*orovirus* outbreak, the investigation shall begin when an epidemiological association between illnesses and the consumption of shellfish is confirmed through sampling; or, if an epidemiological association is determined by linking illnesses from more than one location with the consumption of shellfish.~~ In the case of a suspected *Norovirus* outbreak as defined in A. above, a shellfish harvest area will be considered to pose a risk to human health that is sufficient to warrant public health action when either of the two following criteria is met:

~~(4)~~1. The outbreak occurs at one location; PCR-confirmed *Norovirus* is found in at least one person with symptoms compatible with *Norovirus* illness; food histories of ill persons include consumption of the shellfish during the proper time frame; shellfish eaten were harvested from the same harvest area; and either;
   a. an epidemiologic association is found between illness and consumption of shellfish and there is no indication of contamination by food handlers; or
   b. *Norovirus* of the same genotype is found in both the shellfish and at least one person;
2. The outbreak occurs at more than one location; PCR-confirmed *Norovirus* is found from at least one person from each location who exhibits medical symptoms that are consistent with *Norovirus* illness; and the ill persons share

a common food history of eating shellfish that were harvested from the same harvest area.

Action by 2009 General Assembly

Adopted recommendation of 2009 Task Force II on Proposal 09-205.

Action by USFDA 02/16/2010

FDA does not concur with action by the Conference to adopt Proposal 09-205. Currently the Model Ordinance requires investigation of an illness outbreak within 24 hours and, based on that investigation, specific actions are to be taken to protect public health. Proposal 09-205 adds more stringent requirements for determining when "*a shellfish harvest area will be considered to pose a risk to public health that is sufficient to warrant public health action*" when Norovirus is the suspected agent. This approach is contrary to good public health practice and the manner in which food borne outbreaks implicating molluscan shellfish have been addressed under the NSSP in the past. In accordance with Proposal 09-205, outbreaks involving Norovirus, the human fecal pathogen most often associated with shellfish outbreaks, would require PCR confirmation of clinical samples before an association is officially made and further action, in accordance with Model Ordinance Chapter II, is taken to prevent additional illnesses. When an illness outbreak occurs and an association with shellfish consumption has officially been determined by the state epidemiologist(s), it is incumbent upon health officials and the industry to act promptly and not delay prudent public health measures until clinical confirmation. This very concept was previously debated at length by the ISSC and the consensus of the voting delegates was to require immediate action based on epidemiological association, not etiologic confirmation.

FDA recommends that this Proposal be referred back to the Conference for further deliberation by an appropriately appointed committee. FDA further recommends that such committee include among its members epidemiologists from ISSC member states and FDA.

Action by ISSC Executive Board March 2010

Referred Proposal 09-205 to an appropriate committee as determined by the Board Chairman.