

**ISSC 2019
Committee Report**

Committee Name : Illness Notification
Chairperson: Kim Stryker
Date of Meeting: September 19, 2019

Committee Members Present:

<input checked="" type="checkbox"/> Kim Stryker (Chairperson)	<input checked="" type="checkbox"/> Eric Hickey	<input checked="" type="checkbox"/> Danielle Schools	<input checked="" type="checkbox"/> Kris Phelps (FDA Delegate)
<input type="checkbox"/> Margaret Pilaro	<input checked="" type="checkbox"/> Shawn Nelson	<input checked="" type="checkbox"/> Ned Gaine	<input type="checkbox"/> Jon Bell
<input checked="" type="checkbox"/> Kim Coulbourne	<input checked="" type="checkbox"/> Kim Norgren	<input checked="" type="checkbox"/> Bill Kramer (EPA Delegate)	<input type="checkbox"/> (NOAA Delegate)
<input checked="" type="checkbox"/> Alex Manderson	<input checked="" type="checkbox"/> Ruth Posadas		

Charges

Charge 1: Proposal 17-201: Develop guidance for ensure that State Shellfish Authorities provide relevant and uniform notification information to the ISSC.

The 2017 General Assembly adopted the 2017 Task Force II recommendations to adopt changes to language dealing with notifications of illness outbreaks, recalls, and closures and to ask the Executive Board to appoint a committee to develop guidance that detailed recall and closure information sharing.

The changes made as a result of 17-201 were intended to reduce the time between an incident and notification to FDA and states that may have received recalled product. Additionally, an intended outcome of the changes was to establish an inventory of closures and recalls.

Findings/Conclusions:

The committee developed two examples of notifications that an authority may utilize and adapt.

The first is to be used when notifying its FDA Regional Shellfish Specialist and ISSC of a potential health risk associated with shellfish harvested from an implicated area that has been placed in the closed status where an investigation has indicated illnesses are NOT due to post-harvest contamination or illegal harvesting. This notification is required at Ch II@.01(C)(2). This notification, which will likely be provided fairly early in the process (i.e., after an investigation has determined cause and source, but before the extent of distribution is known), so the committee felt that further distribution of this notification to other states (by ISSC or FDA) would be premature and could cause confusion.

The second example is to be used to convey distribution information to ISSC and FDA. This notification follows the initial notification required at Ch II@.01(C)(2). In accordance with the changes made as a result of 17-201, ISSC will forward this information to states and will retain the information as part of an inventory, but WILL NOT post dealer-identifying information on its website.

Current guidance in Section IV, Chapter V (Illness Outbreaks and Recall Guidance) includes several appendices that are helpful to Authorities in documenting recall and closure events and the recommended examples are intended to supplement that existing guidance.

Recommendations:

The committee requests that the following examples be added to Section IV, Chapter V (Illness Outbreaks and Recall Guidance):

Example Notification

NOTICE OF POTENTIAL HEALTH RISK ASSOCIATED WITH AN IMPLICATED GROWING AREA (Ch II@.01(C)(2))

On **(DATE)**, **(NAME OF AUTHORITY)** determined that an epidemiological association between a **(NAME OF AGENT CAUSING OUTBREAK)** outbreak and **(SPECIES)** consumption existed and began an investigation of the outbreak to determine whether the illness was growing-area related or was the result of post-harvest contamination or mishandling. We have determined that this outbreak is growing-area related and this email serves to notify ISSC and the FDA Shellfish Specialist of these findings.

On **(DATE)**, the **(IMPLICATED HARVEST/GROWING AREA)** was closed to harvest and recall procedures consistent with the Recall Enforcement Policy at 21 CFR Part 7 are being initiated to recall all implicated **(SPECIES)** harvested from **(DATES OF HARVEST)**.

The Point of Contact for this matter is **(NAME OF KEY PERSON WITHIN AUTHORITY AND CONTACT INFORMATION)**.

Example Notification

DISTRIBUTION INFORMATION
RE: PRODUCT RECALL ASSOCIATED WITH OUTBREAK (Ch II@.01(C)(4))

On **(DATE)**, **(NAME OF AUTHORITY)** determined an epidemiological association between a **(NAME OF AGENT CAUSING OUTBREAK)** outbreak and **(SPECIES)** consumption, determined that this outbreak is growing-area related, and initiated recall procedures consistent with the Recall Enforcement Policy at 21 CFR Part 7 to recall all implicated **(SPECIES)** harvested **from (IMPLICATED HARVEST/GROWING AREA)** from **(DATES OF HARVEST)**. This email serves to provide distribution information to ISSC and FDA.

Recalled product was distributed to dealers and/or retailers in the following states: **(NAME OF EACH STATE)**. In accordance with Ch II@.01(I), we have notified each of the receiving states.

The Point of Contact for this matter is **(NAME OF KEY PERSON WITHIN AUTHORITY AND CONTACT INFORMATION)**.

Distribution information is as follows:

Shipping Dealer #1 Name & ICSSL #:								
Harvest Area	Harvest Date	Receiving Dealer, Retailer, or Food Service <i>(include ICSSL #, if known or applicable)</i>	City, State	Sale Date	Lot No. or Date Shucked	Qty Sold	Product Description	Status <i>(consumed, destroyed, returned)</i>

Shipping Dealer #2 Name & ICSSL #:								
Harvest Area	Harvest Date	Receiving Dealer, Retailer, or Food Service <i>(include ICSSL #, if known/applicable)</i>	City, State	Sale Date	Lot No. or Date Shucked	Qty Sold	Product Description	Status <i>(consumed, destroyed, returned)</i>

(include as many tables as needed, depending on number of shipping dealers involved in recall)

Attachments: