

## **HYPOTHETICAL CASE STUDY 1.2: EMERGING SAFETY ISSUES CONCERNING FDA-REGULATED PRODUCTS.**

There is an outbreak of a foodborne pathogen with 50 people ill in five states, many of whom have been hospitalized. State and local epidemiologists and CDC are investigating the human illnesses.

CDC alerts FDA that the epidemiological investigation conducted shows a link to fresh fruit salad consumed at various restaurants. Although recipes varied at the restaurants, three fruits were common to all of the salads consumed. Preliminary data suggests that cantaloupe is the cause. FDA contacts industry and they provide general distribution information indicating that cantaloupe is typically distributed nationwide. FDA has initiated a traceback of cantaloupe.

Produce trade associations have asked FDA and CDC for the information the agency has gathered about the source of the outbreak. These associations tell the agency that they can assist with the investigation if the agency provides them with more information about the outbreak.

### **Issues for Discussion:**

(Note: Because the purpose of the discussion is to elucidate the policy considerations that should be weighed in deciding whether changes to current practice, laws, or regulations are warranted, the issues should be discussed without regard for current practice, laws, or regulations.)

1. Should FDA advise the public about this outbreak? What are the factors that should be considered in deciding whether to do so? Is there anything that should not be communicated?
2. If the agency communicates to the public about the outbreak, what message should be communicated to consumers? What geographic area should be covered?
3. Should FDA communicate to members of industry whose products may be implicated in the outbreak? If so, what is the message?
4. How should FDA work with industry to address the outbreak?
5. Another entity, based on its own analyses, believes the outbreak is due to another fruit and releases a public statement to that effect. How should the agency respond?

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Further epidemiological data identifies that the cantaloupe was not the source of the illness; additional epidemiological data linked honeydew melons as the vehicle causing the outbreak.

### **Issues for Discussion:**

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1. How should FDA communicate to the public about the new information it has learned about the source of the outbreak? What should the agency say?
2. If FDA has already communicated to the public that cantaloupes are a likely source of the illness, what should the agency say now about consuming cantaloupes?
3. FDA receives the information described above on Friday afternoon, which is not the best time to get wide media distribution of a story. Does this affect the analysis as to when the agency should communicate with the public about the outbreak?