INTERNATIONAL FRESH PRODUCE ASSOCIATION℠

Key Questions for Regulators During Outbreak Investigations

DEVELOPED BY A WORKGROUP OF THE IFPA FOOD SAFETY COUNCIL

Objective: The questions below may be helpful as a company that has been contacted by a regulator seeks to better understand a situation. These questions can be considered if a regulator/ investigator approaches a firm with a request for records or other suggestion of involvement in an outbreak.

This document is not intended to be a recall or regulatory visit policy or guide, but, instead is supplemental material for a firm's internal programs.

BASICS & BACKGROUND

The questions below might be appropriate for the investigator who reaches out to you and/or is your primary point of contact. "You" refers to the investigator/agency you are working with.

1. **What agency do you work for? If the FDA, which division are you from?**

   a. **What is the best way for me to reach you? Does this include evenings and weekends?**

   b. **What is the contact information (phone & email) for you and your supervisor?**

   c. **Under what authority is this visit being conducted?**
   (i. Produce Safety Rule, ii. Preventive Control Rule, iii. General Authority of Food, Drug, and Cosmetics Act, iv. Other, such as state authority)

   d. **Who can I contact for additional information about what led you to contact us?**
   (Epi, cases, traceback etc.)

2. If this is a state regulator, which state agency is leading the outbreak investigation?

3. What is the situation/issue that led you to contact me?

   a. Are you in the stage of data gathering vs. focusing in?

4. Is this part of an active outbreak investigation? Or in response to a complaint(s)?

5. Have any product samples been collected?

   a. Any positives?

   b. If no samples have been collected, are you planning on collecting any?

      i. If so, from where will they be collected?

      ii. Will we be notified when samples have been collected and provided any lot/code information?

      iii. If we have questions about the samples, who do we contact?

6. **What is the timeline for analysis, and when would we receive negative, "cannot rule out", and positive results?**

7. **When can I expect to hear from you again? If not you, are there others from your organization who I may be in contact with? (If yes, please provide names and contact information.)**

Note: Put any questions you ask in writing even if you ask them verbally. Second, request them to put anything they ask for in writing even if they ask verbally. If they do not provide it in writing, write it for them to confirm the information request.

TRACEBACK REQUESTS

1. **Is there a format in which you would like to receive traceback information?**

NOTE: If your company is not able to adapt the way that traceability information is shared, you may not want to ask for a format/template that you can't fill out.

2. **What's the time frame in which a response is needed? If 24 hours is not feasible, can we request a longer time frame (e.g., 48 hrs. or another time frame)**

3. **If you have requested information that we do not have in our immediate control, would you prefer for us to get it from 3rd parties to provide to you, or just refer you to the third parties to obtain it directly?**

NOTE: They may ask for you to get information from a 3rd party that you would not have authority or access to. Point this out.

INVESTIGATION DETAILS

Note: The following questions might not be able to be answered by your main regulatory point of contact and might need to be forwarded to others. The point of contact usually serves as a conduit for this information.

1. Are you in the stage of data gathering vs. focusing in?

a. How long have you been working on/investigating this situation?

2. Is the outbreak considered ongoing or has it ended?

a. What is the range of illness onset dates?

b. If ongoing, what is the full range of illness dates for the outbreak strain, not just the illness cases associated with the specific traceback request for my firm?

c. We would like a copy of the CDC line data. We recognize that it would need to be redacted.

3. What information leads the agency to think it is product X? Are you investigating any other products in association with this event?

4. **What traceback information led you to my company?**

   a. **Can I get copies of the POs, BOLs, invoices, etc., that you received from others that relate to my company?**

5. **Which agencies are working on this? Who is gathering all data and summarizing/ evaluating it, and what has been collected thus far?**

   a. **How are the FDA interpreting state info and vice versa?**

   b. **How is CDC involved?**

   c. **If on a conference call, ask who is on the call including their names and (the agency they work for.**

6. **How many individuals and in which states are affected? Are any travel-associated cases? Can we get a copy of the case list showing illness cases by illness onset date and location?**

7. **If currently available, can you share the full lab results with us, including any agency analysis or interpretation of the results and chain of custody?**

8. Has whole genome sequencing been done, and does it match any historical environmental or food isolate sequences in the NCBI database?

a. **Within the number of cases associated with the outbreak, can you tell us the number of SNP/allele differences of the outbreak strain? Are there any illnesses linked to this outbreak where the sequence is an outlier? Can we get a copy of the database screenshot showing SNP proximity?**

b. **Can I get information on the sequence to look it up in the database?**
(When you get the answers, ask them if all the WGS data was given, all alleles, etc.)

9. How did the epidemiologic investigation lead you to my company's product?

a. **How many people were interviewed by public health officials, and how many reported eating this product?**

i. **What is the "expected" level of consumption of this product in the general population?**

ii. **Can you describe the illness case definition? For example, does it include culture confirmation and non-culture confirmed? If it includes non-culture confirmed, why?**

iii. **Was a case control study conducted and does it consider risk difference as opposed to relative risk?**

10. How many traceback legs are being investigated?

    a. How many other companies are being contacted as part of this investigation?

11. How many unrelated cases are part of the traceback leg that led you to my company?

12. Are there any cases that have been dismissed or not included in the summary of illnesses? If yes, why?

13. Do you have a traceback diagram that you can provide to me? If not, when will one be available to share with me?

14. Do you have any products (including from consumers, retailers, distributors, or growers), facilities, or environments that have been sampled? When are results expected? Can we be informed of the results when they are available?

15. **Will you be making any public announcements or press releases soon that our company should know about (whether our company is named or not)?**

    a. **If our company is to be named, will we have a chance to review it before its release?**

    b. **If our company is not named, will you notify us that a press release or alert will be issued?**

16. **Is it possible to "see" how FDA is reviewing the data during an investigation and possibly have discussions along the process to address questions directly with those who will review the information?**

    NOTE: Sometimes in the back and forth, the questions reveal an opportunity to describe some important details about the industry process, especially regarding product ownership, harvest companies, growing companies, harvest equipment, common handling steps, etc. A dialogue in person could make the process more efficient.

17. **When can I expect to hear from you again? Can we schedule a touch-base for (depends on how rapidly things are going: later today, tomorrow, 3 days, next week etc.)**

    a. **If not you, are there others from your organization who I may be in contact with? (If yes, please provide names and contact info)**

18. **As a broader question—are there some examples of specific things in traceback data that are/are not helpful that the industry has provided historically?**

ADDITIONAL NOTES/QUESTIONS

FOR QUESTIONS AND INQUIRIES, CONTACT:

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