

Remaining Questions from Root Cause Analysis: The What and Why

September 7, 2023

Below are the questions from the Q&A session that were not answered due to time. Identifying information has been removed and grammatical or spelling errors corrected (expressed in brackets), but the content of each question has not been changed from how it was submitted.

Corrective actions

1. [T]hinking of the 5 whys and corrective action—what would've been the corrective action with the peaches in the poultry/dairy scenario? Moving fields and replanting is... [a lot]!

Corrective actions are distinct from RCAs. The root cause analysis tells you why something happened. What can or can't be done about it is a different step. Combining them into one step is a bad idea and gives people the sense that, if they can't do anything about it, they might as well turn a blind eye and just not do an RCA.

-JM

2. What kind of corrective action is appropriate for fugitive dust?

There are things you can do about dust – there has been Center for Produce Safety research on ways to physically interrupt transmission (preferred) as well as mitigations if product has been in contact with dust (backup plan).

-JM

Documentation

1. For FDA, when sharing RCA due to any investigation, does this become a public record?

FDA has a process to redact commercial confidential information, for example in case they receive a Freedom of Information Act (FOIA) request. Companies should identify which information they deem trade secret or confidential to aid FDA's review and redaction process.

-JM