



How to Keep your Product out of the Papers and your People out of Prison

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Q: We are now seeing large recalls on Ready To Cook products. What are your thoughts on why we are now seeing these? Where does the responsibility of the consumer to fully cook these products?

A: Although many products are ready-to-cook, FDA will look at the foreseeable uses of the products to make a determination whether they can carry pathogens of concern. So, although we have traditionally considered raw cookie dough or frozen vegetables as ready to cook, FDA is treating them as ready-to-eat because some consumers eat cookie dough raw or juice with frozen vegetables, and thus FDA will expect them to be recalled if contaminated. Yes, consumers shoulder responsibility, but if there is any potential use of the product by consumers that does not include cooking, then FDA will react harshly.

Q: We process raw sunflower seeds. We sell them for further processing. Do we need to swab our facility and what are our risks for liability regarding pathogens if someone eats our product raw and gets sick?

A: As a general matter, yes, under FSMA you will be required to swab your facility and control your environment for pathogens, unless you provide formal notice your customer that the products are raw and untreated, and then ask for and receive from your customer an acknowledgement that it is responsible to control for contaminants, and that it will apply an intervention designed to kill any pathogens that may be present.

Q: At the time an FDA Investigator comes into a facility, shouldn't they read Miranda Rights to company officials?

A: That is a great question. And, the answer likely varies widely based upon the circumstances. Technically, because a criminal investigation is only initiated in the event an outbreak occurs, in the absence of human illness there will typically be no criminal investigation and thus no need to read rights. With that said, if an investigation is initiated, and incriminating statements are solicited without any Miranda rights, then that may be a defense in some circumstances to the admissibility of the evidence obtained.

Q: Phenomenal presentation. What is the risk for a current manager when they reach back before their tenure with a company? Can you be liable for "Past Sins"?

A: Thank you!! Yes, the risk would be the same for "past sins." If an outbreak was linked to an employee's former company, and DOJ conducted an investigation, the former employee could potentially shoulder an equal amount of criminal exposure. With that said, depending upon the conduct, under those circumstances DOJ might be more likely to try to negotiate a separate deal with the former employee to obtain additional evidence against the current company management.

Q: Would you suggest that a company start immediately to evaluate preventive controls and be proactive in implementing changes?

A: Yes, I would start IMMEDIATELY. FDA is becoming extremely aggressive, and the sooner you can begin putting new controls and programs in place, the better protected you will be!!

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