

# Food Safety News

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## The food police are coming — liability and DOJ enforcement

By Tom Stenzel | September 29, 2016

Opinion

The notion that “the food police are coming” motivated attendees at the United Fresh Produce Association’s Washington Conference earlier this month to attend a session featuring Jeffrey Steger, assistant director in the Consumer Protection Branch of the U.S. Department of Justice, and prominent attorney Doug Fellman, a partner, at Hogan Lovells US LLP.

There have been many visible examples of the DOJ’s evolving approach to criminal investigations and prosecution enforcing laws under the Food, Drugs and Cosmetic Act (FD&C). The Act provides for a concept of “strict liability,” meaning that corporate executives can be held criminally responsible for a case of foodborne illness, without regard to negligence or intent. Due diligence doesn’t matter. If illness is linked to a product, the CEO, quality assurance directors, or other corporate executives can be on the hook.

While DOJ very rarely enforced such actions in years past, a new commitment to prosecuting individuals in the case of foodborne outbreaks has left members of the food industry extremely nervous.

This is especially frightening for produce industry executives because fresh produce lacks a kill step. Much of it is grown outside. No matter what steps a company takes to reduce risk, there is no 100 percent way to guarantee zero chance of contamination. Even the Food and Drug Administration has been clear that fully implementing the Produce Safety Rule of the Food Safety Modernization Act (FSMA) can help reduce — but not eliminate — the risk of microbial contamination of fresh fruits and vegetables. And now, the use of whole genome sequencing means that regulators will increasingly be able to link cases of human illness to a particular food or specific facility.

With the ability to link individual cases of illness to specific companies, company executives are at risk for prosecution, but at the same time, consumers may be misled to believe that produce-related illness are increasing and can be blamed on upstanding companies doing their best to prevent contamination. This runs directly



counter to public health advice to eat a diet rich in fresh produce because of the health benefits. The risk of contamination — regardless of how low — along with the increasing risk of criminal prosecution, has caused enough concern that the United Fresh session with the attorneys from opposite perspectives drew a packed crowd.

According to the presenters, there are things fresh produce operators can do to help or hurt themselves during an investigation. They offered the following suggestions:

- Take any inspection or government inquiry seriously. What may sound like an innocent question or request for documents can lead to a personal criminal prosecution down the road. Make sure your senior management team is prepared.
- Be nice: This seems simple, but when FDA, or worse, DOJ shows up, anxiety increases and there may be a natural tendency to get defensive. While you may not want to treat an investigator like an old buddy, it's important to always remain courteous and professional.
- Tell the truth: Hedging the truth never does anyone any good. The documentation required by various FSMA-related regulations means that there will be a lot of evidence to sift through. Consult with an attorney so that you understand the legal bounds of the requests, but always be honest and straightforward.
- Long before an investigation, make sure that you demonstrate a commitment to food safety. How do you manage the company's budget — do you invest in employee food safety training? Have you made investments in infrastructure where necessary? If the company has had prior food safety issues, what did you do about it — not just what the plant manager or QA director did, but what did the CEO and senior executives do? Your past actions paint a picture of the food safety culture within your company, and it is company leadership who set that culture.

People — and prosecutors — have little tolerance for bad people when bad things happen. But the risks to good people who are doing their best have never been higher. That calls for the CEO to demonstrate the highest commitment to food safety, and be prepared in the unlikely event that an illness is connected to your company's product.

We all recognize that sometimes bad things happen to good people. Do all you can to be one of the good people, knowing that, at the end of the day, the decision to prosecute is up to the DOJ.

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