



For many corporate executives in the food industry, the U.S. Department of Justice (DOJ's) [increasing focus on prosecuting "responsible corporate officers" under the criminal misdemeanor provision of the Food, Drug, and Cosmetic Act \(FDCA\)](#) has warranted rapt attention, particularly in light of criminal investigations arising from nationwide contamination outbreaks at companies like [ConAgra](#) and [Blue Bell Creameries](#).

Recent remarks by attorneys from the DOJ's Consumer Protection Branch to industry audiences have underscored the government's expectation that corporate food executives implement a "culture" of food-safety compliance in their companies, and provide timely, truthful responses to both formal and informal inquiries made by regulators at the Food & Drug Administration (FDA). In December 2016, Principal Deputy Assistant Attorney General Benjamin Mizer [addressed the Food and Drug Law Institute's Enforcement, Litigation and](#)

[Compliance Conference](#), reiterating the DOJ's ability and determination to bring criminal charges in cases where companies sell contaminated products to consumers. Separately, in remarks to the United Fresh Produce Association in September 2016, DOJ Assistant Director Jeffrey Steger provided a regulator's viewpoint regarding several concrete ways that food companies can demonstrate their commitment to safety compliance.

**Financial Investment in Food-Safety Compliance** Steger suggested that executives who have implemented a culture of food-safety compliance at their companies have demonstrated their commitment to food safety and would therefore be much less likely to face DOJ scrutiny should a product recall or contamination outbreak occur. To foster this food-safety culture, Steger recommended that executives scrutinize whether they are adequately allocating budget to food-safety programs, and whether they are using that budget, among other resources, to require regular food-safety trainings at all levels, and to invest in the equipment, tools, and technology necessary to carry out food-safety programs. **Sweat the Small Stuff** Steger also noted that less severe food-safety issues, which do not necessarily invite the FDA's scrutiny, provide company executives the opportunity to create a record that will demonstrate to regulators their commitment to food-safety culture. Among other things, executives should keep themselves apprised of food-safety problems as they arise and be an active participant in the remediation. That way, should the FDA later review the companies' food-safety record, regulators can observe the food-safety culture in action.

**The Value of Cooperation** Steger also observed that the tone of a company's relationship with the FDA can go a long way in influencing whether scrutiny will attach to executives in the aftermath of recalls and outbreaks. To foster this relationship, Steger recommended that prompt, respectful and truthful responses always be provided to any inquiries from the FDA or DOJ—regardless of whether it is a routine inspection or a subpoena for records. According to Steger, a prompt and complete response increases the likelihood that the FDA will view the executives and their companies as partners in a cooperative effort to make food safer, and not as impediments to that goal in need of regulatory correction or criminal prosecution.

**Strict Liability Offense** Mizer's remarks emphasized the DOJ's ability to bring both misdemeanor and felony charges under the FDCA in cases involving the introduction of adulterated products into interstate commerce. This includes the highly unusual strict liability offense standard, which does not require the government to prove intent to secure a misdemeanor conviction. As explained by Mizer, "claims of 'I told someone else to take care of that' are not a shield" for responsible corporate executives seeking to avoid potential criminal responsibility. And, as further explained by Mizer, if the DOJ finds clear intent to defraud or mislead on the part of the corporate executive, it will seek to bring felony charges under the FDCA.

**Conclusion** Mizer's remarks acknowledged that those in the industry were likely wondering whether, and how, the DOJ's enforcement priorities might shift under the new administration. He indicated that the DOJ's approach to these cases was expected "to continue well into the future." Meanwhile, there is potential for the DOJ's approach to be tempered by the U.S. Supreme Court, should a pending petition for writ of certiorari filed by [two convicted executives from Quality Egg LLC](#) be granted review. The two executives in the Quality Egg case were both sentenced to three month prison terms following misdemeanor convictions related to a national salmonella outbreak that sickened over 55,000 consumers. It should be noted, however, that the Supreme Court has twice affirmed the ability to hold corporate officers or employees criminally liable for a corporate violation of the FDCA if the defendant failed to use his or her responsibility and authority within the corporation to prevent or to promptly correct the violation (regardless of whether the defendant had knowledge of, or personal participation in, the act). As a result, to prevail, the Quality Egg executives must convince the Supreme Court to review and revise its previous two decisions in [Park](#) and [Dotterweich](#).

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