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insights

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Protecting food industry whistleblowers: FDA, OSHA team up under FSMA

In 2011, when the Food Safety Modernization Act was passed, it sought to revamp food safety in the United States. Since then, the Food and Drug Administration (FDA) has been hard at work passing regulations to implement the FSMA's statutory requirements. To date, these have included revamping the current Good Manufacturing Practices (cGMPs), Hazard Analysis and Risk-Based Preventive Controls (HARPC) for human and animal food, and creating new rules for the Sanitary Transport of Food, and Produce Safety, while also establishing the Foreign Suppler Verification Program and Verified Quality Importer Program. These have been entirely FDA-led and controlled regulatory programs. In April 2016, however, the Occupational Safety and Health Administration (OSHA) finalized its Rule implementing the FSMA's new whistleblower safe harbor provision.

Whistleblower protection provisions are not new to OSHA, which oversees several such provisions as they relate to other administrative agencies. Including the FDA, OSHA's Whistleblower Protection Program enforces the whistleblower provisions of more than 20 whistleblower statutes protecting employees who report violations of various workplace safety and health, airline, commercial motor carrier, consumer product, environmental, financial reform, food safety, health insurance reform, motor vehicle safety, nuclear, pipeline, public transportation agency, railroad, maritime, and securities laws. Rights afforded by these whistleblower protection laws include, but are not limited to, worker participation in safety and health activities, reporting a work-related injury, illness or fatality, or reporting a violation of the statutes therein.

The basis for the new Rule is found in Section 402 of FSMA, codified at 21 U.S.C. § 399d, and applies to any "entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food." 21 U.S.C. § 399d(a).

The New Rule

On April 18, 2016, OSHA published the Final Rule establishing "Procedures for Handling Retaliation Complaints Under Section 402 of the Food Safety Modernization Act." The purpose of this new Rule, codified in 29 C.F.R. § 1987, is to provide protection for an employee from retaliation because the employee has engaged in "protected activity" pertaining to a violation or alleged violation of the Food, Drug and Cosmetics Act (FDCA). These protected activities, while not explicitly defined by the new Rule, include:

- Provided, caused to be provided, is about to provide, or cause to be provided to the employer, the federal government, or another state actor, information relating to any violation, or any act or omission the employee reasonably believes to be a violation of the FDCA, or any rule, regulation, standard or ban under the FDCA;
- Testifying or about to testify in a proceeding concerning an FDCA violation;
- Assisted or participated or is about to assist or participate in such a proceeding;
- Objected to or refused to participate in any activity, policy, practice, or assigned task that the employee (or other such person) reasonably believed to be in violation of the FDCA or any rule, order, regulation, standard or ban under the FDCA.

(See 29 C.F.R. § 1987(b); also 21 U.S.C. § 399d(a)(1)-(4).) This means that an employer can take no actions against an employee who participates in identifying a company's participation in activities that the employee "reasonably believes" violate the FDCA. In the Final Rule, OSHA describes the "reasonable belief" standard applied by the new regulations, and explains it is a standard it has successfully applied in other areas, including whistleblower protections under the Sarbanes-Oxley Act. According to OSHA's comments on the new Rule, in order to fulfill this standard, the employee must have a "subjective, good faith belief and an objectively reasonable

belief" that his employer's conduct violated the FDCA, or any rule, order, regulation, standard or ban under the FDCA. (Citing to *Sylvester v. Parrexel Int'l LLC*, ARB No. 07-123, 2011 WL 2165854, at *11-12 (ARB May 25, 2011), discussing the reasonable belief standard under Sarbanes-Oxley Act whistleblower protections.) It is important to note that this standard is based on the "knowledge available to a reasonable person in the same factual circumstances with the same training and experience" as the employee at issue. *Id.* What this means is that the employee does not have to be correct. Instead, actions taken by an employee that are based on a reasonable – even if mistaken – belief that a violation of the law has occurred are protected.

Implications for employers

For employers in the food industry, which, under FSMA, and later HARPC and cGMP regulations, includes an increasing number of entities, this means that if an employee takes actions as described above regarding company conduct as it relates to food safety and compliance with FDA regulations, the company may not retaliate against the employee for his actions. Retaliation may come in many forms, but under the new regulations, the company may not:

> *discharge or otherwise retaliate against, including, but not limited to, intimidating, threatening, restraining, coercing, blacklisting or disciplining, any employee with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee, whether at the employee's initiative or in the ordinary course of the employee's duties (or any person acting pursuant to a request of the employee), has engaged in any of the activities specified in paragraphs (b)(1) through (4) of this section.*

(29 C.F.R. §1987.02(a).) If an employee participates in one of the protected activities described above and his employer undertakes one of the retaliatory actions in §1987.02(a), the employee is presented with the opportunity to file a Retaliation Complaint with OSHA within 180 days of the retaliatory employer action. This complaint is not like a legal complaint before a court, and does not have to meet federal pleading requirements. Instead, the complaint serves as a method of alerting OSHA to the existence of the alleged retaliation and the employee's desire that OSHA investigate the matter. Once received, OSHA will alert the employer of the receipt of the complaint.

If the complaint "alleges the existence of facts and evidence to make a prima facie showing" that retaliation for protected activities occurred, OSHA will initiate an investigation of the matter. Such an investigation must include facts which focus on whether:

- The employee engaged in protected activity;
- The employer knew or suspected that the employee engaged in the protected activity;
- The employer undertook an adverse action against the employee; and
- The circumstances were sufficient to raise the inference that the protected activity was a contributing factor for the adverse action.

Copies of all materials can be provided to all parties. The employer is allowed the opportunity to show that the alleged retaliatory actions were not related to the protected activities (and the protected activity did not contribute to the alleged retaliatory actions). If, during the course of the investigation, OSHA discovers, or the employer shows, via clear and convincing evidence that the employer would have taken the same actions in the absence of the protected activities, the complaint must be dismissed under 21 C.F.R. § 1987.104(e)(4). This is a much higher standard than that which is applied to the employee and places the burden of proof squarely on the shoulders of the employer.

Once the investigation has been completed, OSHA will release a report detailing its findings and issuing preliminary orders to award damages where appropriate. If the complaint was found to have been frivolous, OSHA can award up to $1,000 to the employer for attorney's fees. OSHA and the Assistant Secretary assigned to the matter may award the employee a wide range of relief. This includes reinstatement to the employee's position, affirmative actions to abate the violation, back pay with interest and compensatory damages. OSHA may also award to the employee the same pay and benefits that he would have received prior to termination from his job, but not actually require that he go back to work.

Either party may file objections to this report and its orders within 60 days of its issuance and request a hearing before an administrative law judge (ALJ), wherein the matter will be reviewed de novo. The ALJ's decision may also be appealed to an administrative review board. However, in both cases the ALJ and ARB have a limited time to deal with the matter, and if that time elapses, the matter may be brought before an appropriate U.S. District Court.

Ultimately, OSHA views 21 U.S.C. § 399d as analogous to similar whistleblower legislation and regulation used by many other administrative agencies. While the companies subject to the new rule might have some exposure to these protections in other circumstances, this is the first time that an employee receives such protection for issues arising out of food safety. This protection is one more way that the FDA, using FSMA, is strengthening the legal protections for the U.S. food supply.

At Thompson Coburn, our life sciences and food and agribusiness practices work together to represent food, food additive and dietary supplement clients to help them understand all of the new regulations affecting the day-to-day operations of the food industry. We have extensive experience in counseling our food clients not only on regulatory compliance and the development of the now-required HARPC plans, but on risks and liabilities that are now a reality under these new regulations. If you have any questions about the issues raised in this article, please feel free to contact us.

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