By Eric F. Greenberg, Attorney-at-law

Noodling on How to Arrange Regulators

Today, let's discuss regulators and how to organize them. These days, sometimes it seems that all you ever hear or read about regulatory officials is that they are evil people who are knowingly conspiring together to ruin your life or your business, for what reason no one ever seems to specify. The theory is not merely that the effects of their actions burden you, but that that's their specific goal.

This is, to use the formal legal term, crap. The regulators that I have encountered are generally people of good faith doing their best to implement the programs and instructions that Congress or state legislatures give them, sometimes under the duress of inadequate or uncertain budgets. They are often too slow to act, and sometimes act in ways that are irrational or needlessly burdensome to business. But they are no more or no less likely than people in private companies to be lazy, incompetent, or the least bit conspiratorial.

Among those who think about regulators with a more realistic perspective, one current topic is whether the job of food safety should be given to a single federal official leading a new federal agency.

As you may know, the job of overseeing food safety in the U.S. is, right now, divided between the Food and Drug Administration, which regulates about 80% of our food supply, including packaging in contact with foods, and the U.S. Department of Agriculture, which regulates most of the rest via its oversight of meat and poultry businesses. Also, depending on how you count, there are a dozen or more other federal agencies with a hand in food safety, including for example the Environmental Protection Agency via its regulation of pesticides and water purity, and the Centers for Disease Control and Prevention, which investigates foodborne illness outbreaks.

Legislators regularly float suggested remedies to this odd dispersion of powers. Now there's one prominent new proposal to take FDA's food safety responsibilities and give them to a newly created agency, rather than, as has often been suggested in the past, combining multiple agencies' powers into one. A common prediction is that the bill will fail, but there's widespread support for revisiting FDA's structure and priorities, so you can expect discussions like these to continue even if the bill doesn't get too far.

The new bill's target is FDA specifically, so to that extent, food safety regulation would appear to be intended to remain a divided affair (although the bill contains a cryptic catch-all provision that would let the President transfer "other offices, services, or agencies" to the new agency, so who knows?) The proposed Food Safety Administration Act of 2022 would make a new agency out of FDA's current food safety powers and give it a new name—Food Safety Administration—and new head—Administrator of Food Safety—who would be chosen specifically for their expertise in food safety. The new bill proposes changing the current FDA's name to the Federal Drug Administration and change its head's name from Commissioner of Food and Drugs to Commissioner of Drugs.

U.S. Senator Dick Durbin (D-IL) has been an advocate of one or another version of FDA food safety reform for many years. This most recent effort, however, was especially inspired for him by the death of an Illinois woman who ate contaminated ice cream in Florida. He believes FDA's inspections of food facilities have been a big part of the problem.

He issued a statement saying in part, "The FDA is failing to uphold its most basic food safety responsibility: inspecting facilities. Over the past decade, the number of inspections it performs has fallen by nearly 60 percent." And, he notes, just 11 years ago Congress was supposed to have goosed FDA's food safety program with passage of the FDA Food Safety Modernization Act "that instructed the FDA to increase the number of inspections it performs." He lamented further that "Even when the FDA performs an inspection—and identifies a threat to public health—it doesn't take timely action."

If FDA is giving food safety short shrift, it might be because the agency is pulled in so many different directions at once, and that naturally leads to difficulties in choosing an FDA commissioner with a deep understanding of the agency's many realms. If you've ever wondered how a President is supposed to pick the head of an agency whose responsibilities include foods and also drugs and medical devices and vaccines and other biological products and cosmetics and animal foods and drugs and tobacco and radiation-emitting products, you are correctly perceiving the dilemma. After all, how often does one find a professional with experience in even two of those fields? And does one choose from academia or industry? That dilemma has most often been solved in the past by choosing commissioners with backgrounds in the medical fields, whether in industry or academia.

Two final thoughts as we watch the debate over these new ideas aimed at regulating food safety:

First, I, along with FDA, am in the habit of reminding companies of this reality essentially every day: As a packager, it's YOUR job to assure your products and processes are safe, with regulators looking over your shoulder. That won't change even if FDA gets more focused on food safety via this law change or otherwise.

Second, to those who would like to improve food safety, I also would politely suggest that they also give a thought to a different target as well. Certainly, foodborne illness outbreaks traced to packaged foods should be battled against at all times, but so should local failures to comply with the Food Code at retail restaurants, groceries, and the like, because those lapses, too, can lead to foodborne illness. **PW**

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