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HOW TO MAKE EFFECTIVE COMMENTS ON THE FDA'S NEW "FSMA" REGULATIONS

If You Want Your Opinion to Count, Think Like a Bureaucrat

As we've previously written, the most sweeping changes to food regulation in decades are underway. To implement the 2011 FDA **Food Safety Modernization Act**, (which is known by its acronym, FSMA), the FDA has proposed two major sets of regulations. The first, the **Produce Standards**, imposes a new and pervasive regulatory regime upon farms. The second, the **Preventive Controls** rule, will affect most facilities that are registered with the FDA, most notably by broadly imposing regulations comparable to the "HACCP" regulations that are currently mandatory only for seafood, juice, meat, and poultry facilities. (If you want to see the official texts of FSMA and the two regulations, follow the embedded hyperlinks above.)

These regulations are not in their final form. The FDA is actively seeking comments about the regulations, and it promises to carefully consider the comments before finalizing the rules. The FDA is doing this, in part, because it has to. In addition, at a recent public meeting, top FDA officials insisted that they genuinely want to receive comments, and that quality input will help them write a better rule. But even taking these sentiments at face value—and the FDA officials did sound sincere—not all comments are created equal. If you want your comment to be *persuasive*, and not just considered and rejected, you need to think like a bureaucrat.

We don't mean that you should surrender to the worst stereotypes of how Washington operates. Rather, to persuade the bureaucrats, you need to put yourself in their shoes. Keep in mind, first of all, that the FDA does not operate with a free hand. While it does have a lot of discretion on some issues, the FDA must always follow Congress' mandates regarding which problems should be addressed, which ones should not be, who can and cannot be regulated, and how they can be regulated. Second, within the mandate provided, the FDA has a job it wants to accomplish. It wants to make America's food supply safer. Even if

you think our food is plenty safe already, you won't get anywhere by saying so.

Third, drafting regulations is difficult work. A rule must be clear and understandable, or no one will know how to comply. It must be strong enough to accomplish its goals but not so blunt that it imposes unnecessary burdens, all the while being flexible enough to accommodate varying circumstances. And every decision made while crafting a rule must be justified. If not, a court may strike down the rule, refuse to enforce it, or make the FDA start over.

So, here are a few simple tips for how your comments can have an impact on the final shape of the rules.

DETAILS MATTER

You could tell the FDA rule-makers that they shouldn't impose requirements that cost a lot of money but do nothing to improve safety. But they already know that. In fact, they think their proposed rules already reflect this principle. If you disagree, you need to show them where they have fallen short. Let them know *which* requirement is unnecessary or unduly costly. If a particular part of a rule is ambiguous, tell the FDA exactly which provision troubles you, why it has more than one meaning or reflects a misunderstanding of how your business operates, and how the rule can be reworded.

MASTERING THE DETAILS MATTERS

The two new proposed FSMA rules, taken together with their preambles and appendices, cover hundreds of pages in the Federal Register with dense prose and technical jargon. Who reads all this stuff? Well, the people you're talking to did. In fact, they wrote it.

You don't need to read every word to provide effective comments. But you will need to find the portion of the rule that causes you concern. And the preamble is where you can find the FDA's explanation for why they wrote the rules the way they did, which regulations they viewed as compelled by Congress and which reflect their judgment, and what choices and trade-offs were part of the rule-making process. It's not very effective to simply ask the FDA to reach a conclusion that the rule-makers already rejected. It is much more effective to explain why the conclusion doesn't fit the facts, and to do that you need to first understand what they had in mind.

FACTS MATTER

If you want to grab the rule-makers' attention, tell them something they don't know.

The regulators are acutely aware that the "real world" is larger and more complex than the view from their desks. This is doubly true regarding farm operations, since to date the FDA has far less experience with farms than with other portions of the food supply chain. The FDA officials said as much at the recent public meeting and emphasized that they view public comments as an important learning tool. And, they have emphasized repeatedly that they want the final rule to be "risk-based" and "flexible." This means that although the FDA will make businesses spend real money to prevent food-borne illness, the FDA does not want to burden operations that do not present such risks. So, one of the best ways to convince the regulators is to give them the information that they currently lack, so that they understand why a particular proposal does not make sense in a real-world situation.

EVIDENCE MATTERS

At the public meeting and elsewhere, FDA officials repeatedly invoked the mantra that their rules are "science-based." To shake their faith in the scientific nature of the proposed regulations, confront the FDA with evidence. This evidence can come in many forms: scientific studies regarding the transmission of pathogens, industry studies regarding best practices, actual costs incurred for a task that the FDA wants to see repeated across all facilities, etc. The assertions in your comments may point the FDA toward issues that should be further explored, but assertions backed by studies or data are much harder to ignore.

The comment period on both rules was recently extended; comments are now due by September 16, 2013. To submit your comments, go to **www.regulations.gov**, search for docket number FDA-2011-N-0921 (for the Produce Standards rule) or FDA-2011-N-0920 (for the Preventative Controls rule), and follow the on-screen directions.

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