

## **Prepared Statement**

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**Subcommittee on Oversight and Investigations**

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Good afternoon Chairman Stupak, Ranking Member Shimkus, and Members of the Committee. My name is Tom Stenzel and I am President and CEO of the United Fresh Produce Association. Our organization represents more than 1,500 growers, packers, shippers, fresh-cut processors, distributors and marketers of fresh fruits and vegetables accounting for the vast majority of produce sold in the United States. We bring together companies across the produce supply chain from farm to retail, including all produce commodities, both raw agricultural products and fresh ready-to-eat fruits and vegetables, and from all regions of production.

Thank you for holding this hearing to begin a detailed examination what has been one of the most frustrating and damaging investigations ever of a foodborne disease outbreak. This investigation has been damaging to consumer confidence in our food safety system, damaging to consumer health in scaring the public away from safe and healthy produce while failing to properly identify the narrow source of contamination, and damaging, of course, to the entire tomato industry and more recently, the jalapeño pepper sector.

Let me state again for the record something you've heard many times before, and will hear many times in the future. Food safety is our industry's top priority. The men and women who grow, pack, and market fresh produce are committed to providing consumers with safe and wholesome foods. And let me add, they are also committed to compliance with the traceability requirements of the Bioterrorism Act and ensuring our ability to effectively track fresh produce from the retail store or restaurant all the way back to the farm.

As you also know, our association strongly supports mandatory, commodity-specific good agricultural practices and good handling practices for those items where experience has shown a certain level of risk. Commodity-specific food safety practices are a vital part of preventing contamination in the first place, and our commitment to these principles is well known on Capitol Hill and at the FDA.

Yet, as I look at the flaws in this outbreak investigation, I am left with the bittersweet observation that our priority has been almost exclusively on *prevention* of foodborne disease from the farm up through the distribution chain, rather than management of outbreaks after they occur. Of course that is a good thing, as industry has implemented

best agricultural practices for tomatoes, leafy greens, and other products to prevent contamination, and devoted extensive resources to auditing systems to measure compliance against these standards. What we have *not* done, however, is spend a commensurate amount of time on how best to investigate and manage an outbreak when it does occur.

Let me suggest an analogy to a forest fire. Both government and industry have focused our attention on preventing forest fires, but sometimes lightening strikes and sets off a fire despite our best efforts at prevention. Then, it's just as important that an expert, well-prepared, and well-drilled firefighting team can leap into action and rapidly contain the fire. Judging from our experience in this outbreak investigation, we have all failed to pay as much attention to fire-fighting. It is time for government, industry and all stakeholders to figure out how we can better fight a fire – or a foodborne disease outbreak – to both protect public health and minimize damage to consumer confidence and industry profitability.

Today I want to comment on five lessons that I believe are important for improving outbreak investigations in the future. These observations are not intended to attack any agency or individual personally, or suggest that anyone has not given their best in what has been a frustrating and complex situation. But I do believe the system in which we have all been operating has fundamental flaws, and I want to address those issues directly.

### **1. There's No One in Charge**

Throughout this investigation, it's become clear that no one is in charge, leaving local, state, and federal officials vying for leadership; various agencies pursuing different priorities; and well-meaning individuals reacting independently to events rather than as part of a coordinated investigation moving forward in a logical and expeditious direction.

The diffuse responsibility for public health in outbreak investigations is something that Congress must look at intensely. Local and state governments are usually first to discover illnesses, and are free to draw their own conclusions and issue press releases at any time. We suspect initial state pronouncements about tomatoes being the cause of this illness, even down to suggesting which grocery stores were involved, forced federal hands to jump on board before they were certain. But how can CDC or FDA stand by when a state seems to be "more protective" of its citizens? Yet, not just today's experience but past history shows us that premature mistakes have consequences. When local officials first blamed strawberries for a cyclospora outbreak in the mid 1990s, their advice may have actually pushed consumers to eat more contaminated raspberries that were eventually found to be the cause.

The diffuse responsibility continues at the federal level, even within the Department of Health and Human Services. CDC has the "official" responsibility to determine what food vehicle is the cause of an illness. FDA must wait on the scientists at CDC to make that call, only after which FDA staff are responsible for the traceback investigation. The tension between CDC and FDA in this case has been palpable to most outside observers, only to heighten as it became more and more clear that tomatoes were likely never involved in the outbreak. Lack of a true chain of command brings lack of accountability, and a rush to protect one's own turf or reputation.

Even in the investigation itself, field investigators are all over the map. Some are FDA field staff employees, some CDC, some state, some local. From what I understand from my members, the interaction with these agents is equally across the board. Some are great and know what they're looking for. Others seem to have no idea of what their mission is or how to best go about a traceback.

Suffice it to say, outbreak investigations today do not resemble a well-prepared, well-organized, or well-drilled team of firefighters operating as a cohesive unit to contain a wildfire.

**Recommendation:** We suggest Congress consider how to put in place a command-and-control structure with a clear chain of command. Take guesswork out of who's in charge, and drive real authority and accountability into the process. Whether this can be achieved in a multi-agency cooperative agreement, or requires new government structures, is something that Congress must ask. We suggest looking at other agencies for insights, such as National Transportation and Safety Board investigations. From afar, such a system seems designed for a 24-7 immediate response, with clear authority and command leadership, supported by a team of well-prepared experts.

## **2. We Need Better Crisis Preparedness and Transparency**

Crisis planning should be done in advance of a crisis, not learned on the job. Let me share three examples.

One of the most important parts of this investigation was the original work by states and CDC with food recall surveys among ill people, CDC's first case control study that showed the strongest association with fresh tomatoes, and its second case control study that showed a greater association with jalapeños. From what we understand, these food questionnaires were adapted for each use, and actually were changed from the first case control study to the second. Did the questionnaire design allow an inaccurate conclusion about tomatoes – which happen to be consumed by 80% of the population at large – and fail to tease out chopped up jalapeños as a sometimes hidden ingredient in tomato-based food dishes? Was the second survey designed better to get at that distinction? Were the food surveys appropriate for the demographics of the ill consumers? Today, these facts are all open to second-guessing, not only because we now know tomatoes were not the sole cause of illness (or perhaps any cause at all), but because no one outside of CDC knows how these studies were conducted. Could there not be consistent food survey protocols set in advance, peer-reviewed by expert epidemiologists outside government, and kept at the ready for a case like this? One might even have a design for Spanish-speaking consumers, or other demographic groups, that are vetted and tested in advance for reliability.

The next example pains me, because it's a case of FDA trying hard to do the right thing, but just not knowing how to do it. When FDA began a "cleared list" of regional tomato production areas, it was responding quite logically to the fact that most tomatoes were not involved in the outbreak. If a farm was not producing tomatoes back in April or May, it could not have been the cause. But the "cleared list" rapidly became problematic as there was no system in place explaining how to get on the list, what geographic boundaries were appropriate and whether there was equal treatment of trading partners, nor even if it was still an appropriate "safe list" as illnesses continued. I'll suggest later that there simply has to be a system to narrow concerns and not effectively ban entire commodity group through public warnings, but those systems need to be well thought out in advance of a crisis, not invented on the fly.

Last, let me talk about data sharing between CDC, FDA and industry. There has been constant confusion about what data could be shared and what could not, as industry has tried to help solve this case. We've been denied data such as the epidemiologic curve showing onset dates of illnesses, the geographic pattern in which illnesses occurred, and the details of CDC's case control studies, citing reasons from state ownership of the data, privacy concerns, or simply that this is an ongoing investigation. Yet, weeks later an official would share the same data we had been denied earlier, or even post it on the CDC website. Could we have helped solve this case with better understanding of how and where people got sick – darn right. But I'm not even arguing that point quite yet. We just want to know

what the rules are for data sharing – in advance – so everyone at CDC, FDA, academia, consumer groups, and anyone else all have a common understanding. That’s a matter of being prepared.

**Recommendation:** Whatever command-and-control structure is put in place for outbreak investigations, plan it, implement it, and test it before a crisis. Take the recommendations from all stakeholders and build a system – in advance – that government and industry alike will follow in the future. Our association teaches workshops on crisis management and our members do recall and traceback drills all the time. We stand ready to cooperate with government in planning and testing overall traceback investigations.

### **3. The Current System Doesn’t Use the Expertise Available**

The government’s failure to use industry’s expertise in outbreak investigations is one of our most important lessons today. Let me first say that this needs to be transparent, supported by consumer groups, and squeaky clean. But there is an abundance of knowledge in the industry about specific commodities, growing regions and handling practices, and specific distribution systems that can be used to protect public health in an outbreak. Let me give you an example.

When this outbreak first began, its concentration in New Mexico and Texas could logically fit with our tomato distribution system that for the most part is regional in nature. Tomatoes are often repacked on a regional basis closer to the point of final consumption to maximize quality. You’ll note that none of us yelled, “It’s not tomatoes,” when the first reports were issued. But when illnesses appeared across many more states, we knew that it was highly unlikely that a common contamination point for tomatoes was possible, whether a farm or packer or repacker. Knowing our distribution systems, it was just not logical that all of these tomatoes could have been contaminated at a common source. FDA’s tracebacks were simultaneously also proving that point, although the agency chose to characterize their results as chasing false leads, rather than recognizing the evidence before them. When FDA tracked tomatoes back to multiple farms and packers, they were actually providing strong evidence that tomatoes were not the common food source causing illnesses. Because our industry knowledge was ignored, the investigation dragged on looking for tomatoes, when it might have shifted to jalapeños much sooner. (Incidentally, once FDA began looking for the right food, they traced it back pretty effectively.)

Similarly, after asking for data on onset and location of illnesses for more than a month, finally on July 9 CDC shared some data and asked us to think about jalapeños as a possible source. We looked at the concentration of illnesses in Texas and New Mexico, compared with the relative lack of illnesses westward toward California. With large jalapeño consumption in California, but few illnesses, what did this suggest about a source of contamination? We also looked at the spread of illnesses north and east from Texas, but not so much to the west, as well as a large group of illnesses in the Chicago area but not downstate Illinois. After talking with half a dozen industry members about these distribution patterns, we communicated to FDA and CDC late that same day that if jalapeños were the cause, the distribution pattern would suggest product moving through McAllen, Texas, the eventual location where an identical positive sample was found. Now, industry opinion is not proof and we can get it wrong too, but I see no reason that government should not build that kind of outside expertise into its deliberations.

FDA and CDC should also welcome outside expertise not just from industry, but also from academia, from USDA experts who certainly better understand produce distribution systems, and even from the states themselves. One of the more interesting developments in this outbreak investigation was the report from Minnesota health officials that they quickly identified jalapeños as the real culprit, not tomatoes, and then quickly traced the peppers back from a small restaurant in Minneapolis, to the distributor, wholesaler and

farm. The Minnesota investigator is quoted in the media saying it takes “a few phone calls and you can work it fairly quickly back to the grower.” That sounds like the kind of expertise I would want in an investigation.

Finally, industry has other resources that could quickly be brought to bear. For example, many produce companies, wholesalers and retailers have said that when FDA has suspicion about a particular product, they would be willing to take samples from their warehouses to provide to FDA certified labs. A system to ensure the validity of samples and testing protocols would have to be put in place, but I am not aware that anyone has ever considered this type of outside-the-box thinking to help speed investigations.

**Recommendation:** Congress and the agencies should find a proper and transparent way to bring industry and other outside expertise into its outbreak investigations. We recommend a broad group of stakeholders be convened to look at all potential options and provide recommendations to Congress and the agencies. We also specifically recommend that a group of experts in major produce commodities be selected and vetted by government well ahead of time, perhaps through a process similar to gaining a security clearance. Then, at a moment’s notice, these pre-cleared experts could be assembled with government investigators to provide counsel in their areas of expertise.

#### **4. Government Is Ill-Prepared To Make Complex Risk-Benefit Decisions**

Every health or safety regulatory decision requires an assessment of risks and benefits. Agencies make risk management decisions every day that attempt to balance risks and benefits broadly to society, whether in automobile design, toy manufacturing, airline safety, or even FDA approval of food additives. Yet in the case of foodborne disease, FDA and CDC seem ill-prepared to grapple with any risk management approach other than “all or nothing.”

In this case, it seems that internal agency decisions on when to warn the public, how broadly to make a warning, and what specifically to advise, are based as much on fear of being second-guessed rather than careful risk analysis. That inevitably leads one toward extreme measures – in effect banning all tomatoes or peppers – in the quest for zero risk of immediate illness. But, is such a consumer message truly without risk, when it needlessly scares the public away from a high-lycopene healthy food that may help prevent prostate cancer? If we know that 99.999% of the tomatoes in the marketplace are perfectly safe, is there not a way to craft risk decisions more appropriately.

FDA has shown a willingness to consider a different approach with its initial warning about jalapeño peppers only to the very young or old, and those who are immuno-compromised. Yet, the pressure is always there to revert to a zero-risk approach. FDA eventually felt the need to expand its warning not to consume any jalapeños whatsoever, only to find some states beginning to openly disregard its warning. That is dangerous ground, but a real consequence of losing faith in broad federal government warnings that people know are not based on reality.

We simply must develop risk management systems that can distinguish those producers or distributors who can assure the safety of their produce in the marketplace from those who cannot. FDA must find appropriate ways to advise consumers that the legal responsibility for food safety assurance lies with individual companies who offer food for sale, not the federal government. How can a grower of summer tomatoes in Michigan maintain his livelihood selling to local retailers? How can a fast food chain that knows every detail of where and how its tomatoes are grown maintain the option to keep sliced tomatoes on its burgers? How can a produce company that invests hundreds of millions of dollars in food safety stay afloat when its business is shut down the same as others who never made those investments? The unintended message to industry is don’t bother investing in food safety,

if you're going to be tarred with the same brush and face the same costly consequences in every single outbreak.

**Recommendation:** Congress needs to empower FDA and CDC to look at risk management decision-making in advance of an outbreak, and develop transparent guidelines for when to take specific action. The broad brush approach taken with tomatoes, then jalapeños, is not an appropriate risk management strategy to best protect public health, either in the short- or long-term.

## **5. Today's Risk Communication Is Unacceptable**

These are complex issues indeed, and tough to explain. But I wonder how many of the committee's staff have listened to FDA and CDC media calls that go something like this – the first five minutes are spent explaining that there is nothing new in the investigation, and then the next 55 minutes are spent speculating about how the outbreak may have occurred, theories on why leads may not be panning out, hypothetical questions based on what-if scenarios, and more.

The principle of timely and candid communication with the press and public cannot be compromised. Yet, any risk communications expert would also advise precision and care in communicating exactly what you want to say, and not speculating beyond what is known. Consider again the example of a National Transportation and Safety Board press conference investigating an airline accident. There's no speculation about whether a crash might have been caused by pilot error, or bad hydraulics, or a flaw in wing design. Those are precisely the things under investigation and are NOT discussed until there's a conclusion by the experts.

This also comes back to our recommendation about a clear chain-of-command – someone has to be in charge of talking with the media. The FDA and CDC speakers on these press calls fluctuate seemingly without reason other than personal availability. People's judgments vary, and they express themselves quite differently. One has the feeling that policy decisions are being made in response to media questions, rather than being well thought out ahead of time and then communicated clearly and concisely.

Even without the changing parts, these calls feature multiple spokespersons from each agency. Often, when FDA has answered a question fully, a CDC representative is invited to answer it again "from their perspective," elaborating further with a different twist. For my members who want to bash the media coverage of this investigation, I often have to remind them that the media don't usually make this stuff up.

Good risk communication is not just an art; it is a science, and a science that needs to be studied in advance and rigorously followed in outbreak investigations.

**Recommendation:** Risk communication must be a central part of an overall crisis management structure, and well planned in advance. As the agencies develop overall management plans, one single office must have authority and accountability for public communications, with one single officer designated as the media spokesperson for the investigation.

## **Conclusion**

I want to thank the committee again for holding this hearing. I could not cover here every lesson from this experience, but hope I've been able to point in some positive directions. Our goal is to improve the system for the future, and that effort is just beginning.

I do believe that progress will require systemic change, not window dressing. The complex web of local, state and even competing federal agencies is not conducive to effective and efficient identification and management of foodborne disease outbreaks.

When it comes to preventing "fires," I am reasonably confident in the ability of FDA, with proper resources and leadership, to provide food safety oversight for our industry. But when it comes to "firefighting" – the complex local, state and federal effort to identify, manage, track and end outbreaks – I am more concerned about duplicative efforts, lack of system-wide planning, inefficiencies in operation, rivalries between those on the same team, and simply lack of cohesion to drive the most effective process for public health.

There are indeed consequences of our actions. You've heard many of those consequences to the industry today, both in lost income and lost confidence in future sales. But I fear the greatest consequence may be lost faith in government's ability to manage our overall food safety system. That doesn't mean Congress should overreact with knee-jerk actions, but I do believe it is time for Congress to examine these issues fully and thoughtfully to help guide real reform in how government approaches foodborne disease outbreaks.