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ONE HUNDRED TWELFTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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January 10, 2012

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Hamburg:

Today, the Committee on Energy and Commerce released a staff report on the findings of an investigation into the recent outbreak of *Listeria monocytogenes* in cantaloupe, which infected 146 people in 28 states and caused 30 deaths. As part of its investigation into this outbreak, the Committee obtained documents from and conducted interviews with high-ranking officials at the Food and Drug Administration, Jensen Farms, where the cantaloupe was grown, Primus Labs, the third-party auditor that inspected Jensen Farms before the outbreak occurred, and Frontera Produce, the distributor of the cantaloupe.

We urge you to review closely the information uncovered during our investigation. In particular, the investigation identified significant problems with the third-party inspection system used by growers and distributors to ensure the safety of fresh produce. This auditing system is often the first and only line of defense against a deadly foodborne disease outbreak.

In the case of the contaminated cantaloupe, FDA officials identified "serious design flaws" in the processing technique used at Jensen Farms and "poor sanitary design of the facility itself" as the causes of the contamination, and they indicated that "everything that was found wrong was addressed in FDA guidance" published in 2009.[1] Yet these flawed facility designs and processing techniques were both recommended by and rated as "superior" by the third-party auditor of Jensen Farms.

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[1] House Committee on Energy and Commerce, Interview with Jeff Farrar, Associate Commissioner for Food Protection, Food and Drug Administration, Roberta Wagner, Deputy Assistant Commissioner for Regulatory Affairs of Field Operations, Food and Drug Administration, and James Gorny, Senior Advisor for Food Safety, Food and Drug Administration (Dec. 8, 2011).

This auditing system failed in the case of the recent *Listeria* outbreak. Our investigation reveals some of the reasons why: the auditors' findings were not based on the practices of the best farms and failed to ensure that the producer met FDA guidance; the auditors missed or failed to prioritize important food safety deficiencies; the auditors lacked any regulatory authority and did not report identified problems to the FDA or other state or federal authorities; the auditors did not ensure that identified problems were resolved; and the auditors provided advance notice of site visits and spent only a short period of time on-site. It also became apparent in the investigation that the auditors had multiple conflicts of interest.

The FDA has an opportunity to correct many of these problems. On January 4, 2011, President Obama signed the Food Safety Modernization Act. This law requires that with respect to imported foods, FDA establish an accreditation system and model auditing standards for third-party audits. While the law requires these steps only for imported foods, industry officials told the Committee that the FDA standards will influence the actions of auditors inspecting domestically grown produce as well. We hope that FDA will consider our findings when drafting these rules, and we suggest that FDA consider developing a voluntary model program for domestic auditors that could become the standard of care for third-party auditing programs in the United States.

Failure to Audit for Compliance with FDA Guidance and Best Industry Practices

The Committee investigation shows that the auditor that inspected Jensen Farms did not examine whether the farm met FDA guidance or best industry practices. The President of Primus Labs, Robert Stovicek, told the Committee that his audits were designed to determine only if a facility met current baseline industry standards, not to improve those standards or push industry towards best practices.[2] Mr. Stovicek said that Primus Labs would "be a rogue element if they tried to pick winners and losers" by holding industry to higher standards.[3] He also said that Primus Labs did not have the "expertise to determine which best practices should be pushed by the industry."[4]

Jerry Walzel, the President of Bio Food Safety, Inc., the subcontractor hired by Primus Labs to conduct the Jensen Farms audit, told the Committee that his company did not consider FDA guidance when conducting audits.[5] FDA has no specific regulations on cantaloupe processing; it provides guidance, which represents the agency's best and most timely advice on how processing should be handled. Despite this, the audits of Jensen Farms deducted from the score only if a method or technique violated FDA regulations. The audit did not deduct from the

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[2] House Committee on Energy and Commerce, Interview of Robert Stovicek, President, Primus Labs (Nov. 7, 2011).

[3] *Id.*

[4] *Id.*

[5] House Committee on Energy and Commerce, Interview of Jerry Walzel, President, Bio Food Safety (Jan. 6, 2011).

score in cases where FDA guidance was not being followed. Mr. Walzel stated that Primus conducted a "check-off audit … and if it was not required, there were no deductions."[6]

Will Steele and Amy Gates, the CEO and Executive Vice President of Frontera Produce, told the Committee they had concerns about the weakness of the standards applied by the auditors. Ms. Gates indicated that there is "no industry standard for validation points" after an audit, while Mr. Steele stated that "[t]his is the industry standard. I've always believed there's got to be more validation points. This case clearly demonstrates that."[7]

In fact, it appears that the auditors who inspected Jensen Farms did more than simply overlook egregious food-safety practices: they specifically recommended these practices.[8] According to Jensen Farms, Bio Food Safety, the subcontractor hired by Primus Labs to conduct the Jensen Farms audit, recommended the production equipment and process that Jensen Farms put in place for the 2011 growing season.[9] These recommendations appear to have increased food safety risks. According to FDA officials, there were "serious design flaws" with the equipment that the auditor recommended, and it did not meet basic standards spelled out in 2009 FDA Guidance.[10]

Failure to Require Correction of Deficiencies

The final Primus Labs audit certificate for Jensen Farms reported the 96% score, but failed to mention any of the particular deficiencies. In a scenario like this, where a grower has been notified of deficiencies but has not failed the audit, there appears to be no process in place for remedying deficiencies. Officials from Frontera Produce indicated that they "primarily look at the score" when reviewing audit reports, and they said that except in the case of a failed audit, growers are not contacted to correct specific deficiencies.[11]

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[6] *Id.*

[7] House Committee on Energy and Commerce, Interview of Will Steele and Amy Gates, CEO and Executive Vice President, Frontera Produce (Nov. 18, 2011).

[8] House Committee on Energy and Commerce, Interview of Eric Jensen and Ryan Jensen (Nov. 8, 2011). Mr. Jerry Walzel, the individual who conducted the 2010 audit of Jensen Farms, indicated that he had no memory of whether he did or did not provide advice to Jensen Farms following this audit. House Committee on Energy and Commerce, Interview of Jerry Walzel, President, Bio Food Safety (Jan. 6, 2011).

[9] House Committee on Energy and Commerce, Interview of Eric Jensen and Ryan Jensen (Nov. 8, 2011).

[10] House Committee on Energy and Commerce, Interview with Jeff Farrar, Associate Commissioner for Food Protection, Food and Drug Administration, Roberta Wagner, Deputy Assistant Commissioner for Regulatory Affairs of Field Operations, Food and Drug Administration, and James Gorny, Senior Advisor for Food Safety, Food and Drug Administration (Dec. 8, 2011).

[11] House Committee on Energy and Commerce, Interview of Amy Gates (Nov. 18, 2011).

Primus Labs also indicated that absent a failed audit, they do not do any follow-up work with companies that have deficiencies to determine if these problems were rectified.[12] Amy Gates, the Executive Vice President of Frontera Produce, told the Committee that Frontera would not ask its growers to address any deficiencies mentioned in a passing audit report unless a buyer had requested that changes be made.[13]

No Reporting to FDA or State Officials

Third-party auditors also do not report findings to FDA or other state or federal safety authorities. While Primus Labs has performed tens of thousands of audits since the mid-1990s, the firm indicated it has never reported any of its findings to FDA, state authorities, or local health officials.[14] This remains true even in cases where Primus Labs found a deficiency that was so egregious that the auditor ended the audit immediately and automatically failed the company. Similarly, Frontera Produce also indicated that they have never notified federal, state, or local officials about audit results.[15] Without this knowledge, FDA and other authorities cannot address potential safety issues with the food supply before problems occur and people get sick.

Concerns about Advance Notice and Thoroughness of Third-Party Audits

Primus Labs audited Jensen Farms on July 25, 2011. In this audit, Primus Labs failed to identify any of the problems that were found by FDA during the September 2011 visit. When Committee staff asked the President of Primus Labs about the differences between the findings of his firm's July audit and FDA's September inspections, Mr. Stovicek identified as possible explanations Jensen Farms' advance knowledge of the Primus Labs audit, the differences in length of time Primus Labs and FDA spent on their visits, and the different cantaloupe production volumes at Jensen Farms on the days of the audits and inspections.[16]

Jensen Farms was prepared for the Primus Labs audit, as it was scheduled two weeks to a month in advance.[17] In addition, a representative from Frontera Produce came to the facility shortly before the Primus Labs visit to ensure that everything was in order for the auditor.[18] Most of the companies that Primus Labs audits similarly know about the visits in advance; only

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[12] House Committee on Energy and Commerce, Interview of Robert Stovicek (Nov. 7, 2011).

[13] House Committee on Energy and Commerce, Interview of Amy Gates (Nov. 18, 2011).

[14] House Committee on Energy and Commerce, Interview of Robert Stovicek (Nov. 7, 2011).

[15] House Committee on Energy and Commerce, Interview of Will Steele and Amy Gates (Nov. 18, 2011).

[16] House Committee on Energy and Commerce, Interview of Robert Stovicek (Nov. 7, 2011).

[17] House Committee on Energy and Commerce, Interview of Eric Jensen and Ryan Jensen (Nov. 8, 2011).

[18] *Id.*

153 Primus Labs audits in 2010 were unscheduled, down from 665 audits in 2008.[19] If companies receive advance notice of third-party audits, auditors will not be able to tell whether they are obtaining an accurate view of day-to-day health and safety practices.

Only one individual, a subcontractor for Primus Labs, performed the 2011 audit of Jensen Farms, and he spent just four hours at the facility.[20] In contrast, multiple officials from FDA, as well as from the Colorado Department of Public Health and Environment, the Colorado Department of Agriculture, and Prowers County Department of Health, were involved in the September visits, which occurred over three separate days.[21] These discrepancies indicate that one four-hour audit may not be adequate to identify potential food safety problems.

Potential Conflicts of Interest in Auditor Relationships

There are inherent conflict of interest concerns with the third party auditor relationship. Although large purchasers must approve auditors (and in the case of Jensen Farms, provided a list of pre-approved auditors that were to be used), Jensen Farms made the final decisions about which of these specific auditors to hire.[22] This creates a conflict for the auditor: a failing audit has significant economic implications for the producer, to the extent an auditor applies more demanding food safety standards, and it may be less likely to be hired by a given producer. This inherent conflict may account for the extraordinarily high pass rates – above 97% – for Primus Labs audits.

In addition to this fundamental conflict, FDA officials raised concerns about the advisory relationship between Primus Labs and Jensen Farms. The Primus Labs subcontractor who conducted the audit of Jensen Farms had recommended that the farm adopt new processing and packing equipment, and gave the facility a "superior" rating when that processing and packing equipment was put in place in 2011. FDA officials had a different view, describing "poor facility design [and] poor equipment design" as potential causes of the outbreak, and noting that "when a third party auditor gives consulting advice, that's a conflict of interest."[23]

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[19] House Committee on Energy and Commerce, Interview of Robert Stovicek (Nov. 7, 2011).

[20] *Id.*

[21] Food and Drug Administration, *Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis* (Oct. 19, 2011) (online at www.fda.gov/Food/FoodSafety/FoodborneIllness/ucm276247.htm) (accessed on Nov. 30, 2011).

[22] House Committee on Energy and Commerce, Interview of Will Steele and Amy Gates (Nov. 18, 2011).

[23] House Committee on Energy and Commerce, Interview with Jeff Farrar, Associate Commissioner for Food Protection, Food and Drug Administration, Roberta Wagner, Deputy Assistant Commissioner for Regulatory Affairs of Field Operations, Food and Drug Administration, and James Gorny, Senior Advisor for Food Safety, Food and Drug Administration (Dec. 8, 2011).

Conclusion

The results of the investigation released today reveal numerous problems with the third-party auditing system used to inspect the Jensen Farms cantaloupes. These problems are unlikely to be limited to Jensen Farms, however. The officials the Committee interviewed indicated that the practices used at Jensen Farms are similar to those used in thousands of other food safety inspections.

Indeed, the problems identified in the audits of Jensen Farms are similar to those that the Committee identified in food safety investigations in 2009 and 2010. In 2009, following the *Salmonella* outbreak in peanut butter products sold by the Peanut Corporation of America (PCA), a Committee investigation revealed that a private, for-profit auditing firm gave the company glowing reviews. The auditor, AIB, was selected by PCA, it was paid by PCA, and it reported to PCA. The auditor awarded a "superior" rating to the company's plant. Six months after the audit, PCA's products killed nine people and sickened 691 people.[24] In 2010, the Committee's investigation into an outbreak of *Salmonella* in eggs produced by Wright County Egg revealed the same problems with third-party audits. Following the outbreak, federal officials inspected Wright County Egg facilities and found serious violations of food safety standards, including barns infested with mice, chicken manure piled eight feet high, and un-caged hens tracking through excrement. There were very different results when Wright County Egg farms were inspected by AIB. AIB gave Wright County Egg an award two months before the outbreak, rating them "superior" and awarding the company a "recognition of achievement."[25]

Weaknesses in third-party auditors represent a significant gap in the food safety system because the auditors are often the only entities to inspect a farm or facility. Although the Food Safety Modernization Act has increased the frequency with which FDA inspects facilities like Jensen Farms, the agency is unlikely to have resources available to inspect these facilities more than once every three to five years. Like it or not, our food safety system relies heavily on third-party auditors to identify dangerous practices and prevent contaminated foods from reaching the market.

We believe reforms in third-party audits are essential. We call on you to address the problems identified in this investigation in regulation and guidance. Thank you for your attention to these concerns.

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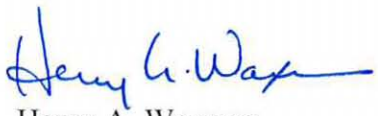
[24] House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *The Salmonella Outbreak: The Role of Industry in Protecting the Nation's Food Supply*, 111th Cong. (Mar. 19, 2009).

[25] House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *The Outbreak of Salmonella in Eggs*, 111th Cong. (Sept. 22, 2010).

Sincerely,



Henry A. Waxman
Ranking Member

Diana DeGette
Ranking Member
Subcommittee on Oversight
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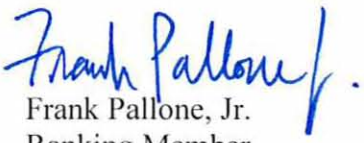

Frank Pallone, Jr.
Ranking Member
Subcommittee on Health

John D. Dingell
Member

cc: The Honorable Fred Upton
Chairman

The Honorable Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations

The Honorable Joseph Pitts
Chairman
Subcommittee on Health