

Testimony

of

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before the

U.S. Small Business Administration Office of Ombudsman
National Regulatory Fairness Region III Board Hearing

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Distinguished Members of the Regional Small Business Regulatory Fairness Board:

My name is Jennifer Gibson, and I am Vice President of Regulatory Affairs for the National Association of Chemical Distributors (NACD). Thank you for holding this timely hearing today and for inviting me to testify on behalf of NACD and our members.

NACD is an international association of nearly 440 chemical distributors and their supply-chain partners. NACD members represent more than 85% of the chemical distribution capacity in the nation and generate 93% of the industry's gross revenue. NACD members, operating in all 50 states through nearly 2,700 facilities, are responsible for more than 130,000 direct and indirect jobs in the United States. Collectively, in 2016 they distributed 35.8 million tons of product to more than 750,000 customers, making a delivery every eight seconds.

While chemical distribution is big business, most NACD members are small businesses that on average have 26 employees and generate \$26 million in annual sales. Many NACD members are multi-generational, family owned, and operate at the local level with the average distributor shipment being delivered within a 35-mile radius of their facilities.

NACD members meet the highest standards in safety and performance through mandatory participation in NACD Responsible Distribution[®], the association's third-party-verified environmental, health, safety, and security program. Through Responsible Distribution, NACD members demonstrate their commitment to continuous performance improvement in every phase of chemical storage, handling, transportation, and disposal operations.

The chemical distribution industry is heavily regulated. While the majority of these regulations are necessary for the business of handling hazardous chemicals, some of the rules are overly burdensome and do little, if anything, to protect health and the environment. In addition, it is a challenge to stay on top of all the regulations and changes, particularly for small businesses that do not have dedicated staff to read the *Federal Register* every day.

Enforcement can be intimidating for NACD members. In too many cases, our members have found themselves on the receiving end of a "find and fine" enforcement approach from federal agencies rather than a compliance assistance approach that would be more effective in enhancing safety.

As small businesses, most NACD members do not have the resources and legal expertise to battle agencies such as the U.S. Environmental Protection Agency (EPA) when charges are levied against them. Because of this, they are pressured into settling and paying the fines, justified or not. To make matters worse, EPA in particular has consistently failed to follow up on inspections and resolve cases in a timely manner, thereby hindering the ability of companies to focus on developing and growing their businesses.

Environmental Protection Agency

NACD has recently urged EPA to review and reform the agency's enforcement policies to make them more fair, reasonable, clear, consistent, and predictable.

Compliance Assistance and Grace Periods Over “Find and Fine”

Environmental protection would be enhanced if EPA would take a more collaborative, compliance assistance-oriented approach rather than the too-common “find and fine” approach. There are several steps the agency could take to improve the process while still ensuring those in violation of the rules are appropriately penalized.

EPA should work with facilities to ensure they are aware of their regulatory obligations before issuing penalties. In many cases, facilities, particularly small businesses, may be out of compliance not out of malice, but because they are simply unaware of the requirements or do not understand them. In small companies, the individual charged with regulatory compliance typically has other duties in addition to keeping current of all the federal, state, and local regulations to which the business is subject. Rather than issuing penalties without question, EPA should provide a period of time within which to comply.

For example, if an issue is easily correctable, such as a minor paperwork oversight, EPA should give the company no more than 30 days to submit the proper/correct information. If it is a more complex issue such as failure to develop a Risk Management Plan, EPA should give the company 180 days to submit the plan. If the company fails to comply within these timeframes, it is justifiable for EPA to issue penalties.

In addition, EPA should reform its self-disclosure policy to encourage companies to report minor oversights such as paperwork violations without fear of severe repercussions. NACD is familiar with cases where small businesses have self-reported Toxic Substances Control Act Chemical Data Reporting errors to EPA only to be presented with six-figure penalties. This is unjustified and has the adverse effect of discouraging companies from reporting. EPA should refrain from issuing penalties upon a first self-disclosure, particularly if the oversight was a paperwork mistake that did not threaten health or the environment.

Clear Time Limits Between Inspection and Next Steps/Clear Resolution of Cases

NACD has also urged EPA to adopt limits between the time of an inspection and the time when the agency presents a company with a notice of violation (NOV). There have been far too many cases in which EPA conducts an inspection and raises some issues but then the company does not hear anything until one, two, or even three years later when they are presented with an NOV and proposed six-figure penalties. If a violation is so severe that it deserves a six-figure penalty, it does not make sense for EPA to keep that company in limbo for up to three years. NACD has asked EPA to adopt a policy in which inspectors are straightforward with facilities and provide them with a clear description of the next steps and the timeframe for additional action.

For minor paperwork issues such as failure to report on a substance or misreporting an amount, it should be EPA’s policy to notify the company of the violation **no later than 60 days following the inspection**. For more complex issues such as failure to implement a Risk Management Plan properly, it should be EPA’s policy to notify the company of the violation **no later than 120 days following the inspection**.

Further, these notifications must include *all* items of concern identified by EPA. NACD members have reported that, in many cases during negotiations with EPA, the agency has raised additional issues that were not included in the original notices.

If EPA fails to follow these timelines, the case should be considered closed and EPA prohibited from taking additional action against that company on the matter.

Once EPA has issued a violation notice and the company has responded, EPA should be held to the same timelines for response as the company. For example, if a company has 15 days to respond to an EPA order, the agency should have 15 days to follow up on that response. If EPA fails to follow the prescribed timeline, proposed penalties should be reduced, for example, 10 percent for each day over the required response date. EPA should be required to follow these prescribed timelines through final settlement of the case.

In addition, following an inspection in which EPA finds no violations, the agency should notify the company it is in good standing **no later than 60 days following the date of the inspection.**

Written closure that the issue has been resolved is critical for small businesses, including NACD members.

U.S. Food and Drug Administration

Standardization of Enforcement Efforts

NACD members have experienced Food and Drug Administration (FDA) inspections for many years. Inspection frequency is now increasing with implementation of the Food Safety Modernization Act (FSMA) and will continue to do so.

NACD member reports of their FDA inspections have been mixed, but the majority have raised serious concerns. In many instances, FDA inspectors have arrived unprepared to inspect chemical distribution operations and often do not understand the industry. Although the necessity of providing some education about the business is expected, we remain concerned about how often our members must correct inspectors on what regulations do and do not apply to their facilities.

The functions and operations of chemical distribution facilities are by nature extremely different than those of traditional food facilities. Most distributors handle chemicals for a wide variety of customers, with food being only a portion of the business. For example, when required under food safety regulations, the food-grade chemicals will be physically separated from other chemicals; but when not required because the chemicals will be used in non-food applications, the distributor may organize their products in the most efficient way for their operations, with safety always a priority.

NACD understands it is challenging for FDA to ensure coordination across multiple offices, states, and industries. We are aware that inspectors in smaller offices must inspect multiple sectors, including human food, animal food, drugs, biologics, devices, and more. We have urged FDA to dedicate the time and resources to allow inspectors to specialize in industry areas, where they can become subject matter experts on industries. Too often, inspectors in our members' facilities have asked to see reporting requirements not applicable to these facilities, issued citations not appropriate for packaged food ingredient facilities, or otherwise demonstrated lack of understanding about the facilities and/or the industry.

In May, FDA took a first step in improving this situation with the launch of its Program Alignment Initiative that shifts geography-based district offices to program-specific division offices that will be either food-based or medical-based. This will allow inspectors to narrow their focus to either food or medical products. While this is a step in the right direction, the

food industry is vast, and NACD continues to believe FDA must gain a greater understanding of unique segments of the industry such as chemical distribution.

Compliance Assistance and Efforts to “Educate While We Regulate”

Regarding FSMA, FDA has stated its objective to “educate while we regulate.” While this sounds positive, FDA still must take steps to work more collaboratively with regulated facilities. One example in which FDA demonstrated an uncooperative spirit occurred when the agency inspected one of our members’ chemical distribution facilities in California. After the inspection was completed, the company’s corporate compliance director was told he would receive an inspection report in the mail within a few weeks. After receiving nothing for over a month, he contacted the inspector and learned the report had been sent two weeks prior. He assumed it had been lost in the mail and asked the inspector to send another copy. The inspector refused and said that if our member would like a copy of the report, he would need to file a Freedom of Information Act request to obtain it as it was their office policy not to re-send inspection reports.

NACD has urged FDA to allow companies to receive additional copies of their reports and, more importantly, consider all reasonable requests for assistance from industry, especially when those requests will facilitate greater compliance with FDA regulations. NACD finds this example concerning and has urged FDA to standardize policies across all district offices in a way that is collaborative and follows FDA’s own policy to “educate while we regulate.” FDA headquarters should not allow FDA district offices to create policies that undermine the FDA’s own efforts to assist businesses with compliance.

Need of Additional Guidances on the FSMA Rules

NACD has also strongly urged FDA to complete and publish additional draft guidances pertaining to the foundational rules of FSMA. The swift publication of these guidances and the opportunity to comment on draft guidances will provide regulatory certainty and industry feedback. Several deadlines for compliance with the rules have already passed, but FDA has not yet released many guidances to provide further information on what the agency expects of regulated businesses.

NACD has also recommended that FDA provide specific compliance guidances for the FSMA rules that have requirements for small businesses. Regulatory requirements are proportionally more burdensome on smaller businesses, such as most NACD members, than larger ones, even when the requirements are different; and the guidance documents provide a consolidated way for those businesses to allocate their limited time and resources.

Adoption of these recommendations would significantly increase regulatory certainty for NACD members and small businesses at large.

Thank you for the opportunity to present this testimony. If you have questions or need additional information, please do not hesitate to follow up with me.

Sincerely,



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