Consumer and industry stakeholders embraced section 103 reforms as an effective, consensus approach to solving the problems caused by the nation's antiquated food safety system.

The formulation of section 103 recognizes that hazard analysis and preventive control systems are already widely adopted by the industry. Therefore, Congress rightly anticipated that larger food businesses would have little difficulty complying. Even so, it gave these businesses 18 months to make changes in their existing safety programs that would meet the requirements of the new law. Given this statutory forbearance, additional time only serves the interests of the handful of medium-to-large businesses that wish to escape accountability for their unsafe practices. Meanwhile, failing to require compliance undermines those responsible businesses that have invested significant capital in prevention programs that protect their customers from foodborne hazards.

We believe FDA should reconsider its decision. Even if FDA exercises enforcement discretion with regard to compliance, it should still utilize authority within section 103 to access records of a facility's food safety plan, monitoring actions and verification testing. This would permit the agency during inspections to review a facility's conformance to its existing plan, and ascertain whether the plan includes likely hazards and adequately controls for them.

The one industry association that released its petition argued against enforcing section 103 because FDA has not issued regulations identifying who is a small and very small business. This argument does not justify the agency's decision to delay enforcing compliance as there are other approaches to addressing the industry's concern. FDA has repeatedly and clearly defined small food manufacturing businesses using the Small Business Administration's definition of 500, or fewer, employees.[1] To provide clarification the agency would only need to issue a statement that it intends to follow past practice. If FDA wished to vary from this definition, it could do so by issuing an interpretive ruling. The agency could augment such a ruling by considering petitions for enforcement discretion on a case-by-case basis, as it did under the Seafood HACCP rule. Any of these steps would provide the industry with the necessary certainty as to who is covered.

In contrast to the Administration's policy on transparency, FDA made its decision without an open and public process. Instead, it conducted ex parte discussions with industry that failed to balance that stakeholder's claims with information from other affected stakeholders. The only conclusion we can reach is the agency's decision is arbitrary and made without adequate consideration of the health data and other information that should have gone into it. As a result, millions of Americans who hoped for stronger food safety laws will continue at risk from foodborne disease. While claiming commitment to food safety and transparency, FDA, in this case, has demonstrated neither.

Sincerely,

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[1] The agency does not need to define "very small business" for purposes of enforcing the self-executing provisions.