Questions for Stakeholders
GAO Engagement 107394

Background: GAO is currently undertaking a review of the U.S. Food and Drug Administration's (FDA) implementation of the FDA Food Safety Modernization Act (FSMA). GAO's review is focused on the implementation of nine rules that FDA has indicated provide a foundation for implementing FSMA and reducing the incidence of foodborne illness. The nine rules are:

1. Preventive Controls for Human Food—Section 103 of FSMA
2. Preventive Controls for Animal Food—Section 103
3. Produce Safety—Section 105
4. Intentional Adulteration—Section 106
5. Sanitary Transportation—Section 111
6. Laboratory Accreditation for Analysis of Foods—Section 202
7. Food Traceability—Section 204
8. Foreign Supplier Verification Program—Section 301
9. Third-Party Certification—Section 307

Background Questions

1) Please provide a brief overview of your organization's work as it relates to food safety and discuss how, if at all, your organization is involved in implementing FSMA.

ASTA's mission is to ensure the supply of pure, safe spice to consumers. Our top priority is supporting public health and protecting consumers through education, research, and advocacy efforts. Food safety is crucial for preventing foodborne illnesses, protecting public health, and ensuring the quality and integrity of food. Maintaining food safety standards in spices helps to minimize the risk of contamination by pathogens, chemicals, and other hazardous substances, ensuring that spices are safe to consume and supporting overall health.

ASTA has committed significant resources to helping its members comply with the regulations FDA has adopted under the FDA Food Safety Modernization Act (FSMA). Our primary areas of focus have been:

- Microbial hazards, including Salmonella
- Chemical hazards, including heavy metals
- Cross-contact with allergens, such as peanuts
- Packaging hazards, such as fragments from equipment or packaging

Since FSMA was enacted, ASTA has held meetings with FDA, provided FDA with input from members through comments and in meetings, and assisted members with compliance issues. We issue white papers, hold webinars, hold industry meetings, answer member questions, and engaged in many other initiatives on an ongoing basis.

Questions about the sanitary transportation rule (Section 111 of FSMA)

2) FSMA required FDA to complete certain actions to implement the sanitary transportation rule. For example, Section 111 required FDA to conduct a study of the transportation of food for consumption in the United States, including transportation by air, that includes an

examination of the unique needs of rural and frontier areas with regard to the delivery of safe food. *What are your organization's views—positive and negative—regarding the actions FDA has taken with respect to conducting this study?*

ASTA recognizes that FDA has limited resources and we support FDA focusing its efforts on the issues that present the highest risk, given current funding levels. We are not aware of member concerns about food safety tied to transportation, nor of any unique needs of rural and frontier areas for safe food delivery for fully-packaged and shelf-stable foods, such as spices. The requirement in Section 111 for FDA to conduct this study was added through an amendment from Senator Murkowski (R-Alaska), which was intended to evaluate food safety throughout rural areas of Alaska where it is difficult to transport fresh foods and perishable foods. (See https://www.murkowski.senate.gov/press/release/senate-health-panel-approves-food-safety-bill-that-includes-murkowski-initiatives-involving-seafood-safety-and-bush-food-shipments). As such, spices are not a concern for this project completion of this study is not a priority for our members.

3) Section 111 also required FDA to promulgate regulations described in section 416(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350e(b)). *What are your organization's views—positive and negative—regarding the actions FDA has taken with in this regard?*

FDA's Sanitary Food Transportation of Human and Animal Food regulation, issued on April 6, 2016 (81 Fed. Reg. 20092), was issued under the 2005 Sanitary Food Transportation Act of 2005 and as directed by section 111(a) of FSMA. ASTA considers FDA to have met its statutory obligations through issuance of this regulation. This is a reasonable, practical regulation and overall our members have a positive view of FDA's actions in issuing this rule.

4) In your organization's view, what challenges, if any, do businesses face implementing and complying with the sanitary transportation rule?
    a. To your knowledge, has FDA taken any actions to address these challenges? If yes, please describe.
    b. To what extent do you think these actions have been effective in addressing the relevant challenge(s)?

Our members evaluated the rule carefully when it was issued in 2016 and focused on whether additional communications were needed throughout their supply chains in order to comply. Because the regulation was written in large part with a focus on the risks posed by bulk transportation and foods that require temperature control, our members generally have not found compliance to pose a significant burden.

Notably, the Sanitary Food Transportation rule exempts transportation of food that is fully enclosed by a container (with a few exceptions that generally are not applicable to the spice supply chain). Accordingly, we are not aware of challenges that ASTA members face when implementing and complying with the rule.

5) Earlier this year, we issued a report (GAO-24-106563) on challenges businesses, FDA, and its nonfederal regulatory partners could face *as they implement and enforce the food traceability rule*. Below is a list of the challenges we identified. In your organization's view, to what extent, if at all, does FDA face the same challenges implementing and enforcing the sanitary transportation rule?

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Challenge	Description	To a very great extent/To a great extent/To some extent/To little extent/No extent/No basis to judge/unsure
Resources for Implementation and Enforcement	Needing additional resources to implement the rule, such as for staffing and funding, or to provide inspector training and support.	No extent – Our members have not required additional resources from FDA to comply with this rule.
Outreach and Education to Certain Sectors	Needing to outreach to and educate sectors with which FDA does not have extensive experience working, such as small businesses, businesses that export food to the U.S., and farms.	No extent – Our members have not faced educational challenges for this rule.
Uncertainty about Enforcement Process, Roles, and Responsibilities	Needing to understand what compliance and enforcement tools FDA will use, when FDA intends to begin enforcement, roles and responsibilities, and what FDA's enforcement plan is.	No extent – FDA has taken a practical approach to enforcement of this rule, as an adjunct to its other inspections.
Coordination with Nonfederal Regulatory Partners	Needing to improve coordination with, and guidance to, nonfederal regulatory partners, to ensure consistent implementation of the rule.	No extent – We have not seen inconsistency from state regulators on this rule, nor heard of any inspections from state regulators.

Data Management During an Outbreak	Technology limitations that could hamper FDA's and industry's ability to respond effectively during an outbreak, such as constraints on FDA's ability to compile and analyze the significant amount of data received during an outbreak.	No extent – Technology issues are not a significant component of compliance with this rule.

a. For each challenge your organization indicated "to some extent", "to a great extent" or "to a very great extent", please briefly describe why and provide an example.
b. In your organization's view, are there any other challenges that FDA faces in implementing and enforcing the sanitary transportation rule? If yes, please describe. No. The requirements largely reflect industry practice before implementation of the regulation.

6) What steps, if any, could FDA take to help address any concerns your organization has with FDA's implementation of the sanitary transportation rule and why? We do not have concerns with FDA's implementation of the sanitary transportation rule because it reflects the longstanding industry practices and our impression is that there is widespread compliance.

7) What legislative actions, if any, do you think would be needed to help address any concerns your organization has with FDA's implementation of the sanitary transportation rule and why? None. We do not think legislative revision of the sanitary food transportation rule is warranted at this time.

Questions about the foreign supplier verification program rule (Section 301 of FSMA)

8) FSMA required FDA to complete certain actions to implement the foreign supplier verification program rule. For example, Section 301 required FDA to issue regulations, such as to provide assurances that each foreign supplier to the importer produces imported food in compliance with processes and procedures, including reasonably appropriate risk-based preventive controls. *What are your organization's views—positive and negative—regarding the actions FDA has taken with respect to issuing regulations?*

Specifically requiring the requirement to issue regulations, ASTA's position is positive because FDA met the requirement under the statute and took account of industry feedback during the rulemaking process. The regulations could have been clearer in how "importer" is defined since this still causes confusion in the supply chain. However, the regulation has been in place for several years and there is generally compliance by companies that are aware of the rule or that they are covered.

9) Section 301 also required FDA to issue guidance, such as guidance to assist importers in developing foreign supplier verification programs. *What are your organization's views—positive and negative—regarding the actions FDA has taken with respect to issuing guidance?*

ASTA has a positive view on FDA's guidance under the FSVP rule. The agency issued a detailed, practical draft guidance document and did so in a timely manner. Further, FDA revised and finalized the draft guidance based on industry feedback, issuing a final version of the

document just over 2 years after the draft was issued. This is much faster than FDA sometimes acts when moving from draft to final guidance. It would be helpful if FDA issued additional guidance in the form of (1) model FSVP templates, and (2) more detailed examples, including model contracts, regarding identifying the FSVP importer and allocating responsibility contractually.

10) In your organization's view, what challenges, if any, do businesses face implementing and complying with the foreign supplier verification program rule?

We understand that industry continues to face challenges identifying who bears responsibility as the "importer" under the FSVP rule. This is a particular challenge given that there can be multiple entities in the supply chain who meet the definition and because the DUNS number provided to FDA at entry does not require verification by the identified party that they have agreed to take on the FSVP responsibilities. Since the rule is inspected and enforced retroactively, there are situations where FDA conducts an inspection of an entity whose DUNS number was provided at entry but who is not aware that they are responsible for compliance. Although FDA has established a process whereby entities can issue a FOIA request for all of the import entry data where their DUNS was submitted, very few companies understand this option or have the resources to manage compliance through this auditing process. It would be helpful if FDA issued more practical guidance about how to identify the FSVP importer and how to designate this entity contractually, so as to prevent confusion when there are multiple entities and make the designation clear for FDA inspectors.

There also are substantive challenges for FSVP, such as helping foreign entities understand that they need to provide third-parties with confidential proprietary information (e.g., Food Safety Plans) so that their compliance can be evaluated.

a. To your knowledge, has FDA taken any actions to address these challenges? If yes, please describe. FDA has worked to educate the importing community about their responsibility under the regulation. However, the significant number of warning letters that focus on total non-compliance by the inspected importers suggests that many companies remain unaware of their FSVP obligations. It would be helpful if FDA issued guidance specific to identifying the FSVP importer, including model agreements that the industry could use to make this designation when there are multiple parties in the supply chain that meet the legal definition.

b. To what extent do you think these actions have been effective in addressing the relevant challenge(s)? Not particularly because a widespread lack of understanding and compliance remains among importers. ASTA has worked to educate our members and their business partners about FSVP, including holding a recent webinar about the rule.

11) Earlier this year, we issued a report (GAO-24-106563) on challenges businesses, FDA, and its nonfederal regulatory partners could face *as they implement and enforce the food traceability rule*. Below is a list of the challenges we identified. In your organization's view, to what extent, if at all, does FDA face the same challenges implementing and enforcing the foreign supplier verification program rule?

Challenge	Description	To a very great extent/To a great extent/To some extent/To little extent/No extent/No basis to judge/unsure
Resources for Implementation and Enforcement	Needing additional resources to implement the rule, such as for staffing and funding, or to provide inspector training and support.	To some extent – Although FDA has consistently been trying to drive awareness of the rule, it is possible that there are not sufficient resources and this could be part of the reason there is still a lack of awareness. We also have heard members report that the inspectorate is quite varied in their understanding of the rule and approach to evaluating compliance.
Outreach and Education to Certain Sectors	Needing to outreach to and educate sectors with which FDA does not have extensive experience working, such as small businesses, businesses that export food to the U.S., and farms.	To a very great extent – FDA needs to continue focusing on education for

		the import sector.
Uncertainty about Enforcement Process, Roles, and Responsibilities	Needing to understand what compliance and enforcement tools FDA will use, when FDA intends to begin enforcement, roles and responsibilities, and what FDA's enforcement plan is.	No extent – FDA's enforcement approach and the consequences for non-compliance are well established.
Coordination with Nonfederal Regulatory Partners	Needing to improve coordination with, and guidance to, nonfederal regulatory partners, to ensure consistent implementation of the rule.	No extent – We have not heard of inspections conducted by nonfederal regulatory partners.
Data Management During an Outbreak	Technology limitations that could hamper FDA's and industry's ability to respond effectively during an outbreak, such as constraints on FDA's ability to compile and analyze the significant amount of data received during an outbreak.	No extent – FDA can readily identify the FSVP importer for food that is later associated with an outbreak.

a. For each challenge your organization indicated "to some extent", "to a great extent" or "to a very great extent", please briefly describe why and provide an example. As noted above, the need for FDA to continue to conduct outreach and education is demonstrated by the vast number of importers who lack an FSVP. FDA likely needs additional resources to educate, inspect, and take action when noncompliance is found.
b. In your organization's view, are there any other challenges that FDA faces in implementing and enforcing the foreign supplier verification program rule? If yes, please describe. This is a complex rule that requires the regulated entity to have a detailed understanding of the regulatory requirements and compliance strategies. Given that it applies to companies that may not operate food businesses (i.e., importers), we believe this poses compliance challenges.

12) What steps, if any, could FDA take to help address any concerns your organization has with FDA's implementation of the foreign supplier verification program rule and why? Consider issuing model FSVP plans/templates that companies could follow to assist with compliance and issuing guidance and model contracts specific to identification of the FSVP importer.

13) What legislative actions, if any, do you think would be needed to help address any concerns your organization has with FDA's implementation of the foreign supplier verification program rule and why? Given the widespread compliance issues, FDA may want to consider requesting that Congress grant the agency with additional enforcement authorities to further drive compliance.

Questions about the preventive controls for human food rule (Section 103 of FSMA)

14) FSMA required FDA to complete certain actions to implement the preventive controls for human food rule. For example, Section 103 required FDA to undertake rulemaking. *What are your organization's views—positive and negative—regarding the actions FDA has taken with respect to rulemaking?*

ASTA has a favorable view of FDA's actions to implement the Preventive Controls for Human Food (PCHF) rule. The agency did so in a timely manner and took into account industry stakeholder input during the rulemaking process, including issuing a supplemental proposed rule.

15) Section 103 also required FDA to issue regulations, such as to establish science-based minimum standards for conducting a hazard analysis and to define terms such as 'small business' and 'very small business'. *What are your organization's views—positive and negative—regarding the actions FDA has taken with respect to issuing regulations?*

FDA defined these terms as part of the PCHF rulemaking and we have a positive view of FDA's approach, particularly considering the statutory requirements on this issue.

16) Section 103 also required FDA to conduct a study of the food processing sector and submit that report to Congress. *What are your organization's views—positive and negative—regarding the actions FDA has taken with respect to this study?*

FDA issued this required report on June 9, 2016, so ASTA has a positive view of FDA's actions to complete the required study.

17) Section 103 also required FDA to issue guidance, such as a small entity compliance policy guide. *What are your organization's views—positive and negative—regarding the actions FDA has taken with respect to issuing guidance?*

"ASTA has been engaged with FDA during the FSMA implementation process, and we stand ready to further engage with FDA on future initiatives. In particular, we stand ready to assist FDA with releasing long overdue guidance documents. There are numerous chapters of the planned guidance that have not yet been issued in draft form, even though the final rule was issued 9 years ago. This includes significant topics such as validation and sanitation controls, which are critical issues for the safe processing of spices, as well as control of chemical hazards. There also are important issues that are not included in the list of forthcoming draft guidance chapters, such as guidance for root cause investigations in connection with environmental monitoring programs.

For the Appendix 1 draft guidance on potential hazards, ASTA appreciates FDA issuing a revised draft that took account of some of the input provided by industry. However, it took a significant time for the agency to issue this revised document, during which inspectors were

inspecting against Appendix 1 even though it was in draft form and had errors and inconsistencies.

ASTA also is concerned that FDA's guidance on Allergen Controls, including the supplier oversight expectations, is not sufficiently risk-based or consistent with FSMA.

18) In *your organization's* view, what challenges, if any, do businesses face implementing and complying with the preventive controls for human food rule?
    a. To your knowledge, has FDA taken any actions to address these challenges? If yes, please describe.
    b. To what extent do you think these actions have been effective in addressing the relevant challenge(s)?

Because of the range of spice products and their varying physical properties, our members face challenges developing validation data. We have worked with FDA to explain why it is appropriate to engage in grouping of like spices for purposes of validation and FDA has generally been supportive of this approach. However, without guidance from FDA, our members continue to request additional assistance from ASTA to aid their validation efforts. The agency has issued a few Warning Letters related to validation that suggest the agency's expectations are not fully understood by industry and further guidance is warranted.

FDA's letter to the spice industry after the lead in cinnamon apple sauce incident was helpful in reinforcing the foundational requirements for preventive controls. However, it would be been more useful to drive compliance if it had more expressly directed companies to engage in reanalysis for lead in cinnamon and if FDA would establish a specific limit for lead in cinnamon, rather than only doing so indirectly through its enforcement actions.

19) Earlier this year, we issued a report (GAO-24-106563) on challenges businesses, FDA, and its nonfederal regulatory partners could face *as they implement and enforce the food traceability rule*. Below is a list of the challenges we identified. In *your organization's* view, to what extent, if at all, does FDA face the same challenges implementing and enforcing the preventive controls for human food rule?

Challenge	**Description**	**To a very great extent/To a great extent/To some extent/To little extent/No extent/No basis to judge/unsure**
Resources for Implementation and Enforcement	Needing additional resources to implement the rule, such as for staffing and funding, or to provide inspector training and support.	To some extent – Additional resources likely would help FDA issue

		guidance more quickly and expand the knowledge of the inspectorate
Outreach and Education to Certain Sectors	Needing to outreach to and educate sectors with which FDA does not have extensive experience working, such as small businesses, businesses that export food to the U.S., and farms.	To little extent – We encourage FDA to engage in more outreach internationally to small businesses that are covered by the PCHF rule.
Uncertainty about Enforcement Process, Roles, and Responsibilities	Needing to understand what compliance and enforcement tools FDA will use, when FDA intends to begin enforcement, roles and responsibilities, and what FDA's enforcement plan is.	No extent – FDA's enforcement approach and the consequences for non-compliance are well established.
Coordination with Nonfederal Regulatory Partners	Needing to improve coordination with, and guidance to, nonfederal regulatory partners, to ensure consistent implementation of the rule.	To some extent – We continue to hear reports of inconsistencies between federal and state PCHF inspections.
Data Management During an Outbreak	Technology limitations that could hamper FDA's and industry's ability to respond effectively during an outbreak, such as constraints on FDA's ability to compile and analyze the significant amount of data received during an outbreak.	No extent – The PCHF rule is flexible about the form in which data is maintained and is clear about the requirements for when it needs to be provided to FDA.

a. For each challenge your organization indicated "to some extent", "to a great extent" or "to a very great extent", please briefly describe why and provide an example. As indicated, FDA likely needs additional resources to continue to issue PCHF guidance and to do so in a more timely way.
b. In your organization's view, are there any other challenges that FDA faces in implementing and enforcing the preventive controls for human food rule? If yes, please describe. Overall, this is a complex rule and requires a sophisticated and experienced inspectorate to enforce it. FDA continues to be challenged by developing a sufficient team of knowledgeable investigators to educate industry and enforce the preventive controls rule.

20) What steps, if any, could FDA take to help address any concerns your organization has with FDA's implementation of the preventive controls for human food rule and why?

FDA should continue to focus resources on issuing the remaining chapters of draft guidance and finalizing the existing guidance chapters based on consideration of industry comments. If FDA is clearer about strategies and expectations, this will help industry understand what they are expected to do to comply, particularly for some of the significant and technical areas about which the agency has not issued draft guidance.

21) What legislative actions, if any, do you think would be needed to help address any concerns your organization has with FDA's implementation of the preventive controls for human food rule and why?

None. We do not think legislative revision of the PCHF rule is warranted at this time. However, FDA could benefit from additional enforcement authorities that it could use to drive compliance, such as an intermediate remedy between a Warning Letter/regulatory meeting and Consent Decree. FDA also is not using all of its enforcement powers related to the rule, such as issuing invoices for reinspection fees.