

Strategies for Reducing FSMA Implementation Operation Risks and Costs

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Where the **Global Petfood Industry** does business

PetfoodIndustry



The Case For Exercising Due Care While Implementing FSMA



- Largest overhaul of the nation's human and animal food safety laws in the past 70 years.
- FDA enforcement efforts have increased.



The Case For Exercising Due Care While Implementing FSMA

- The number of class action lawsuits filed has substantially increased over the last decade, with multi-million dollar class action settlements becoming the norm.



PET FOOD RECALL ALERT



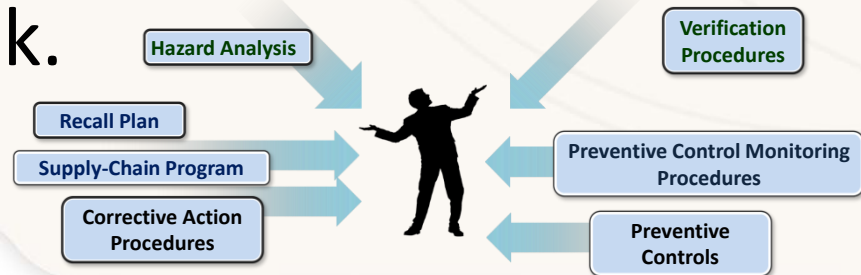
The Case For Exercising Due Care While Implementing FSMA



- Failure to strategically approach FSMA implementation could lead to financially devastating consequences!

The Case For Exercising Due Care While Implementing FSMA

- Implementing a few simple best practices during this FSMA implementation phase can substantially reduce regulatory and litigation exposure risk.



FSMA Best Practices



1. Review and Revise Your Agreements.

- Old form contracts are no longer adequate
- Review existing agreement templates or proposed contracts carefully





FSMA Best Practices

- Use contracts to proactively address FSMA-related risks, as well as compliance with laws and regulations.
 - Better than litigation later



FSMA Best Practices

➤ Examples of Key Contract Provisions:

- Address potential supply chain interruptions
 - Force Majeure clause
 - Allocation of risk/costs associated with interruptions

FSMA Best Practices

➤ Examples of Key Contract Provisions:

- Notice requirements
- Indemnification
- Insurance coverage requirements





FSMA Best Practices

➤ Examples of Key Contract Provisions

- Recall obligations and related costs
- Proof of certifications and/or FSMA compliance

FSMA Best Practices



2. Consider Requiring FSMA Audits Along Your Supply Chain.

- Assessment standards
- Performance criteria
- Frequency of audits



FSMA Best Practices

- Time limits for remedying regulatory noncompliance
- Allocation of audit costs
- Note: If third-party auditors are employed, include provisions regarding how third-party audit reports will be used



FSMA Best Practices



3. Engage Legal Counsel Early and Often

- FSMA's flexible approach created gray areas



FSMA Best Practices



- Choices must be made along the way:
 - during the development of HARPC plans
 - educational programs
 - reporting documents

****Cloak choice with the protections afforded by attorney-client privilege when possible.**

FSMA Best Practices



- Attorney should review all required FSMA compliance documents and responses to FDA requests for information.
 - Providing too much information can lead to additional enforcement actions
 - Submissions to FDA will be discoverable in litigation



FSMA Best Practices

- Example: The facility has identified multiple points of potential bacterial adulteration that were not previously addressed.



FSMA Best Practices

- Revise to: The facility has identified ~~multiple points of~~ potential ~~areas where~~ bacterial adulteration, ~~although unlikely, could potentially occur that were not previously addressed.~~



FSMA Best Practices

- Attorneys should review all components of plans and submissions, including those required of non-exempt facilities such as the Food Safety Plan and its components:
 - Written hazard analysis (§ 507.33(a)(2))

FSMA Best Practices



- Written preventive controls (§ 507.34(b))
- Written supply-chain program (subpart E)
- Written recall plan (§ 507.38(a)(1))
- Written preventive control monitoring procedures (§ 507.40(a)(1))



FSMA Best Practices

- Written corrective action procedures (§ 507.42(a)(1))
- Written verification procedures (§ 507.49(b))

Compliance Audits

- Consider engaging counsel to periodically perform compliance audits
 - Review Documents/Compliance
 - Review Information Sharing Systems In Place
 - Review Recordkeeping Policies and Practices
 - Recommend New Procedures/Revisions



Questions?



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