FSMA Preventive Control Rule for Animal Food
The Pet Food Industry's Response

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April 1, 2014

FSMA

Enacted on January 4, 2011

- Most significant change in food regulation since establishment of the FD&C Act in 1938
- "It's a call for a new, prevention-oriented food safety system"

Food Safety Modernization Act

Most significant food safety legislation since FD&C Act of 1938

Increased FDA Enforcement – Effective Now

Mandatory Recall Authority
- FDA has authority to mandate a recall if the company refuses to do so voluntarily and the hazard meets the criteria for a Class 1 recall

Suspension of Registration
- FDA has authority to suspend a company's registration (license to operate) when the food presents a reasonable probability of causing serious adverse health consequences or death.

Administrative Detention Authority
- Standard for administrative detention of food is broadened to "has reason to believe" the food is "adulterated or misbranded."
  - Under prior law, detention limited to where "credible evidence" that the food presents a "threat of serious adverse health consequences or death" existed.

More Frequent FDA Inspections
- Domestic facilities inspected based on risk – pet food likely to be low risk.

Records Access
- Must be immediately available to FDA upon request.

Pending Requirements

Written Food Safety/Defense Plans

Documentation describing the procedures utilized by facility to:
- Analyze hazards
- Establishment of preventive controls for those hazards
- Records regarding preventive control implementation & monitoring, instances of nonconformance, testing, and verification of correction actions, and efficacy of controls
- Defense program in place to prevent intentional and/or unintentional adulteration.

Written Recall Plan/Strategy
- Identifies responsible individuals and functions
- Outlines procedures for investigating issues and executing recall

Hazard Analysis and Preventive Controls
- Hazard analysis of reasonably foreseeable hazards required
- Implement preventive controls to minimize or prevent hazards
- Monitor effectiveness of preventive controls & corrective action via appropriate testing.

Supply Chain Management
- Required to verify that food and food ingredients are produced in accordance with U.S. requirements.

FSMA – Proposed Rules

- Preventive Controls for Human Food
  - Comment period closed 22 November 2013
- Foreign Supplier Verification Program
  - Comment period closed 27 January 2014
- Accreditation of Third-Party Auditors
  - Comment period closed 27 January 2014
- Preventive Controls for Animal Food
  - Comment period closed 31 March 2014

Initial Areas of Concern Regarding FSMA Proposed Rules

- Science-Based Regulations:
- Do the data/science support the current/proposed scrutiny of pet food?
- "An important distinction in the risk analysis approach is the understanding of risk, i.e., the likelihood and magnitude of a public health impact, as a result of a hazard in a food versus simply the presence of the hazard." – Mead et al (2010)

Statements Attributed to FDA Officials

"FDA would inform producers that their food must be nutritionally balanced."

"Unlike safeguards already in place to protect human foods, there are currently no regulations governing the safe production of most animal foods. This rule would change all that."

"For the first time, the Food and Drug Administration (FDA) is proposing preventive measures to protect all animal foods from disease-causing bacteria, chemicals and other contaminants."

Industry Preparation of FSMA Comments

- Formed 5 individual working groups
- Working groups addressed all aspects of proposed rules affecting pet food
- Webinars with CVM to identify and address questions, concerns
- Submitted requests to extend the comment periods
- Intent is to use sound science and data in our comments and provide suggested solutions for any areas of concern

FSMA Response Team Volunteers

James Bowes – Ainsworth Pet Nutrition
Aaron Maxfield – Ainsworth Pet Nutrition
Angele Thompson – Rep. Ainsworth
Nicole Birmingham – Big Heart Pet
Mike Hayes – Big Heart Pet
Eric Ney – Big Heart Pet
Allen Bingham - Bil Jac
Lynn Bingham - Bil Jac
Nancy K Cook – Rep. Bil Jac/Sunshine
Lorri Chavez - Central Garden & Pet
Denise Fung - Central Garden & Pet
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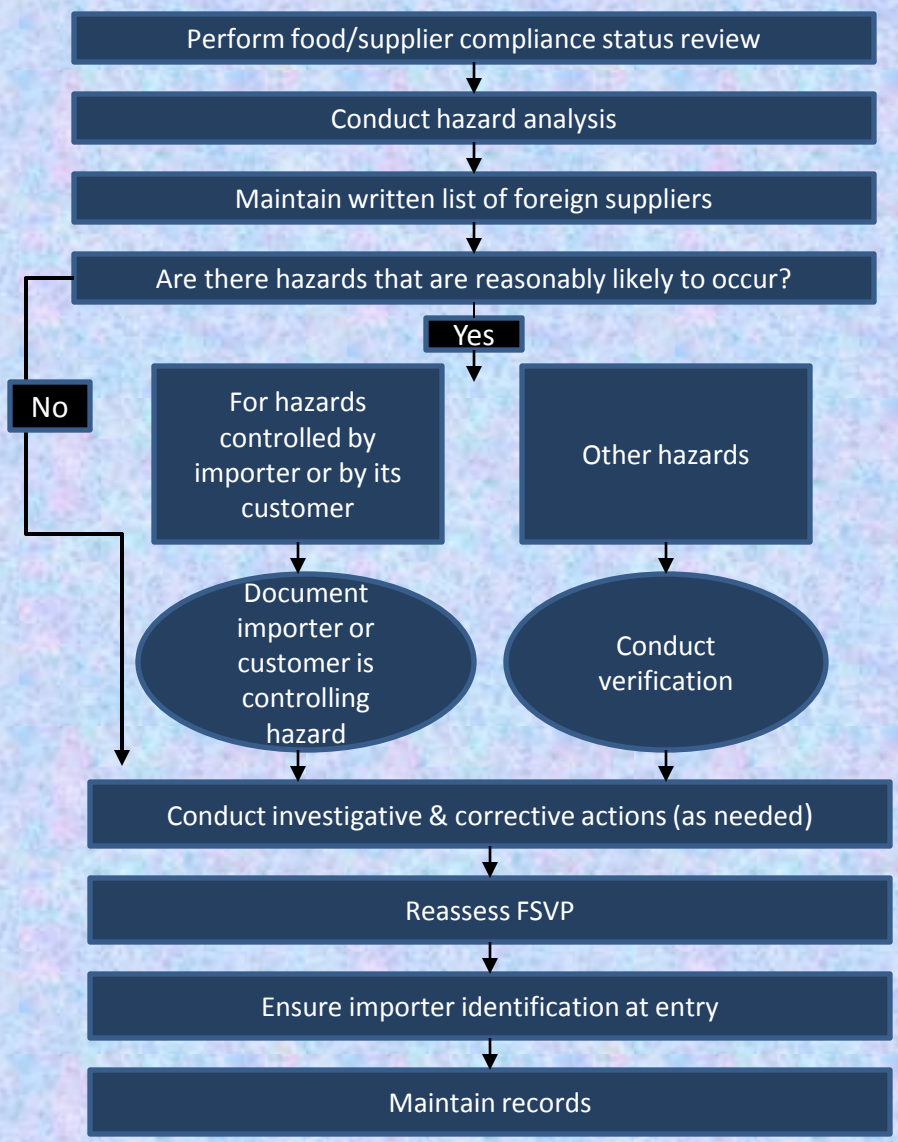
Michele Evans - Diamond Pet
Mark Mascarenhas - Diamond Pet
Diane Loiselle – Hill's Pet Nutrition
Steve Traylor – Hill's Pet Nutrition
Natasha Bangel – Hill's Pet Nutrition
Mike Davis – Hill's Pet Nutrition

Tom Forster – Hill's Pet Nutrition
Jerry May -- Kemin
Jim Barritt- Mars Pet Care
Katie Burrell – Mars Pet Care
Jill Franks - Mars Pet Care
Tami Sergent - Mars Pet Care
Chris Cowell - Nestle Purina
VeRonica Daenzer - Nestle Purina
Kelvin Hawkins - Nestle Purina
Richard Driggs – Nestle Purina
Randy King – P&G Pet Care
Candace Doepker – Rep. P&G
Jason Vickers - P&G Pet Care
Shelley Volpenhein - P&G Pet Care
Billie Johnson – Simmons
Heather Clarkson -United Pet Group
Tomas Belloso – Wilbur Ellis
Kristin Malone – P&G Pet Care

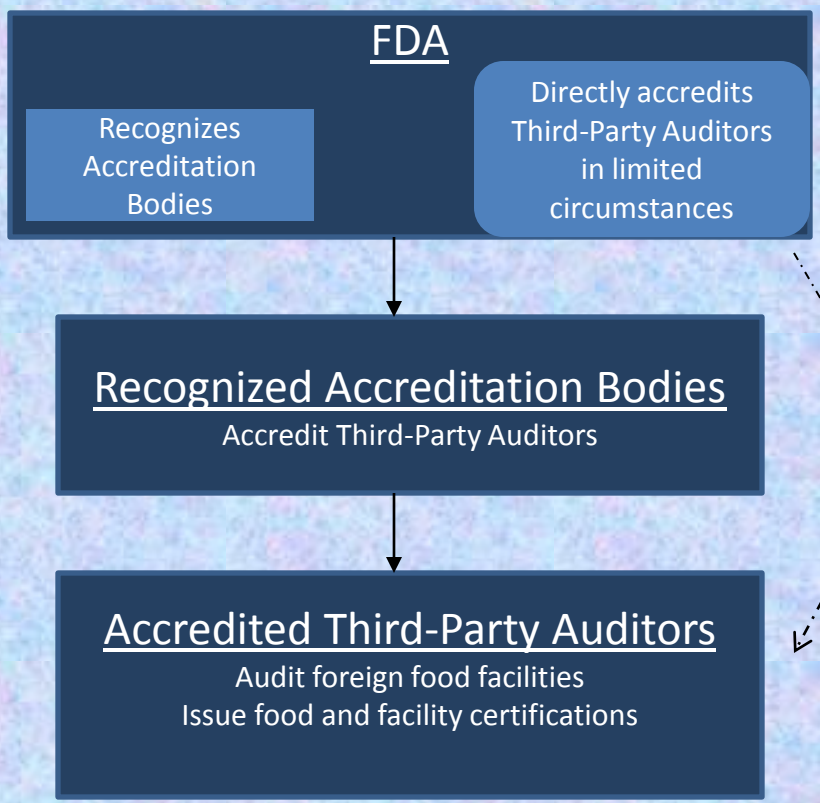
Foreign Supplier Verification Programs



Key Concerns

- Records access
- Clear language facilitating entry of pet food/ingredients
- FDA criteria for determining high-risk foods/countries/facilities
- Foreign suppliers under the same corporate umbrella
- Role of importer's history with a foreign supplier
- Need for importer flexibility, discretion
- Implications for domestic supplier approval and verification

Accreditation of Third-Party Auditors



Key Concerns

- Model accreditation standards
- FDA determination of high-risk foods
- Ensure auditors have pet food knowledge
- FDA access to consultative audits findings
- Accreditation body, auditor capacity challenges
- Confidentiality of information shared
- Implications for domestic use of third-party audits

PFI Comments on Foreign Supplier Verification Programs and 3rd Party Accreditation

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Texas Farm Products

January 27, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

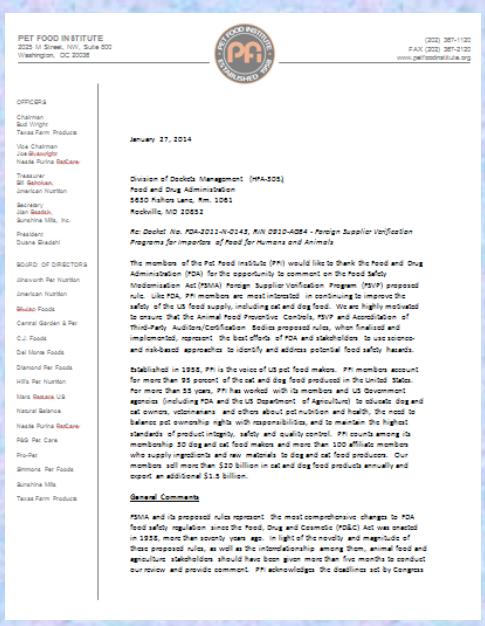
Re: Docket No. FDA-2011-N-0146, RIN 0910-AG66 - Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications

The Pet Food Institute (PFI) would like to thank the Food and Drug Administration (FDA or the agency) for the opportunity to comment on the Food Safety Modernization Act (FSMA) Accreditation of Third-Party Auditors/Certification Bodies proposed rule (Third-Party rule/proposed rule). Like FDA, PFI members are most interested in continuing to improve the safety of the US food supply, including cat and dog food. We are highly motivated to ensure that the Animal Food Preventive Controls, Foreign Supplier Verification Program (FSVP) and Third-Party rules, when finalized and implemented, represent the best efforts of FDA and stakeholders to use science- and risk-based approaches to identify and address potential food safety hazards.

Established in 1958, PFI is the voice of US pet food makers. PFI members account for more than 95 percent of the cat and dog food produced in the United States. For more than 55 years, PFI has worked with its members and US Government agencies (including FDA and the US Department of Agriculture) to educate dog and cat owners, veterinarians and others about pet nutrition and health, the need to balance pet ownership rights with responsibilities, and to maintain the highest standards of product integrity, safety and quality control. PFI counts among its membership 30 dog and cat food makers and more than 100 affiliate members who supply ingredients and raw materials to dog and cat food producers. Our members sell more than $20 billion in cat and dog food products annually and export an additional $1.5 billion.

General Comments

FSMA and its proposed rules represent the most comprehensive changes to FDA food safety regulation since the Food, Drug and Cosmetic (FD&C) Act was enacted in 1938, more than seventy years ago. In light of the novelty and magnitude of these proposed rules, as well as the interrelationship among them, animal food and agriculture stakeholders should have been given more than five months to conduct our review and provide comment. PFI acknowledges the deadlines set by Congress



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Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2011-N-0143, RIN 0910-AG64 - Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

The members of the Pet Food Institute (PFI) would like to thank the Food and Drug Administration (FDA) for the opportunity to comment on the Food Safety Modernization Act (FSMA) Foreign Supplier Verification Program (FSVP) proposed rule. Like FDA, PFI members are most interested in continuing to improve the safety of the US food supply, including cat and dog food. We are highly motivated to ensure that the Animal Food Preventive Controls, FSVP and Accreditation of Third-Party Auditors/Certification Bodies proposed rules, when finalized and implemented, represent the best efforts of FDA and stakeholders to use science- and risk-based approaches to identify and address potential food safety hazards.

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- Both comments submitted to the docket January 2014
- Final rule due March 2016

FSMA – Preventive Controls for Animal Food

- Establishes Current Good Manufacturing Practices
- Hazard analysis and risk-based preventive controls
- Qualified Individual
- Records Access
- Requests for comment on:
    - Supplier approval and verification
    - Product testing
    - Environmental monitoring

Preventive Controls for Animal Food
PFI Comments Based on 4 Core Principles

1) Regulation should reflect the Congressional intent specified in the statute requiring that the rules be based on science and risk analysis;

2) Animal food is not human food, and FDA regulations should accommodate the differences;

3) Should be one animal food regulation applicable to all animal food categories

4) Should be no exemptions for animal food producers based on either number of employees or volume of sales.

Animal Food Proposed Rule – PFI Areas of Concern

<u>Animal Food proposed rule is modeled after the Human Food proposed rule</u>

- Human Food CGMPs (not AAFCO or PAS-222 GMPs) as template for our CGMPs

<u>Economic Impact - PRIA</u>

- Environmental monitoring
  - FDA: $3,457/facility; $636,000 industry-wide
  - PFI: Up to $800k/facility
- FSMA Animal Food Rule compliance
  - FDA: $93m-95m industry-wide one-time cost
  - PFI: As high as $11m/company annually

Animal Food Proposed Rule – PFI Areas of Concern

Records Access

- Context is critical to FDA decision making
- Challenges of maintaining/updating records
  - Facility profiles, food safety plans, archiving

Testing Programs

- Environmental, ingredient and finished product
- Flexibility to use the appropriate tools

Animal Food Proposed Rule – PFI Areas of Concern

Exemptions

- Research and pilot plant facilities that do not place food into commerce
- NO exemptions based on company size

Training of FDA Inspectors

- Use proper (i.e., animal – not human – food) criteria

CGMPs

- Surprised and disappointed to see that the animal food CGMPs so closely resemble the human food CGMPs
- International standard PAS 222 or the AAFCO Model GMPs should have been the basis
- PFI recommended that one set of CGMP requirements for all animal foods.
- Differences in risk across animal food products can be addressed in each animal food facility's food safety plan

Hazard Analysis and Risk-Based Preventive Controls

- Concept of “reasonably likely to occur” (RLTO) is unnecessary
- Statutory requirement that an owner, operator or agent in charge of a facility “identify known or reasonably foreseeable hazards that may be associated with the facility”
- PFI recommended the removal of the term RLTO and any attempt to incorporate HACCP principles in this rule.
- PFI recommended that the final rule replace “RLTO” with “known or reasonably foreseeable hazards.”

Hazard Analysis and Risk-Based Preventive Controls

- As FDA acknowledges in the preamble to the proposed rule that not all preventive controls will have critical control points, nor will critical limits be required for all preventive controls.
- Many aspects of food safety can be and are addressed through “prerequisite programs” rather than “preventive controls”
- Prerequisite programs, including pest control , training , documentation and facility maintenance, are not amenable to a critical control point approach.

Role of Testing

- FDA did not include specific requirements for either environmental, ingredient or product testing, but instead solicited comments on whether such requirements should be included.
- PFI's position is that any testing program be both risk-based and facility-specific
- Ingredient, environmental and finished product testing are each useful tools however…
- FDA should allow flexibility for animal food producers to determine the approach
- Recommend that details of suggested programs be captured via guidance documents instead of via codification in specific FSMA rules.

Cost and Benefit

- FDA has significantly underestimated the costs for FSMA compliance.
- FDA estimates environmental monitoring will cost approximately $3,457 per facility annually and $636,000 industry-wide
  - PFI survey of members indicated costs up to $800,000 annually for each facility depending on the type of pet food produced
- FDA also includes in the Animal Food proposed rule PRIA an estimate of the one-time cost for compliance of approximately a $93-$95 million for the entire animal food industry, of which pet food is a relatively small category

Cost and Benefit

- The survey of PFI members shows that increased recordkeeping requirements alone could cost as much as $500,000 per company
- Increased personnel costs could easily exceed $1 million and be as high as $11 million per company annually
- Increased audit costs will average more than $150,000 annually per company

Compliance Dates

- CGMPs and preventive controls are new for the animal food industry and that the animal food industry will require sufficient time to achieve compliance
- It will not be easier for larger animal food producers to achieve compliance than smaller producers
- PFI recommended that the compliance date for **all** animal food producers (including ingredient suppliers), regardless of size, should be 3 years from the effective date of the final rule.

7th FSMA rule Published in Federal Register 2/5/14

Sanitary Transport of Human and Animal Food

- PFI member commenting team is forming
- Comments due to docket 5/31/14

Notice on Methodology for High Risk Food Determination

- Not a proposed rule, but FDA is asking for comment, scientific data and information.
- Required by Section 204 of FSMA
- HRFs will require additional recordkeeping
- HRF designation "must be based on the historical public health significance of the food…"
- Does not appear that pet food would be high risk, but FDA specifically asks for more information on animal food (feed and pet food)
- Response due to docket 5/22/2014

Final Comment

Pet Food Manufacturers are strongly committed to improving the quality of the pet food products they produce and despite the low risk to animal or public health, pet food makers are committed to continuously improving the safety of their products.

Questions?