

Food Safety Modernization Act (FSMA)


**FOOD SAFETY MODERNIZATION
ACT ("FSMA")**

DOOM AND GLOOM???




Animal Feeds (ingredients and mixed) have a good safety record, however...

- potential human and animal health problems can be hidden. So-o-o, the FDA has taken steps...




First, there's...



- **The Animal Feed Safety System** or AFSS.
 - **Who?** FDA's Center for Veterinary Medicine along with state feed control offices.
 - **What?** Comprehensive and risk-based feed regulatory program to ensure production and distribution of feed that is safe.
 - **When?** Initially introduced in 2003
 - **How?** Identification of gaps in feed safety measures and the means to address them.

Next, development of the....




- **Rapid Response Teams** or RRTs
 - **Who?** FDA and State Food Regulatory Partners. To date 19 States have been awarded the grant. In the FDCA the term "food" is defined as food for man or other animals, and includes animal feed.
 - **What?** Developing models that can be used and adopted by other programs to build core capabilities and explore new ideas for approaches to response to food borne illness incidents.
 - **When?** The first nine states (including Virginia) were awarded grants in 2008/2009 and the next 10 were awarded grants in 2012.
 - **How?** Each state develops response plans that *work* in their specific state taking into account government structure, geography, laws, resources and the like that influence (either positively or negatively) response capabilities.

Food Safety Modernization Act (FSMA)

And finally came....

THE FOOD SAFETY MODERNIZATION ACT (FSMA)




3

AFSS, RRTS AND FSMA TOGETHER:

- The Animal Feed Safety System team works towards guidance for industry in identifying hazards likely to be found in animal feed.
- The Rapid Response Teams work towards developing plans to quickly respond to food-borne illness incidents and assist in identifying critical control points in manufacturing.
- The Food Safety Modernization Act provides a means for a proactive approach to Food and Feed Safety in the United States.

□ All serve as part of building an *Integrated National Food Safety System* that will prioritize prevention, strengthen surveillance and enforcement, and improve response and recovery.


Preventing harm to consumers is the top priority.




6

Why, Oh Why???

□ FDA believes that a shift from a reaction focus to a prevention focus will result in more immediate corrective actions to protect public health.



instead of



7

Do they understand how this could affect my business???

□ FDA also knows that its rules and oversight practices must take full account of the diversity of operations covered by FSMA, be risk-based and flexible, address small business issues and be backed up by guidance, technical assistance, and educational outreach to support private sector implementation of FSMA's new prevention paradigm.

□ Fully implementing the sweeping change called for by FSMA will take years.

8

Food Safety Modernization Act (FSMA)

"Hypothetical FSMA Time Frame"

- Dr. Leanne Skelton, a senior policy analyst, FDA Center of Food Safety and Applied Nutrition, stated this summer that the large operations would comply first, then down to smallest farms over several years. (Discussing produce regulations)
- In this time line, beginning in August, it would still be 2016 before the earliest adopters would have to comply and the last on the schedule would likely not be subject to the rules until 2020.

The Process...

- Proposed rules on Preventive Controls for Human Food and Standards for Produce Safety were released on January 4, 2013.
- Comments on the proposed rules are due within **120 days** of their publication in the Federal Register. These comments will be reviewed for consideration before issuance of the final rules. *(Just a fun fact: The Preventive Controls for Human Food proposed rule is 680 pages)*
- Expect proposed rules on importer foreign supplier verification soon
- Future proposed rules will address **preventive control rules for animal food**, and accreditation of third-party auditors.

"Educate us before you regulate us."



OK...BUT HOW???

1. Better targeting of inspections based on inherent risk and past performance.
2. Streamlined procedures for making public health decisions during inspections, seeking and obtaining voluntary compliance and using administrative enforcement tools when appropriate.
3. Working more closely with state and local government partners on inspections and follow up actions to protect consumers.

Food Safety Modernization Act (FSMA)

Food Safety Preventive Controls Alliance (FSPCA)

- FDA along with the Illinois Institute of Technology's Institute for Food Safety and Health has created the FSPCA to develop training courses and materials on preventing food contamination during production.
- Some of the things FSPCA will develop:
 - "Train-the-trainer" materials and student education delivery systems
 - Standardized hazard analysis and preventive controls training
 - A technical assistance network for small- and medium-sized food companies
 - Commodity/industry sector-specific guidelines for preventive controls
 - Identify and prioritize the need for, and compile, critical limits for widely used preventive controls.

What does all that mean?

1. **Hazard** - an adverse affect; a chance or source of danger
2. **Risk**- likelihood and health consequence of a hazard
3. **Risk-Based Priority**: Identify the most significant foodborne hazards and take action to address them with the knowledge that priorities will change as new hazards emerge.
4. **Working With Others**: Working with external stakeholders and partners by seeking input on many aspects of FSMA implementation.
5. **Federal-State Integration**: Joint planning of inspections, expanded reliance on state inspections and mutual reliance on inspection results and laboratory analyses.

What we *DO* know...

1. There are four foundational proposed rules of FSMA. They are:
 - Preventative controls for animal feed
 - Preventative controls for human food
 - Produce safety
 - Foreign supplier import verification program
2. The Food and Drug Administration has published 3 final rules in the Federal Register and published several draft and final guidance documents
3. Some implementation dates have been modified as work continues to complete the 90 deliverables FSMA directs FDA to accomplish.

Main Themes of Legislation



Food Safety Modernization Act (FSMA)

General Principles of FSMA

- ❑ Science-based : controls that are minimally necessary to protect public health
- ❑ Flexibility : where specific preventive controls are mandated, alternatives are accepted if validated
- ❑ Risk-based : burden tracks risk
- ❑ Small business sensitivity



What will I have to do to meet FSMA requirements????

- ❑ ALL facilities will be required to maintain records.
- ❑ ALL manufacturing facilities must adhere to the *Current Good Manufacturing Practices (cGMP's)* which will form the foundation for preventive controls.
- ❑ SOME facilities will be required to implement preventive controls.
- ❑ SOME exceptions will apply.

cGMP Elements

- Personnel
- Plant and Grounds
- Sanitary Operations
- Sanitary Facilities and Controls
- Equipment and Utensils
- Processes and controls
- Warehousing and distribution



WHAT'S INCLUDED IN "PREVENTIVE CONTROLS"?

- ❑ Process controls
- ❑ Supplier controls
- ❑ Sanitation Controls, that impact animal food safety
- ❑ Submission and monitoring of Feed Safety Plans
- ❑ Record keeping

Food Safety Modernization Act (FSMA)

EXCEPTIONS TO REQUIREMENTS??

- There are **two** criteria sited in the act that must be met for a facility to qualify for an exception or modification to conducting hazard analyses and implementing preventive controls.



1. "Annual Monetary Value of Sales"

2. "Small and Very Small Business"



Monetary Values and Definitions

- Effective Date:** 60 days after the final rule is published
- In the **proposed** rule for human food facilities, FDA, in recognizing that small and very small businesses may need more time to comply with the requirements, has adjusted the compliance dates as follows:
- Compliance Dates:**
 - Very Small Businesses**—Three options are being proposed for the definition of a very small business: less than \$250,000, less than \$500,000, and less than \$1,000,000 in total annual sales of food, adjusted for inflation. Very small businesses, which would be considered "qualified facilities" and *subject to modified requirements for preventive controls*, would have to comply three years after publication of the final rule.
 - Small Businesses**—a business that employs fewer than 500 persons and that *does not qualify for an exemption* would have to comply two years after publication of the final rule.
 - Other Businesses**—a business that is *not small or very small* and *does not qualify for an exemption* would have to comply one year after publication of the final rule.

§418, (m): Authority with respect to certain facilities....

- §418 Hazard Analysis and Risk-Based Preventative Controls identifies the exceptions, modifications and exemptions that may be identified by regulation.
- One of interest:** "The Secretary may, by regulation, exempt or modify the requirements for compliance under this section with respect to facilities that are solely engaged in the *production of food for animals other than man...*"



CONFUSED? WORRIED?



What do I do? What do I dooo???

Food Safety Modernization Act (FSMA)

What do the preventive controls address???

- Food safety at human food facilities
- Food safety at animal food facilities ***
- Prevention of intentional contamination at human and animal food facilities, dairy farms and produce farms and packing facilities***
- Food safety at produce farms and unregistered packing facilities
- Food safety during transportation of human and animal food***

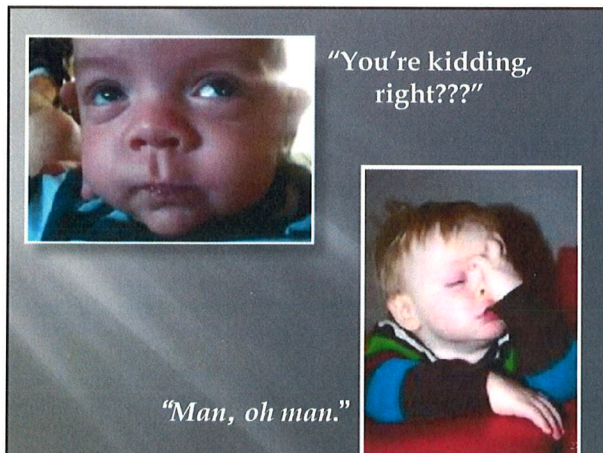
*** pertain to feed manufacturing

23

Preventive Control Elements

- Plan must be written.
- Hazard analysis must be conducted.
- Preventive controls for hazards that are reasonably likely to occur must be developed.
- Recall plans must be written.
- The plan must be monitored.
- Corrective actions must be developed and implemented.
- Verification that the developed plan is effective must be recorded.
- Supplier approval and verification program must be developed.
- Records must be maintained of all aspects of the plan.

26



Food Safety Modernization Act (FSMA)

The 7 Principles of *HACCP*

1. Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards can occur and describe the preventive measures.
2. Identify the Critical Control Points (CCPs) in the process.
3. Establish critical limits for preventive measures associated with each identified CCP.
4. Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control.

HACCP (continued)

5. Establish corrective actions to be taken when monitoring indicates that there is a deviation from an established critical limit.
6. Establish effective record-keeping procedures that document the HACCP system.
7. Establish procedures for verification that the HACCP system is working correctly.



AAFCO WebPages for information and planning

HACCP for Feed Mills:

http://www.aafco.org/Portals/0/AAFCO/haccp_2010

Good Manufacturing Practices Guidance:

<http://www.aafco.org/Portals/0/AAFCO/Guidance%20DocFinal.pdf>

GMP Guidance Checklist:

http://www.aafco.org/Portals/0/AAFCO/GMP_Checklist.pdf


(or go to www.aafco.org, click on "regulatory info" at the bar on the top of the page to get to the page you want.)

What else do we need to know?

- Additional categories for food products, including animal feed have been identified to allow for more rapid communications concerning actual or potential bioterrorist attacks, other food-related emergencies or food safety incidents.
- There is a mandated inspection frequency that requires FDA to consider new ways to inspect.
- Sanitary food/feed transportation: applies to "motor vehicle" transport (includes trucks and railcar, not ships, barges or planes). Intention is for DOT and state "DOT" agencies (i.e. state police) to enforce.
- FSMA provides new tools for achieving compliance:
 - Mandatory recall
 - Expanded records access
 - Expanded administrative detention
 - Enhanced product tracing
 - Third party laboratory testing.
 - Suspension of registration



Food Safety Modernization Act (FSMA)



Registering...

- FSMA amended section 415 of the FD&C Act which states that all domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the U.S. to register with FDA. The amendment requires **biennial registration renewal**. FDA Unified Registration and Listing Systems (FURLS): www.fda.gov/furlis
- The biennial registration renewal period of October 1 through December 31 of every even-numbered year was to be implemented beginning October 1, 2012. However, the registration renewal was not available at that time. Registration renewal became available on October 22, 2012 with a deadline extension until January 31, 2013. Registration renewals should now be completed.
- Regulations will be promulgated on requirements for registration suspension (i.e. when a facility is deemed responsible for or knew of and packed, received or held a food with a reasonable probability of causing serious adverse health consequences or death to humans or animals).

FSMA provides for FDA to collect a variety of fees:

- Export certificate for food/feed
- Support and establish Foreign Supplier Verification Program (FSVP) including third party certification.
- Re-inspection** and **recall order non-compliance** fees for domestic and imported products
 - Fees for non-compliance with a recall order is self-explanatory
 - Re-inspection fees are for re-inspections to evaluate corrective actions following a previous FDA inspection that was classified Official Action Indicated (OAI) on a non-compliance that was materially related to a food safety requirement.

Fees (continued)

- Fiscal Year 2012 **hourly rate is \$224.00** sans foreign travel; with foreign travel, \$325.00. Assessment is based on the number of **hours FDA spends directly on the reinspection-related activities or food recall activities** associated with a recall order.
- These "activities" include conducting the inspections, preparing and arranging for the inspection, travel to and from the facility, analyzing records and samples, recall audit checks, reviewing status reports, etc.
- The FD&C Act provides a general annual limitation on the collection of "non-compliance with a recall" fees of \$20 million and on "reinspection" fees of \$25 million.

Import Safety



Foreign Supplier Verification Program

- Requires food from abroad to be as safe as domestic
- Importers now responsible for ensuring that their foreign suppliers have adequate preventive controls in place

Food Safety Modernization Act (FSMA)

Import Safety: cont.

3. FDA can rely on third parties to certify that foreign food facilities meet U.S. requirements
4. Can require mandatory certification for high-risk foods
5. Voluntary qualified importer program - expedited review
6. Can deny entry if FDA access for inspection is denied.

How will all of this be implemented??

- Plans are under development regarding training.
- Plans are under development regarding the inspection program.
- Initial work planning is going on.
- Implementation will be phased-in as pieces develop.

THERE ARE IMPLEMENTATION PLANS.



But, they're a little difficult to grasp...

To stay on top of things...

- ☐ FDA has an interactive FSMA webpage where you can sign up for updates on FSMA by email: <http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>
- ☐ You can get to the FDA FSMA page from the AAFCO website as well. Just click on "General Info".
- ☐ For Food Facility biennial registration renewal information:
FAQs: <http://www.fda.gov/Food/FoodSafety/FSMA/ucm314178.htm#FAQs>
Guidance and Rules: <http://www.fda.gov/Food/FoodSafety/FSMA/ucm314178.htm#GuidanceDockets>
Links to Registration Form 3537 and online system: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/default.htm>

PROVIDE INPUT!

- ☐ Look for the proposed rules.
- ☐ Take note of comment periods and their deadlines
- ☐ **COMMENT!**
- ☐ FDA is required to review every comment.
- ☐ FDA is seeking input from industry in the development of both the rules and guidance documents for those rules.

Food Safety Modernization Act (FSMA)

Proposed Rules Open for Comment on Regulations.gov

- The Proposed Rule [Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food](#) is open for comments on regulations.gov. See Docket Number [FDA-2011-N-0920](#).
- The Proposed Rule [Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption](#) is open for comments on regulations.gov. See Docket Number: [FDA-2011-N-0921](#).
- For more information on FDA's Food Safety Modernization Act, visit <http://www.fda.gov/fsma>.

11

DOOM AND GLOOM ???

Naw. Patience is power.



12

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13