



# **Food Safety Modernization Act – Animal Foods Proposed Rule and Brewers’ Spent Grains**

Patricia Pratt, PhD

MillerCoors LLC

Golden, Colorado

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## What is the Food Safety Modernization Act (FSMA)?

- FSMA was passed into law on 4<sup>th</sup> January 2011
- It is the first major revision of the U.S. federal food safety laws since the Food, Drug and Cosmetic Act of 1938, over seventy (70) years ago
- It aims to better protect human and animal health by implementing requirements to ensure the safety and security of food and feed supply
- It embraces the need for a global approach to food and feed safety and brings significant changes to the U.S. food safety landscape
- Its Framework consists of **seven** foundational Proposed Rules, of which six **directly** impact the Brewing Industry and was presented as an Oral Presentation yesterday.



## What is the Animal Food Proposed Rule?

- Officially known as, Current Good Manufacturing Practice (CGMP) and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals
- It was proposed by the U.S. Food and Drug Administration (FDA) on 29<sup>th</sup> October 2013
- It is the fifth major Rule under the FSMA rule-making initiatives
- It requires facilities producing animal food to address preventive steps to ensure the production of safe animal food



## Why the Animal Food Rule?

- There was a lack of federal regulations in the animal food safety system
- To improve the safety of animal food, including pet food and animal feed
- To prevent foodborne illnesses in both human and animals
- To prevent food safety hazards for domestic and imported animal foods for:
  - Animals consuming the food
  - Humans handling the food
- As a result of food recalls associated with animal foods



# Pet Food Recall



- **Companies:** 12 including Menu Foods
- **Date of Outbreak:** March 2007
- **Chemical Hazard:** Melamine
- **Commodities:** Pet, Fish, Farm Animals Food
- **Brands:** 180
- **Country of Origin of Ingredients:** China
- **Deaths:** 17 confirmed during taste test at Menu foods Canada
- **Confirmed Illnesses:** Uncertain
- **Region:** North America, Europe and South Africa
- **Findings:** Intentional contamination of wheat and rice gluten protein from China
- **Status:** Chinese and US Companies indicted

*The largest Pet Food Recall in North America!*



# Current Requirements

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## What are the current Requirements under the Rule?

- It requires facilities producing pet food, animal feed, raw materials and ingredients for animal food to:
  - **Have written Food Safety Plans that identify hazards (hazard analysis)**
  - Specify controls that will be implemented to minimize or prevent those hazards (preventative controls/hazard analysis)
  - Identify monitoring procedures
  - Record monitoring results (record-keeping)
  - Implement verification activities
  - Specify corrective action procedures in the event problems arise
- **Implement Hazard Analysis Risk-based Preventive Controls** in accordance with section 103 of FSMA



# Current Requirements

## What are the current Requirements under the Rule?

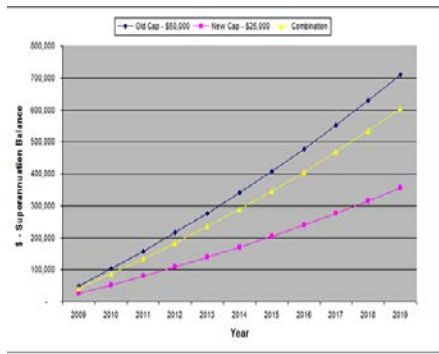
- Facilities producing pet food, animal feed, raw materials and ingredients to implement CGMP such as:
  - Hygienic personnel practices
  - Employee training
  - Facility operations
  - Facility maintenance
  - Facility sanitation
  - Equipment and utensil design, use and maintenance
  - Processes and controls
  - Warehouse and distribution
- Register as a food facility under section 415 of FD&C Act





# Exemptions

## Who is currently exempted from the proposed Rule?



- Based on sales/annum
- Low-acid canned animal foods
- Warehouses that store packaged animal foods
- Small business definition



## Who is currently covered by the proposed Rule?

- Majority of facilities required to register with the FDA
- Manufacturers
- Processors
- Packers
- Holders

**FDA Industry Systems** SYSTEM STATUS

**LOGIN**

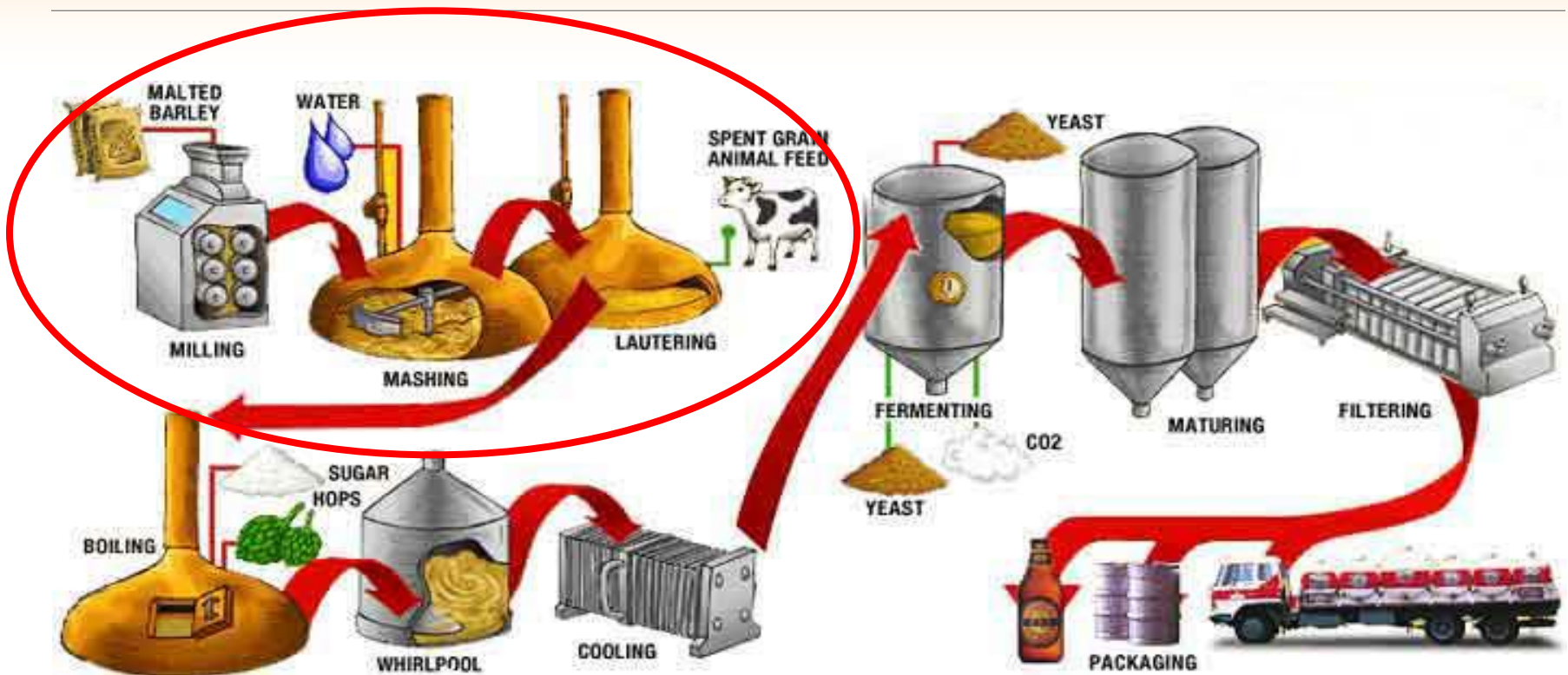
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Account ID:

Password:



# Brewers' Spent Grains Production Process



- FDA suggested that beer companies are in 2 businesses:
  - Brewing beer/selling beer
  - Producing spent grains/selling spent grains
- Spent grains are the natural by-product or residue of brewing beer

# Brewing Industry Concerns

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- Brewers will have to comply with human food safety requirements for spent grains
- Brewers will have to comply with additional and redundant animal feed standards for spent grains
- These requirements would be cost prohibitive and would not add value for food, or feed safety.
- The onerous potential costs, possibly at a minimum of \$128.75 million per annum, may require Brewers to send spent grains to landfill.
- Why propose such a rule when there is no reportable linkage between spent grains and animal, or human food-borne illness; nor any reported cases of contamination?



**Sen. Johanns Urges FDA to Change FSMA-Proposed Rule for Animal Feed and Pet Food**

**Dairy Interests Criticize Proposed FDA Animal Feed Rules, Ask for Rewrite**

**FEED AND GRAIN ASSOCIATIONS REQUEST MORE TIME TO COMMENT ON FSMA RULES**

**FDA stretches FSMA rule comment period**

**‘Double whammy’: Senator insists FDA rule could cripple craft brewers**

**The FDA wants to regulate spent grains, and the beer industry is not having it**

**Feed prices could soar if brewer grains not exempted from FSMA, says US dairy lobby**

**FDA reviewing part of animal feed rule after fury over spent grains proposal**

**FDA admits language used in FSMA feed rule muddied the waters: agency set to revise grain proposal**

**Getting it Right on Spent Grains**

Posted on [April 24, 2014](#) by [FDA Voice](#)

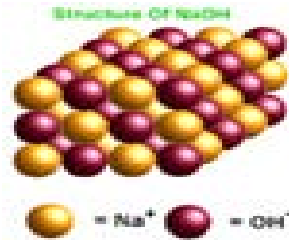


# FDA – Comments on the Revision of the Rule

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- The intent of the Rule is not to disrupt, or eliminate the practice of using spent grains for animal feed
- The potential hazards associated with spent grains are minimal
- Brewers should take reasonable measures to ensure that food for animal is safe from:

- Chemical hazards -



- Physical hazards -

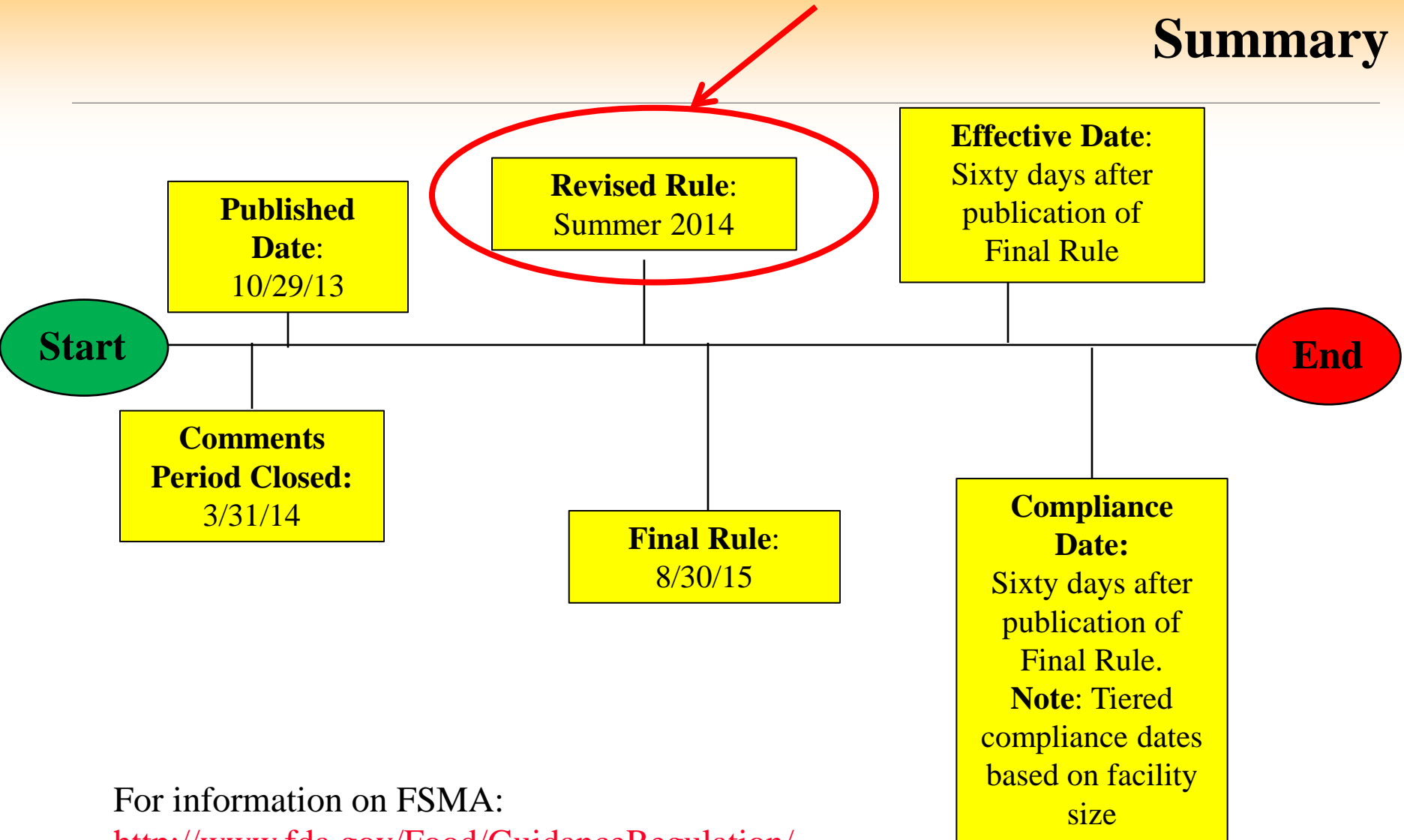


# FDA – Comments on the Revision of the Rule

- The Rule is being revised to avoid inconsistencies, duplication of efforts and confusion (e.g. drying of spent grains)
- CGMP would still be a requirement due to making alcoholic beverages for human consumption
- The written food safety plan would be as minimal as ensuring spent grains are stored in conditions that prevent contamination (e.g. the use of appropriate storage containers)
- Food safety control measures for animal feed safety can be included in the written food safety plan for human product
  - A separate animal feed safety plan is not required



# Summary



For information on FSMA:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>





# Acknowledgements/Questions

- MBAA
- MillerCoors
- You, the audience for listening!

