

# Distillers Grains Regulatory Challenges

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Presented to:  
*23<sup>rd</sup> Annual Int'l Fuel Ethanol Workshop*  
*Workshop 17: Distillers Dried Grains*

*St. Louis, Missouri*  
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# Distillers Products\*

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- Molasses Distillers Dried Solubles ('43)
- Molasses Distillers Condensed Solubles ('46)
- Potato Distillers Dried Residue ('47)
- Distillers Dried Solubles ('64)
- Distillers Dried Grains ('64)
- Distillers Dried Grains with Solubles ('64)
- Condensed Distillers Solubles ('70)
- Distillers Wet Grains ('82)

*\* Association of American Feed Control Officials Official Publication (AAFCO OP)*



# Distillers Dried Grains

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..... is obtained after the removal of ethyl alcohol by distillation from the yeast fermentation of a grain or a grain mixture by separating the resultant coarse grain fraction of the whole stillage and drying it by methods employed in the grain distilling industry. ....

# Distillers Dried Grains

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..... is obtained after the removal of ethyl alcohol by distillation from the **yeast fermentation** of a **grain or a grain mixture** by separating the resultant coarse grain fraction of the whole stillage and **drying** it by methods employed in the grain distilling industry. ....



# Mission Statement

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The Center for Veterinary Medicine (CVM) fosters public and animal health by approving **safe** and **effective** products for animals and by enforcing other applicable provisions of the Federal Food, Drug, and Cosmetic Act and other authorities.



# Regulatory Challenges

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CVM tasked with reviewing the **safety of distillers grains** and the **regulatory status of ingredients** used in process.

- Feedstock
  - *Grain Quality, Next Generation Grains*
- Processing Aids
  - *Enzymes, Yeasts, Defoamers, Antibiotics, etc.*
- Post Processing Aids
  - *Mycotoxin Binders, Flow Agents, etc.*



# Outline

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- Mycotoxins
- Processing Aids
  - Regulatory requirements
  - Antibiotic residue
  - Sulfur levels
  - Salt levels

# Mycotoxins (1994 – 2004)

- Distillers grains collected as part of routine surveillance sampling

<b>Mycotoxin Feed Ingredient Category</b>	<b>Mycotoxin</b>	<b>Units</b>	<b>Total Samples</b>	<b>% Positive</b>
corn and corn by products	Aflatoxin	PPB	1471	19.44%
corn and corn by products	Zearalenone	PPB	282	7.09%
corn and corn by products	Fumonisin	PPM	665	52.48%
corn and corn by products	Vomitoxin	PPM	4	0.00%
corn and corn by products	Ochratoxin A	PPB	26	0.00%
DDGS	Aflatoxin	PPB	37	0.00%
DDGS	Zearalenone	PPB	6	0.00%
DDGS	Fumonisin	PPM	9	44.44%



# Nationwide Survey of Distillers Grains for Aflatoxin

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- November 21, 2006
- Objectives
  - *To determine levels of aflatoxin,*
  - *To prevent distillers grains that contain unacceptable levels of aflatoxins from entering interstate commerce for use in animal feeds, and*
  - *To initiate procedures to remove distillers grains that contain unacceptable levels of aflatoxins from interstate commerce.*

*<http://www.fda.gov/cvm/AflatoxinAssign.htm>*



# Distillers Grains Survey

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- November 2006 to September 30, 2007
- Distribution as follows:
  - *DAL, DEN & KAN: 4-samples per district*
  - *BLT, CHI, CIN, DET, MIN & PHI: 3-samples per district*
  - *ATL, FLA, NOL, SJN, NWE, NWJ, NYK, SAN, SEA & LOS: 1-sample per district*
- Aflatoxin rapid test kits
  - *Charm Sciences, Neogen Corp., R-BioPharm, Vicam*

# Mycotoxins (FY07)

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- Distillers grains collected as part of a special surveillance sampling

<b>Mycotoxin</b>	<b>DDG from Corn</b>	<b>DDG from corn and milo</b>
Aflatoxin, ppb	0/11	0/1
Zearalenone, ppb	1/1	0/0
Fumonisin, ppm	1/4	0/0
Vomitoxin, ppm	0/1	0/0



# Findings and Next Step

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- Findings

- No aflatoxin or vomitoxin were found in samples
- Low levels of fumonisin and zearalenone were present in samples

- Next Step

- Investigating aflatoxin results
- Preparing field assignment for FY08



# Outline

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- Mycotoxins
- Processing Aids
  - Regulatory requirements
  - Antibiotic usage
  - Sulfur levels
  - Salt levels

# Regulatory Requirements

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- A **feed ingredient** is a component part or constituent or any combination/mixture added to and comprising the feed.
- A **food additive** is any substance intentionally added to an animal feed, including pet food, must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use.
- Federal Food, Drug, and Cosmetic Act
  - A food is adulterated
    - If it bears or contains any poisonous or deleterious substance which may render it injurious to health, or
    - If it bears or contains any added poisonous or deleterious substances.

What antibiotic can be used during (fuel) ethanol fermentation

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# What antibiotic can be used during (fuel) ethanol fermentation

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To date, only Lactrol® has been submitted to and reviewed by CVM for use in fuel ethanol production.



# Lactrol®

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- Smith Kline Beecham → PhibroChem
- Virginiamycin with lactose; Lactose replaced with dextrose ('94)
- Antimicrobial - reduction of bacterial contamination during alcohol fermentation
  - Added during fermentation phase
  - Addition rates 2-6 ppm
  - Residue levels 0.2-0.5 ppm
- Safety assessment based on incorporation of 20% Distillers Grains



# But.....

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- Increased use rate of Distillers Grains
  - Currently looking at use levels up to 50%
  - Safety review on Lactrol® based on a 20% incorporation of distillers grains in feed



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- Increased use rate of Distillers Grains
  - Currently looking at use levels up to 50%
  - Safety review on Lactrol® based on a 20% incorporation of distillers grains in feed
  
- Expanded use of Distillers Grains
  - Currently looking at non-ruminant species
    - swine, poultry, etc.
  - Virginiamycin not approved for use in all species and animal classes

# Virginiamycin\*

## Distillers Grains

1994

- Chickens (2-20 g/ton)
- Turkey (10-20 g/ton)
- Swine (5-100 g/ton)

2007

- Broilers<sup>1</sup> (5-20 g/ton)
- Turkey (10-20 g/ton)
- Swine<sup>2</sup> (5-100 g/ton)
- Cattle<sup>3</sup> (11-22.5 g/ton)

Traditional Usage

- Beef Cattle
- Dairy Cattle

Expanded Usage

- Broilers
- Turkeys
- Laying Hens
- Swine

\* 21 CFR 558.635

<sup>1</sup> Not for use in layers

<sup>2</sup> Not for use in breeding swine over 120 lbs

<sup>3</sup> Not for use in breeding cattle

# Virginiamycin\*

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# Unknowns.....

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- Use of other antibiotics
  - *May degrade to toxic metabolites*
  - *Not approved for use in all species*
  - *Not approved for use in feed*
  - *May have negative interaction with other antibiotics*
- Antibiotic resistance in non-targeted microbes
- May function as growth promoters
- Market demands



# Next Steps

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- Continued Education
  - Distillers grains users
  - Distillers grains supplier
  - Antibiotic suppliers
  
- Preparing field assignment for FY08
  - Antibiotic residue
    - *Multi-analyte residue method currently under development*



# Sulfur Levels in Distillers Grains

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- '84 NRC max tolerable level - 0.4%ration
- Finding 0.6 to 1.3% sulfur (as is) in DDG
- Regional Concerns
  - South Dakota
    - *High sulfur content in water*
    - *To reduce threat of sulfur toxicity, passed rule in 2004 to guarantee sulfur (max) levels in distiller feed products*
  - North Dakota is also working on rules
  - Missouri has some unofficial complaints about feed refusal by cattle fed DDG; Finding sulfur levels of 0.77% as is in DDG



# Salt Levels in Distillers Grains

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- '84 NRC requirements for poultry
  - 0.15% Na
  - 0.12% to 0.17% Cl
- Finding 0.4 to 1.0% salt levels in DDG
- Regional Concern
  - States would like to see a guarantee
  - Market driven



# Summary

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Rapid expansion in the ethanol industry is leading to both an **increased use rate** of distillers grains and **expanded use** of distillers grains.

## ■ Safety

- *Mycotoxins, pesticides, heavy metals, dioxins, etc.*
- *Antibiotic residues, sulfur and salt levels*
- *Grains, process modifications*

## ■ Regulatory Status

- *Grains, enzymes, yeasts, antibiotics, defoamers, mycotoxin binders, flow agents, etc.*

# FDA Letter to Feed and Feed Ingredient Manufacturers

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May 16, 2007

- The U.S. Food and Drug Administration (FDA) is taking this opportunity to remind **feed and feed ingredient manufacturers of their legal responsibility to ensure that every ingredient used in their products is safe for its intended use**, whether the product is meant to be used to feed animals intended for human consumption or non-food animals such as pets.
- **Manufacturers are responsible for taking their own measures to ensure the safety of their products.** Manufacturers should not wait for possible FDA testing of their materials as manufacturers bear the responsibility of ensuring only safe products are put on the market.



# If you are not sure.....

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- FDA ([www.fda.gov](http://www.fda.gov))
  - Center for Veterinary Medicine
  - Code of Federal Regulations (21 CFR)
- State Feed Control Official
- AAFCO OP ([www.aafco.org](http://www.aafco.org))

# Questions

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