

Date: December 19, 2007

From: Director, Office of Surveillance and Compliance (HFV-200)

Subject: Nationwide Survey of Distillers Grains for Antibiotic Residues

To: All FDA District Directors, FDA Regional and District Laboratory Directors, FDA District Investigations Branch Directors, and FDA District Compliance Branch Directors

ORA Concurrence # 2008103001

FACTS Assignment # 909372

Regional Food and Drug Administration Directors

Objectives

To collect samples of distiller by-products (distillers wet grains, distillers dried grains, and distillers dried grains with solubles) for shipment to FDA's Center for Veterinary Medicine (CVM), Office of Research (OR) to determine the extent of antibiotic residues in a limited number of distillers by-products.

Background

FDA's CVM is concerned about the potential animal and human health hazards from the use of distiller by-products, hereafter referred to as distiller grains, containing antibiotic residues as an ingredient in animal feeds. Distiller grains are a co-product of the distillery industries with approximately 98% coming from fuel alcohol production and the remaining 1-2% from beverage alcohol production. Approximately 3.2 to 3.5 million metric tonnes of distiller grains are produced annually in North America with about 2.65 million metric tonnes available for domestic use in the U.S. and Canada. Of this 2.65 million metric tonnes approximately 90% is used in animal feed with currently over 80% used in ruminant diets. Distiller grains are also finding their way into poultry and swine feed. However, because of the increased demand for fuel ethanol, the production of distiller grains is expected to increase over the next couple of years further increasing the quantity of distiller grains available for all types of animal feed.

Bacterial contamination of the fermenter is an ongoing problem for commercial fuel ethanol production facilities. Both chronic and acute contamination is of concern, due to the fact that bacteria compete with the ethanol-producing yeast for sugar substrates and micronutrients. Lactic acid levels often rise during bouts of contamination, suggesting that the most common contaminants are lactic acid bacteria. Currently, antibiotics such as virginiamycin (VIR) and penicillin (PEN) are frequently used as antimicrobials during the fermentation process to control bacterial contamination. Available literature has shown that antibiotics are not destroyed during ethanol production, but are concentrated in the distillers grains where they may be present at levels as high as three times the added level.

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In 1994, the Kansas State Veterinary Diagnostic Laboratory attributed the deaths of more than 700 feedlot cattle to toxicosis from feeding antibiotic contaminated milo-based distillers dried grain in combination with monensin. The contamination occurred when industrial waste solids and the milo fermentation solids became accidentally mixed. Solids from a particular lot of waste alcohol that originated at a large pharmaceutical company contained a mixture of compounds closely related to clarithromycin (clarithromycin is chemically synthesized from erythromycin). At several large feedlots, the clarithromycin/erythromycin contaminated distiller grains were incorporated into diets that contained monensin. The combination of clarithromycin/erythromycin and monensin resulted in the deaths of over 700 feed lot cattle. Cattle consuming distiller grains without monensin in the diet were not affected in this incident. Thus, distiller grains contaminated with antibiotic residues can pose risks to the safety of animals consuming these products and with the widespread use of distiller grains in dairy cattle and poultry feed there is also a potential human safety concern due to antibiotic residues in the milk, meat and/or eggs.

Currently, we have only limited data on the extent and levels of antibiotics in distiller grains that are produced by U.S. ethanol facilities and marketed as animal feed ingredients. Because of this limited data and because of the marked increase in the amount of distiller grains used in animal feed, CVM believes it is important for the agency to conduct a limited nationwide survey at this time to determine the extent and levels of antibiotic residues in distiller grains produced by U.S. ethanol production facilities.

Assignment

1. Overview of Samples to Collect

Resources have been allocated under the fiscal year (FY) 2008 workplan to collect 60 distiller grains samples under PAC code 71003C – Feed Contaminants Program Mycotoxins/Aflatoxins. These 60 distiller grains samples will be collected as investigational samples and sent to CVM-OR.

For the purposes of this assignment, distiller grains are feed ingredients that meet the Association of American Feed Control Officials Incorporated (AAFCO) definitions for distillers dried grains (ddg), distillers dried grains with solubles (ddgs), or distillers wet grains and are offered for sale or for use in animal feed. The definition numbers for these AAFCO feed ingredients are 27.5, 27.6, and 27.8 and are found on pages 273 and 274 of the AAFCO 2007 Official Publication. If you do not have, or cannot locate, a copy of the AAFCO Official Publication, please contact Dr. Linda Benjamin at CVM, Division of Animal Feeds (DAF) for assistance in obtaining copies of these definitions (phone: 240-453-6851; e-mail: linda.benjamin@fda.hhs.gov).

There are currently more than 120 fuel ethanol facilities that manufacture distiller grains. Most of the ethanol production facilities are located in districts covered by the FDA Central and Southwest Regional Offices. The distiller grains should be collected at the fuel ethanol production facilities and are offered for sale or for use in animal feeds. The 60 distiller grains samples to be collected

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during this assignment are divided among 14 FDA district offices as described below.

District	Number of Samples
Northeast Region	1
NYK-DO	1
NWE-DO	0
Central Region	28
PHI-DO	0
CHI-DO	4
BLT-DO	0
CIN-DO	1
DET-DO	4
MIN-DO	19
Southwest Region	27
DAL-DO	1
DEN-DO	2
KAN-DO	24
Pacific Region	4
SEA-DO	0
SAN-DO	2
LOS-DO	2
Total	60

CVM does not anticipate that districts will have any problems in locating fuel ethanol production facilities that produce distiller grains for interstate sale as feed ingredients. However, districts that have difficulty identifying fuel ethanol production facilities that produce distiller grains should contact Dr. Linda Benjamin at CVM-DAF for assistance (phone: 240-453-6855; e-mail: linda.benjamin@fda.hhs.gov). As needed, samples may be collected from the same distillery at different locations.

2. Collection, Handling and Shipment of Investigational Samples

For collection of the distiller grains investigational samples refer to the FDA Investigations Operations Manual (IOM) Chapter 4. Please note that special handling containers are not necessary for the wet distiller grain samples. As referenced in IOM 4.1.7, these samples do not need to be collected from lots in interstate commerce or under federal jurisdiction. However, as investigational samples are typically collected to document observations or support regulatory actions they must be sealed and their integrity and chain of custody protected. Collect 10 sub-samples of the distiller grains product, each weighing ~454 grams (1 lb), as shown in IOM Chapter 4, Sample Schedule

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Chart 6 for corn-shelled, meal flour or grits. Each of these 10 sub-samples already includes the 702(b) portions so there is no need to collect additional 702(b) portions.

For handling and shipment of the distiller grains investigational samples refer to Chapter 4 of the IOM. Samples collected under this assignment will in general not require refrigeration, but should be shipped by overnight mail to the FDA, CVM-OR as soon as possible after collection. For those samples where refrigeration may be indicated (e. g., high moisture ddg or distillers wet grains), investigators should refer to the IOM, or contact Dr. Benjamin, for guidance on handling and shipment.

Each investigational sample will be used for research purposes only, and will be sent to Dr. David Heller at CVM, Office of Research , 8401 Muirkirk Road, Laurel, MD 20708; Phone: (301) 210-4579 ; E-mail address: David.Heller@fda.hhs.gov or his designee and should be labeled “Investigational Sample for Research Purposes Only.”

For identification of the distiller grains investigational samples refer to Chapter 4 of the IOM. The investigational sample should be identified with the FACTS sample number, the collector’s name, the date of collection, the state (New Jersey, Maryland, etc) in which the sample was collected. Additional information to be recorded on the Collection Report includes the name of the distillery where the sample originated from and as thorough a description of the sample as possible. The description of the sample should include 1) the type of distiller grains product collected (ddg, ddgs or distillers wet grains), 2) the source material for the fermentation (corn, sorghum, wheat, etc.) and 3) from where the sample was taken (on-line, holding tank, etc). If known, the investigator should identify the antibiotic/antimicrobial agent used by the firm, the level added and where the antibiotic/antimicrobial agent was added during the manufacturing process.

Refer to the Feed Contaminants Compliance Program (<http://www.fda.gov/cvm/Documents/7371-003.pdf>) and the FDA IOM for more detailed information about sample collection, sample handling and shipment.

The time spent collecting, preparing and shipping the 60 investigational samples, which will be used for research purposes only, should be reported under PAC code 71003C.

4. Sample Analysis

The servicing laboratories will not analyze any of the investigational samples collected under PAC 71003C in this assignment for antibiotic residues. The CVM-OR will be analyzing the investigational samples collected under PAC 71003C in this assignment for antibiotic residues.

5. Primary Contact:

The primary contact for this assignment is Dr. Linda Benjamin. Please contact her at Linda.benjamin@fda.hhs.gov or 240-453-6855 if you have any questions about sample collection, sample handling and shipment.

Regulatory/Administrative Follow-up

At this time, as the objective of the assignment is to determine the extent of antibiotic residues in distiller grains, the center does not anticipate regulatory follow-up. However, the Center may support regulatory or administrative follow-up if a distiller product contains either an unsafe level of virginiamycin or residues from an antibiotic other than virginiamycin.

Priority/Timeframe/Resources

This assignment has a routine priority and the concurrence of ORA. The assignment is directly associated with the Feed Contaminants Program and resources have previously been allocated to it under the FY 2008 Work Plan. The ORA concurrence # is 2008103001.

Report time for the collection, preparation and shipment of samples under PAC 71003C – Feed Contaminants Program Mycotoxins/Aflatoxins.

The anticipated sample collection time for each sample is about four hours.

Contacts: CVM

Scientific and Technical Questions:

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Please refer to FACTS assignment # 909372 when referring to this assignment.

/signed/
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