



Memorandum

Date: March 26, 2010

From: Consumer Safety Officer, Division of Field Programs and Guidance, Field Programs Branch

Through: Team Leader, Field Programs Branch

Subject: **Sampling for Presence of DON (Deoxynivalenol or vomitoxin) in Milled Wheat Products, Grains and Grain By-products Due to Cool and Wet Conditions in Eastern and Midwestern U.S.—**High Priority, DFIG No: 10-15, ORA
Concurrence No: 2010031001,
FACTS No: pending

To: DIBs: ATL, BLT, CIN, NOL, NWJ, NYK, PHI, KAN, SEA, MIN, CHI, DET, NWE, DEN,
DCBs: ATL, BLT, CIN, NOL, NWJ, NYK, PHI, KAN, SEA, MIN, CHI, DET, NWE, DEN
Director of Laboratory Branches: All

Info: RFDDs: CE, NE, SE, SW, PA (all regional directors)
DDs: ATL, BLT, CIN, NOL, NWJ, NYK, PHI, KAN, SEA, MIN, CHI, DET, NWE, DEN

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BACKGROUND

Due to unusually wet and cool weather during May and June of 2009 in the Eastern U.S. and in the Midwest during October and November of 2009, high levels of deoxynivalenol (DON) or vomitoxin, have been detected in recently harvested wheat, corn, and other grains. The potential food safety issues associated with DON include acute gastrointestinal illnesses, e.g., nausea and vomiting. Similar symptoms along with refusal of feed have been noted for animals that have ingested DON contaminated animal feeds.

DON is produced by several molds of the genus *Fusarium*, especially *F. graminearum*, which causes pink scab disease in wheat. It is not possible to completely avoid the presence of DON in wheat and other grains. DON is

sometimes found in wheat and other grains grown under normal weather conditions; however, the fungus thrives in cool, wet conditions.

FDA issued guidance to industry in [September 1993](#) that provided the following advisory levels for DON:

- 1 ppm DON on finished wheat products, e.g. flour, bran, and germ that may potentially be consumed by humans. FDA is not stating an advisory level for wheat intended for milling because normal manufacturing practices and additional technology available to millers can substantially reduce DON levels in the finished wheat product from those found in the original raw wheat. Because there is significant variability in manufacturing processes, an advisory level for raw wheat is not practical.
- 10 ppm DON on grains and grain by-products destined for ruminating beef and feedlot cattle older than 4 months and for chickens with the added recommendation that these ingredients not exceed 50% of the diet of cattle or chickens.
- 5 ppm DON on grains and grain by-products destined for swine with the added recommendation that these ingredients not exceed 20% of their diet.
- 5 ppm DON on grains and grain by-products destined for all other animals with the added recommendation that these ingredients not exceed 40% of their diet.

FDA's approach under the FD&C Act is to handle instances of DON contamination on a case-by-case basis. If DON levels exceeding the guidance level is detected in a food, FDA will review the relevant information to determine whether the DON levels found in that food may pose a health hazard such that it would be deemed adulterated and subject to enforcement actions under the FD&C Act.

FDA sample collections will be mirrored by participating States. The States will **not** be collecting samples under FDA contract or as FDA commissioned individuals but will utilize the information included in this assignment for state sampling activities. FDA and the States should coordinate determining sampling establishments (to avoid duplication of efforts), sample results, any necessary follow-up activities and work collaboratively on this assignment.

OBJECTIVES

- To collect and analyze samples of milled wheat products intended for human consumption and grains (corn, wheat, barley, oats and rye) and grain by-products intended for animal feed, to determine the levels of DON present.

- To conduct follow-up sampling of select finished food products and complete feeds manufactured using milled wheat products, grains, and/or grain by-products that exceed the FDA advisory levels.
- To review and evaluate the data. Specifically, 1) to determine if the products tested are adhering to the advisory level of 1 ppm of DON in milled wheat products intended for human consumption and 5 to 10 ppm of DON in animal feed grains and grain by-products; and 2) to assess the potential risk to human and animal health associated with exposure to DON.
- Work in conjunction with State counterparts to coordinate sampling locations and sharing of sample results.

Implementation

This sampling assignment for human food and animal feed is to begin the week of March 29, 2010. Prior to sample collection, Districts should contact their State counterparts to coordinate sampling locations to minimize duplication of efforts. Emphasis is on collecting grains and grain products harvested in 2009. However, if 2010 harvested grains are available it is acceptable to collect a sample.

Human Food

Milled wheat products derived from wheat harvested in 2009 from the following states should be sampled: North Carolina, Pennsylvania, West Virginia, Virginia, Maryland, Delaware, Ohio, New Jersey and New York. FDA districts will work with their State counterparts to collect and analyze samples of milled wheat products from the 2009 crop for DON. More specifically, samples of milled wheat flour, wheat bran, and wheat germ will be collected from millers operating in the above states.

Animal Feed Ingredients

Grains (barley, corn, oats, rye, and wheat) harvested in 2009 to present from the following states should be sampled: Colorado, Wyoming, Idaho, Montana, North Dakota, South Dakota, Iowa, Nebraska, Kansas, Missouri, Illinois, Michigan, Indiana, Ohio, West Virginia, Kentucky, Tennessee, North Carolina, Virginia, Maryland, Delaware, New Jersey, Pennsylvania, New York, Connecticut, Rhode Island, Massachusetts, Vermont, New Hampshire and Maine.

In addition, grain by-products (corn distillers dried grains and/or solubles, corn brewers dried grains and/or solubles, corn gluten meal, corn gluten feed, wheat middlings, wheat shorts, wheat bran, wheat germ meal, and wheat mill run) derived from the above grains should also be sampled from the above mentioned states.

These animal feed ingredients should be collected at feed mills, grain elevators, millers, distilleries and breweries operating in the above states.

All animal feed samples should be of or derived from grains harvested in 2009 to present from the states mentioned above.

Firm Selection

Human Food

Firms to be visited for purposes of collecting official surveillance samples include millers of wheat products (e.g., flour, bran, germ, etc.) intended for use in human food.

Attachment A consists of a list of millers broken out by the districts where product is to be collected and a sampling schedule. In addition to this list, the state of Pennsylvania has provided the following link as a reference to businesses identified as Flour and Other Grain Mill Products:

http://www.manta.com/mb_34_C2029_000/flour_and_other_grain_mill_products

FDA Districts will work with their State counterparts to assure adequate coverage through coordinated sampling of millers in each affected State.

State Feed and Food Regulatory Programs will be able to assist their respective FDA Districts in identifying additional establishments through state license and registration inventories whether or not they are actively participating in the sampling assignment.

Animal Feed Ingredients

If districts need assistance in finding a feed mill, grain elevator, miller, distillery or brewery to collect grain or grain product samples intended for use in animal feeds, then please contact Dr. Michael Henry (phone 240-453-6861; e-mail mike.henry@fda.hhs.gov).

CVM advises that ORA field investigators are to collect the samples in this assignment at facilities during routine surveillance inspections.

Sample Collection

Milled Wheat Products Intended for Human Consumption

A total of 100 samples of milled wheat product intended for use in the further manufacture of finished human food products are to be collected.

Instructions for collecting milled wheat products intended for use in human food are listed in the [Domestic and Import Mycotoxin Compliance Program](#) (7307.001). Samples collected for this assignment are for surveillance purposes but are official samples and should be collected in accordance with the Compliance Program and Investigations Operations Manual (IOM).

Samples to be collected at millers will include whole wheat flour, white flour, germ, or bran. Districts may collect a sample of wheat product if available at the same firm.

The following information must be obtained and captured in the Collection Remarks section of the Collection Report for each milled wheat product sampled:

- Geographic location of the harvest area
- Identifying information for the lot from which the sample was collected (i.e. lot codes);
- Disposition of any distributed product, e.g., firm name, location, date and volume shipped; and
- Intended use, if known, of any distributed product, e.g., food or animal use, if food, what type of food is manufactured.

Follow-up collection at manufacturers receiving the milled wheat product will occur if milled wheat product is found to exceed the 1 ppm advisory level. Districts must use the above information to locate the firms that received the contaminated product and if necessary, the original collecting district must issue an assignment to the appropriate district to conduct the follow-up sampling as instructed below.

For follow-up sample collections, collect only bread, pasta, pretzels and cereal manufactured using milled wheat product from the implicated lot collected from the miller. Each sample will consist of 10 retail units/subsamples. Each subsample must consist of 1 lb. of product.

If a State sample is found to be greater than 1 ppm in milled wheat product FDA will work with the appropriate State to coordinate follow-up collections. State analytical records need to be shared, evaluated and verified by FDA's Division of Field Science (DFS). Please refer to the DFS contact listed at the end of this assignment if this occurs. If applicable, any follow-up sample collections resulting from State analytical findings will be collected and analyzed by FDA.

Animal Feed Ingredients

Animal feed samples to be collected at feed mills, grain elevators, millers, distilleries, and breweries will include corn, barley, oats, rye, and wheat and by-products derived from corn (distillers dried grains/solubles; brewers dried grains/solubles; corn gluten meal; corn gluten feed) and from wheat (bran, middling, shorts, germ meal, mill run). The feed ingredient samples should be of or derived from grains harvested in 2009 to present from a state listed in the Implementation section of this assignment.

The 100 animal feed samples (70 grains and 30 grain-by-products) to be collected during this assignment are divided among FDA district offices and regions as described below. The number of animal feed samples to be collected for each FDA region and district are also shown in the table below.

Central Region (BLT, CHI, CIN, DET, MIN, NWJ & PHI districts) – 61 samples (17 corn, 10 corn by-products, 8 wheat, 8 wheat by-products, 6 barley, 6 oats, and 6 rye)

Northeast Region (NYK and NWE districts) - 10 samples (2 corn, 2 wheat, 2 wheat by-products, 1 barley, 1 oats, 1 rye, and 1 corn by-product)

Pacific Region (SEA district) - 7 samples (1 barley, 1 corn, 1 oats, 1 rye, 1 wheat, 1 corn by-product and 1 wheat by-product)

Southeast Region (ATL and NOL districts) – 10 samples (2 corn, 2 wheat, 2 wheat by-products, 1 barley, 1 oats, 1 rye and 1 corn by-product)

Southwest Region (KAN and DEN districts) - 12 samples (3 corn, 2 wheat, 2 corn by-products, 2 wheat by-product, 1 barley, 1 oats and 1 rye).

Participating State Programs will be requested to obtain similar sample numbers by Region and District. It is critical that the District Offices coordinate the sampling assignment with participating states.

	NUMBER OF ANIMAL FEED INGREDIENT SAMPLES TO COLLECT BY FDA DISTRICT							TOTALS
	<u>BARLEY</u>	<u>CORN</u>	<u>OATS</u>	<u>RYE</u>	<u>WHEAT</u>	<u>CORN By-Products*</u>	<u>WHEAT By-Products●</u>	
CENTRAL REGION								
Baltimore District	1	1	1	1	1	1	1	7
Chicago District	1	4	1	1	1	2	1	11
Cincinnati District	1	3	1	1	1	2	1	10
Detroit District	1	2	1	1	1	1	1	8
Minneapolis District	1	4	1	1	1	2	1	11
New Jersey District		1			1	1	1	4
Philadelphia District	1	2	1	1	2	1	2	10
NORTHEAST REGION								
New England District	1	1	1		1		1	5
New York District		1		1	1	1	1	5
PACIFIC REGION								
Seattle District	1	1	1	1	1	1	1	7
SOUTHEAST REGION								
Atlanta District	1	1	1	1	1		1	6
New Orleans District		1			1	1	1	4

SOUTHWEST REGION								
Denver District		1			1	1	1	4
Kansas City District	1	2	1	1	1	1	1	8
TOTALS	10	25	10	10	15	15	15	100

* includes corn distillers/brewers dried grains &/or solubles, corn gluten feed and corn gluten meal

• includes wheat middlings, wheat bran, wheat shorts, wheat mill run, wheat germ meal and wheat red dog

Please note that sample collection for this assignment will include products intended for human consumption and products intended for animal feed, therefore they will be reported under separate PAC's as provided below under Reporting.

Instructions for collecting feed ingredient samples for mycotoxin analysis are listed in the Feeds Contaminant Compliance Program Guidance Manual (7371.003) (<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UCM113409.pdf>). Samples collected for this assignment are for surveillance purposes but are official samples and should be collected in accordance with the Compliance Program and IOM.

The following information must be obtained and captured in the Collection Remarks section of the Collection Report for each animal feed product sampled:

- Geographic location of the harvest area;
- Identifying information for the lot from which the sample was collected;
- Disposition of any distributed product, e.g., firm name, location, date and volume shipped; and
- Intended use, if known, of any distributed feed, e.g., animal species and class, what type of feed is manufactured; complete feed or premix.

Follow-up collection at manufacturers receiving the grain and grain by-products will occur if products are found to exceed the 5 ppm advisory level. Districts must use the above information to locate the firms that received the contaminated product and if necessary, the original collecting district must issue an assignment to the appropriate district to conduct the follow-up sampling as instructed below.

For follow-up sample collections, collect complete feeds from the implicated lot collected from the manufacturer. Additionally, identify and verify the animal species intended for consumption of the feed(s). Please collect samples per the Feeds Contaminant Compliance Program and IOM.

If a State sample is found to be greater than 5 ppm in grains and grain by-products FDA will work with the appropriate State to coordinate follow-up collections. State analytical records need to be shared, evaluated and verified by FDA's Division of Field Science (DFS). Please refer to the DFS contact listed at the end of this assignment. If applicable, any follow-up sample collections resulting from State analytical findings will be collected and analyzed by FDA.

Analytical Approach

Milled Wheat Products Intended for Human Consumption

Field servicing labs will only test for *DON*. Laboratories should notify the collecting district immediately of findings above the FDA advisory level of 1 ppm.

Follow the method as detailed in the [Domestic and Import Mycotoxin Program](#). For these samples, it is not necessary to submit the worksheets to CFSAN for review. Rather, lab findings above the 1 ppm advisory level should be reported to the collecting district so that follow-up sampling of finished product ([bread, pasta, pretzels and cereal](#)) can be conducted at the consignee(s) for the milled wheat product(s).

Finished Human Food Products Collected at Manufacturer

Samples will be forwarded to field servicing laboratories for analysis.

Follow the method as described in the email attachment (Determination of DON in Processed Foods). Check and confirmatory analyses must be performed for these samples. Analytical worksheets for lab findings above the levels noted above must be forwarded to the compliance branch for subsequent submission to CFSAN, Division of Enforcement for review and regulatory follow-up.

Animal Feed Ingredients

Field servicing labs should only test for *DON* in the feed ingredient samples collected in this assignment. Laboratories should notify the collecting district immediately of findings above the FDA advisory level of 5 ppm. The analytical method for *DON* in feed ingredients is listed in the Compliance Program Guidance Manual (<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UCM113409.pdf>). For these samples, it is not necessary to submit the worksheets to CVM for review. Lab findings above the advisory levels noted above should be reported to the collecting district so that follow-up sampling of complete feeds containing these grains or grain products can be conducted by the district.

REGULATORY/ADMINISTRATIVE FOLLOW-UP

Products Intended for Human Consumption

Milled Wheat Products

Findings in excess of the 1 ppm advisory level for milled wheat products intended for human food use will be shared with the miller by hardcopy communication (via 704 (d) letter) from the appropriate FDA District Office. **FDA District will share inspectional and sample findings with their State counterparts.** A copy of such correspondence will be sent to the general assignment contact person at CFSAN and DFSR.

Finished Products (breads, pretzels, breakfast cereals, and pasta)

Regulatory follow-up will concentrate on foods consumed at a relatively high rate and for which wheat flour is the major ingredient. Samples of bread, pretzels, breakfast cereals, and pasta found to contain DON above 1 ppm are adulterated under section 402(a)(1) of the Act. Districts should notify the manufacturer of the FDA findings and encourage the firm to remove the product containing DON above 1 ppm from commerce and/or hold it for destruction. Violative product may also be deferred for animal feed (Contact CFSAN DE Contact for instructions). Districts should consider seizure of the adulterated food if the firm is unwilling to cease distribution of adulterated product in interstate commerce. FDA would consider issuing press if the firm is unwilling to conduct a voluntary recall of distributed product.

Enforcement action recommendations should be submitted via MARCS- Compliance Management Services (MARCS-CMS) to CFSAN's Division of Enforcement. Access MARCS-CMS on FDA's IT Applications Page under ORA Applications: <http://fdswa090.fda.gov/vts/>. Contact the CFSAN Regulatory Contact for early discussion concerning seizures under this assignment.

Animal Feed Ingredients

Follow-up collection of complete feeds will occur if the grains or grain products are found to exceed the advisory level for intend species and class of animal. Districts should use the information in the collection report to locate complete feeds containing these grains or grain products and if necessary issue an assignment to the appropriate district to conduct the follow-up sampling. A copy of such correspondence concerning feed ingredients will be sent to CVM, Office of Compliance, [HFV-230](#).

Analytical worksheets for complete animal feeds that exceed the levels noted in the FDA advisory must be forwarded to and CVM, Office of Compliance, [HFV-230](#) for complete animal feeds.

CFSAN or CVM as appropriate and DFI will work with the Districts and States to determine appropriate follow-up for milled wheat products intended for human consumption, for finished human food products, for animal feed ingredients (grains and grain products), and for complete animal feeds that exceed the advisory levels.

Resources and Reporting

Attached is a DON Assignment Tracker spreadsheet. Please provide this spreadsheet to the listed DFI contact by 1700 (5 pm) EST on every Friday for the duration of the sampling assignment.

Milled Wheat Products Intended for Human Consumption

Resources for the collection and analyses of milled wheat products intended for human food should be taken from the Domestic Food Safety Program.

Resources for the collection and analysis of finished human food products should be taken from the Mycotoxin Program (07001). If additional resources are required, they should be taken from the Domestic Food Safety program (03803).

Report ALL operations for these samples against PAC 07001.

Product codes for human foods include: 02 A 01 (barley), 02 A 09 (wheat), 02 E (wheat flour), 02 F (milled wheat product), 02 G 01 (M) (barley flour).

Please place the assignment number (#) in the Collection Remarks of the Collection Report.

Animal Feed Ingredients

Resources for the collection and analysis of animal feed ingredients should be taken from the Feed Contaminant Program (71003).

Resources for the collection and analysis of follow-up samples of complete animal feeds should be taken from the Feed Contaminant Program.

Product codes for feed ingredient samples and the number to be collected are listed below:

Grains	Product codes	Number of Samples
Barley	70 A 01	10
Corn	70 A 02	25
Oats	70 A 03	10
Rye	70 A 05	10
Wheat	70 A 07	15
Grain By-products		
Corn By-products		15
Distillers dried grains/solubles	71 G 99	

Brewers dried grains/solubles	71 G 99	
Corn gluten meal or feed	71 G 02	
Wheat By-products		15
bran,	71 H 01	
middling	71 H 02	
shorts	71 H 03	
germ meal or mill run	71 H 99	

Please place the assignment number (#) in the Collection Remarks of the Collection Report.

Report all operations for these samples against PAC 71003C

CONTACTS

General Assignment Contact:

CFSAN

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TIMEFRAME

The assignment has the concurrence of ORA (**ORA Concurrence#: 2010031001**) and has been designated as a **High Priority**. **Sampling should begin immediately upon receipt.**

Monali Yajnik

Cc:

HFC-100 (Elder, Romano)
HFC-130 (Clausen)
HFC-132 (Fogg)
HFC-150 (Reardon)
HFC-140 (McGrath)
HFC-141 (Dhoostelaere)
HFS-300 (Beru)
HFS-317 (Kim, Johnson)
HFS-302 (Zink)
HFS-600 (Wagner)
HFS-605 (Thomas)
HFS-607 (Correll, Robbs)
HFS-615 (Aloi, Bass, Barringer, MF/Yajnik)
HFV-200 (McChesney)
HFV-220 (Benz)
HFV-222 (Henry, Lovell, Proescholdt)