Deoxynivalenol (DON)

Background: Deoxynivalenol (DON), also referred to as vomitoxin, is a naturally occurring mycotoxin produced by several species of *Fusarium* fungi. Wet and cool weather from flowering time to maturity promotes infection, resulting in scab or head blight in barley, wheat, oats, and rye. Wheat infected with scab has a tendency to have lighter weight kernels, some of which are removed during normal harvesting and cleaning operations. DON does not represent a threat to public health among the general population. However, it can--in rare cases--produce acute temporary nausea and vomiting in humans and animals.

GIPSA's Role in DON Testing. GIPSA provides DON testing service for wheat, barley, oats, and corn, as official criteria under the United States Grain Standards Act (USGSA). Even though USDA does not require domestic or export shipments to be tested for DON, GIPSA does provide *voluntary* DON testing services locally, at various field locations, for both domestic and export lots. USDA DON testing services are available nationwide, upon request and for a fee, as either a qualitative (screening above or below a threshold determined by the customer) or as a quantitative (actual results in parts per million (ppm)) service.

Testing Methods. GIPSA has approved several different types of test kits that use either fluorescence or enzyme linked immunosorbent assay (ELISA) technology. The commercial test methods approved by GIPSA for official testing of barley, malted barley, corn, oats, and wheat for DON are: Biopharm - RidaScreen Fast SC, Charm Science - Rosa Don P/N, Diachemix - DON FPA, Diagnostix - EZ- Quant, EZ- Tox, Neogen- -5/5, Agriscreen, Veratox,Romer - Accutox, Fluoroquant, Strategic Diagnostic Inc - Myco✓, Vicam - Don FQ. To further assist the grain industry, GIPSA also provides DON analysis for Board Appeal inspections using the more complex, High Performance Liquid Chromatography (HPLC) method, at the GIPSA Technical Center in Kansas City, Missouri. All USDA DON tests are performed as prescribed in GIPSA directives by authorized employees of GIPSA or licensed delegated/designated agency personnel.

Variability of Results. Any inspection result that GIPSA reports on an official certificate is deemed accurate (within a certain statistical variation) and is accepted by buyers and sellers of U.S. grain as a final result. The following table contains estimates of the reproducibility that can be expected for DON test results. These estimates are based on data from Barley samples monitored by the Grand Forks Field Office during August 1999.

DON Variability Table for Barley

PPM Level	Standard Deviation	Range of Results
0.5	0.19	0.1 – 0.9
1.0	0.22	0.6 – 1.4
1.5	0.26	1.0 – 2.0
2.0	0.29	1.4 – 2.6
2.5	0.33	1.8 – 3.2
3.0	0.36	2.3 – 3.7
3.5	0.40	2.7 – 4.3
4.0	0.43	3.1 – 4.9
4.5	0.47	3.6 – 5.4
5.0	0.51	4.0 – 6.0

***95% confidence level**

Variability of measurements from an analytical process can be attributable to three primary sources: 1) the sample, 2) sample preparation, and 3) the analytical method. In DON analysis, no single source is clearly the dominant source of variation. The variation among measurements is the cumulative result of many steps in the process and may not be consistent from lot to lot. In addition, measurement variability will be significantly increased, if technicians are poorly trained, laboratory facilities are inadequate, or kit components are improperly stored.

FDA Role: The Food and Drug Administration (FDA) currently uses *advisory levels* to provide guidance to the grain industry concerning levels of DON present in food or feed. These levels provide an adequate margin of safety to protect human and animal health.

Note: FDA advisory levels should not be confused with FDA action levels/limits.

GIPSA is not required to report any lots which exceed FDA′s advisory levels, and such lots are not subject to FDA seizure.

Currently, FDA does not have an advisory level for DON in raw wheat intended for milling purposes, and will rely on processors to reduce the level in finished products for human consumption to a level that does not exceed 1 part-per-million (ppm).

The FDA advisory levels for DON are as follows:

1 ppm - Finished wheat products for human consumption.

5 ppm - Grain and grain byproducts destined for swine and other animal species (except cattle and chickens); not to exceed 20 percent of the diet for swine, and not to exceed 40 percent for other animal species.

10 ppm - Grain and grain byproducts for ruminating beef and feedlot cattle older than 4 months and for chickens; not to exceed 50 percent of the diet.

DON Testing Fees: GIPSA's fee for DON testing depends on the type of service requested (original or appeal inspection), and the site of the GIPSA laboratory where the testing is performed. GIPSA's fees for original and appeal DON testing services performed at an applicant's facility in an onsite GIPSA laboratory are $12.50 per test for qualitative analysis and $18.50 per test for quantitative analysis. An hourly inspection and sampling fee is also charged to applicants in addition to the unit fee listed above.

Fees for DON analysis initiated as an original inspection service at other than an applicant's facility in a GIPSA laboratory are $31.00 per test for qualitative analysis and $38.50 per test for quantitative analysis. Appeal analysis fees are $41.00 per test for qualitative and $47.00 per test for quantitative service performed at these locations. An hourly inspection and sampling fee may also be charged to applicants, when appropriate.

HPLC testing for Board Appeal inspections are billed at a rate of $141.00 per test.

GIPSA's Objective: GIPSA will continue to monitor the official DON testing program in place, work with FDA to safeguard the public's health, and provide the market with rapid, accurate DON testing services. The Department believes that these actions will promote the common good and allow the marketplace to effectively merchandise U.S. grain.

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