

Sampling for Defensible Decisions: Oregon Department of Agriculture Pilot

Guidance on Obtaining Defensible Samples (GOODSamples)

The Oregon Department of Agriculture (ODA) initiated an ongoing sampling pilot based on the principles of *GOODSamples*. There were two components to the pilot. The first was to investigate the high violation rate for feed products in Oregon. The second objective was to "pilot" cooperation between state regulatory and small feed mills to monitor feed safety as a cooperative venture by jointly characterizing incoming raw materials.

With a violation rate of 32% on samples collected to verify nutrient guarantees, the ODA questioned if the feed products were truly in violation or if the high rate was an artifact of the sampling procedures. In 2014, Chuck Ramsey visited Oregon to observe field sampling procedures. After a tutorial and a year of discussion, ODA implemented the following changes in sampling procedures:

- Establishing of Sample Quality Criteria prior to sampling.
- » Document the analyte of concern and the action levels of concern for each analyte.
- » Establish the decision unit. What does the sample represent: a production run, or a bag, or something else?
- » Estimate the ODA sampling error, sample preparation error, and analytical error so that confidence can be estimated.
- Eliminating the probe as a sampling tool. Feed materials are now sampled with a cross-stream



Starting to unload a pup trailer of corn.



Sampling corn at the auger discharge. cutter while pouring bags out so that every element of the feed has an equal chance of being selected.

• Grinding the entire laboratory sample prior to splitting unless the material is under 2 mm. This was the biggest improvement and the most challenging of the changes, but error was reduced and the violations rate decreased.

The Joint Regulatory Industry Pilot Study

In March 2016, a sampling pilot study was undertaken to compare the sampling recommendations of *GOODSamples* with the traditional practice of taking grab samples and to pilot the possibility of industry collecting samples for both industry and ODA objectives. This study incorporated quality control to estimate the error associated with the sampling, sample preparation, and analytical procedures.

We've used the SQC process in two recalls now. The confidence in the process and the laboratory results makes decisions so much easier. We have no second guessing or trying to test our way back into compliance. Under the new federal hazard identification and prevention regulations, in addition to the traditional percent level protein, fat, and fiber, we need to start looking for trace-level hazards





Replicate samples for QC. and nutrients. The sampling needs to evolve with the regulations. —Richard TenEyck, ODA

Replicates were collected to assess total sampling error, sample preparation error, and analytical uncertainty.

Industry Objective

Many times a feed mill is provided a historical certificate of analysis (COA) rather than a COA specific to the unit purchased. There is often no way to determine what data were used to produce the COA, yet mills are dependent on this information for formulation. The feed mill's interest was to find a way to evaluate the quality of incoming bulk ingredient materials and eliminate dependence on a historical COA.

Sampling Study Variables

Corn was sampled with the historical "grab sample" technique. In addition to applying the newly learned principle of *GOODSamples*, as corn was being augured into a holding bin, cross-stream cuts (increments) were taken. Increments were taken at various intervals to determine the optimal timing of increments, and to compare results observed.

Past Union Mills sampling methods were to grab a handful of grain from the bottom of each hopper of the grain truck during unloading. After attending the GOODSamples course, we recognized that three handfuls of grain does not accurately represent 35 tons of grain; neither would 12 probes from the top of the grain truck be an accurate representation of the whole decision unit. Learning that the best method for sampling is to sample in motion, we now use a cross-stream cutting system that takes scheduled interval increments as the truck is unloading. We now have a higher confidence level that these primary samples represent the decision unit. —Heather Mann, Union Mills

The primary samples were simultaneously ground and split in their entirety with a Romer Mill to control error. One-third of the ground material was ground again using a Retsch PT 100 Mill equipped with a 0.75-mm screen. A final split with a rotary splitter yielded the final analytical sample. Triplicate samples were taken to assess sampling error and test portion selection error.

Outcomes of the Oregon Pilot Project

• Union Mills made permanent changes within facility to allow for efficient cross-stream sampling. (No more grab samples!!)

• Union Mills personnel went on to attend a four-day sampling course following the initial training and become qualified to collect samples for regulatory objectives.

• The ODA Feed Safety Program no longer pokes holes in bags (no more probing). The ODA is now using cross-stream sampling.

• The ODA decides what the decision unit is and what the analyte action levels are prior to sampling and laboratory submission.

• The ODA is experienced at disassembly and cleaning of the Romer grinder/ splitter. The time is well worth the reduced sample preparation error.

• The ODA now takes action on samples collected by Union Mills, and Union Mills checks COA claims against the actual data on the material they received.



This publication was supported by Cooperative Agreement #U18FD004710 from FDA. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of FDA. This project was 100% funded with federal funds from a federal program of \$1.5 million.