

Directive

9181.4 1-01-08

PROTOCOL FOR SAMPLING AND TESTING RICE FOR THE EUROPEAN UNION

1. PURPOSE

The purpose of this directive is to articulate the method of sampling and testing U.S. long grain rice shipments to Europe for the presence of the LibertyLink® trait. Shipments tested in accordance with this protocol, and accompanied by the documentation outlined herein, will satisfy certain conditions for acceptance in the European Community.

2. BACKGROUND

In August 2006 the U.S. Department of Agriculture (USDA) and the Food and Drug Administration announced that trace amounts of regulated genetically engineered (GE) rice had been detected in samples taken from commercial long grain rice. The GE trait, LibertyLink®, has since been deregulated in the United States, but the European Commission (EC) adopted measures requiring all imports of U.S. long grain rice to be tested for the presence of the LibertyLink® trait.

In November 2006, the EC amended their original measures to require the testing to be conducted upon arrival in Europe. In December 2007, the EC voted to amend their measures to allow testing to be done in the United States if based on official samples drawn by GIPSA according to EC recommendations as outlined in this directive.

3. SAMPLING

Each consignment (lot) of U.S. long grain rice to be shipped to Europe will be officially sampled by GIPSA personnel in accordance with established sampling procedures. These procedures appear in the [Rice Inspection Handbook, Chapter 2, Sampling](#).

Note: The entire lot presented for inspection must be accessible for sampling services. Additionally, samples acquired with a probe must reach the bottom of the carrier.

a. Sample Size.

For lots that are less than 50 metric tons (approximately 110,000 pounds), GIPSA personnel will sample the lot in such a manner as to acquire a minimum of 5,000 grams of bulk sample. For lots between 50 and 500 metric tons (110,000 - 1,100,000 lbs), samplers will draw a bulk sample equal to 0.01% of the lot size. For example: a lot size of 250 metric tons (approximately 551,000 pounds) will require a sample size of 25,000 grams. Lots in excess of 500 metric tons (1,100,000 pounds) will require a bulk sample size of 50,000 grams.

Lot Size (Metric Tons)	Lot Size (Pounds)	Sample Size (Minimum)
< 50	< 110,000	5,000 grams
50 – 500	110,000 – 1,100,000	0.01% of lot size
> 500	> 1,100,000	50,000 grams

b. Sample Preparation.

From the bulk sample obtained according to section 3(a) above, GIPSA personnel will prepare a representative 2,500 gram lot composite sample for the testing laboratory and will retain an identical 2,500 gram file sample. GIPSA will apply a seal to the laboratory sample and record the seal number for future reference.

The applicant for service will forward the sealed sample to one of the commercial testing laboratories participating successfully in the LibertyLink® rice proficiency program administered by GIPSA and listed at this location: <http://archive.gipsa.usda.gov/rdd/lriceprof.pdf>.

4. TESTING PROCEDURES

The laboratory will record the seal number, break the seal, and test four 240-gram samples taken from the single laboratory sample. One extraction will be made from each sample. Two PCR (polymerase chain reaction) analyses will be made for each extraction using the 35S:BAR method developed by Bayer CropScience and verified by both GIPSA and Europe’s Community Reference Laboratory. The lot will be considered negative only when all sample results are negative.

5. REPORTING RESULTS

The laboratory will report the test results and the GIPSA seal number on the lab report and provide it to the applicant for service. The applicant will provide the lab report (via email or fax) to the GIPSA office that sampled the lot. GIPSA will issue a letterhead statement as follows, and provide it to the applicant:

“GIPSA officially sampled the lot of rice identified as (*specify lot identification*) and applied seal number (*enter seal number*). (*Enter lab name*), who participates in the LibertyLink® rice proficiency program administered by GIPSA, tested a sample identified with this seal number and did not detect LibertyLink® rice based on the verified 35S:BAR method. The lab report is attached.”

6. QUESTIONS

Direct any questions concerning this directive to the Policies and Procedures Branch at (202) 720-0224.

/s/ John Giler

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