

U.S. DEPARTMENT OF AGRICULTURE  
Grain Inspection, Packers and Stockyards Administration

CERTIFICATE NO. GIPSA 2004-001

**CERTIFICATE OF PERFORMANCE**

**Cry9C ELISA Plate Kit #AP 008, Quantitative Microtiter Well Assay for Corn**

**For: EnviroLogix, Inc.**

Method: Microtiter Well Assay

Submitted By:

EnviroLogix, Inc.

500 Riverside Industrial Parkway

Portland, ME 04103

(207) 797-0300

Contact: Dean Layton

**Standard Features and Options**

<u>Model</u>	<u>Event(s) Detected</u>	<u>Sample Preparation</u>	<u>Extraction</u>	<u>Temperature Range</u>
Part #AP 008 Cry9C ELISA Plate Kit	Genetic Events expressing the Cry9C Protein (StarLink)	Grind	1XGrain Extraction Solution	Not Applicable

Test kits must be operated according to the manufacturer's instructions.

This test kit was initially certified as a Qualitative Microtiter Well Assay under the authority of the Agricultural Marketing Act of 1946, as amended, and was found to meet all test performance criteria as defined in "Performance Verification of Rapid Tests for the Detection of Biotech Events" February 2002 version. The original certification expired February 2004. It has been submitted for re-certification. Evaluation tests that were passed are summarized in Attachment 1.

For further information, contact:

USDA, Grain Inspection, Packers and Stockyards Administration  
Technical Services Division  
Biotechnology Branch  
10383 N. Ambassador Drive  
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Steven N. Tanner, Director  
Technical Services Division

02/27/04  
Date

*This Certificate expires three years from the date signed. GIPSA reserves the right to rescind the Certificate of Performance if the manufacturer fails to notify GIPSA of changes or alterations to the test or the test is found to produce invalid results identified by users or through GIPSA's Quality Programs.*

NOTE: The mention of firm name or trade products does not imply that they are endorsed or recommended by the United States Department of Agriculture over other firms or similar products not mentioned.

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ATTACHMENT 1

Manufacturer: EnviroLogix, Inc.  
500 Riverside Industrial Parkway  
Portland, ME 04103  
(207) 797-0300

**TEST 1: CAPABILITY FOR ANALYZING FOR THE Cry9C PROTEIN (StarLink)**

Data submitted by the manufacturer showed that the test kit was capable of detecting the Cry9C protein (StarLink) at a threshold of 1 kernel in 2400 kernels of corn following the Rapid Protocol and at a threshold of 1 kernel in 10,000 kernels of corn for the High Sensitivity Protocol.

**TEST 2: TEMPERATURE SENSITIVITY**

The manufacturer requires this test to be conducted in a laboratory environment with temperature controls.

**TEST 3: REPRODUCIBILITY**

Data submitted by the manufacturer supported reproducibility claims.

**TEST 4: RUGGEDNESS**

Data submitted by the manufacturer supported ruggedness claims.

**TEST 5: GIPSA EVALUATION**

Data generated by GIPSA staff showed this test kit was capable of detecting the Cry9C protein (StarLink) at a threshold of 1 kernel in 2400 kernels of corn following the Rapid Protocol and at a threshold of 1 kernel in 10,000 kernels of corn for the High Sensitivity Protocol.