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Overview of DAS Quality Assurance Requirements for

7 Oct 2011

Herculex® Corn Quality Assurance Requirements

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Herculex® brand corn is a type of transgenic corn which demonstrates inherent insecticide activity, and herbicide tolerance characteristics.

- **Quality Assurance (QA) requirements are designed to ensure that commercial hybrids and inbreds demonstrate the desired characteristics, prior to sale of grain or seed.**

- **QA requirements can be found in the appropriate Quality Assurance manual or Appendix C of the appropriate Commercial License Agreement.**

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Insecticide Activity:

- QA requirements are based on the expression of various Bt protein(s) which are toxic to the insects of interest.

- The type and quantity of these proteins is determined using:

  - Qualitative ELISA testing – determines *if* the protein is present. (Also called +/- ELISA).

  - Quantitative ELISA testing – determines *how much* of the protein is present.

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Minimum Protein Expression Levels

HERCULEX® I Insect Protection

Cry1F protein

(Inbred: 140 pg Cry1F/ug protein)
(Hybrid: 70 pg Cry1F/ug protein)

HERCULEX® RW Rootworm Protection

Cry34Ab & Cry 35Ab proteins

(Inbred: >500 pg Cry34Ab1 and 200 pg Cry35Ab1/ug protein)
(Hybrid: >250 pg Cry34Ab1 and 100 pg Cry35Ab1/ug protein)

HERCULEX® XTRA Insect Protection

Cry1F, Cry34Ab, & Cry 35Ab proteins

(Inbred: >500 pg Cry34Ab1,200 pg Cry35Ab1,140 pg Cry1F/ug protein)
(Hybrid: >250 pg Cry34Ab1,100 pg Cry35Ab1,70 pg Cry1F/ug protein)

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Herbicide Tolerance:

- QA requirements are based on tolerance to glufosinate based, Liberty® herbicide. Licensed technology from Bayer CropSciences.

- QA requirements are based on the Liberty Link Quality Standard from Bayer CropSciences.

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New Inbred QA Requirements:

- **Required level of protein expression –Quantitative ELISA test showing a minimum level of the appropriate protein is being expressed. 9 seedling test.**
- **Verification that the correct gene is producing the protein. Event specific PCR test. 90 seed test.**
- **Verification of the absence of Unintended genetic events. Typically a 3000 seed PCR test.**

All data must be submitted to DAS for approval prior to commercial release. feltrqa@eximc.nam.dow.com

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Approved Inbred QA Requirements:

- **Required level of protein expression – Quantitative ELISA test showing a minimum level of the appropriate protein is being expressed, for each Gen 1 increase.** ***9 seedling test.*** ***Results must be submitted to DAS.***

- **Presence of the correct protein – Qualitative ELISA test. (360 seed test).**

- **Glufosinate tolerance:**
  - **Tester Row method – Qualitative ELISA** ***or***
  - **Field application of glufosinate (spray 10,000 plants) + Qualitative ELISA (360 seed test)**

All data must be available upon request.

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New Hybrid QA Requirements:

- **Required level of protein expression –Quantitative ELISA test showing a minimum level of the appropriate protein is being expressed. 9 seedling test.**
- **Yield - equivalent or greater than the isogenic hybrid, or one of a similar type and maturity.**
- **Glufosinate tolerance field test* – 2 locations, 2 reps., 10 plants per rep. minimum.**

***must be available upon request.**

All data must be submitted to DAS for approval prior to commercial release. ***feltrqa@eximc.nam.dow.com***

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Approved Hybrid QA Requirements:

- **Presence of the correct protein – Qualitative ELISA test, each *bulk* lot. 90 seed test.**

- **Glufosinate tolerance – Lab bioassay test. 400 seed test.**

All data must be available upon request.

Herculex® Corn Quality Assurance Requirements

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Summary of Annual Information Submission

New Licensed Corn Product (New Hybrid)			
Test Description	**Submission Date**	**Timing**	**Data**
Quantitative ELISA	31-Dec	Prior to first year of sales	Submit
Yield Performance	31-Dec	Prior to first year of sales	Submit
Glufosinate Tolerance	upon request	Prior to first year of sales	Available*

Approved Corn Products (Hybrids)			
Test Description	**Submission Date**	**Timing**	**Data**
Seed Production Protocols	upon request	Prior to first year of sales	Available
Glufosinate Tolerance Bioassay	upon request	All commercial lots	Available
Qualitative ELISA	upon request	All bulk lots	Available

New Licensed Corn Line (New Inbred)			
Test Description	**Submission Date**	**Timing**	**Data**
Presence of correct Gene – PCR	31-Dec	Prior to first year of sales	Submit
Absence of unintended events – PCR	31-Dec	Prior to first year of sales	Submit
Quantitative ELISA	31-Dec	Prior to first year of sales	Submit

Approved Corn Line (Inbred)			
Test Description	**Submission Date**	**Timing**	**Data**
Seed Production Protocols	upon request	Prior to first year of sales	Available
Quantitative ELISA	31-Dec	Each Gen 1 increase	Submit
Qualitative ELISA	upon request	All Gen 1 and Gen 2 increases	Available
Glufosinate Tolerance - Field application (optional)	upon request	All Gen 1 and Gen 2 increases	Available

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Approved Labs:

A DAS approved lab must be used when conducting the required PCR and ELISA tests for Herculex. A list of approved labs is provided in the Herculex Quality Assurance manual. Laboratories owned or managed by a licensee will also need to be approved prior to testing.

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Notes:

- **The QA requirements discussed today are considered minimums. Any additional testing is encouraged.**

- **The requirements discussed today are in addition to those required by the Federal Seed Act and any other regulatory agencies.**

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Questions?

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