

Overview of DAS Quality Assurance Requirements

HERCULEX® I
Insect Protection



TM

HERCULEX® RW
Rootworm Protection



TM

HERCULEX® XTRA
Insect Protection



TM



Dow AgroSciences

Solutions for the Growing World

Herculex[®] Corn Quality Assurance Requirements

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.**

Herculex[®] Corn Quality Assurance Requirements

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.

Herculex[®] Corn Quality Assurance Requirements

Minimum Protein Expression Levels



Cry1F protein

(Inbred: 140 pg Cry1F / ug protein)

(Hybrid: 70 pg Cry1F / ug protein)



Cry34Ab1 & Cry35Ab1 proteins

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

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



Cry1F, Cry34Ab1 & Cry35Ab1 proteins

(Inbred: 140 pg Cry1F, >500 pg Cry34Ab1 and 200 pg Cry35Ab1 / ug protein)

(Hybrid: 70 pg Cry1F, >250 pg Cry34Ab1 and 100 pg Cry35Ab1 / ug protein)



Herculex[®] Corn Quality Assurance Requirements

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.

Herculex[®] Corn Quality Assurance Requirements

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.

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Herculex[®] Corn Quality Assurance Requirements

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.

Herculex[®] Corn Quality Assurance Requirements

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.

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Herculex[®] Corn Quality Assurance Requirements

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

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



Herculex[®] Corn Quality Assurance Requirements

- **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.**

Thank you!

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