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Additional Guidance on Agronomic Performance Data of Corn

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Corn, in addition to being the most widely grown crop in the United States, is the most frequently targeted crop for improvements through genetic engineering.

Fortunately, much is known about the biology of this crop, and the high degree of familiarity is helpful in risk assessments. In developing crop data requirements,

APHIS considers the biology of the crop, interactions with the environment, and the nature of the inserted gene. In the case of corn, key biological features of the plant are that it has no sexually compatible relatives in the United States, it does not tend toward weediness, and it is wind pollinated. The nature of the inserted gene is also considered. Some data requirements may be specific according to the function of the gene. Other data requirements are more general and are aimed at whether the engineered crop has unanticipated effects that would render it phenotypically different from a near isogenic control.

Recommended Parameters

For corn, the following list comprises factors which would be appropriate for inclusion in a data package and that would support a decision that the engineered plant was unchanged from a near isogenic control except for the desired change.

Germination and Seedling Emergence - Standard laboratory germination tests and field emergence measurements will be useful to indicate not only general seed quality and viability, but also to detect changes in dormancy characteristics.

Growth Habit - Plants should be observed for any changes in basic morphology. Quantitative data must be included. Possible parameters might include, but are not limited to plant height, ear height, stalk diameter, number of leaves, and leaf area index.

Vegetative Vigor - This might include plant biomass accumulation over time, vigor ratings, final stand count, etc

Days to Pollen Shed (Duration of Pollen Shed) - For corn the number of days to 50 percent pollination may be the appropriate. Also growing degree days (GDD) or some similar measure of heat units may be used instead of days to allow for comparison across sites. Days to silking may be substituted as an appropriate indicator of plants having reached reproductive stage.

Days to Maturity - Physiological maturity indicates that the seeds are fully mature and that the crop is suitable for harvesting. At maturity, milk has disappeared from all kernels and has been replaced by hard starch. The formation of the “black layer” at the base of each kernel indicates abscission from the cob. Applicants may substitute other types of observations indicative of the progression toward maturity

such as “dry down” or late-season greenness ratings, time to stages which shortly precede maturity such as milk or dough. Again, growing degree days (GDD) or some similar measure of heat units may be used instead of days.

Yield and Seed Retention - Corn yield is traditionally measured on a per area basis. Data on lodging and dropped ears are also useful measures related to the likelihood of seed being left on the ground that can contribute to volunteers.

Pollen Parameters - Pollen should be analyzed in such a way that changes in viability and/or dispersal could be detected. The proportion of viable pollen and, the duration of viability are recommended parameters. Changes in physical parameters such as stickiness, shape, and weight that might affect the viability or performance of the pollen should also be addressed.

Data Types and Descriptions

While objective, numerical data are most desirable, APHIS recognizes that not all parameters easily lend themselves to these types of measurements. In some cases data may be taken using subjective ratings using a descriptive scale. In other cases, data may be purely observational. What is required in all cases is that the methodologies are described in detail, such that the reader has an accurate understanding of the nature of the data and number of data points which make up a study and on which conclusions are drawn and the methods for analyzing the data. For example, is the unit on which data is taken a leaf, a plant, a row, or some other unit? Describe the total number of observations by describing numbers of replicate samples, rows, replicate blocks, locations, etc.

Numbers of Sites and Years

The above data should be collected on enough sites to adequately represent the major growing regions targeted by the product. The sites should also be selected in a way to ensure exposure to a reasonably wide range of environmental conditions. For corn with common agronomic traits or previously deregulated traits, APHIS recommends a minimum of eight sites be selected to represent the major growing regions in the U.S. Data from the eight sites may be collected in one or more years. When field-testing corn with less familiar traits or for traits where there is a reason to expect plant pest effects, more sites should be considered.

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