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Experiences of an academic with the regulatory environment

*Thomas Clemente*, Department of Agronomy and Horticulture, University of Nebraska-Lincoln, Nebraska, USA

Evaluation of plant traits derived from biotechnology requires field-testing, beyond the characterization of the target phenotype, to determine if the agronomic qualities of the event(s) expressing the novel trait have not been compromised. In the USA field testing on regulated transgenic material must be conducted in accordance with the Federal guidelines governing the movement and release of regulated items. These guidelines are designed to maximize confinement and, therefore, mitigate the likelihood of escape of the regulated material outside of the designated location(s). The University of Nebraska has strengthened its capabilities in the area of field-testing of regulated plants by building infrastructure to ensure identity preservation, containment and chain of custody tracking of the regulated items. These resources include a Field coordinator, with responsibilities for training of personnel, and oversight of all field-testing of regulated items. In addition, resource allocations for isolated storage facility, separate planting and harvesting equipment, and dedicated acreage for regulated plantings were allocated. The latter includes two sites at locations situated on the eastern and western sides of the state of Nebraska. The University's plant biotechnology field facility is certified under the APHIS Biotechnology Quality Management System (BQMS) program, a compliance assistance program that aids participants to properly address the Federal guidelines associated with movement and release of regulated plants. This infrastructure in conjunction with the University's capacity to development transgenic commodity crops through our plant transformation core research facility is collectively referred to as the agriculture biotechnology pipeline. The agriculture biotechnology pipeline enables researchers to evaluate transgenic traits from the lab to the field under strict identity preservation.