



# Low-Level Presence of Regulated Materials

Plant breeding programs involve the development and testing of thousands of plant varieties, and plant breeders go to great lengths to prevent these varieties from mixing. U.S. Department of Agriculture regulations are designed to minimize the occurrence of the low-level presence of regulated genetically engineered (GE) products in commercial seeds and grain. Occasionally, however, with both conventionally bred plants as well as GE plants, low-level mixing may occur.

**Current regulation:** Current regulations do not expressly allow for the low-level presence (LLP) of regulated GE products in commercial commodities and seeds. Biotechnology Regulatory Services (BRS) responds to such occurrences with actions that are appropriate and proportionate to the level of risk.

**Proposed change:** Establish criteria under which LLP of some regulated GE products would not require action by BRS as long as the products meet pre-established safety criteria.

A product's ability to meet or not meet the safety criteria would determine the requirements under which it must be field tested. Products not meeting the safety criteria would require more stringent confinement.

This change could be integrated easily into BRS' proposed tiered permitting system (see "Multi-Tiered Permitting System" poster). GE plants would be assigned to permit tiers that feature oversight and management practices corresponding to their safety evaluation.

The safety criteria for the tiered system's least restrictive level could also serve as the criteria under which low levels of regulated materials would not require remedial action by BRS when detected in commerce. However, this option is independent of the tiered permitting system and the criteria for LLP could be adopted even if the tiered permitting system is not.



*This image of one yellow tulip growing in a field of red tulips illustrates the concept of low-level mixing.*



*Plant material remaining within crevices of machines can violate field release conditions. Proper cleaning can help prevent the spread and establishment of regulated GE material.*