



Multi-Tiered Permitting System

Current regulation: Biotechnology Regulatory Services (BRS) regulates genetically engineered (GE) organisms through a two-tiered system that includes permits and notifications. The notification process is streamlined and may be used only for familiar plants and traits that meet certain safety-based criteria. Permits are required for any GE introductions that are not covered under notifications.

Proposed change: Establish an expanded, multi-tiered permitting system based on potential environmental risk and familiarity. The degree of confinement and oversight would be risk-proportionate and vary by tier.

- Familiar, GE organisms with low plant pest or noxious weed potential would continue to be processed under a system similar to the current notification process and would be introduced under the least restrictive tier “permit.”
- Additional tiers could be established to accommodate plants with higher plant pest or noxious weed potential, plants engineered to express traits with which BRS is less familiar, such as plants that produce pharmaceutical or industrial compounds, or plants that express traits that are likely to pose a hazard to human health and the environment.

The tiered system would increase transparency with respect to how the agency intends to handle various types of GE organisms and would also be highly flexible, allowing the movement of GE organisms among the tiers as new information becomes available.

The tiered system’s various levels and their associated safety criteria could be integrated with the other regulatory revisions under consideration. For example:

- 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 (see “Low-Level Presence” poster).
- The tiered system’s level representing the most studied and familiar GE organisms could be exempt from the permit requirement for interstate movement (see “Import and Movement” poster).



Inspections are important to help ensure compliance with established confinement measures.



Detasseling, shown here, is done to prevent pollination and is one strategy to prevent the spread and establishment of GE material.