

Biotechnology Regulatory Services

Imports and Movement

Biotechnology Regulatory Services (BRS) regulates the importation and interstate movement of genetically engineered (GE) organisms. BRS' goal is to improve this system through new practices that will enhance environmental safety, increase public confidence, and make more efficient use of resources while maintaining scientific integrity, reducing the regulatory burden, and increasing transparency to the public.

Current regulation: BRS currently handles requests involving the importation of low-risk GE organisms intended for non-propagative use -- that is, for food, feed, or processing -- on a case-by-case basis. BRS anticipates the number of importation requests will increase. The current system of permits and notifications does not have a separate process for reviewing (or exempting from review) these products.

multi-tiered permitting system but could be adopted even if the multi-tiered permitting system is not.

Current regulation: GE material regulated under permits must be shipped in specified containers. BRS regulations include approved packaging methods and BRS issues variances to allow the use of other suitable containers when appropriate.

Proposed change: Use performance-based standards for all shipping containers for regulated GE material. Numerous types of appropriate containers could meet given safety standards.



Proposed change: Develop a new regulatory mechanism to allow for imports of commodities that are for non-propagative use and that have not been deregulated in the United States. BRS would establish criteria to ensure safety and to provide for environmental review commensurate with their risk with the aim of protecting U.S. agriculture and human health without creating unnecessary trade barriers. Allowing such imports would not preclude the need to comply with requirements at other agencies, such as the Food and Drug Administration and the Environmental Protection Agency.

Current regulation: GE *Arabidopsis,* small flowering plants related to cabbage and mustard, are exempt from interstate movement regulatory requirements because they are well understood, extensively used in research, and are not a plant pest.

Proposed change: Exempt all organisms in the tier representing the most well-studied and familiar GE organisms from the requirement of a permit for interstate movement (see "Tiered Permitting System" poster). Shippers would notify BRS that they plan to ship the

BRS oversees the importation and interstate movement of regulated GE organisms.



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organisms. No agency response would be required. BRS would still

regulate the types of containers used to safely ship the organisms.

This change could be integrated easily into BRS' proposed

Regulated GE material must be properly packaged and labeled.