



Biotechnology Regulatory Services (BRS) is considering revising its regulations in order to keep pace with the latest science and to utilize the broad regulatory authority of the Plant Protection Act (PPA) of 2000. The PPA combines the authorities of several previous acts under which BRS regulated genetically engineered (GE) organisms, including the Noxious Weed Act, the Federal Plant Pest Act, and the Plant Quarantine Act.

Current regulation: BRS regulates GE organisms to ensure that they are not a plant pest or cause damage, injury, or disease to plants.

Proposed change: Increase BRS oversight of GE organisms with the potential to damage plants to include:

- GE biological control agents
- GE organisms that have the potential to be noxious weeds, and may pose a broader array of risks to agriculture, the environment, and public health.

Current regulation: BRS does not regulate nonviable GE material, i.e., material that cannot propagate successfully. This nonviable material, such as plant stems and leaves, has been regarded as posing an insignificant plant pest risk, but in some circumstances it might pose other types of environmental risks.

Proposed change: Regulate nonviable plant material originating from field tests in certain circumstances, such as when:

- There is reason to believe that such material might be harmful to the environment if it were allowed to remain, or
- There is a violation of regulations or permit conditions, creating the potential for nonviable material to pose a hazard.



BRS is the program within the U.S. Department of Agriculture's Animal and Plant Health Inspection Service responsible for regulating GE organisms.



BRS regulates GE organisms under the authority of the PPA to protect agriculture and the environment.

Current regulation: Developers of new GE organisms can petition BRS for a determination of nonregulated status. Organisms are granted nonregulated status if BRS officials determine that they are not a plant pest. BRS does not currently place any restrictions or requirements on the use of GE organisms that have been granted nonregulated status.

Proposed change: Develop appropriate safety criteria and procedures through which GE organisms can be either:

- Fully deregulated and removed from agency oversight, or
- Granted conditional approval and retained under some degree of oversight as necessary to mitigate any minor plant pest risks.