



Plants that Produce Pharmaceutical or Industrial Compounds

Plants engineered to produce pharmaceutical or industrial compounds are handled very differently from those plants developed for use as food or feed. The U.S. Department of Agriculture applies extraordinary measures to keep these types of genetically engineered (GE) plants from becoming mixed in commercial crops and seeds.

Current regulation: Plants that produce pharmaceutical or industrial compounds are grown under highly stringent conditions and with rigorous oversight. These plants must be field tested under permits, which are issued on a case-by-case basis after scientific experts complete an extensive assessment.

Proposed change: Maintain current rigorous oversight and allow field testing of food or feed crops engineered to produce pharmaceutical or industrial compounds, but consider food safety of the new substance in the confinement measures.

Current regulation: To date, no GE plants that produce pharmaceutical or industrial compounds have been deregulated. Although the permit process was designed for field tests, these plants are being grown under permits when used for commercial purposes. BRS reviews a full permit application for these crops each year, even when the locations and protocols have not changed.

Proposed change: Establish an alternative process for the commercial production of plants that produce pharmaceutical or industrial compounds. The new system would provide continued oversight through multiyear permits, and would incorporate intensive reviews of standard operating procedures, audits, and inspections. Regulatory rigor would remain high to protect the environment. The new system would increase the efficiency and transparency of BRS' regulatory efforts. The system may also be appropriate for other types of GE plants.



Genetic engineering is a method used to introduce new traits into plants.



Fallow zones--areas left unplanted--are one of the many requirements for field testing plants that produce pharmaceutical and industrial compounds.