

Regulation of Field Releases of Genetically Engineered Organisms at USDA/APHIS/BRS

Plant Made Pharmaceutical Industrial & Phytoremediation Permits

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Plant Made Pharmaceutical, Industrial, & Phytoremediation Permits



- Plants engineered for pharmaceutical, industrial, and phytoremediation purposes require permits which carry substantial additional requirements over other permits for GE plants.
- These additional requirements, along with additional oversight from BRS, ensure that these plants remain strictly confined and do not impact the environment or the food supply.



Pharmaceutical



If commercialization of the plant product (pharmaceutical) will require approval from FDA's Center for Drug Evaluation and Research (human drug, human biologic), Center for Veterinary Medicine (animal drug), or USDA's Center for Veterinary Biologics (animal biologic), then the engineered plant is considered to have been engineered with pharmaceutical intent.

Industrial



Meet all following three criteria

1. Plants are engineered to produce compounds that are new to the plant.
2. The new compound has not been commonly found in food or feed.
3. The new compound is being expressed for non-food, non-feed industrial uses.



Phytoremediation



Special permits are required for plants being engineered for bioremediation if the plants which accumulate heavy metals or other toxins.



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OCT 15 2002



FERGUSON





Perimeter Fallow Zone 50 ft.

Land Use for the Following Growing Season

Restrict the production of food and feed crops for the following growing season

Storage Facilities

Dedicated facilities for storage of equipment & regulated articles

Approved cleaning of storage facilities prior to general use

Seed Cleaning & Drying - APHIS approved protocols

Training - APHIS approved training program

Records

Permittee must maintain records

APHIS will increase auditing of record

Planters and Harvesters

- Dedicated to use, in the permitted test site(s) for the duration of the test
- Notify APHIS if moved between field test site (s)
- APHIS approved cleaning procedures
- APHIS inspection before use other than permit use

All Other Field Equipment

Cleaned according to APHIS approved protocols

Increased Isolation Distances

- Required distances are many times those used for producing registered seed, e.g. for corn, the minimum is 1 mile.
- Distance is often used in conjunction with other measures such as male sterility, flower removal, or asynchronous flowering.
- In current permits, the fields are regionally removed from primary growing regions if food crops are used:
 - GE pharmaceutical rice is grown in Kansas, 400 miles away from nearest known rice production. System is closed-loop, i.e. extraction and processing is done on the farm.

7 Inspections

Before Planting – Site selection

At Planting - Planters

Mid-Season – Pollination

At Harvest - Harvesters

After Harvest – Site clean up

Post Season (2X) – Monitoring for volunteers

Additional Data Requirements

- Description of gene product and current and potential uses.
- If the product is for therapeutic use (e.g. an antibody or vaccine) provide type and the epitope or antigen and the disease or target component of the immune system.
- Indicate if product is new to the plant or is commonly found in plants used for food or feed.
- Gene sequence homology to known toxicants or proteins known to or likely to harm non-targets.
- If the amino acid sequence of the protein is altered, and if so if it changes the biological properties.

Additional Data Requirements

- Compare the properties of the engineered protein or enzyme with the native molecule.
- Compare levels produced in the GE plant with those of known, naturally occurring toxic compounds and address possible non-target exposure routes.
- Address whether the engineered protein is expected to affect worker safety or have effects (dermal, inhalation, toxicity, etc.) on non-target invertebrates and vertebrates.
- Indicate whether engineering has or is likely to affect biological properties related to confinement measures.
- Status of regulatory review process with other agencies.

BRS Website



[http://www.aphis.usda.gov/biotechnology/
brs_main.shtml](http://www.aphis.usda.gov/biotechnology/brs_main.shtml)

[http://www.aphis.usda.gov/biotechnology/
downloads/permit_guidance.pdf](http://www.aphis.usda.gov/biotechnology/downloads/permit_guidance.pdf)