



APHIS currently uses a two-tier system of permits and notifications to authorize importations, interstate movements, and releases into the environment of certain genetically engineered (GE) organisms. APHIS proposes to remove the notification procedure and authorize all activities under permits, including a new five-category system for environmental releases.

APHIS proposes to authorize regulated activities for a GE organism only when the activity is unlikely to result in the introduction or dissemination of a plant pest or noxious weed.

New Permit Categories for Environmental Releases

APHIS would initially sort proposed environmental releases into categories that pose broadly similar risks and management issues. Once sorted, APHIS would conduct an evaluation of the actual risk of the proposed release.

The proposed sorting system for environmental release permits includes five categories: four for releases of GE plants (Categories A-D) (see Table) and one for releases of all other GE organisms (Category E).

Sorting System for Releases of GE Plants:

- Based on persistence risk of the recipient plant and potential damage or harm of the engineered trait.
- Category assignment may be modified based on other factors, such as scientific uncertainty.
- Data requirements, oversight, and permit conditions will be proportionate to the level of risk.



Using the proposed five-category system for environmental releases facilitates APHIS' ability to tailor oversight to be proportional to the actual risk of the release.



Potential Harm or Damage of Engineered Trait

	Low	Moderate	High	Severe
Low	A	A	C	D
Moderate	A	B	C	D
High	B	B	C	D
Severe	D	D	D	D

Persistence risk of the recipient plant species

“Low,” “Moderate,” “High,” and “Severe” for each factor are defined in the proposed rule.