



# Compliance, Enforcement and Remediation

In recent years, APHIS has strengthened its program in order to:

- Improve permit holders' compliance with regulations
- Augment the approaches used to prevent or remediate potential risks to plant health
- Better utilize appropriate enforcement strategies

This proposal provides an opportunity to clarify the compliance, enforcement, and remediation tools and administrative practices APHIS may employ as part of an integrated approach to prevent the introduction or dissemination of plant pests and noxious weeds.

## New Compliance, Enforcement, and Remediation Regulations

The proposed regulations include several key features:

### Compliance

- Additional recordkeeping requirements
- New requirements to develop communication, training, and contingency plans
- Requirement that responsible parties acknowledge permit conditions before issuance

### Enforcement

- Underscores APHIS' ability to inspect facilities and audit records
- Clarifies the liability of responsible parties for the actions of their agents
- Outlines possible consequences of failure to comply with the regulations, including denial of future permits, revocation of current permits, and issuance of penalties

### Remediation

- Clarifies the actions APHIS may take or order to remediate unauthorized releases of genetically engineered (GE) organisms, such as destruction, treatment, or removal of the GE organisms

## Low-Level Presence (LLP) of Regulated GE Materials

APHIS proposes to establish criteria under which the occurrence of low levels of unauthorized GE plant materials in commodities or seeds may not be cause for agency remedial action. These criteria include:

- Similarity of the GE organism to one previously granted nonregulated status
- Function of inserted sequences are known and unlikely to pose a plant pest or noxious weed risk
- Key food safety issues have been addressed by appropriate authorities

APHIS would still use its discretion when ordering corrective or remedial action where appropriate.

This would codify into regulation the LLP policy APHIS published in 2007.



APHIS inspects environmental release sites in order to ensure compliance with regulations.



This image of one yellow tulip growing in a field of red tulips illustrates the concept of low-level mixing.