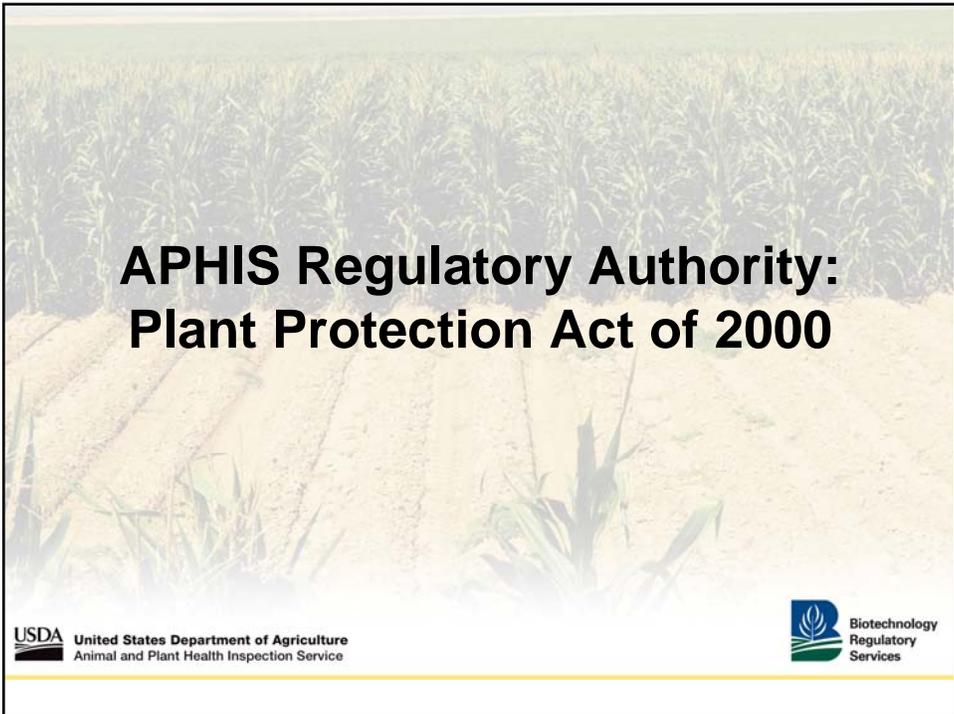


Public Meeting on Proposed Rule for Biotechnology Regulations

April 29-30, 2009
Riverdale, Maryland

 **United States Department of Agriculture**
Animal and Plant Health Inspection Service

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APHIS Regulatory Authority: Plant Protection Act of 2000

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Current Regulations



■ APHIS' Current Regulations

- Importation, interstate movement, and environmental release of certain genetically engineered organisms
- Organisms which are plant pests or for which there is a reason to believe are *plant pests*
- Based on plant pest authorities:
 - Federal Plant Pest Act (1957)
 - Plant Quarantine Act (1912)



Plant Protection Act



■ Plant Protection Act of 2000

- Combined several related Acts
- Grants the Secretary of Agriculture the authority to develop regulations in order to detect, control, eradicate, suppress, prevent, or retard the spread of plant pests or noxious weeds.

Plant Pests

- **Plant Pest Definition**

The term “plant pest” means any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product:

 - A protozoan.
 - A nonhuman animal.
 - A parasitic plant.
 - A bacterium.
 - A fungus.
 - A virus or viroid.
 - An infectious agent or other pathogen.
 - Any article similar to or allied with any of the articles specified in the preceding subparagraphs.

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Plant Pests

- **APHIS Regulation of Plant Pests**



The slide features three images illustrating plant pests. On the left is a photograph of a longhorn beetle (Cerambycidae) with a dark body and long, segmented antennae, set against a red background. In the center is a photograph of a root system with several small, yellow, spherical nodules attached to the roots. On the right is a photograph of green leaves showing signs of damage, including yellowing and necrotic spots.

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Noxious Weeds

- **Noxious Weed Definition**

The term “noxious weed” means any plant or plant product that can directly or indirectly injure or cause damage to:

 - crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture,
 - irrigation,
 - navigation,
 - the natural resources of the United States,
 - the public health,
 - or the environment.

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Noxious Weeds

- **APHIS Regulation of Noxious Weeds**



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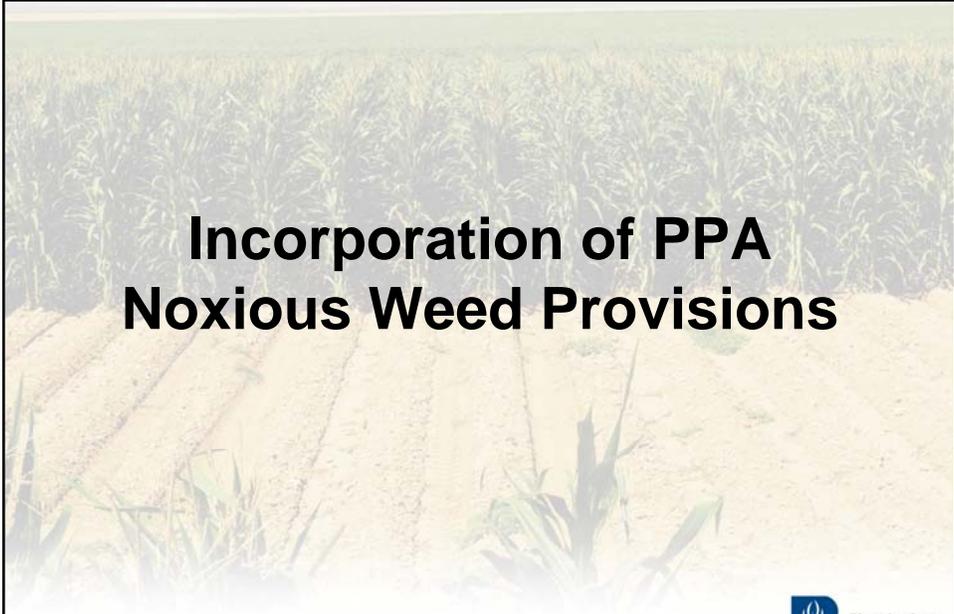


Noxious Weed Provisions

- **Incorporation of Noxious Weed Provisions**

APHIS is proposing to revise its regulations to also incorporate the noxious weed provisions of the Plant Protection Act.

But before we get to that...



Incorporation of PPA Noxious Weed Provisions

Noxious Weed Authority

■ Goals of Proposed Regulation

- Prevent potential gaps in oversight
 - Regulate GE organisms which may pose a noxious weed risk but not a plant pest risk
- Consider a broader range of harms
- Improve clarity and transparency of risk assessments
- Regulate non-living material derived from a GE plant, if APHIS concludes that such material is likely to pose a noxious weed risk

Consistency with Current Noxious Weed Regulation

- **APHIS has a history of regulating noxious weeds**
 - Useful experience and precedent
- **APHIS must consistently apply its PPA authority to both GE and non-GE plants**
- **APHIS' noxious weed assessment of GE and non-GE plants must be consistent**



Comments on Noxious Weed

■ **Broad range of harmful impacts**

- Narrowly limit interpretation of the noxious weed definition
- vs-
- Be as inclusive as possible

■ **Concerned that bar set too low**

- Few GE plants could ever rise to the level of harm of non-GE “noxious weeds”



APHIS Current Thinking

■ **Incorporate noxious weed authority**

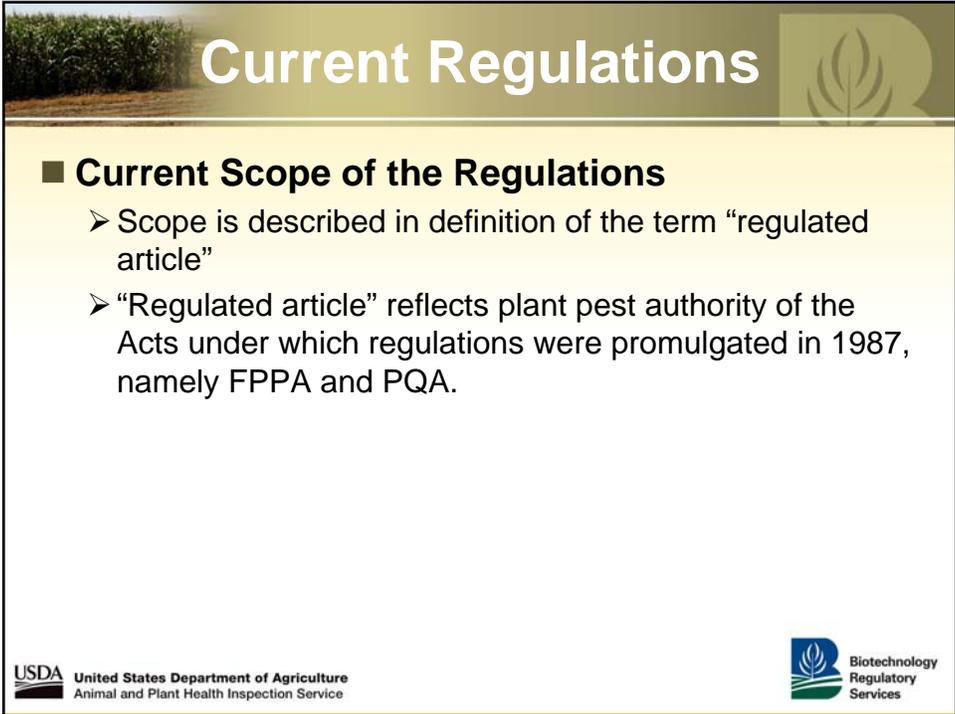
- Allow regulatory oversight of GE organisms that do not fall within the jurisdiction of the current regulations.
- Consider a broader range of factors

■ **Must be consistent with APHIS noxious weed precedent**

■ **Criteria and standards incorporated into the regulations**



Scope of the Regulation



Current Regulations

■ Current Scope of the Regulations

- Scope is described in definition of the term “regulated article”
- “Regulated article” reflects plant pest authority of the Acts under which regulations were promulgated in 1987, namely FPPA and PQA.

Proposed Regulatory Scope

■ Goal of Proposed Scope

- Align with PPA authority for plant pests and noxious weeds
- Clearly describe which GE organisms fall within scope

■ Scope Criteria

- Consider characteristics related to plant pest and noxious weed risks
- Consider unknown or uncharacterized GE organisms with respect to plant pest or noxious weed risks
- The criteria are intended to be sufficiently clear and definitive.

■ Consultation Process

- If uncertain about scope, a person can consult with APHIS for an initial evaluation of whether a specific GE organism falls within the jurisdiction (scope) of the regulations.

Comments on Scope

■ Description of the scope

- Lack of clarity undermines the effectiveness and goals of the regulatory scheme.

■ Weakens APHIS ability to regulate

- Weakens the agency's ability to regulate GE organisms.
- Lacks sufficient protections for adequate oversight.

■ Voluntary regulations

- Regulatory scheme appears voluntary.
- Presumes ability of the GE developer to independently evaluate the scope criteria.



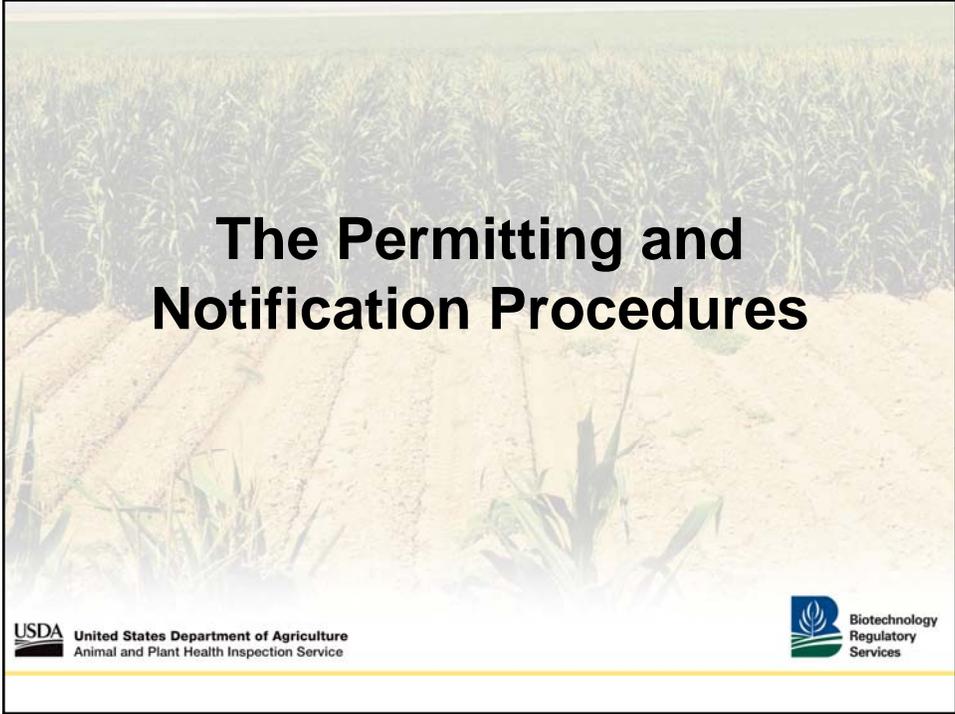
APHIS Position on Scope

■ Scope should be unambiguous

- Clearly describe which GE organisms falls within the jurisdiction (scope) of the regulations.
- APHIS determines which GE organisms fall within the scope

■ Scope criteria

- Aligned with statutory authority of PPA to regulate plant pests and noxious weeds



The Permitting and Notification Procedures



Current System for Regulated Introductions



- **Two-tiered system that includes a notification and a permit procedure**

- **Notification Procedure**
 - Expedited permitting procedure for GE plants that APHIS considers lower risk and has extensive experience regulating.



Proposed Permitting Procedure



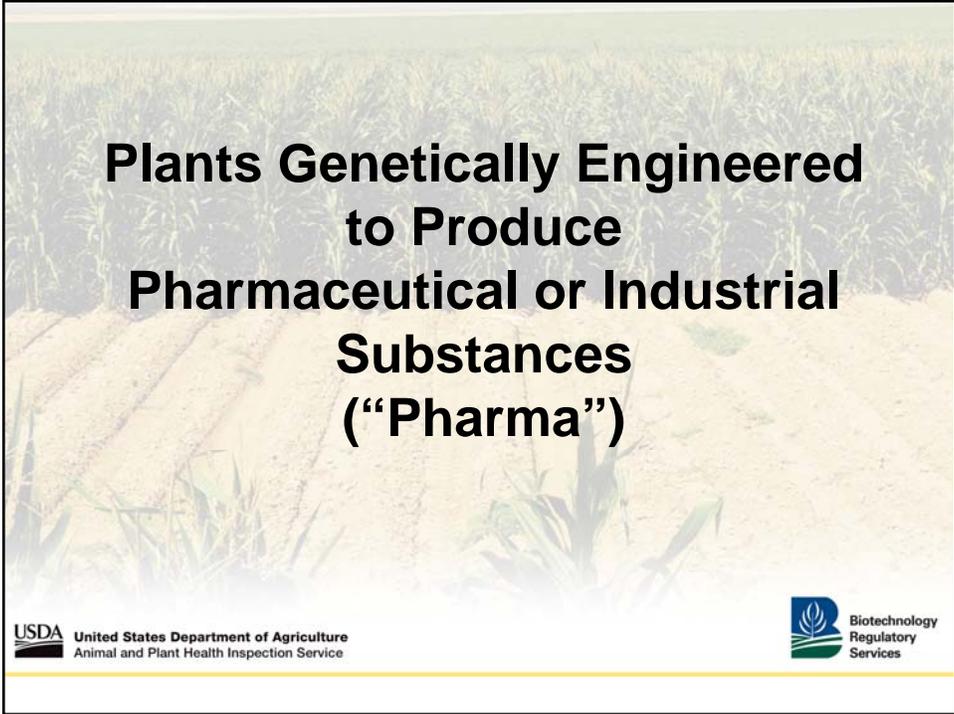
- **Goal of the Changes to Notification and Permitting Procedures**
 - Provide more flexible, risk-appropriate oversight, better regulatory enforcement, and improved transparency.
 - Address recommendations of OIG and provisions in 2008 Farm Bill
- **APHIS Proposed System**
 - Authorize all importations, interstate movements, and environmental releases under permitting procedure.

Comments on Permitting

- **Eliminating notifications increases APHIS oversight.**
 - Requires APHIS involvement in tailoring specific conditions.
- **Substantial problems with proposal.**
 - Longer timeframes, a lack of clarity about the information needed, and vague descriptions of increased regulatory demands
- **Increased regulatory burden does not correspond to the low-risk nature of GE plants.**
 - Existing notification procedure should be more streamlined.
- **Categories for permits were not adequately based on risk.**
 - Risk assessment procedure for permitting was not described adequately.

APHIS Position on Permitting

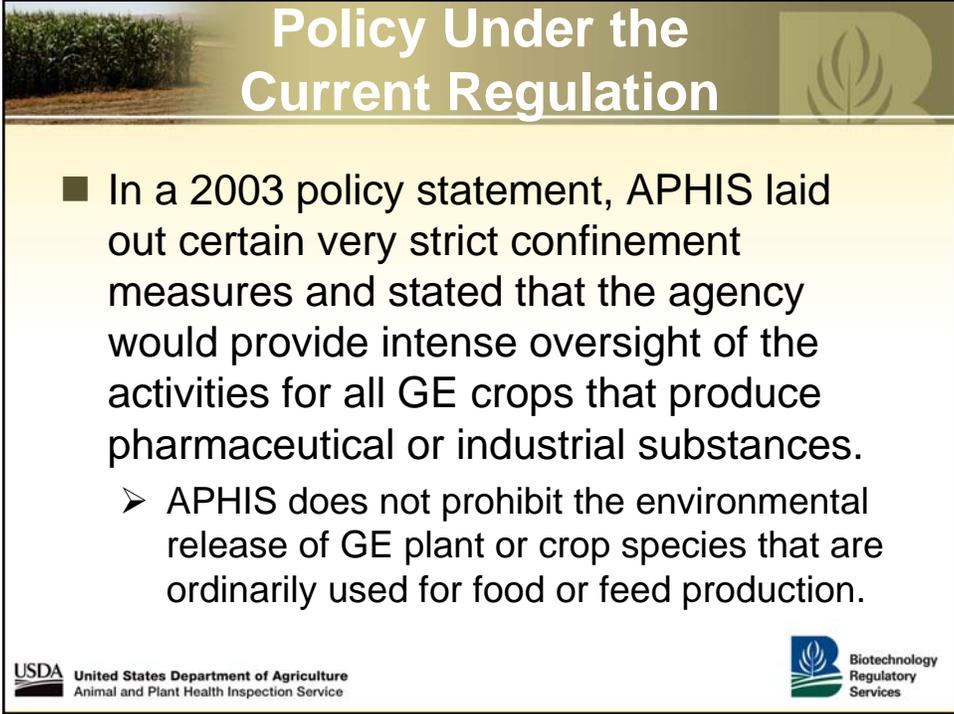
- **Eliminating the notification procedure and revising the permitting procedure:**
 - Achieves goal of more flexible, risk-appropriate oversight, better regulatory enforcement, and improved transparency.
 - May need clearer description regarding categories, permit conditions, and category requirements.
- **APHIS considers that timeframes needed for issuing a permit will be based on degree of APHIS familiarity with similar GE plants.**
- **Proposed recordkeeping and reporting requirements could be substantial increase for some permit holders**
 - APHIS is attempting to balance these burdens with the need to have information available to verify compliance.



Plants Genetically Engineered to Produce Pharmaceutical or Industrial Substances ("Pharma")

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Policy Under the Current Regulation

- In a 2003 policy statement, APHIS laid out certain very strict confinement measures and stated that the agency would provide intense oversight of the activities for all GE crops that produce pharmaceutical or industrial substances.
 - APHIS does not prohibit the environmental release of GE plant or crop species that are ordinarily used for food or feed production.

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Proposed Regulation



■ Risk-based Permitting System

- GE plants are regulated based on risk of the plant and the trait, not on their intended use.
- Issuance of environmental release permits for GE plants that produce pharmaceutical or industrial substances if APHIS determined that the release is unlikely to result in the introduction or dissemination of a plant pest or noxious weed.
- Confinement measures would be determined case-by-case and based on the risk posed by the particular environmental release.



Comments on Pharma



■ Public Comments

- APHIS has received the most comments on this issue.

■ Food or Feed Crops

- Opposition to the use of GE food or feed crop species for producing pharma/industrial products in outdoor settings.
- Concerns about public health, environmental consequences, and market disruptions



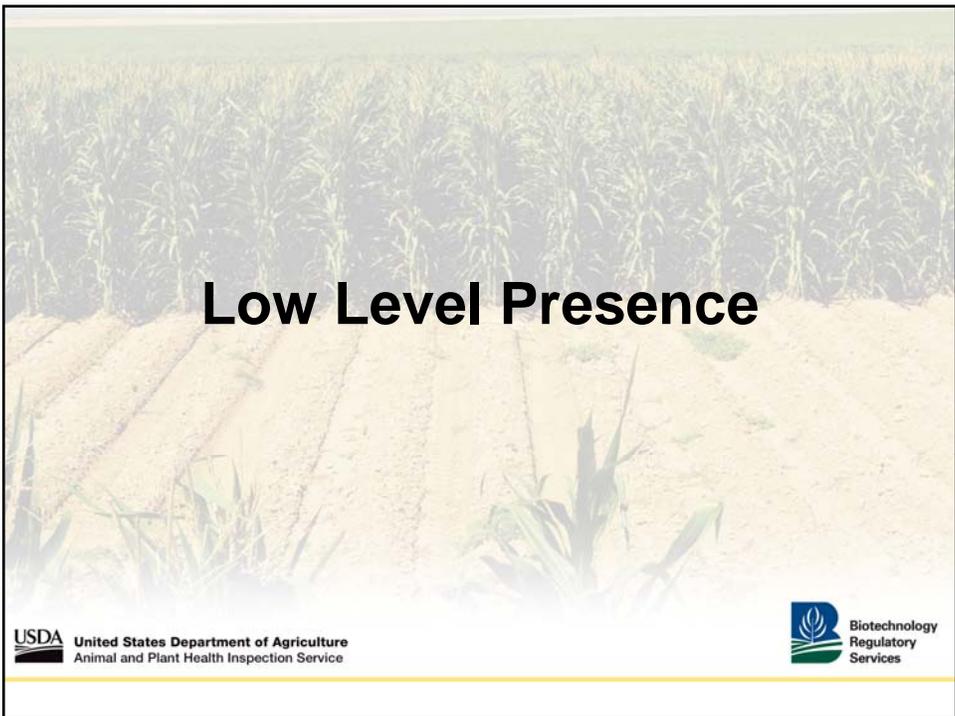
APHIS Position on Pharma

■ Environmental Release Permits

- Issue permits for crop species, including food or feed, that produce pharmaceutical or industrial substances.
- Apply conditions with strict confinement protocols to prevent dissemination of materials which could be plant pests or noxious weeds.

■ PPA Authority

- PPA authorizes regulation only for the purpose of preventing the dissemination of plant pests and noxious weeds (not intended use).



Low Level Presence



Low Level Presence



- **Low Level Presence (LLP) Definition**
 - The unintended mixing of small amounts of regulated GE materials which may occur in commercial seeds or grain.
- **Goal of LLP Policy**
 - Establish in the regulations an effective and transparent policy that describes the criteria APHIS will use when determining that a LLP event will or will not require remediation.

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Low Level Presence



- **LLP Policy in proposed rule**
 - Safety-based
 - Remediation not necessarily required
 - Modeled on LLP policy statement issued in a March 2007 *Federal Register* notice, but also incorporates key components of the noxious weed authority.
- **Remedial Action Criteria**
 - APHIS uses a plant pest-based criteria list when determining whether or not to take remedial action based upon the plant pest risk associated with the LLP incident. These criteria, along with some new criteria taking in to account noxious weed risks, together comprise new proposed policy.

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Low Level Presence



■ **LLP Remedial Action Criteria**

- Based on plant pest risks and noxious weed risks.
- Describes when the agency is likely to take or not take remedial action in response to LLP incidents.
- Agency retains discretion on need for remedial action
- No specific threshold level for remedial action; should always be made on a case-by-case basis.
- Remedial action separate from compliance and enforcement efforts.



Comments on Low Level Presence



■ **Comments opposing the policy**

- There should be a zero tolerance for LLP
- APHIS should consider the economic impacts of LLP to organic and/or conventional farmers
- APHIS should be aware of certain consumer market sensitivities to LLP
- Field trials should be designed to achieve strict containment of GE material.

■ **Comments not opposing the policy in general**

- Those not necessarily opposed to all aspects of the policy commented:
- There is no need to incorporate the LLP policy with its changes into the regulations. The agency only needs to update the 2007 LLP policy statement to reflect the addition of the noxious weed risk criteria.
- The LLP regulatory policy criteria in the proposal are focused on safety of the gene and protein and do not adequately take into account environmental effects or gene flow potentially resulting from the GE material mixing with the commercial commodity or seed.
- Agreed that the APHIS 2007 LLP policy should be incorporated into the rule and that violators would not be absolved from causing LLP incidents, but thought the agency should develop regulatory guidance that would prevent LLP from occurring.
- APHIS should establish tolerances for LLP.



Comments on Low Level Presence



■ Other comments on the policy

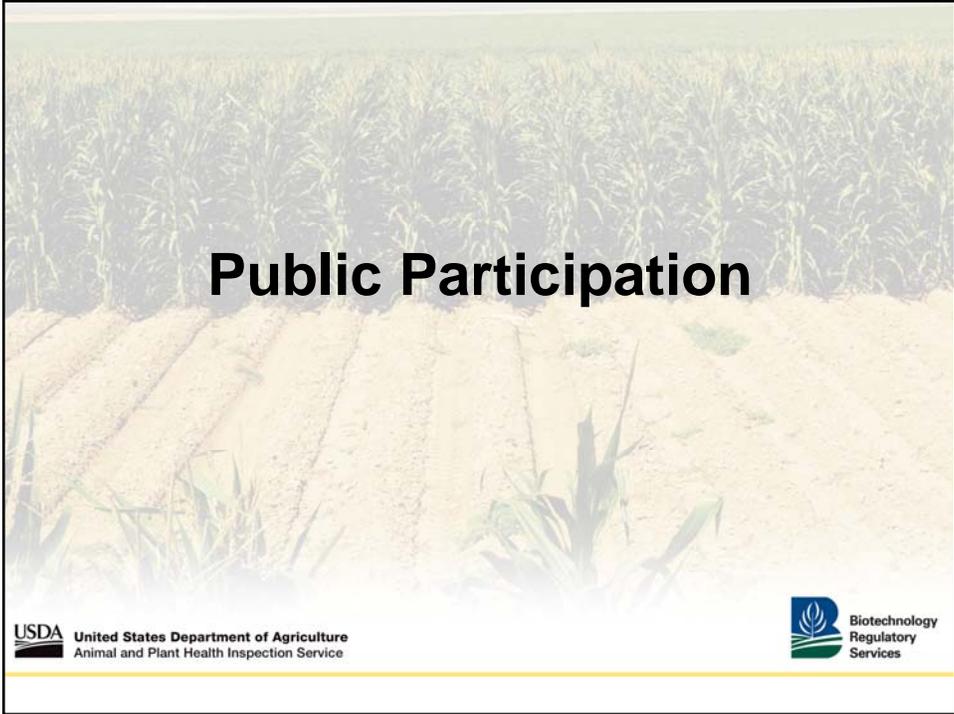
- No need to incorporate the LLP policy with its changes into the regulations.
- The LLP regulatory policy criteria do not adequately take into account environmental effects or gene flow.
- Agreed that the APHIS 2007 LLP policy should be incorporated into the rule; thought the agency should develop regulatory guidance that would prevent LLP from occurring.
- APHIS should establish tolerances for LLP.



APHIS Position on Low Level Presence



- APHIS believes that it is prudent to have an effective science-based LLP policy incorporated into the regulatory text of the rule.



Public Participation

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Public Participation

■ **Current Regulations**

- 60-day comment on petitions for nonregulated status

■ **Proposed Regulations**

- Same comment on petitions for nonregulated status
- 60-day comment on petitions to grant new exemptions

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The slide features a header with a photograph of a cornfield on the left and a stylized leaf logo on the right. The title "Public Participation" is centered in white text on a dark green background.

Public Participation

■ Other opportunities

■ NEPA

- Comment on draft EAs and EISs
- Petitions
- Some environmental releases

■ Rule making

- Comment on proposed rules