

## Highlights of the Federal Register Notice

### Changes in the Permit Conditions for 2003

1. Current:

A fallow zone around test sites had been set in 2002 at 25 feet to avoid the potential mixing of plant materials caused by equipment activities surrounding the test site.

FR Notice:

APHIS now requires that 50 feet be the minimum separation distance from any other crop.

2. Current:

Previous APHIS restrictions required that the same crop, if non transgenic, not be grown on the site of production of the regulated crop because of the difficulty of detecting volunteer plants from the previous season.

FR Notice:

In 2003, production of food or feed crops on the test site or in the fallow zone surrounding the pharm crop in the subsequent year will be restricted, especially when a concern exists about the ability to identify and remove volunteer plants in the subsequent crop.

3. Current:

APHIS formerly required that adequate cleaning of all farm equipment be accomplished at the test site.

FR Notice:

Under the new permit conditions, farm equipment such as harvesters and planters will need to be dedicated to pharmaceutical production only. Non dedicated mechanical farm equipment such as tractors and tillage equipment will continue to need special cleaning after use at permit sites and these procedures must be approved by APHIS.

4. Current:

Previous rules specified that regulated articles, if stored, must be maintained in a destination facility so that the regulated articles could not be disseminated.

FR Notice:

APHIS now requires dedicated facilities for storage of both the regulated article and farm equipment used at the field test site.

5. Current:

APHIS has required protocols from each company detailing how the regulated crop will be produced.

FR Notice:

APHIS now requires protocols that producers must specify procedures for seed cleaning and drying and both sets of procedures must be submitted to APHIS for approval.

6. Current:

Previously, each company provided the requisite level of instructions for its staff and cooperators that it deemed adequate to perform the production tasks that were needed.

FR Notice:

An approved training program is now required by APHIS so that personnel are prepared to implement and comply with the permit conditions assigned by APHIS.

## **Strengthening Field Test Conditions for Pharmaceutical Corn**

### 1. Current:

The confinement strategies for transgenic corn produced under permit include conditions that confine corn pollen so that it may not pollinate surrounding corn. APHIS rules in 2002 prevented growing any open-pollinated corn within a radius of one half mile of the field test and all corn from one half mile to one mile must be planted no less than 21 days before or after the pharmaceutical corn.

### FR Notice:

APHIS will now require isolation by one mile (5280 feet), which is eight times greater than the distance required for production of foundation corn seed.

### 2. Current:

APHIS rules in 2002 for corn produced under controlled pollination (using detasseling or bagging procedures) required that all corn within one quarter mile be isolated temporally from the regulated corn by 21 days and that such corn also be bagged or detasseled. Corn grown between one quarter and four-tenths miles needed to be only temporally isolated from the field test.

### FR Notice:

In the new policies stated in the FR notice, corn may be grown within one half mile (2640 feet) of the test site if the test site corn is controlled pollinated. Surrounding corn must be temporally isolated by planting it no less than 28 days before or after the regulated corn being field tested; these conditions apply to corn grown between one half and one mile of the regulated line.

### 3. Current:

Previously, border rows of non transgenic corn could be used to reduce isolation distance requirements.

### FR Notice:

Border rows will no longer be used as a condition for reducing isolation distances.

## **Developments in Compliance**

### 1. Current:

APHIS has made a goal of inspecting all field test sites for pharmaceutical plants at least once during the growing season.

### FR Notice:

The new FR notice announces an increase in the number of field site inspections to assure compliance with regulations and the assigned permit conditions. Every test site would be inspected more than once and inspections would correspond to critical times in the production. A sample inspection plan might be five site visits made during the growing season, and another two for assessing volunteers of the regulated line in the year subsequent to the field test.

## 2. Current:

APHIS requires field data reports for all field tests. APHIS regulations required that these reports document any deleterious effects of regulated plants during field testing such as unusual events, impacts on other plants, on nontarget organisms, or on the environment. These reports are submitted to APHIS.

### FR Notice:

APHIS now requires that record keeping should document all those activities specified by the permit conditions, including planting dates of regulated and adjacent crops if applicable, dates of bagging and assessment of detasseling operations and so forth. Using these records, APHIS will be capable of more effectively overseeing and auditing the field tests and identifying any problems before mitigation is needed.

## **Enhancing Transparency of APHIS**

### 1. Current:

APHIS has in the past provided information to the public about field tests conducted under notifications and permits. Recently, the field test conditions required for permits for the testing of various crops were published on the APHIS website.

### FR Notice:

As reported in the FR notice, APHIS recognizes the need to provide additional information about field testing and is considering how to make information about specific permits and necessary confinement standards available for each field test under permit. The FR Notice provides permit condition changes in a more formal way to the public and allows the public to provide comments on the regulatory process.

### 2. Current:

APHIS recognizes that a public dialogue is necessary for refining the regulatory system and has sought out seminars and workshops at which to present policy issues and agency decisions. APHIS is seeking new opportunities for pursuing that dialogue, and has already begun discussions with consumer and environmental groups as well as other stakeholders.

### FR Notice:

APHIS is looking for additional venues to hear and exchange views with the public and various organizations about the future regulation of biotechnology. The FR Notice asks specific questions on:

- Releasing information about the genes being field tested, and other steps that might be taken to increase agency transparency;
- Additional methods or procedures that might further improve confinement;
- Additional methods that could be used for monitoring and promoting compliance, such as changing training procedures, engaging either auditors or standard setting organizations in the role of assessing the confinement protocols and their execution by the permit holder; and
- Any other suggestions for APHIS to improve its oversight of field testing of engineered crops.

## **Requests for comment**

1. Current:

APHIS has provided information about some of the pharmaceutical crops being produced using the Informational Systems for Biotechnology Website, and the information made available is consistent with the limits of confidential business information claimed by many permit holders. APHIS has also provided descriptions of the permit process, and details of current confinement efforts.

FR Notice:

APHIS, however, has further proposed to release information about the genes being field tested and now solicits other steps that might be taken to increase agency transparency.

2. Current:

APHIS has continued to improve and strengthen conditions required for growing crops under permit as new information becomes available.

FR Notice:

APHIS is now requesting that submitted comments include proposals regarding additional methods or procedures that might further improve field test confinement.

3. Current:

APHIS compliance has been maintained by site visits of inspectors, and assessment by APHIS staff scientists of protocols used at the test sites. Fines have been assessed for negligence and consistent noncompliance with APHIS conditions.

FR Notice:

The new Federal Register notice seeks comment for additional methods that could be used for monitoring and promoting compliance, such as by changes in training procedures, engaging either auditors or standard-setting organizations in the role of assessing the confinement protocols, and execution of confinement protocols by the permit holder.

4. Current:

As the previous rules that have been promulgated were subjected to public comment, APHIS would like to receive further comments on the approach and scope of the actions that are proposed in this FR document.

FR Notice:

Any other pertinent suggestions for guidance of APHIS and its oversight of field testing of engineered crops are also sought.

## Planned Next Steps

1. As always, APHIS will continue to review its regulatory system to ensure safety. APHIS will continue to build enhancements and redundancies into the system to ensure that it is keeping pace with technology.

2. Because plants engineered to produce industrials and pharmaceuticals are never meant to enter the food supply, APHIS believes a very stringent system is called for. APHIS will lead a public dialogue on this issue, as well as issuing new regulations, in the coming months.

3. It is the intention of APHIS to publish an interim final rule which will require a permit for the field testing of industrials for the 2003 growing season. Until such time as this rule can be established, APHIS will be strongly encouraging applicants to request a permit for field testing of industrials.