

do not persist in the environment. For example, a field test may have five inspections during the growing season and two additional inspections post-harvest; however APHIS may inspect more frequently in some cases.

The permittee must, as always, maintain records of activities related to meeting the permitting conditions. APHIS will increase the auditing of the permittee's records to verify that required permit conditions were accomplished. APHIS will continue to require permittees to regularly inspect sites and maintain accurate records that will be available for APHIS auditing. The permittee will be required to record all efforts undertaken to meet the confinement protocols and other permit conditions. Some of this information will be related to agronomic information (*i.e.*, detasselling, pollination time of test crop, pollination time of surrounding crops, etc.). Frequent APHIS audits will enable the Agency to identify any discrepancies and mitigate any potential adverse effects.

#### IV. Information to the Public—Transparency

Transparency of the regulatory system and information about its effectiveness are essential ingredients for informed dialogue with the public. APHIS believes that effective communication and dialogue with interested parties and the public are necessary to enable continued refinement of its regulatory system and help instill confidence in the safety of field testing.

APHIS recognizes the need to provide relevant and timely information to the public on all aspects of the regulations, including information on APHIS authorizations for field testing. APHIS is responding to the increased public interest in the types of genetically engineered plants that are being developed for potential use in medical, veterinary, food processing, and other applications in addition to the more traditional uses in plant variety development for growers.

For example, APHIS provides information on its website on field tests the Agency has authorized and also those pending authorization. In light of increased public interest in the types of confinement standards APHIS uses for field tests of plants engineered to produce pharmaceutical compounds, the Agency posted a letter to potential permit applicants regarding such standards on its website ([http://www.aphis.usda.gov/ppq/biotech/pdf/pharma\\_2000.pdf](http://www.aphis.usda.gov/ppq/biotech/pdf/pharma_2000.pdf)).

In addition, FDA, in collaboration with APHIS's Biotechnology Regulatory Services and Center for Veterinary

Biologics, recently published draft guidance for scientific questions and information to be considered during development of a protein pharmaceutical in a genetically engineered crop (*see* 67 FR 57828, published September 12, 2002). The document outlines manufacturing and pre-clinical considerations for such products in addition to the stringent procedures for drug and biologic approval under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*). In the coming months, the agencies will respond to comments received regarding the notice.

This **Federal Register** notice is a step in our program to increase awareness and establish effective dialogue about APHIS' regulatory program and the permit system. APHIS anticipates providing further opportunities for public involvement in coming months as the Agency continues to evaluate its regulatory program.

#### V. Issues for Comment

1. As explained above, APHIS is taking steps to increase transparency of its regulatory approach to plants engineered to produce pharmaceutical and industrial compounds. APHIS seeks comment on additional measures that the Agency can take or employ to increase transparency and to enhance the flow of information to interested parties and the public.

2. APHIS seeks comment on alternative procedures, and the scientific data or technical rationale on which they are based, for ensuring adequate confinement for field tests.

3. APHIS seeks comment on appropriate training standards, the use of third party auditors, standard-setting organizations, or other quality control mechanisms to monitor and ensure compliance. In addition, commenters are asked to provide information on other measures or approaches that APHIS might use to verify compliance.

#### VI. Conclusion

We welcome all comments on the scope and approach of the actions outlined above and encourage the submission of ideas on any associated topics or other suggestions. APHIS will consider all comments and recommendations in developing additional guidance.

#### Paperwork Reduction Act

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements associated with the

application of the procedures described in this notice were submitted for emergency approval to the Office of Management and Budget (OMB). OMB has assigned control number 0579-0216 to the information collection and recordkeeping requirements.

We plan to request continuation of that approval for 3 years. Please send written comments on the 3-year approval request to the following addresses: (1) Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503; and (2) Docket No. 03-031-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 03-031-1 and send your comments within 60 days of publication of this notice.

The changes in permit conditions described in this notice will result in additional recordkeeping and reporting.

We are soliciting comments from the public (as well as affected agencies) concerning our information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses).

*Estimate of burden:* Public reporting burden for this collection of information is estimated to average 7.4444 hours per response.

*Respondents:* Universities and pharmaceutical companies.

*Estimated annual number of respondents:* 12.

*Estimated annual number of responses per respondent:* 9.

*Estimated annual number of responses:* 108.

*Estimated total annual burden on respondents:* 804 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)