February 2007

Supporting Statement
7 CFR Part 340: Introduction of Organisms and Products Altered or Produced Through Genetic Engineering
OMB 0579-0085

NOTE: This collection is being combined with the burden from 0579-0216, "Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds." Once OMB grants approval for 0579-0085, 0579-0216 will be retired.

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

The information Biotechnology Regulatory Services (BRS) collects is required to determine the risks to agriculture and the environment from certain genetically engineered organisms and products. Advances in molecular biology, including the development and widespread use of recombinant DNA technology, may present the potential for the introduction of plant pests into the United States. The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), is charged with preventing the introduction of plant pests into the United States or their dissemination within the United States. The statutory requirements for the information collection activity are found in the Plant Protection Act (PPA).

Section 11 of the PPA provides that no plant pest shall be moved from a foreign country into or through the United States or interstate unless the movement is authorized under a permit issued by the Secretary of Agriculture. In addition, the movement must be made in accordance with the conditions the Secretary may prescribe to prevent the dissemination of plant pests into the United States.

The PPA provides that the Secretary of Agriculture may promulgate regulations requiring inspection of any products or articles as a condition of movement into or through the United States or interstate as APHIS deems necessary to prevent the dissemination of plant pests.

The regulations in 7 CFR § 340 implement the provisions of the PPA by providing the information necessary to establish conditions for proposed introductions of certain genetically engineered organisms and products which present a risk of plant pest introduction.

APHIS is asking OMB to approve, for 3 years, its use of this information collection.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

BRS collects the information through a notification procedure or a permit requirement (APHIS Form 2000) to ensure that certain genetically engineered organisms, when imported, moved interstate or released into the environment will not present a risk of plant pest introduction. The information APHIS collects through the petition process is used to determine whether a genetically engineered organism will pose a risk to agriculture or the environment if grown in the absence of regulations by APHIS.

This information is also provided to State departments of agriculture for review and made available to the public and private sectors on the Internet to ensure that all sectors are kept informed concerning any potential risks posed through the use of genetic engineering technology.

The information currently requested is as follows:

Notification Procedures

Certain regulated articles may be introduced into the environment without a permit provided the introduction is in compliance with the eligibility requirements and performance standards of 7 CFR § 340.3. Notification must include all information necessary to identify the regulated article, the method by which the recipient organism was transformed, the names and locations of the origination and destination facilities for movement or the field site location for the environmental release, the size of the introduction, the date, and in the case of environmental release, the expected duration of the release.

Field Test Reports

The holder of a notification acknowledged by APHIS must provide field test reports to BRS which include an analysis of all deleterious effects on plants, nontarget organisms, or the environment and notification to APHIS of any unusual occurrences.

Permit Application (APHIS Form 2000)

Any person planning to import, move interstate, or release into the environment a genetically engineered organism that is a regulated article not eligible for introduction under the notification procedure in 7 CFR § 340.3 must submit a permit application under 7 CFR § 340.4. The applicant must provide a complete description of the organism including the donor organism, recipient organism, vector or vector agent, as well as a description of the expression of the altered genetic material, molecular biology of the system, any safeguards to be used in preventing escape, and the destination or field test locations.

Reports on Characteristics

The holder of a release permit is now generally required to supplement this information with reports to BRS on performance characteristics of the regulated article over time in order to determine the stability of the genetic modifications.

Appeal of Withdrawal of Permit

If a permit should be withdrawn because of a threat to plant health or any other reason, a permit holder may appeal the withdrawal of the permit in writing. Such actions occur infrequently.

Petition to Amend List of Organisms

Any person may submit to the Administrator a petition to amend the list of organisms in 7 CFR § 340.2 by adding or deleting any genus, species, or subspecies. A petition to amend the list of organisms shall be submitted in accordance with the procedures and format specified by this section.

Labeling (APHIS 2050-2054)

The movement provisions under 7 CFR § 340 are administered by BRS through the use of APHIS labels 2050-2054. APHIS label 2050 facilitates the interstate movement of genetically engineered organisms and identifies the contents of the container, and APHIS labels 2051-2054 identify the designated port of entry into the United States for such organisms.

In summary, the agency has used the information collected under 7 CFR § 340 to prevent the introduction into and establishment of plant pests in the United States. The information has also been used to determine that a genetically engineered organism does not present a plant pest risk and no longer needs to be regulated by APHIS under the PPA.

Notification of Certain Occurrences

APHIS shall be notified within the time periods and manner as specified below, in the event of the following occurrences:

1. Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the related article;

2. In writing as possible but not later than within 5 working days if the regulated article or associated lost organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms).

Appeal of Denial of Petition

The Administrator's written notification of denial of a petition shall briefly set forth the reason for such denial. The written notification shall be sent by certified mail. Any persons whose petition has been denied may appeal the determination in writing to the Administrator within 10 days from receipt of the written notification of denial.

Documentation for Approved Training Program

Access shall be allowed for APHIS and State regulatory officials to inspect facilities and/or the field test site and any records necessary to evaluate compliance. The responsible person shipping a regulated article interstate shall keep records for one year demonstrating that the regulated article arrived at its intended destination.

Request for Determination Extension

The Administrator may determine that a regulated article does not pose a potential for plant pest risk, and should therefore not be regulated under this part, based on the similarity of that organism to an antecedent organism.

A person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request shall include information to establish the similarity of the antecedent organism and the regulated articles in question.

APHIS will announce in the Federal Register all preliminary decisions to extend determinations of nonregulated status 30 days before the decisions become final and effective. If additional information becomes available that APHIS believes justifies changing its decision, it will issue a revised decision.

If a request to APHIS to extend a determination of nonregulated status under this part is denied, APHIS will inform the submitter of that request of the reasons for denial. The submitter may submit a modified request or a separate petition for determination of nonregulated status without prejudice.

Petition for Nonregulated Status

This allows a petitioner to provide information and data to support a determination issued by APHIS that the regulated article is not a plant pest and should no longer be regulated under 7 CFR § 340.

After a genetically engineered crop has been field-tested extensively and the developer/applicant can show that the product does not pose a plant pest risk and can safely be removed from APHIS BRS oversight, the developer may file a petition for deregulation, or nonregulatory status. APHIS BRS reviews the petition for completeness and often asks for additional data. Once sufficient data have been received, the petition is deemed complete. Please see the additional

information that is provided in our regulations that's supports the need for this type of information:

340.5 Petition to amend the list of organisms.10

10 See footnote 5 in 340.3

(a) General. Any person may submit to the Administrator a petition to amend the list of organisms in 340.2 of this part by adding or deleting any genus, species, or subspecies. A petitioner may supplement, amend, or withdraw a petition in writing without prior approval of the Administrator and without prejudice to resubmission at any time until the Administrator rules on the petition. A petition to amend the list of organisms shall be submitted in accordance with the procedures and format specified by this section.

(b) Submission procedures and format. A person shall submit two copies of a petition to Biotechnology and Scientific Services, PPQ Animal and Plant Health Inspection Service, U.S. Department of Agriculture, 4700 River Rd, Unit 147, Riverdale, MD 20737.

The petition should be dated, and structured as follows:

PETITION TO AMEND 7 CFR 340.2

The undersigned submits this petition under 7 CFR 340.4 to request that the Administrator, [add the following genus, species, or subspecies to the list of organisms in 7 CFR 340.2] or [to remove the following genus, species, or subspecies from the list of organisms in 340.2].

A. Statement of Grounds

(A person must present a full statement explaining the factual grounds why the genus, species, or subspecies to be added to 340.2 of this part is a plant pest or why there is reason to believe the genus, species, or subspecies is a plant pest or why the genus, species, or subspecies sought to be removed is not a plant pest or why there is reason to believe the genus, species, or subspecies is not a plant pest. The petition should include copies of scientific literature which the petitioner is relying upon, copies of unpublished studies, or data from tests performed. The petition should not include trade secret or confidential business information.

A person should also include representative information known to the petitioner which would be unfavorable to a petition for listing or delisting. (If a person is not aware of any unfavorable information the petition should state, Unfavorable Information: NONE).

B. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petitioner relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature) ----------
(Name of petitioner) ----------

(Mailing address) ----------
(Telephone number) ----------

(c) Administrative action on a petition.

(1) A petition to amend the list of organisms which meets the requirements of paragraph (b) of this section will be filed by the Administrator, stamped with the date of filing, and assigned a docket number. The docket number shall identify the file established for all submissions relating to the petition. APHIS will promptly notify the petitioner in writing of the filing and docket number of a petition. If a petition does not meet the requirements of paragraph (b) of this section, the petitioner shall be sent a notice indicating how the petition is deficient.

(2) After the filing of a petition to amend the list or organisms USDA shall publish a proposal in the Federal Register to amend 340.2 and solicit comments thereon from the public. An interested person may submit written comments to APHIS on a filed petition, which shall become part of the docket file.

(3) The Administrator shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either: (i) Approve the petition in whole or in part in which case the Administrator shall concurrently take appropriate action (publication of a document in the Federal Register amending 340.2 of this part; or (ii) deny the petition in whole or in part. The petitioner shall be notified in writing of the Administrator's decision. The decision shall be placed in the public docket file in the offices of APHIS, and in the form of a notice published in the Federal Register.

340.6 Petition for determination of nonregulated status. 11
11 See footnote 5 in 340.3

(a) General. Any person may submit to the Administrator, a petition to seek a determination that an article should not be regulated under this part. A petitioner may supplement, amend, or withdraw a petition in writing without prior approval of the Administrator, and without affecting resubmission at any time until the Administrator rules on the petition. A petition for determination of nonregulated status shall be submitted in accordance with the procedure and format specified in this section.

(b) Submission procedures and format. A person shall submit two copies of a petition to the Administrator c/o, Plant Protection and Quarantine, Biotechnology and Scientific Services, APHIS, USDA, 4700 River Road, Unit 147, Riverdale, MD 20737.

The petition shall be dated and structured as follows:

Petition for Determination of Nonregulated Status

The undersigned submits this petition under 7 CFR 340.6 to request that the Administrator make a determination that the article should not be regulated under 7 CFR part 340.

(Signature)

A. Statement of Grounds

A person must present a full statement explaining the factual grounds why the organism should not be regulated under 7 CFR part 340. The petitioner shall include copies of scientific literature, copies of unpublished studies, when available, and data from tests performed upon which to base a determination.

The petition shall include all information set forth in paragraph (c) of 7 CFR 340.6. If there are portions of the petition deemed to contain trade secret or confidential business information (CBI), each page of the petition containing such information should be marked "CBI Copy". In addition, those portions of the petition which are deemed "CBI" shall be so designated.

The second copy shall have all such CBI deleted and shall have marked on each page where the CBI was deleted: "CBI Deleted." If a petition does not contain CBI, the first page of both copies shall be marked: "No CBI."

A person shall also include information known to the petitioner which would be unfavorable to a petition. If a person is not aware of any unfavorable information, the petition should state, "Unfavorable information: NONE."

B. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which to base a determination, and that it includes relevant data and information known to the petitioner which are unfavorable to the petition.

(Signature)----------
(Name of Petitioner)----------
(Mailing Address)----------
(Telephone Number)----------

(c) Required data and information.

The petition shall include the following information:

(1) Description of the biology of the nonmodified recipient plant and information necessary to identify the recipient plant in the narrowest taxonomic grouping applicable.

(2) Relevant experimental data and publications.

(3) A detailed description of the differences in genotype between the regulated article and the nonmodified recipient organism. Include all scientific, common, or trade names, and all designations necessary to identify: the donor organism(s), the nature of the transformation system (vector or vector agent(s)), the inserted genetic material and its product(s), and the regulated article. Include country and locality where the donor, the recipient, and the vector organisms and the regulated articles are collected, developed, and produced.

(4) A detailed description of the phenotype of the regulated article. Describe known and potential differences from the unmodified recipient organism that would substantiate that the regulated article is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived, including but not limited to: Plant pest risk characteristics, disease and pest susceptibilities, expression of the gene product, new enzymes, or changes to plant metabolism, weediness of the regulated article, impact on the weediness of any other plant with which it can interbreed, agricultural or cultivation practices, effects of the regulated article on nontarget organisms, indirect plant pest effects on other agricultural products, transfer of genetic information to organisms with which it cannot interbreed, and any other information which the Administrator believes to be relevant to a determination. Any information known to the petitioner that indicates that a regulated article may pose a greater plant pest risk than the unmodified recipient organism shall also be included.

(5) Field test reports for all trials conducted under permit or notification procedures, involving the regulated article, that were submitted prior to submission of a petition for determination of nonregulated status or prior to submission of a request for extension of a determination of nonregulated status under paragraph (e) of this part. Field test reports shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

(d) Administrative action on a petition.

(1) A petition for determination of nonregulated status under this part which meets the requirements of paragraphs (b) and (c) of this section will be filed by the Administrator stamped with the date of filing, and assigned a petition number. The petition number shall identify the file established for all submissions relating to the petition. APHIS will promptly notify the petitioner in writing of the filing and the assigned petition number. If a petition does not meet the requirements specified in this section, the petitioner shall be sent a notice indicating how the petition is deficient.

(2) After the filing of a completed petition, APHIS shall publish a notice in the Federal Register. This notice shall specify that comments will be accepted from the public on the filed petition during a 60 day period commencing with the date of the notice. During the comment period, any interested person may submit to the Administrator written comments, regarding the filed petition, which shall become part of the petition file.

(3) The Administrator shall, based upon available information, furnish a response to each petitioner within 180 days of receipt of a completed petition. The response will either:

(i) Approve the petition in whole or in part; or
(ii) deny the petition.

The petitioner shall be notified in writing of the Administrator's decision. The decision shall be placed in the public petition file in the offices of APHIS and notice of availability published in the Federal Register.

Recordkeeping

Records for documentation for approved training program and the APHIS 2000 Permit Application must be retained for 5 years before being retired to the Federal Records enter and destroyed 30 years after the permit is issued or denied, according to the APHIS retention schedule.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Electronic transfer technology is used by BRS in receiving and processing the information required for notifications under 7 CFR § 340.3 and for permits under 7 CFR § 340 .4 as described above. Currently, APHIS utilizes the APHIS Form 2000 to allow for electronic submissions of permit applications. This is a standardized form that allows for electronic transfer of permit information to APHIS. APHIS also receives electronic versions of notifications which also help alleviate the burden of hard copies. We anticipate a great increase in electronic versions, and we also anticipate an increase in electronic data transfers from respondents, states, and interested parties to help relieve all document requirements (hard copies) as well. The site for the APHIS form is: www.aphis.usda.gov/brs/pdf/2000.pdf

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

Biotechnology Regulatory Services' (BRS) management currently participates in ongoing monthly meetings with both the FDA and EPA. The meetings are part of the "Interagency Working Group" that meets monthly to address specific issues such as overlaps in work and data collection, future policies, and efficiency improvements in streamlined processes. A perfect example of the type of action that results from these meetings would be the "Process for Sharing Information on Herbicide Tolerant Crops-Memorandum of Understanding" developed and signed by both EPA & BRS. Under this agreement, EPA and BRS exchange scientific reviews to streamline data requirements and improve efficiencies for both the applicants and Government. Also, due to the nature in which both agencies are given regulatory authority and the specific nature in the types of questions and information needed by both the EPA & BRS, there may be

times when some information is similar but the context and issues it addresses varies due to the complexity and specific nature of the questions and information the applicant is addressing and is required for a permit or notification.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

The information APHIS collects in connection with this program is the minimum needed to ensure that regulated entities (such as importers) do not inadvertently introduce plant pests into the United States.

6. Describe the consequences to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If the information required in 7 CFR § 340 were not collected, BRS could not carry out its mission to prevent the introduction or dissemination of plant pests in the United States. Less frequent collection would not meet the requirements of the PPA and would prevent effective plant protection by APHIS for the United States.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

No information collection is inconsistent with the information collection guidelines in 5 CFR 1320.5.

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

APHIS' efforts to consult with persons outside the agency to determine their views on the information collection effort under 7 CFR § 340 take place on a nearly daily basis because of the interactive process through which the information is collected for both notification and permitting. APHIS ensures that the information provided by the applicant is complete, and advises applicants of any deficiencies in a timely manner.

On a yearly basis, APHIS meets with representatives of all parties involved in the collection of information under 7 CFR § 340. These efforts include presentations to and discussions with industry organizations, professional societies and groups, universities and colleges, and environmental organizations.

Productive consultations concerning our information collection activities were made with the following individuals (representing agricultural companies) during 2004:

Dr. Ronald W. Schneider
Regulatory Affairs Manager
Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Telephone: 314-694-1000

Dr. Jeff Stein
Regulatory Affairs
Novartis Seeds
3054 Cornwallis Road
Res. Triangle Park, NC 27709-2257
Telephone: 919-541-8683
Fax: 919-541-8585

Dr. David J. Glass
Chief Executive Officer
Applied PhtoGenetics, Inc.
110 Riverbend Road, Room 169
Athens, GA 30602
Telephone: 706-843-8083

On Thursday, July 13, 2006, pages 39655-39656, APHIS published in the Federal Register a 60-day notice seeking public comments on its plans to request a 3-year renewal of this collection of information. No comments from the public were received. A copy of the Federal Register notice is attached.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.

This information collection activity involves no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

Proprietary or trade secret information is protected as outlined in the "Policy Statement on the Protection of Privileged or Confidential Information," which was published in the Federal Register on September 13, 1985.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and others that are considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity asks no questions of a personal or sensitive nature.

12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

• Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.

See APHIS Form 71 for hour burden estimates. These estimates were developed using historical data, the calculated average number of permits requested and notifications needed, and discussions with field and industry personnel.

• Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.

The total cost to respondents is computed by multiplying their average wage by the total number of hours needed to complete the work.

3,308 burden hours X $15.00 average hourly wage = $49,620.

13. Provide estimates of the total annual cost burden to respondents or recordkeepers resulting from the collection of information (do not include the cost of any hour burden shown in items 12 and 14). The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

There is zero annual cost burden associated with capital and start-up costs, maintenance costs, and purchase of services in connection with this program.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

See the APHIS Form 79 for the annualized cost to the Federal Government. This cost is based on the estimated average time required to process permit applications and notifications. The cost is currently estimated to be $137,562.24 (including overhead) per year.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

There was an increase of 632 hours because of the combination of the two collections and increase in the number of respondents.

There was an increase in the number of applications processed within BRS which created a larger response rate. Please see the table below for additional information.

All Permits Processed Fiscal Years 2005 vs. 2006													
2005 Fiscal	4-Oct 17	4-Nov 40	4-Dec 37	5-Jan 28	5-Feb 48	5-Mar 41	5-Apr 67	5-May 58	5-Jun 57	5-Jul 41	5-Aug 39	5-Sep 31	Total 504
2006 Fiscal	5-Oct 42	5-Nov 29	5-Dec 87	6-Jan 50	6-Feb 63	6-Mar 31	6-Apr 69	6-May 40	6-Jun 35	6-Jul 26	6-Aug 57	6-Sep 45	Total 574
								Percent increase FY 06 compared to FY 05					14% Increase

All Notifications Processed Fiscal Years 2005 vs 2006													
2005 Fiscal	4-Oct 67	4-Nov 76	4-Dec 111	5-Jan 207	5-Feb 285	5-Mar 181	5-Apr 109	5-May 111	5-Jun 63	5-Jul 89	5-Aug 100	5-Sep 100	Total 1499
2006 Fiscal	5-Oct 77	5-Nov 80	5-Dec 74	6-Jan 130	6-Feb 225	6-Mar 272	6-Apr 131	6-May 146	6-Jun 97	6-Jul 79	6-Aug 119	6-Sep 93	Total 1523
								Percent increase FY 06 compared to FY 05					2% Increase

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

APHIS has no plans to tabulate or publish the information collected.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

If forms were to be discarded because of an outdated OMB expiration date, but were otherwise usable, higher printing costs would be incurred by the Federal Government. Therefore, APHIS is seeking approval to not display the OMB expiration date on its forms.

18. Explain each exception to the certification statement identified in the"Certification for Paperwork Reduction Act."

APHIS is able to certify compliance with all the provisions in the Act.

B. Collections of Information Employing Statistical Methods

Statistical methods are not used in this information collection.