November 2014

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

TERMS OF CLEARANCE:

In accordance with the terms of 5 CFR 1320, OMB approves this collection of information for a period of one year. On resubmission, APHIS should provide a written response to all comments received during this period of Notice and the next period of Notice and explain what, if any changes it has made to the collection to reduce burden or increase practical utility.

APHIS plans on conducting an OMB approved fast track/low burden survey of our respondents (big and small entities) to re-estimate how long required activities take to and what other activities the regulated community may be doing as part of the "downstreaming" of information that we may not have properly accounted for in our previous information collections. APHIS will also inquire about respondents' level of satisfaction with this program and any ideas for improvement. The comments from the Biotechnology Industry Organization (BIO) have been eye-opening for APHIS and we are ready to further explore their comments and considering efforts to reduce burden.

APHIS is in the midst of simplifying some of the information collection activities surrounding our permitting processes by creating a new IT system, titled APHIS eFile. This system will encompass the business processes surrounding certifications, accreditations, registrations, permits, and other licensing activities for all of APHIS. This new system will not only be fully electronic, but is aimed at streamlining these business processes by using a wizard approach, making sure we need everything that we are asking for, and pre-populating data from what we already know from what has been entered into the system previously. The APHIS eFile permitting section is scheduled to be completed in 2017.

Along with APHIS eFile, APHIS will work with the scientific community (i.e.; BIO) to determine if any currently regulated activities may be deemed exempted from our regulatory requirements. APHIS provides guidance on our regulated permitting activities through its web site at: http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology/sa_library/!ut/p/a1/pZFNU4MwFEV_iwuXTJ4pEFhCq3y0qKMyLWyYFPmIAwmF1FF_vUBduCnFMbs3Ofe-zAmK0Q7FnL6zgkomOK2GOdYT_8HFNzZgz3FubfDu7zaPZO1jwFoPRBPAWpuXXzqWq5INAKgGBm9luytiBgCePi8PZ44Fl_JbFKM45bKRJYpoU7IuSQWXGZdJxfYtbT-voaOJOLZJLtJjN057JmSWllxUojjd_7BDWZOyVxQZJM0oYFXRM01TVGwuFEoMqpiEmphgg6qEnJZf0DcCU35GYEJA1BsiZ1f0Dc9_fLU_409wGyyDoq-lslQYzwXa_bLUA-ztcIitXv0g-0Oi3f_dN3UYhrWx0J_cr5e83hqddfUNFmWtTQ!!/?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_our_focus%2Fsa_biotechnology%2Fsa_permits_notifications_and_petitions%2Fsa_guidance_documents%2Fct_guidance .

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 will 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.

Biotechnology Regulatory Services 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 all State departments of agriculture for review and made available to the public and private sectors on the Internet (see https://www.aphis.usda.gov/aphis/ourfocus/biotechnology) 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:

340.3(a)-(e): 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 contact information for the responsible person, 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. In addition, certain field tests may be required and field test reports must be submitted to APHIS within 6 months after termination of the field test. Field test reports shall include the APHSI reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, and the environment.

340.4(a)-(c), 340.4(h)(2), 340.8(c): 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 contact information for the responsible person, contact information for those that developed and/or supplied the regulated article, 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, methods for final disposition, and the destination or field test locations.

340.4(f)(g): 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.

340.4(f)(10): Notification of Certain Occurrences
APHIS will 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 notified in writing within 24 hours in the event of any accidental or unauthorized release of the related article;

2. In writing, as soon 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).

340.4(g): 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.

340.5: 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 will be submitted in accordance with the procedures and format specified by this section.

340.4(f)(6) and 340.7: Marking Identify/Labeling (APHIS 2050-2054)
The movement provisions under 7 CFR § 340 are administered by BRS through the use of APHIS labels 2050 through2054. APHIS label 2050 facilitates the interstate movement of genetically

engineered organisms and identifies the contents of the container, and APHIS labels 2051 through2054 identify the designated port of entry into the United States for such organisms.

340.6(a)-(d): 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.

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.

340.6(e): 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 will 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.

340.6(e): 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 will 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.

340.3(d)(4): Submission of 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.

340: Documentation for Approved Training Program
Access will 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.

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

340.3: State Review
When permit applications are submitted to BRS for the importation into, interstate movement through, or controlled outdoor use in of a regulated product of biotechnology, BRS' provides the permit application information with State regulatory officials in applicable States for review and comments. Comments received from these State regulatory officials may be considered by the Administrator prior to permit issuance.

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. Both regulated activities are herein referred to as permitting activities. Currently, APHIS utilizes the APHIS Form 2000 to allow for electronic submissions of permit applications through its APHIS ePermit System. This is a standardized form that allows for electronic transfer of permit information to APHIS. By receiving electronic versions of notification and permit information this also helps alleviate the burden of hard copies. APHIS anticipates a great increase in electronic versions, and also anticipates 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 electronic APHIS form – Form 2000 -- is: www.aphis.usda.gov/brs/pdf/2000.pdf Using the APHIS ePermit System, applicants can directly input their application here: https://epermits.aphis.usda.gov/epermits/index.cfm?ACTION=applicantHome . In addition, APHIS is currently developing a new system, APHIS eFile, that will aid our regulated community in completing the necessary information collection activities found in other APHIS programs. This will further reduce the burden of time placed on our regulated community to produce and provide required information.

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.

APHIS is the only USDA agency charged with enforcing the regulations in 7 CFR § 340; therefore, there is no duplication of this effort.

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

There are no small business entities.

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:

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**

  In writing, as soon 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).

- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

No other special circumstances exist that would require this collection to be conducted in a manner inconsistent with the general 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. APHIS has conducted stakeholder meetings, which included BIO.

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 APHIS' information collection activities were made with the following individuals (representing agricultural companies):

Claudette Deatherage
Monsanto
USDA Field Trail Team Lead
800 North Lindberg
St. Louis, MO 63167
Phone: 314-694-7191

Jeff Bottoms
Syngenta
Regulatory Permitting Manager
3054 East Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-541-8535

Cynthia Allen
Bayer Crop Science
Regulatory Compliance Specialist
2TW Alexander Drive
Research Triangle Park, NC 27709
Phone: 919-451-0868

On Monday, August 11, 2014, page 46769, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plan to request a **3-year renewal** of this collection of information. Three comments were received from concerned citizens about their perception of the general disregard of the testing for Genetically Engineered Products by USDA. It had no relevance to the purpose of the collection.

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.

3,315 burden hours X $20.90 average hourly wage = $69,284

$ 20.90 is the hourly rate derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2013 Report - Occupational Employment and Wages in the United States. See http://www.bls.gov/news.release/pdf/ocwage.pdf

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 $171,501 (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.

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ICR Summary of Burden:

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	3,501	0	1	0	0	3,500
Annual Time Burden (Hr)	3,315	0	1	6	0	3,308
Annual Cost Burden ($)	0	0	0	0	0	0

APHIS added State Review as a new burden item to this information collection which was previously inadvertently overlooked resulting in 1 additional burden hour. In addition, pervious mathematical errors were corrected.

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.

Not applicable.

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.