Supporting Statement
OMB Clearance 0579-NEW

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

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).

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, Introduction of Organisms and Products Altered or Produced through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests, 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 proposes to revise its regulations in 7 CFR 340. These revisions/rule changes will affect the type of documentation required by the responsible person, known as the applicant. These changes will include requirements for the responsible person to establish and maintain records related to the permit, as well as allowing APHIS to review those records.

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.

<u>Recordkeeping</u>

Records related to permitted activities of sufficient quality and completeness to demonstrate compliance with all permit conditions and requirements under this part, must be maintained. APHIS BRS will collect the information during its inspection process, audit process, and for

verification of compliance. The following records will be maintained:

- Information identifying the general nature and quantity of the organism being shipped;
- Name and address of sender, owner, or person shipping the organism;
- Name, address, and telephone number of recipient;
- Any invoices, packing lists, or bills of lading used for the shipment;
- The shipper's name and identifying shipper's mark and number;
- A description of any containers that were used to transport the genetically engineered organisms, and a copy of any label used on these containers during transport; and
- Any documents that identify the country and locality where the genetically engineered organism was collected, developed, manufactured, reared, cultivated, or cultured.

Inspectors will have access to audit and review all records required to be maintained under this part. Records must be retained for at least 2 years after completion of importation or interstate movement, and all other records must be retained for at least 5 years after completion of all obligations required under a relevant permit or exemption.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques 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.

The collection of information is mainly conducted through electronic transfer technology. APHIS BRS receives and processes information through the APHIS ePermits system. Approximately 90% of the information is collected this way. Additional documentation, available onsite with each responsible person (applicant) will be in either electronic or paper format.

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

APHIS is the only USDA agency charged with enforcing the regulations in 7 CFR part 340; therefore, there is no duplication of this effort. Only the responsible person (applicant) proposing to introduce a regulated article has the information required by BRS to determine the plant pest risk potential of an organism that has been modified through the use of genetic engineering technology.

5. If the collection of information impacts small businesses or other small entities (Item 5 of OMB 83-1), describe any methods used to minimize burden.

The information APHIS collects in connection with this rule change is the minimum needed to ensure that regulated entities do not inadvertently introduce a plant pest into the United States. APHIS estimates that 130 of the total 160 respondents are small 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, APHIS would not be in alignment with the provisions of the Plant Protection Act (PPA). If not collected, APHIS would hinder or limit its view of records related to inspections, regulated movement, and verification of compliance conditions. From a larger perspective, APHIS could not carry out its mission to prevent the introduction or dissemination of plant pests in the United States. Less information would not meet the requirements of the PPA and would prevent effective plant production 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.

The information collected is consistent 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 forms, and on the data elements to be recorded, disclosed, ore 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.

Productive consultations concerning these information collection activities were made with the following individuals (representing agricultural companies) during 2008:

Jeff Bottoms
Regulatory Affairs
Syngenta
3054 E. Cornwallis Rd.
Research Triangle Park, NC 27709-2257
919-765-3110

Jessica Johnson
Biotech Field Compliance
Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167
314-694-5410

Scott Mundell
Pioneer High Bred International
7250 NW 62nd Ave.
Johnston, IA 50131
515-270-3499

APHIS' proposed rule (08-023-1) will describe its information gathering requirements, and also provide a 60-day comment period. During this time, interested members of the public will have the opportunity to provide APHIS with their input concerning the usefulness, legitimacy, and merit of the information collection activities APHIS is proposing.

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

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

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

No additional assurance of confidentiality is provided with this information collection. However, the confidentiality of information is protected under 5 U.S.C. 552a.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly 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 83-1.

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

See APHIS Form 71 for hour burden estimates. These estimates were developed using the number of applicants that currently exist in APHIS' ePermits Database (160), calculated by the average number of responses (2 per applicant) and the amount of time (1 hour per response) based on discussions with field and industry personnel – 640 hours times $25.03 equals $16,019.

$25.03 is the hourly rate derived from the U.S. Department of Labor, Bureau of Labor Statistics June 2005 Report - National Compensation Survey: Occupational Wages in the United States, August 2006. See http://www.bls.gov/ncs/ocs/sp/ncbl0832.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 are several cost areas associated with this proposed rule. Costs associated with the proposed rule that regulated entities would incur include costs of learning and adapting procedures to changed requirements, providing more or different information in permit applications, and additional recordkeeping for some entities. Other entities would have recordkeeping reduced by the proposal, since recordkeeping requirements are more individualized. Many provisions of the proposed regulations are revisions of the current regulations, and it is not expected that familiarization costs would be substantial. However, estimates of these costs are not available; therefore, APHIS invites public comment on the costs the regulated community may incur with respect to rule familiarization and changes to their application systems.

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.

Costs to APHIS are currently incurred in the regulatory assessment and review of submitted materials. Because the new permit process is largely similar to the current process, it is expected that ongoing permit processing costs to APHIS would remain essentially unchanged. As a start-up cost to change the permit system to accommodate requirements of the proposed rule, APHIS may potentially incur an additional cost of $500,000. However, the current system is adaptable to the new regulations and it is not anticipated that there would be any efficiency loss during the transitional period. APHIS would potentially incur incremental costs conducting outreach activities for the propose rule, developing guidance documents to ensure that the regulatory community is familiar with the requirements of the rule, and providing staff training that may be necessary.

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

This is a new collection. There is a program change of 640 recordkeeping hours resulting from a change in regulations affecting the type of documentation required by applicants relating to the permit as well as allowing APHIS to review those records.

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

APHIS has no plans to publish information it collects in connection with this program.

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

There are no forms associated with this information collection.

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

APHIS can 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.