SUPPORTING STATEMENT
Movement of Certain Genetically Engineered Organisms
OMB Control Number: 0579-XXXX.

NOTE: Upon publication of the associated final rule and OMB approval of this information collection package, APHIS plans to merge this information collection into its existing information collection (OMB Control Number 0579-0085).

June 2019

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 Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), is charged with preventing the introduction of plant pests and noxious weeds 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 or noxious weed 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 and noxious weeds.

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.

The information APHIS 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 and noxious weeds into the United States. Additionally, GE techniques have been developed that do not employ plant pests as donor organisms, recipient organisms, vectors, or vector agents yet may result in GE organisms that pose a plant pest risk. Given these

developments, as well as legal and policy issues, it has become necessary, in our view, to update our regulations and information collection activity, accordingly.

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

2. Indicate how, by whom, how frequently, 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.

APHIS will use the following information collection activities 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 (GE) organism does not present a plant pest risk and no longer needs to be regulated by APHIS under the PPA.

7 CFR 340.1: CONFIRMATION LETTERS (Private Sector)
A plant would not be subject to the regulation and subsequent regulatory controls for their importation, interstate movement, or environmental release if: (1) the genetic modification to the organism is solely a deletion of any size; or (2) the genetic modification is a single base pair substitution; or (3) The genetic modification is solely introducing nucleic acid sequences from within the plant's natural gene pool or editing nucleic acid sequences in a plant to correspond to a sequence known to occur in that plant's natural gene pool; or (4) the plant is an offspring of a GE plant that doesn't retain the genetic modification in the parent; or (5) GE plant has a plant-trait-MOA combination that has already been subjected to a jurisdictional analysis and found by the Administrator to be unlikely to pose a plant pest risk; or (6) The plant is modified in a way that is determined by the Administrator, after appropriate analysis, to be outside the scope of these regulations.

Developers may self-determine whether their plant whether fit into one of the exempted categories and are therefore not subject to APHIS' regulatory jurisdiction. A developer who makes a self-determination would have the option to request written confirmation from APHIS that the self-determination is valid.

7 CFR 340.5: PROCEDURE FOR PERMITS (APHIS Form 2000 or equivalent); RECORD REPORTING; AND MARKING/LABEL (APHIS Forms 2050, 2051, 2052, 2053, and 2054 or equivalent) (new community of permittees only) (Private Sector)
Under the proposed 340 Regulatory Framework Model, any person moving a GE organism as defined under 7 CFR § 340.1, must submit information characterizing the nature of the GE organism, including detailed molecular biology information about the expression of the introduced genetic material. The proposed rule requires more detailed information about the type of movement and/or use planned than the current 7 CFR § 340 information. The proposed rule requires more description of the applicant's plans and methods to prevent unauthorized releases, and to respond to unauthorized releases if they occur. This information is used in part by APHIS to formulate the specific permit conditions.

Any person submitting a permit application, must agree to required general permit conditions. These requirements address maintenance of the product of biotechnology's identity, prevention of the GE organisms' unauthorized release and dissemination, the application of remedial measures in the event of an unauthorized release or dissemination, maintenance of records related to the permit activity, and requirements for communicating with APHIS. The required general conditions proposed in § 340.5 would apply to all permits.

A permit is required for the importation, interstate movement, or environmental release of any organism that is subject to this part, as described in § 340.5. The responsible person seeking a permit for the importation, interstate movement, or environmental release of such organisms shall submit an application for a permit to APHIS in accordance with paragraph (b) with sufficient information about the specific nature of the organism and a detailed description of the proposed procedures, processes, and safeguards which will be used to prevent the unauthorized release and dissemination of the regulated product of biotechnology so that the Administrator is able to consider whether the proposed importation, interstate movement, or environmental release is likely to result in the unauthorized release or dissemination of a plant pest or noxious weed.

General application requirements can be found on the APHIS Web site athttps://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision/2017_perdue_proposed_rule/340_2017_perdue_biotechreg. The Web site also contains all the categories of information that must be included in the application for the type of permit being requested.

APHIS would review the application to determine if it is complete. APHIS would notify the applicant in writing if the application is incomplete, and the applicant would be provided the opportunity to revise the application. Once an application is complete, APHIS would review it to determine whether to approve or deny the application.

As a permit condition, the responsible person must notify APHIS, 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).

In addition, to respond to the recommendations of the 2015 Office of the Inspector General (OIG) audit, APHIS would add a requirement as a general permitting condition that the responsible person must notify the Agency in writing if any activity associated with environmental release under permit will not be conducted. Specifically, APHIS is proposing to require the submission of a report of no release to account for all approved test fields under an authorization.

Also, in the event of a possible or actual unauthorized release, the responsible person would have to contact APHIS, as described in the permit, within 24 hours of discovery, and subsequently supply a statement of facts in writing or electronically no later than 5 business days after discovery.

APHIS believes that these additional details will better communicate to applicants what the general permitting conditions are and will better support administration of the permitting program, including compliance and enforcement.

7 CFR 340.5: PROCEDURE FOR PERMIT APPEAL (Private Sector)

While the current regulations provide for any person whose permit has been withdrawn or any person who has been denied a permit may appeal this decision, APHIS is again proposing that any person may appeal a denial or withdrawal of permit. Any person whose permit application has been denied or whose permit has been withdrawn may appeal the decision in writing to the Administrator. Any appeal must occur within 10 days after receiving the written notification of the denial or revocation. The appeal must state all of the facts and reasons upon which the person relies to assert that the permit was wrongfully denied or revoked. The Administrator will grant or deny the appeal in writing, stating the reasons for the decision as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Administrator.

7 CFR 340.5: STATE AND TRIBAL REVIEW (State, Local, and Tribal Governments)

While the current regulations provide for review of permit applications by State regulatory officials, they do not include review by Tribal officials when a permit application is submitted for the importation into, interstate movement through, or environmental release on Tribal lands of a GE organism. To correct this oversight, APHIS proposes to add tribal reviews. Comments received from the State or Tribal regulatory official may be considered by the Administrator prior to permit issuance.

7 CFR 340.4: REGULATORY STATUS REVIEW (Private Sector)

Developers may request APHIS evaluate a GE plant subject to the regulations as defined in 340.1 in accordance with § 340.4. Information needed for such a request is found on the Internet, at: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision/2017_perdue_proposed_rule/340_2017_perdue_biotechreg.

7 CFR 340.4: RECONSIDER REGULATORY STATUS REVIEW (Private Sector)

If a person disagrees with APHIS' finding that a GE plant was subject to the regulation, they would be able to provide additional information in support of their request to reevaluate an organism. APHIS would then be able to reconsider a plant's regulatory status review in light of any new information and conduct a new evaluation.

7 CFR 340.6: RECORD RETENTION (Private Sector)

APHIS proposes to extend the record retention requirement that demonstrates that a regulated organism that was imported or moved interstate arrived at its intended destination from 1 to 2 years. In the event that there is uncertainty regarding whether the organism arrived at this location, it may take APHIS more than 1 year to investigate the matter. APHIS is also proposing to require that all other records must be retained for 5 years following permit expiration, unless APHIS determines otherwise and documents an alternate record retention requirement in the supplemental permit conditions or other regulatory requirements. In the event of an investigation

into the possible unauthorized environmental release of a regulated organism, or the escape of a regulated organism from a containment facility, a thorough record of activities taken under the permit is necessary in order for APHIS to assess compliance and determine whether enforcement actions are needed. When APHIS has investigated unauthorized environmental releases of regulated organisms, this has necessitated obtaining information from field trials that were conducted up to 10 years prior to the investigation. In instances in which the information was not available, this adversely impacted APHIS' ability to do an expeditious and thorough investigation.

APHIS Inspectors shall be provided with all records required to be maintained under this part upon request. Responsible persons and their agents engaged in the importation, interstate movement, or environmental release of an organism subject to the regulations of this part are required to establish and keep the following records and reports: (1) All records and reports required as a condition of a permit; (2) Addresses and any other information needed to identify all contained facilities where the regulated organism was stored or utilized, and all locations where the regulated organism was used in a controlled outdoor use; (3) A record identifying which APHIS permit, if any, authorized the importation, interstate movement, or controlled outdoor use; and (4) Copies of contracts between the responsible person and all agents that conduct activities subject to this part for the responsible person, and copies of other records (e.g., emails, telephone records) for such agreements made without a written contract.

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.

Electronic transfer technology will continue to be used by BRS in receiving and processing the information required for permit applications under 7 CFR § 340 as described above.

Currently, APHIS utilizes the APHIS Form 2000 (or equivalent) to allow for electronic submissions of permit applications. This is a standardized form and its associated electronic data fields allow for electronic transfer of permit information to APHIS. APHIS anticipates an increase in additional electronic capabilities to include the implementation of requests for Regulatory Status Reviews and Reconsiderations. APHIS plans to utilize its Web site and/or a future electronic platform, known as eFile, for these activities.

In addition, APHIS accepts information via email.

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 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.

APHIS estimates that 5% of the private sector respondents may considered small entities. Some of the impacts are indirect benefits which include a reduced cost for regulatory approvals through APHIS. Also, APHIS anticipates a shortened time for regulatory approvals which may result in quicker international approvals. In addition, earlier APHIS approvals may lead to increased ease in raising venture capital-easier to begin field trials-venture capital may more easily pay for proof of concept. Plus, reduced regulatory requirements by APHIS may make it easier for public sector to engage in product development.

6. Describe the consequence 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 and noxious weeds 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.

- **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;**

Procedures for Permits: The responsible person must notify APHIS, 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).

In addition, to respond to the recommendations of the 2015 Office of the Inspector General (OIG) audit, APHIS would add a requirement as a general permitting condition that the responsible person must notify the Agency in writing if any activity associated with environmental release under permit will not be conducted. Specifically, APHIS is proposing to require the submission of a report of no release to account for all approved test fields under an authorization.

Also, in the event of a possible or actual unauthorized release, the responsible person would have to contact APHIS, as described in the permit, within 24 hours of discovery, and subsequently supply a statement of facts in writing or electronically no later than 5 business days after discovery.

Procedure for Permit Appeal: Any person whose permit application has been denied or whose permit has been withdrawn may appeal the decision in writing to the Administrator. Any appeal must occur within 10 days after receiving the written notification of the denial or revocation. The appeal must state all of the facts and reasons upon which the person relies to assert that the permit was wrongfully denied or revoked. The Administrator will grant or deny the appeal in writing, stating the reasons for the decision as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Administrator.

APHIS believes that these additional details will better communicate to applicants what the general permitting conditions are and will better support administration of the permitting program, including compliance and enforcement.

- **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;**

Records indicating that an organism under permit that was imported or moved interstate reached its intended destination must be retained for at least 2 years. All other records related to a permit must be retained for 5 years following the expiration of the permit, unless a longer retention period is determined to be needed by the Administrator and documented in the supplemental permit conditions.

Responsible persons and their agents must comply with all of the requirements of this part. Failure to comply with any of the requirements of this part may result in any or all of the following: Denial of a permit application or withdrawal of a permit in accordance with 340.5; Application of remedial measures in accordance with the Plant Protection Act, 7 U.S.C. 7701 et seq.; and Criminal and/or civil penalties in accordance with the Plant Protection Act, 7 U.S.C. 7701 et seq.

- **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 engaged in productive consultations with the following individuals concerning the information collection requirements associated with this program:

Jeffrey Bottoms and Paul Miles
Syngenta
Syngenta Crop Protection, LLC
P.O. Box 12257
9 Davis Drive
Research Triangle Park, NC 27709-2257
919-281-5851

Brad Shurdut and Eric Aasen
Intrexon
20374 Seneca Meadows Parkway,
Germantown, Maryland 20876
301-556-9900

Jeff Wolt, Professor
Crop Bioengineering Center
http://cropbioengineering.iastate.edu/
Iowa State University
G405 Agronomy Hall
716 Farmhouse Lane
Ames, IA 50011-1010, USA

Discussions with Syngenta surrounded our procedures for permit, record reporting, and record retention and the burden on our regulated community. Specifically, they welcomed an updated assessment of our recordkeeping and retention burden from the current the regulations. Discussions with Intrexon surrounded the concept of a regulatory status review in context with

our current risk assessment. Intrexon encouraged regulatory flexibility to spur innovation. In addition, APHIS hosted several public meeting and engagement activities to seek input. Specifically, APHIS spoke with several universities, including Iowa State University.

APHIS' proposed rule (Docket Number APHIS-2018-0034) published in the Federal Register on Thursday, June 6, 2019. It describes its information gathering requirements, among other things, and also provides a 60-day comment period. During this time, interested members of the public 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 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 (volume 50, issue, 184, page 38561) on Monday, September 13, 1985. No other assurances of confidentiality will be provided to respondents.

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-I.

See APHIS Form 71 for hour burden estimates. These estimates were developed using historical data, the calculated average number of permits, notifications and petitions from APHIS' existing collection, along with the number of "Am I Regulated" inquires received, 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.

APHIS estimates the total annualized cost to the respondents to be $952,060. APHIS arrived at this figure by multiplying the 19,453 total burden hours by the respondents' estimated average hourly wage of $33.28, and then multiplying the result by 1.4706 to capture benefit costs.

Respondents are from Tribal governments and the private sector who are considered regulated by 7 CFR 340.

The wage estimated was obtained from the U.S. Department of Labor, Bureau of Labor Statistics Occupational Outlook Handbook, 2019 Report - Occupational Employment and Wages in the United States. https://www.bls.gov/ooh/healthcare/veterinarians.htm.

According to DOL BLS news release USDL-18-1499, dated September 18, 2018 (see https://www.bls.gov/news.release/pdf/ecec.pdf), benefits account for 32% of employee costs, and wages account for the remaining 68%. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.4706.

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.

The annualized cost to the Federal government is estimated at $1,143,302. (See APHIS Form 79.)

In addition, the proposed rule's economic analysis estimates the current annual APHIS personnel costs for conducting those GE activities that would be affected by the proposed rule total about $3.5 million. These include compliance activities, inspection activities, AIR process activities, notification activities, permit activities, and petition activities. Under the proposed rule, APHIS'

overall annual personnel costs of regulating GE organisms are not expected to change. While the volume of specific activities would change, the overall volume of regulatory activities, the general nature of those activities and level of skill necessary to perform those activities would not. There would be costs to APHIS of implementing the proposed rule, which would include outreach activities, developing guidance documents, training, and adjusting the current permit system. APHIS estimates that the public outreach, guidance and training would cost about $77,000. Requests for regulatory status and response letters under the proposed rule could be handled in a manner similar to the current AIR process outside the electronic permitting system without incurring new costs.

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

	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	1,097	0	0	0	0	0
Annual Time Burden (Hr)	19,453	0	0	0	0	0
Annual Cost Burden ($)	0	0	0	0	0	0

This is a new information collection resulting in 19,453 total burden hours.

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 the information collection, explain the reasons that display would be inappropriate.

APHIS Form 2000 is used in two information collections; therefore, it is not practical to include an OMB expiration date because of the differing expiration dates for each information collection. APHIS is seeking approval to not display the OMB expiration date on the form at this time. However, upon publication of the associated final rule and OMB approval of this information collection package, APHIS will merge this information collection into the existing information collection, OMB Control Number 0579-0085, at which time APHIS will display the single expiration date.

APHIS Forms 2050, 2051, 2052, 2053, and 2054 are small labels which display the OMB Control Numbers. Adding all of the OMB information, including the expiration date, impairs their utility. APHIS is seeking approval to not display the OMB expiration date on these forms/labels.

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

APHIS certifies compliance with all provisions of the Act.

B. Collections of Information Employing Statistical Methods

Statistical methods are not used in this information collection.