SUPPORTING STATEMENT
Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms

OMB Control Number: 0579-XXXX.

2016

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.

APHIS is proposing to revise its regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms in order to update the

regulations in response to advances in genetic engineering and understanding of the plant pest and noxious weed risk posed by genetically engineered (GE) organisms, thereby reducing burden for regulated entities whose organisms pose no plant pest or noxious weed risks. This would be the first comprehensive revision of the regulations since they were established in 1987.

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 and noxious weeds in the United States. The information has also been used to determine that a genetically engineered (GE) organism does not present a plant pest or noxious weed risk and no longer needs to be regulated by APHIS under the PPA.

7 CFR 340.3: PROCEDURE FOR PERMITS (new community of permittees only) – APHIS 2000 or equivalent (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 § 340.4 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 § 340.3. 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 at http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule. 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. If the applicant does not respond to the request for additional information within 30 days of receipt of APHIS's request, APHIS would deem the application withdrawn. Once an application is complete, APHIS would review it to determine whether to approve or deny the application.

7 CFR 340.4: REGULATORY STATUS EVALUATION (Private Sector)

Except as provided in paragraph (a)(2) of proposed § 340.3, APHIS must have evaluated a regulated organism in accordance with § 340.4 before it will issue permits for importation, interstate movement, or release into the environment of a GE organism. Information needed for such a request is found on the Internet, at http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule. .

An organism would not be considered a GE organism and would be exempt from regulatory status evaluation and subsequent regulatory controls for their importation, movement or environmental release if: (1) the genetic modification to the organism is solely a deletion of any size or a single base pair substitution which could otherwise be obtained through the use of chemical- or radiation-based mutagenesis; or
(2) The genetic modification to the organism is solely introducing only naturally occurring nucleic acid sequences from a sexually compatible relative that could otherwise cross with the recipient organism and produce viable progeny through traditional breeding (including, but not limited to, marker-assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion); or (3) The organism is a "null segregant," that is, the progeny of a GE organism where the only genetic modification was the insertion of donor nucleic acid into the recipient's genome, but the donor nucleic acid is not passed to the recipient organism's progeny and the donor nucleic acid has not altered the DNA sequence of the progeny.

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

If a person disagrees with APHIS' regulatory status determination, they would be able to provide additional information in support of their request to reevaluate the regulatory status of a previously evaluated organism. APHIS would then be able to reconsider an organism's regulatory status determination in light of any new information and conduct a new risk analysis.

7 CFR 340.3: 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 controlled outdoor use on Tribal lands of a regulated product of biotechnology. To correct this oversight, APHIS proposes to state in proposed § 340.3(d (4) that APHIS will include relevant Tribal officials when it provides copies of permit applications to State regulatory officials. Comments received from the State or Tribal regulatory official may be considered by the Administrator prior to permit issuance.

7 CFR 340.5: 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 10 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.

7 CFR 340.3: Marking/Labeling – APHIS 2050-2054 or equivalents (Private Sector)
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.

7 CFR 340.3: Reports of Characteristics (Private Sector)
The holder of a release permit is now generally required to supplement this information with reports to BRS on performance characteristics of the regulated organism over time in order to determine the stability of the genetic modifications.

7 CFR 340.3: Notification of Certain Occurrences (Private Sector)
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 of discovery.

7 CFR 340.3: Appeal of Withdrawal of Permit (Private Sector)
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.

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 to allow for electronic submissions of permit applications. This is a standardized form that allows for electronic transfer of permit information to APHIS. APHIS anticipates a great increase in electronic versions with the implementation of requests for REGULATORY STATUS EVALUATION and re-evalutaions. APHIS plans to utilize its Web site and/or a future electronic platform, known as eFile to receive inquiries regarding regulatory status. We anticipate an increase in electronic data transfers from respondents, states, tribes and interested parties to help relieve all document requirements (hard copies) as well. We encourage our users to become eAuthenticated and make use of our ePermits database for APHIS permitting. Both the applicant and APHIS exchange information through the ePermits system. The applicant is permitted to use any email system to reach any APHIS employee involved in our regulatory activities.

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.

APHIS estimates that this information collection and proposed rule will impact small entities. Indirect benefits include a reduced cost for regulatory approvals through USDA APHIS. APHIS anticipates a shortened time for regulatory approvals which may result in quicker international approvals. Earlier USDA 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. Reduced regulatory requirements by USDA 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;**

In writing, as soon as possible, but not later than within 5 working days upon discovery of the unauthorized release of a regulated organism.

- **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;**

APHIS proposes to require that all records related to permit conditions, other than those demonstrating that a regulated organism that was imported or moved interstate arrived at its intended destination would have to be retained by the responsible person for 10 years following permit expiration, unless APHIS determines otherwise and documents an alternate record retention requirement. 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.

- **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:

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APHIS' proposed rule (Docket Number APHIS-2015-0057) published in the Federal Register on Thursday, January 19, 2017. It describes its information gathering requirements, among other things, and also provides a 120-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 on September 13, 1985. No other assurances of confidentiality are 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.

Respondents are Tribal governments and businesses considered regulated by 7 CFR 340. APHIS estimates the total annualized cost to these respondents to be $138,911. APHIS arrived at this figure by multiplying the total burden hours 4,174 hours by the estimated average hourly wage of the above respondents ($33.28). The average hourly rate was derived from: http://www.bls.gov/oes/current/oes_nat.htm#19-0000]

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 $3,053,695. (See APHIS

Form 79.)

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

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	5,035	0	5,035	0	0	0
Annual Time Burden (Hr)	4,174	0	4,174	0	0	0
Annual Cost Burden ($)	0	0	0	0	0	0

This is a new information collection resulting in 4,174 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.

These forms are 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. In addition, 5 of the forms are actually labels. APHIS is seeking approval to not display the OMB expiration date on this form.

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.