February 2020

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

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 another 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 or its electronic equivalent) 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 publicly available via the internet (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:

Notification Procedures (APHIS 2000 or its equivalent); (7 CFR 340.3(a-e)); (Private Sector; State, Local, Tribal Gov't)
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.

Permit Application (Includes Request for Container Variance and Courtesy Permit) (APHIS Form 2000 or its equivalent); (7 CFR 340.4(a-c), 340.4(h)(2), 340.8(c); (Private Sector; State, Local, Tribal Gov't)
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.

Report on Characteristics Permit; (7 CFR 340.4(f, g)); (Private Sector; State, Local, Tribal Gov't)
The holder of a release permit is 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.

Notification of Certain Occurences; (7 CFR 340.4(f)(10)); (Private Sector; State, Local, Tribal Gov't)
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).

Appeal or Withdrawal of Permit; (7 CFR 340.4(g)); (Private Sector; State, Local, Tribal Gov't)
If a permit should be withdrawn because of a threat to plant health or any other reason, a permit holder may appeal the withdrawal of the permit in writing. Such actions occur infrequently.

Petition to Amend List of Organisms; (7 CFR 340.5); (Private Sector)
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.

Marking Identity (Importation Interstate and Labels for Permits) (APHIS 2050-2054); (7 CFR 340.4(f)(6) and 340.7); (Private Sector)
The movement provisions under 7 CFR § 340 are administered by BRS through the use of APHIS Labels 2050 through 2054. Label 2050 facilitates the interstate movement of genetically engineered organisms and identifies the contents of the container, and Labels 2051 through 2054 identify the designated port of entry into the United States for such organisms.

Petition for Nonregulated Status; 7 CFR 340.6(a-d)); (Private Sector; State, Local, Tribal Gov't)
Any petitioner may submit 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.

Request for Determination Extension; (7 CFR 340.6(e)); (Private Sector)

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.

Appeal of Denial of Petition; (7 CFR 340.6(e)); (Private Sector)

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.

Submission of Field Test Reports (Notifications); (7 CFR 340.3(d)(4)); (Private Sector; State, Local, Tribal Gov't)

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.

Documentation for Approved Training Program; (7 CFR 340); (Private Sector; State, Local, Tribal Gov't)

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. [WHERE IS THE TRAINING PROGRAM?]

The responsible party must keep records of interstate shipping of regulated materials for one year to demonstrate an approved amount of regulated material was shipped from an approved origin location to an approved destination location. The regulated community must train their staff and cooperators on internal processes that must be used for record keeping activities. BRAP reviews and approves training materials when reviewing permit applications for trials for plants that produce pharmaceutical or industrial compounds, but not when reviewing notification and traditional permit applications.

Recordkeeping; (7 CFR 340); (Private Sector; State, Local, Tribal Gov't)

Records for documentation for approved training program and the APHIS Form 2000 Permit Application (or equivalent) and associated files, notification and associated files, data/monitoring reports, and petition files 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.

State Review; (7 CFR 340.3); (Private Sector; State, Local, Tribal Gov't)
Discontinued

Nonregulatory Solution: Am I Regulated Process; (Private Sector; State, Local, Tribal Gov't)
(NEW) USDA provides oversight of certain genetically engineered (GE) organisms to protect plant health, by regulating the introduction—meaning the importation, interstate movement, and environmental release—of those GE organisms that may pose a pest risk to plants. The definition of a regulated article is found at 7 CFR § 340.1. If a GE organism meets the definition of a regulated article and a developer plans to import it, move it interstate or release it into the environment, they will need to apply for a permit or notification as described above.

If a developer is unsure whether a GE organism meets the definition of a regulated article as described in 7 CFR part 340, prior to proceeding with an application for a permit or notification, they may seek a confirmation of regulatory status of the GE organism from USDA under the "Am I Regulated" process available at the APHIS BRS website https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated. Using this link, developers are instructed to follow the instructions in the *Guidance for Submission of Am I Regulated Inquiries*. Guidance is at https://www.aphis.usda.gov/brs/pdf/AIR_Guidance.pdf

USDA APHIS BRS makes this non regulatory solution transparent to the public through our website by publishing previously reviewed letters of inquiry along with the Agency's response to the developer. We make this known through our website link here: View AIR Letters of Inquiry and APHIS Responses

We communicate with the developer upon first receipt of a letter of inquiry to determine if Confidential Business Information (CBI) has been claimed. Before reviewing the inquiry and again before we publish the cbi deleted or no-cbi letter, USDA APHIS BRS communicates back to the developer in a letter stating the following:

> "To facilitate public transparency regarding the regulatory status of GE organisms, we intend to publish on our website the attached CBI-deleted letter of inquiry to the agency and the agency response to your inquiry. APHIS-BRS follows the practices of the APHIS Freedom of Information Act (FOIA) Office. Just as when APHIS-FOIA responses to requests are shared with the public, we are notifying you that disclosure of your CBI-deleted letter of inquiry is being considered for publication on our website. To protect trade secrets and CBI, we are providing you a final opportunity to provide any additional CBI claims to your letter (enclosed). If you are intending to alter or add any additional CBI claims, we will need both CBI and CBI-deleted versions of your letter of inquiry, along with a CBI justification from you explaining

how competitors could use your information to cause competitive harm to your business. We will need this response within 15 days of the date of this letter."

If a developer responds with additional claims of Confidential Business Information or now removes its original claims of CBI, we publish on our website the update cbi-deleted and/or no-cbi version of the letter of inquiry and any supporting material provided. This response letter, along with our APHIS BRS determination of regulatory status response are all published on our public website as referenced above.

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. Many applicants use commonly known "xml" files to import data fields into what becomes the electronic version of the APHIS form 2000. By receiving electronic versions of notification and permit information, this also helps alleviate the burden of hard copies. APHIS sees nearly 100 percent usage of electronic versions, and also receives nearly 100 percent electronic data transfers from respondents, states, and interested parties to help relieve all document requirements (hard copies) as well. The APHIS 2000 may be downloaded from www.aphis.usda.gov/brs/ pdf/2000.pdf. Using the APHIS ePermit System, applicants can directly input their application online at 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 system will include continued availability to upload an xml file, which is preferred by our regulatory community. 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. However, USDA works within a coordinated framework related to biotechnology regulatory authorities with the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) to ensure no duplication of efforts.

USDA APHIS BRS and members of FDA and EPA involved in review of biotechnology products participate in a monthly interagency conference call to share updates of submissions of permits, petitions and requests for regulated status. In addition, all three agencies invite presubmission meetings for developers of biotechnology products so that information requirements can be discussed in advance and coordinated with other agencies so that the information requested can be most efficiently obtained while meeting the agencies' needs, and safety and quality standards. Sometimes these presubmissions meetings are held jointly between USDA APHIS BRS and the other relevant agencies.

The 2017 Update to the Coordinated Framework (CF), at https://www.aphis.usda.gov/biotechnology/downloads/2017_coordinated_framework_update.pdf), clarified the current roles and responsibilities of the primary agencies involved in the regulation of biotechnology products. Section E (pp 36-38) clarifies mechanisms in place, including three current Memorandums of Understanding (MOUs), that enable communication and information sharing, as appropriate and necessary, among EPA, FDA and APHIS. These mechanisms are helpful with respect to products that fall under the purview of more than one agency or may necessitate close coordination prior to decision making. These are also used to identify whether information which is or may be requested by another agency is similar to information which BRS could use to inform decisions under 7 CFR Part 340 and could thus be shared between agencies. Also, due to the nature in which both agencies are given regulatory authority and the specific nature in the types of questions and information needed by both the EPA & BRS, there may be times when some information is similar but the context and issues it addresses varies due to the complexity and specific nature of the questions and information the applicant is addressing and is required for a permit or notification.

Examples of coordination in information sharing include 1) information submitted to and analyzed by EPA to support registration of a herbicide to be used with a plant engineered for resistance to that herbicide for which a petition for deregulation is pending with BRS can be used by BRS to support evaluation of cumulative impacts to human health, the environment, and selection of herbicide resistant weeds and effectiveness of management practices; 2) information submitted to EPA regarding exposure and the safety of PIPs or microbial pesticides to human health and nontargets can be used by BRS to support analysis of unintended impacts on nontargets organisms that could impact plant health as well as analysis of cumulative impacts under the NEPA; 3) BRS frequently refers to safety and nutritional assessment information submitted to and analyzed by the FDA for voluntary premarket consultations of new foods derived from biotechnology to support NEPA cumulative impact analysis to human and animal health. Sharing of information from FDA and EPA can also be used to inform decisions on USDA APHIS BRS permit conditions or reporting requirements.

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

APHIS estimates 2% of the respondents are small businesses. The information APHIS collects in connection with permitting and the notification process is the minimum needed to ensure that regulated entities (such as importers) do not inadvertently introduce plant pests into the United

States. The information APHIS collects in connection to the "Am I Regulated" process is solely dependent upon what the developer voluntarily sends to USDA APHIS. The "Am I Regulated" process is a nonregulatory solution.

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;**

  APHIS will be notified (Notification of Certain Occurrences) 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).

- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**

  APHIS will be notified (Notification of Certain Occurrences) 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).

- **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 for documentation for approved training program and the APHIS Form 2000 Permit Application (or equivalent) and associated files, notification and associated files, data/monitoring reports, and petition files 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.

- **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.

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. Other productive discussions take place daily and at public stakeholder meetings where the agency provides responses to/clarification around its regulatory process. Productive consultations concerning APHIS' information collection activities were also made with the below listed individuals (representing agricultural companies).

Discussions included the staffing involved in submitting notifications, permits, petitions and associated supplemental documents; recordkeeping requirements; and staffing involved in reporting on characteristics related to permit conditions. The agency was informed of the frequency respondents exchanged information with the agency, and the number of record keepers involved in this process and the amount of time they devoted to this activity. The agency solicited and was provided information for how many people were involved in submitting field test reports and how long it takes to develop these reports. For the Approved Training Program, respondents provided information on how many people were in charge of training for permitting, dealing with compliance, and the staff involved in creating/maintaining the training program.

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On Friday, October 25, 2019, APHIS published in the Federal Register on pages 57385 and 57386, a 60-day notice seeking public comments on its plan to request a 3-year renewal of this collection of information. APHIS received three comments. One comment was not relevant to

the information collection request. Another commenter asked when APHIS will replace APHIS 2000 with an automated one. APHIS is adopting the use of xml submissions to do this. The commenter also asked APHIS to reevaluate its estimated responses for compliance reports. APHIS has made adjustments with this information collection. The third commenter remarked that the burden estimates were underestimated. With the development of our ePermit and eFile systems, and the nearly 100% use of xml as an electronic submission, we strive to reduce the burden. This same commenter stated that there has been no formal opportunity for affected stakeholders to provide input on information collections. APHIS routinely reaches out to industry, academia, developers and our regulated community at large through public stakeholder meetings, on site visits, and regularly holds both in-person and conference calls to receive public feedback. Changes to the CFR are processed in accordance with Federal rulemaking procedures.

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. The following is a list of all agreements and/or Memorandums of Understanding between USDA APHIS BRS and the listed party.

Dept. of Health & Human Services	College Park	MD
North Carolina Department of Agriculture and Consumer Services	Raleigh	NC
Florida Department of Agriculture and Consumer Services	Tallahassee	FL
Kansas Department of Agriculture	Topeka	KS
USDA Agricultural Marketing Service	Washington	DC
USDA Grain Inspection, Packers & Stockyards Administration	Washington	DC
Arkansas State Plant Board	Little Rock	AR
Wisconsin Department of Agriculture, Trade and Consumer Protection	Madison	WI
North Dakota Department of Agriculture	Bismarck	ND

USDA APHIS BRS uses the SF 424-series forms to provide grants. The burden time in using these forms is 1.1 hours.

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 71.

- **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 $693,737. APHIS arrived at this figure by multiplying the total burden hours (12,983) by the respondents' estimated average hourly wage ($36.34), and then multiplying the result by 1.4706 to capture benefit costs.

  This estimated average hourly rate was derived from the wages for government agricultural officials ($38.43) and researchers ($34.24) as listed in the U.S. Department of Labor, Bureau of Labor Statistics May 2018 Report - Occupational Employment and Wages in the United States. According to DOL BLS news release USDL-18-1499, dated September 18, 2018, 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.

See APHIS Form 79. The estimated annual cost for the Federal Government is $1,883,504.

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	8,780	0	1,455	3,824	0	3,501
Annual Time Burden (Hr)	12,983	0	2,687	6,981	0	3,315

This information collection request includes 483 respondents. This increase of 372 over the previous submission is due to adding State, Local, and Tribal Government officials as respondents to current activities, and revising the estimated number of respondents for permit applications. Further estimate adjustments and discretionary changes also resulted in 5,279 additional responses and 9,668 additional burden hours over the previous submission.

Estimate Adjustments

All but four activities have increased estimates for number of respondents and estimated total responses. Six activities had their response times increased. These estimate changes resulted in an increase of 3,824 responses and 6,981 hours of burden.

Discretionary Changes

Seven activities added State, Local, or Tribal Government respondents as respondent types, and one added Private Sector. This accounts for 1,355 responses and 2,229 hours of burden.

All of the activities except two added recordkeeping requirements resulting in an increase of 61 responses and 229 hours of burden.

One activity, State Review, was discontinued, removing 1 response and 1 hour of burden.

One new activity was added. "Am I Regulated" Process adds 40 responses and 230 hours of burden.

See "0579-0085 2020 Summary of ICR Changes.xls" for a side by side comparison of responses and burden hours for the activities reported in 2017 with those in this submission.

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.