

May 2020

SUPPORTING STATEMENT
MOVEMENT OF CERTAIN GENETICALLY ENGINEERED ORGANISMS
APHIS Docket 2018-0034
OMB CFN: 0579-0471

NOTE: APHIS plans to merge this information collection into 0579-0085 at the latter's next renewal.

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).

The PPA provides the Secretary of Agriculture with broad authority to protect plants by regulating the movement of, among other items, plants and articles in order to prevent the introduction or dissemination of a plant pest within the United States. The PPA specifically provides that no plant pest or noxious weed will be moved into or through the United States 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 plants, 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 Part 340 implement the provisions of the PPA by providing the information necessary to establish conditions for proposed introductions of certain organisms developed using genetic engineering, 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 organisms developed using genetic engineering. 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. Additionally, genetic engineering techniques have been developed that do not employ plant pests as donor organisms, recipient organisms, vectors, or vector agents yet

may result in organisms that pose a plant pest risk. Given these developments, and based on nearly 30 decades of experience regulated organisms developed using genetic engineering and advancements in science and technology, APHIS has updated the regulations in 7 CFR Part 340 and the activities in this information collection request.

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 Part 340 to prevent the introduction into and establishment of plant pests in the United States. The information has also been used to determine that an organism developed using genetic engineering 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 and Expanded Exemption Requests (Private Sector)

A plant is exempt from regulation and regulatory requirements, if : (1) it has been modified to contain a single genetic modification that is a change resulting from a cellular repair of a targeted DNA break in the absence of an externally provided repair template; or (2) it has been modified to contain a single genetic modification that is a single base pair substitution; or (3) it has been modified to contain a single that genetic modification introduces a gene known to occur in the plant's gene pool or makes changes in a targeted sequence to correspond to such a known allele of such a gene or to a known structural variation present in the gene pool.; or (4) it has been modified to contain a plant-trait-MOA combination that has previously undergone an analysis by APHIS and been determined by APHIS not to be subject to the regulations; or (5) it has been modified to contain a plant-trait-mechanism of action combination found in a plant that APHIS determined to be deregulated in response to a petition submitted prior to October 1, 2021; or (6) it is a plant determined by APHIS not to require regulation under this part pursuant to the "Am I Regulated" process.

The Administrator may propose to exempt plants with additional modifications, based on what could be achieved through conventional breeding. Such proposals may be Agency-initiated or in response to a request from the public.

Developers may request confirmation from APHIS that a plant is not within the scope of 7 CFR Part 340. APHIS will provide a written response (confirmation letter) within 120 days of receiving a sufficiently detailed confirmation request, except in circumstances that could not reasonably have been anticipated.

7 CFR 340.4: REGULATORY STATUS REVIEW (Private Sector)

Developers may request APHIS evaluate a plant developed using genetic engineering in accordance with § 340.4. Information needed for such a request is found on the APHIS website at <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology>.

7 CFR 340.4: RE-REVIEW OF REGULATORY STATUS REVIEW (Private Sector)

If APHIS finds that a plant developed using genetic engineering is subject to the regulation, any person may request a re-review supported by new, scientifically valid evidence bearing on the plant pest risk associated with movement of the plant. APHIS will then be re-evaluate a plant's regulatory status in light of any new information.

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)

A permit is required for the importation, interstate movement, or environmental release of any organism subject to 7 CFR Part 340, 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 § 340.5(b) with sufficient information about the specific nature of the organism and a detailed description of the proposed procedures, processes, and safeguards that will be used to prevent the unauthorized release of the organism so that the Administrator is able to consider whether the proposed activity is likely to result in the unauthorized release or dissemination of a plant pest.

General application requirements can be found on the APHIS website at <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology>. The website also contains all the categories of information that must be included in the application for the type of permit being requested.

APHIS will review the application to determine if it is complete. APHIS will notify the applicant orally or 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.

Any person submitting a permit application, must agree in writing to required standard permit conditions. These requirements address maintenance of organism's identity, prevention of its unauthorized release, spread, dispersal, and/or persistence in the environment, maintenance of records related to the permit activity, and requirements for communicating with APHIS in the event of an unauthorized release. The required standard conditions proposed in § 340.5 would apply to all permits.

The responsible person may request amendment(s) to a permit if there is a change in circumstances since issuance of the permit. The request must be made by contacting APHIS directly. The responsible person must provide justification for the amendment(s). A request in substantive changes to a permit will require a new permit application.

In addition, to respond to the recommendations of the 2015 Office of the Inspector General (OIG) audit, APHIS would add a requirement as a standard 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. To account for all approved test fields under an authorization, APHIS will require the submission of a report of no environmental release for all authorized locations where an environmental release did not occur.

Also, in the event of a possible or actual unauthorized release, the responsible person must contact APHIS and subsequently supply a statement of facts in writing.

APHIS will continue the status quo to exercise its authority under the PPA to maintain regulatory oversight of PMPI-producing plants. In this final rule, we are adding this requirement to §340.2, as a paragraph (e) which states that a permit is required for the movement of a plant that encodes a product intended for pharmaceutical or industrial use. The regulatory compliance costs that are associated with this final rule only occur in conjunction with activities that occur under permit.

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)

Consistent with the existing regulations, any person whose permit has been withdrawn or any person who has been denied a permit may appeal this decision in writing to the Administrator. The applicant must submit a statement of intent to appeal within 10 days after receiving the written notification of the denial or withdrawal. 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.

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

Although the existing 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 an organism developed using genetic engineering. Under the revised regulations, APHIS will provide the appropriate State or Tribal regulatory official notice and opportunity to review a copy of the permit application, without confidential business information (CBI), and any permit conditions. Comments received from the State or Tribal regulatory official will be considered by the Administrator prior to permit issuance.

7 CFR 340.6: RECORD RETENTION (Private Sector)

APHIS will extend the record retention requirement, from 1 to 2 years, for an organism under permit that was imported or moved interstate and reached its intended destination. 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 will also require that all other records must be retained for 5 years following permit expiration, unless a longer retention period is determined to be needed by the Administrator and documented in supplemental permit conditions. 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 for APHIS to assess compliance and determine whether additional enforcement activities are needed. When APHIS has investigated unauthorized environmental releases of regulated organisms, it has required 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 7 CFR Part 340. Responsible persons and their agents engaged in the importation, interstate movement, or environmental release of an organism subject to 7 CFR Part 340, 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 locations where the regulated organism under permit was stored or utilized, including all contained facilities and environmental release locations; (3) A copy of the APHIS permit authorizing the permitted activity; and (4) Legible 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 documents relating to 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.

APHIS allows for the use of both paper and electronic submissions for permit applications under 7 CFR Part 340 as described above. APHIS uses 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 Re-Reviews. APHIS plans to use its website, email addresses, and/or a future electronic platform, e.g., eFile, for these activities.

APHIS Forms 2050 through 2054 are labels.

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.

The information collected in connection with this program is not available from any other source. APHIS is the only Agency charged with administering the regulations in 7 CFR Part 340; therefore, there are no duplication of efforts.

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

APHIS estimates that 95% of the private sector respondents may be 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, facilitating more efficient entry into international markets. 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. Also, reduced regulatory requirements by APHIS may make it easier for academic, smaller research institutions, and the 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 Part 340 were not collected, APHIS 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, presenting unnecessary risks to American agriculture.

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

Also, to respond to the recommendations of the 2015 Office of the Inspector General (OIG) audit, APHIS would add a requirement as a standard 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.

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. The applicant must submit a statement of intent to appeal within 10 days after receiving the written notification of the denial or withdrawal. 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.

- **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 and 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 in 7 CFR Part 340. 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(j); Application of remedial measures in accordance with the Plant Protection Act, 7 U.S.C. 7701, et seq.; and sanctions as authorized in 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. 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 record-keeping 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.

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APHIS' published the proposed rule notice in the Federal Register on Thursday, June 6, 2019 (see 84 FR 26514). It included a description of the information collection requirements as well as a 60-day comment period for interested members of the public to provide APHIS with their input concerning the usefulness, legitimacy, and merit of the information collection activities. APHIS received and reviewed 6,152 comments about the proposed rule, and detailed discussion on them can be found in the final rule announcement published in the Federal Register on Monday, May 18, 2020. One comment resulted in the adjustment of estimated responses for the Confirmation Letters activity.

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

This information collection activity involves no payments or 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 Monday, September 13, 1985 (see 50 FR 38561). 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. Burden estimates were developed using historical data; calculated averages of permits, notifications and petitions from an APHIS’ existing information collection, along with the number of online 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 \$1,573,575. APHIS arrived at this figure by multiplying the 21,853 total burden hours by the respondents’ estimated average hourly wage of \$50.39, and then multiplying the result by 1.429 to capture benefit costs.

Respondents are from Tribal governments and the private sector who are considered regulated by 7 CFR part 340. Wages are based on the occupational group 29-1131 found in the May 2019 Bureau of Labor Statistics Occupational Employment Statistics webpage <https://www.bls.gov/oes/current/oes291131.htm>.

According to the Department of Labor Bureau of Labor Statistics notice USDL-20-0451, Employer Costs for Employee Compensation - Dec 2019, released March 19, 2020

(<https://www.bls.gov/bls/news-release/ecec.htm>), employee benefits account for 30% of employee costs and wages account for the remaining 70%. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.429.

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 annualized cost to the Federal government is estimated at \$3,416,050.

The economic analysis includes compliance activities, inspection activities, and activities associated with obtaining authorization to engage in regulated activities, obtaining written opinions on regulated status, and seeking deregulated status for organisms developed using genetic engineering. Under the final rule, APHIS' overall annual personnel costs of regulating organisms developed using genetic engineering are not expected to change. Although 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 final 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 final 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.

This is a new information collection with an estimated 321 respondents, 1,337 responses, and 21,853 hours of burden.

These are increases of 20 respondents, 240 responses, and 2,400 hours from the proposed rule. A commenter suggested the scope of the exemptions listed in proposed § 340.1(b)(1) through (b)(3) should be broadened to encompass the range of genetic modifications that are accessible to plant breeders through conventional breeding methods. APHIS added a process to request additional exemptions under Section 340.1(b) and adjusted the ICR for that burden.

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 the future merger of this information collection into 0579-0085, 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.