

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), 7 U.S.C. 7701.

APHIS exercises its regulatory authority through a system that includes both permits and notifications. A researcher or developer (business applicant) may also request that APHIS no longer regulate an organism by submitting a petition for nonregulated status. BRS also works closely with States to ensure that they are aware of field tests taking place within their jurisdiction and to allow the States to request any additional conditions they may require of the business applicant. Often, however, APHIS receives information from business applicants that is declared to be Confidential Business Information (CBI). As such, APHIS is required to restrict access to only authorized and trained personnel within APHIS. CBI can include information that, if withheld, could make it very difficult for the States and Tribal governments to review the applicant's proposal. Currently, the States and Tribal governments must make contact with the business applicant to gain access to their CBI.

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 proposed regulations in 7 CFR § 340.10 establish conditions under the PPA for BRS is to create an efficient and streamlined system of CBI information sharing with the States and Tribal governments so as to ensure that the review process is conducted in a timely manner. Currently, permit applications may take up to 120 days to process and notifications may take up to 30 days for review and approval or disapproval. The States would be required to enter into an agreement or Memorandum of Understanding with APHIS; designate proper safekeeping of collected CBI information; and complete an agreed upon CBI training.

On June 7, 2004, APHIS convened a meeting with the National Association of State Directors of Agriculture (NASDA). One of the main purposes of the meeting was to evaluate the quality

of interactions between APHIS and State governments, especially with respect to biotechnology issues. At that meeting, State officials expressed the view that cooperation and collaboration between APHIS and the States in regulatory activities for agricultural biotechnology may not be as effective as possible because information withheld as CBI from notification and permit applications often appeared to be important to the State's review. State officials expressed concern about the adequacy of reviews conducted when important information was not available to them. The discussions regarding sharing of designated CBI information initiated at the 2004 NASDA meeting have continued over time, along with discussions covering a range of regulatory activities and compliance and enforcement issues arising within agricultural biotechnology. These discussions focused on methods of sharing designated CBI with the States that would be consistent with the ability of the States to prevent disclosure under State FOIA laws and other applicable disclosure statutes or policies of the States. As a result of these discussions, APHIS has developed this proposed rule to allow the sharing of certain business information desired by State and Tribal government authorities.

The purpose of this proposed rule is to solicit comments from the public (as well as affected agencies) concerning this information collection activity.

APHIS is asking OMB to approve, for 3 years, its use of this information collection to ensure that the permitting process used in development, testing, and use of the products of biotechnology occur in a manner that is safe for plant and animal health, human health, and the environment.

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.

BRS will collect the information through a notification procedure or a permit requirement (APHIS Form 2000/USDA APHIS ePermits Web site) 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. This information is currently being collected under 0579-0085.

Currently a CBI-deleted version of this information is also provided to State departments of agriculture and Tribal governments for review of additional conditions. The proposed CBI information to be provided for the State or Tribal government's review process would allow the States or Tribal governments to better assess their conditional needs. The following conditions would have to be agreed upon with each State or Tribal government:

Proposed § 340.10 (a) (1) would require the State or Tribal government officials to state their authority to protect from public disclosure, permit and compliance information that has been designated CBI in the written agreement. Based on APHIS' preliminary review of State authorities, APHIS realizes that only some States have the legal authority to protect the specified types of business information from public disclosures. For example, the four States that participated in the APHIS pilot program in 2009 -- Arkansas, Florida, Kansas, and North

Carolina -- were able to provide letters indicating that shared confidential business information could be protected if disclosed to State inspectors by the applicant.

Proposed § 340.10(a)(2) would require the State or Tribal government to have in place suitable procedures to ensure the security of the shared confidential business information and to specify and restrict which specific State or Tribal agency or agencies and their respective officials are allowed access to it. These officials would be required to complete the same annual “Confidential Business Information and Records Management” training that APHIS requires of employees handling CBI. State and Tribal procedures would have to be equivalent to those currently used by APHIS, which are specified in APHIS' "Policy Statement on the Protection of Privileged or Confidential Business Information" cited above. At this time, APHIS would not allow State or Tribal agencies to store in electronic form or otherwise create any records of any CBI received from APHIS. Nevertheless, APHIS is exploring and seeking input on sharing certain business information with State and Tribal government agencies by electronic means.

The goal of these security measures would be to safeguard documents containing information disclosed under the proposed provisions, i.e., to account for the location of documents at all times, control access to documents, and provide for secure transmittal, destruction, or return of documents to APHIS. APHIS is confident that it can review this information while effectively maintaining document security if State or Tribal agencies employ methods equivalent to those used by APHIS,. Adaptations of these procedures that achieve an equivalent effect would be specified in the required written agreement between APHIS and a State or Tribal government agency.

Proposed § 340.10(a)(3) would require a commitment in the written agreement between APHIS and the State or Tribal government not to disclose CBI without the written permission of the submitter or written confirmation from APHIS that the information is no longer considered CBI as determined by APHIS pursuant to the applicable Federal laws. Proposed § 340.10(a)(4) would require a commitment in the written agreement by the State or Tribal government that all persons authorized to have access to CBI provided by APHIS will be trained by the State or Tribal authority on how to maintain the security of the shared CBI before having access to it. APHIS would provide the content of the required training.

This training requirement would also apply to situations where a State or Tribal authority needs to share certain business information with State or Tribal employees who are not regulatory officials (such as faculty of State universities) and APHIS will agree to allow the non-regulatory State or Tribal employees access to the shared CBI. Such persons would need training to protect this information from disclosure and in these cases, the parties would need to establish additional safeguards within the written agreement before those non-regulatory State or Tribal employees were allowed access to the shared CBI. For example, the State or Tribal authority would have to agree to appoint regulatory officials to oversee confidentiality rules and responsibilities for safeguarding business information shared with these other employees.

Each government agency entering into a written agreement with APHIS to receive certain business information would be obligated under the terms of the written agreement to safeguard the entrusted information. If a State or Tribal government intentionally or even unintentionally

releases certain authorized business information, APHIS would make a determination of whether or not to immediately void the written agreement and revoke the agency's privilege to receive future authorized information or whether to impose appropriate corrective actions, conditions, and/or requirements into the written agreement for the agency. Also, individuals who release protected information may be subject to penalties under applicable State or Tribal laws for the protection of trade secrets and confidential business information.

The final provision for the written agreement, proposed § 340.10(a)(5), would require inclusion of other needed terms agreed to by APHIS and the State or Tribal government regarding the shared information. This provision could take into account and incorporate administrative procedures or authorities that are unique to a State or Tribe.

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.

APHIS proposes to allow sharing of paper documents by only certain States or Tribal governments which are capable of preventing disclosure of such paper records to the public. These States or Tribal governments must also be able to comply with the requirements set forth in the proposed rule. Only the storage of paper documents will be authorized, not the storage of electronic documents, so no computer security would be incurred. However, if security and other concerns are fulfilled, leveraging future IT systems and solutions could be considered which will make the information sharing more efficient and effective.

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 Federal agency responsible for ensuring 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 is collecting is its only source for the information and is not being collected through other forms or reports.

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

APHIS has no small entities involved with this information collection.

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.

APHIS considered a “no action” alternative under which it would continue to delete CBI information from notification and permit applications, and then share only the CBI-deleted documents with States and Tribal governments. This alternative would avoid the implementation costs identified for this proposal, but would not accrue any of the benefits identified for sharing certain business information. The no action alternative could also result in continuing costs to the Federal government through reduced effectiveness of the regulatory program.

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;**
- **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;**
- **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 information collection is inconsistent with the information collection guidelines in 5 CFR 1320.5.

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting 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.

Productive consultations concerning our information collection activities were made with the following individuals during 2012:

Robin Pruisner,
State Entomologist & Bureau Chief
Entomology and Plant Science Bureau
Iowa Dept. of Agriculture and Land Stewardship
2230 South Ankeny Boulevard
Ankeny, IA 50023
515-725-1470

Terry Walker
Division of Plant Industry
Arkansas State Plant Board
PO Box 1069
Little Rock, AR 72203
501-225-1598

Jeff Vogel, Program Manager
Kansas Department of Agriculture
Plant Protection and Weed Control
(785) 862-2180

The **proposed** rule, Docket Number APHIS-2006-0124, was published in the Federal Register on February 27, 2013, with a 60-day comment period. During this time, interested members of the public will have the opportunity to provide APHIS with their input concerning the usefulness, legitimacy, and merit of the information collection activities APHIS is proposing.

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

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

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

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with

5 U.S.C. 552a.

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

See APHIS Form 71 for burden estimates. The cost to the public was determined by multiplying the total number of burden hours (408) x the wage per hour (\$18.55) which equals \$ 7,568.

\$18.55 is the hourly rate derived from the U.S. Department of Labor, Bureau of Labor Statistics Report - National Compensation Survey: Occupational Wages in the United States, May, 2012. See <http://www.bls.gov/news.release/ocwage.t01.htm>.

See APHIS Form 71 for hour burden estimates.

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, operation and maintenance, 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 estimated cost to the Federal Government is \$21,808. (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.

This is a new program.

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.

There are no forms associated with this information collection.

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

APHIS 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.