



Animal and Plant
Health Inspection
Service

Fiscal Year (FY): 2014

September 1, 2014

Marketing and
Regulatory
Programs

RE: Annual Report of Research Facility Column E and Exception Attachments

Animal and
Plant Health
Inspection
Service

Dear Registrant:

Legislative and
Public Affairs

Because of the enormous amount of resources expended each FY to review the Annual Report of Research Facility Column E and Exception Attachments (Report Attachments), and because of the continued public interest in this information, APHIS is making a proactive effort to streamline the review process for Report Attachments.

Freedom of
Information

Typically, these types of records may contain confidential commercial or business information ("CBI") within the meaning of FOIA Exemption 4, 5 U.S.C. 552(b)(4). Exemption 4 protects from public disclosure trade secrets and commercial or financial information obtained from a person that is privileged or confidential. In order to protect the information, APHIS must first establish that the information is commercial or financial and that it was obtained from a person, company, organization, state government, or other outside entity. Next APHIS must establish that the information is "confidential" which typically means that release of the information would cause substantial competitive harm to the submitter. In order to establish substantial competitive harm, APHIS must identify the competition in the relevant market. Accordingly, FOIA Exemption 4 permits agencies to withhold CBI, the disclosure of which is likely to cause substantial competitive harm.

4700 River Road
Unit 50
Riverdale, MD
20737-1232

Whenever a USDA agency cannot readily determine whether responsive records contain CBI, the agency must obtain and consider the views of the organization that submitted the information. In addition, the agency must provide the organization with an opportunity to object to any decision to disclose the information. See E.O. 12,600 and 7 C.F.R. 1.12 (copy enclosed).

APHIS wishes to take into account your organization's views on whether any or all of the information contained in the enclosed records should be considered CBI and therefore exempt from disclosure under the FOIA. This notice seeks your organization's position on our determination, including, but not limited to, whether the enclosed records contain information that:

- is commercial or financial;
- was submitted by a person, company, organization, etc.; and
- if released, would cause substantial competitive harm to the submitter.

In your submission, please highlight all information you believe is protected by Exemption 4 (CBI deleted copy) and prepare a detailed, written justification to support protection of the designated information. Please note that when documents contain information that qualifies as exempt from disclosure, the entire document is not necessarily exempt. The FOIA specifically provides that any reasonably segregable portions of a document must be provided to a requester after deletion of the portions that are exempt. For that reason, please specifically indicate which portions of the records that you believe contain CBI. Please be aware that comments provided by your organization in response to this letter may be subject to disclosure under FOIA.

You should submit your CBI deleted copy and justification no later than **December 30, 2014**, to the **AR Review Coordinator** at:

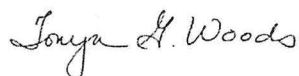
Animal and Plant Health Inspection Service
Legislative and Public Affairs
4700 River Road, Unit 50
Riverdale, Maryland 20737-1232
Phone: 301-851-4102
Fax: 301-734-5941

Please provide the name and contact information for the individual responsible for reviewing APHIS's final determination and include your facility name and license number on all documents.

As of this date, APHIS has not received a request seeking your facility's Report Attachments nor is the Agency still bound by the 2009 Settlement Agreement that required the yearly web posting of all Reports and Attachments. Therefore, upon receipt of a FOIA request for this information or a decision to continue posting these records, APHIS will review your submission. If your organization objects to the release of the information, APHIS will consider your response carefully in making a final determination. Should APHIS decide to release any of the information, we will advise you in writing before such disclosure takes place in order to provide your organization with an opportunity to seek judicial intervention. If you fail to provide comments, we will assume that you have no objections to disclosure of this information. However, if your organization does not object to disclosure of this information, we prefer that you notify the Agency of this position in writing.

To prepare your response, you may find it helpful to consult the Justice Department's Guide to the FOIA at <http://www.usdoj.gov/oip/foia.htm>. You also may wish to obtain the advice of counsel to ensure you provide the level of detail required to support any Exemption 4 assertions. Additionally, enclosed is a copy of our CBI Justification Instructions. If you have any questions, you may call the APHIS FOIA/PA office at (301) 851-4102.

Sincerely,



Tonya G. Woods
Director
Freedom of Information & Privacy Act
Legislative and Public Affairs

Enclosures:

1. Executive Order (E.O.) 12600
2. 7 C.F.R. 1.12
3. Instructions for CBI Justification

Code of Federal Regulations

Title 7 - Agriculture

Volume: 1

Date: 2010-01-01

Original Date: 2010-01-01

Title: Section 1.12 - Handling information from a private business.

Context: Title 7 - Agriculture. Subtitle A - Office of the Secretary of Agriculture. PART 1 - ADMINISTRATIVE REGULATIONS. Subpart A - Official Records.

§ 1.12 Handling information from a private business.

Each USDA agency is responsible for making the final determination with regard to the disclosure or nondisclosure of information in agency records that has been submitted by a business. When, in the course of responding to an FOIA request, an agency cannot readily determine whether the information obtained from a person is privileged or confidential business information, the policy of USDA is to obtain and consider the views of the submitter of the information and to provide the submitter an opportunity to object to any decision to disclose the information. If a request (including a subpoena duces tecum as described in § 1.215) is received in USDA for information that has been submitted by a business, the agency shall:

(a) Provide the business information submitter with prompt notification of a request for that information (unless it is readily determined by the agency that the information requested should not be disclosed or, on the other hand, that the information is not exempt by law from disclosure). Afford business information submitter reasonable time in which to object to the disclosure of any specified portion of the information. The submitter must explain fully all grounds upon which disclosure is opposed. For example, if the submitter maintains that disclosure is likely to cause substantial harm to its competitive position, the submitter must explain item-by-item why disclosure would cause such harm. Information provided by a business submitter pursuant to this paragraph may itself be subject to disclosure under FOIA;

(b) Notify the requester of the need to inform the submitter of a request for submitted business information;

(c) Determine whether the requested records are exempt from disclosure or must be released;

(d) Provide business information submitters with notice of any determination to disclose such records prior to the disclosure date, in order that the matter may be considered for possible judicial intervention; and

(e) Notify business information submitters promptly of all instances in which FOIA requesters bring suit seeking to compel disclosure of submitted information.

[65 FR 46339, July 28, 2000]

INSTRUCTIONS FOR CONFIDENTIAL BUSINESS INFORMATION(CBI) JUSTIFICATION

The justification should be provided in the format below. The language used to prepare your justification should be in non-technical terms when possible. Maintain the documents in the order provided and do not remove any documents. The FOIA Office will make a final decision as to whether the information qualifies for protection under the FOIA.

FORMAT

I. Introduction.

Provide general information describing the competitive market of your business. Include any background information which provides relevancy to comments used in your justification. If any information belongs to cooperating businesses, include a discussion of how information is maintained confidential, i.e., secrecy agreements.

II. In Your Justification, Categorize Like Pieces of Information.

A. Review the documents (e.g. permits/notifications, outlines of productions, efficacy/potency/safety test reports, technical/business proposals, etc.) we have referred to your organization for review under Executive Order 12600.

B. Highlight the information your company has claimed as CBI.

C. Categorize like pieces of information (gene description, bacterin strain, production/research methods, testing results, financial information, cooperators, etc.) that can be easily identified.

D. Provide a discussion for each category identified. The discussion should describe:

- 1) What each category of information reveals about your organization's business.
- 2) How a competitor could use this information to cause your company competitive harm.
- 3) The specific competitive harm (e.g., financial, research & development, etc.) that could result if the information is released. Essential for our release determination.

III. Summary.

Summarize the importance of the information that you have identified as CBI to the viability of your company's business operations. Provide the name and telephone number of a company official who should be contacted for further information.

IV. Index. (Optional)

Provide an index of the referred documents that your company designated as containing CBI. The index should match each appropriate categorical justification to the documents containing information claimed as CBI.



<http://www.archives.gov/>

Monday, July 16, 2012

Executive Order 12600--Predisclosure Notification Procedures for Confidential Commercial Information

Source: The provisions of Executive Order 12600 of June 23, 1987, appear at 52 FR 23781, 3 CFR, 1987 Comp., p. 235, unless otherwise noted.

By the authority vested in me as President by the Constitution and statutes of the United States of America, and in order to provide predisclosure notification procedures under the Freedom of Information Act concerning confidential commercial information, and to make existing agency notification provisions more uniform, it is hereby ordered as follows:

Section 1. The head of each Executive department and agency subject to the Freedom of Information Act shall, to the extent permitted by law, establish procedures to notify submitters of records containing confidential commercial information as described in section 3 of this Order, when those records are requested under the Freedom of Information Act (FOIA), 5 U.S.C. 552, as amended, if after reviewing the request, the responsive records, and any appeal by the requester, the department or agency determines that it may be required to disclose the records. Such notice requires that an agency use good faith efforts to advise submitters of confidential commercial information of the procedures established under this Order. Further, where notification of a voluminous number of submitters is required, such notification may be accomplished by posting or publishing the notice in a place reasonably calculated to accomplish notification.

Sec. 2. For purposes of this Order, the following definitions apply:

(a) "Confidential commercial information" means records provided to the government by a submitter that arguably contain material exempt from release under Exemption 4 of the Freedom of Information Act, 5 U.S.C. 552(b)(4), because disclosure could reasonably be expected to cause substantial competitive harm.

(b) "Submitter" means any person or entity who provides confidential commercial information to the government. The term "submitter" includes, but is not limited to, corporations, state governments, and foreign governments.

Sec. 3. (a) For confidential commercial information submitted prior to January 1, 1988, the head of each Executive department or agency shall, to the extent permitted by law, provide a submitter with notice pursuant to section 1 whenever:

(i) the records are less than 10 years old and the information has been designated by the submitter as confidential commercial information; or

(ii) the department or agency has reason to believe that disclosure of the information could reasonably be expected to cause substantial competitive harm.

(b) For confidential commercial information submitted on or after January 1, 1988, the head of each Executive department or agency shall, to the extent permitted by law, establish procedures to permit submitters of confidential commercial information to designate, at the time the information is submitted to the Federal government or a reasonable time thereafter, any information the disclosure of which the submitter claims could reasonably be expected to cause substantial competitive harm. Such agency procedures may provide for the expiration, after a specified period of time or changes in circumstances, of designations of competitive harm made by submitters. Additionally, such

procedures may permit the agency to designate specific classes of information that will be treated by the agency as if the information had been so designated by the submitter. The head of each Executive department or agency shall, to the extent permitted by law, provide the submitter notice in accordance with section 1 of this Order whenever the department or agency determines that it may be required to disclose records:

- (i) designated pursuant to this subsection; or
- (ii) the disclosure of which the department or agency has reason to believe could reasonably be expected to cause substantial competitive harm,

Sec. 4. When notification is made pursuant to section 1, each agency's procedures shall, to the extent permitted by law, afford the submitter a reasonable period of time in which the submitter or its designee may object to the disclosure of any specified portion of the information and to state all grounds upon which disclosure is opposed.

Sec. 5. Each agency shall give careful consideration to all such specified grounds for nondisclosure prior to making an administrative determination of the issue. In all instances when the agency determines to disclose the requested records, its procedures shall provide that the agency give the submitter a written statement briefly explaining why the submitter's objections are not sustained. Such statement shall, to the extent permitted by law, be provided a reasonable number of days prior to a specified disclosure date.

Sec. 6. Whenever a FOIA requester brings suit seeking to compel disclosure of confidential commercial information, each agency's procedures shall require that the submitter be promptly notified.

Sec. 7. The designation and notification procedures required by this Order shall be established by regulations, after notice and public comment. If similar procedures or regulations already exist, they should be reviewed for conformity and revised where necessary. Existing procedures or regulations need not be modified if they are in compliance with this Order.

Sec. 8. The notice requirements of this Order need not be followed if:

- (a) The agency determines that the information should not be disclosed;
- (b) The information has been published or has been officially made available to the public;
- (c) Disclosure of the information is required by law (other than 5 U.S.C. 552);
- (d) The disclosure is required by an agency rule that (1) was adopted pursuant to notice and public comment, (2) specifies narrow classes of records submitted to the agency that are to be released under the Freedom of Information Act, and (3) provides in exceptional circumstances for notice when the submitter provides written justification, at the time the information is submitted or a reasonable time thereafter, that disclosure of the information could reasonably be expected to cause substantial competitive harm;
- (e) The information requested is not designated by the submitter as exempt from disclosure in accordance with agency regulations promulgated pursuant to section 7, when the submitter had an opportunity to do so at the time of submission of the information or a reasonable time thereafter, unless the agency has substantial reason to believe that disclosure of the information would result in competitive harm; or
- (f) The designation made by the submitter in accordance with agency regulations promulgated pursuant to section 7 appears obviously frivolous; except that, in such case, the agency must provide the submitter with written notice of any final administrative disclosure determination within a reasonable number of days prior to the specified disclosure date.

Sec. 9. Whenever an agency notifies a submitter that it may be required to disclose information pursuant to section 1 of this Order, the agency shall also notify the requester that notice and an opportunity to comment are being provided the submitter. Whenever an agency notifies a submitter of a final decision pursuant to section 5 of this Order, the agency shall also notify the requester.

Sec. 10. This Order is intended only to improve the internal management of the Federal government, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.

Page URL: <http://www.archives.gov/about/laws/appendix/12600.html>