

Instructions for Competition of APHIS Form 7023

(Refer to 9 CFR, Part 2, Subpart C, Section 2.33 and 2.36)

Item 1- Enter registration number as assigned to the Research Facility by the United States Department of Agriculture (USDA).

Item 2- Enter the complete name and mailing address of the Headquarters Research Facility as registered with the USDA.

Item 3- List location of each site where the animals are housed and used in actual research, teaching, experimentation, or held for these purposes. (Attached additional sheets if necessary).

Item 4-13- DO NOT enter numbers in Column A. DO NOT add numbers entered in Column B into the totals in Column F. Column F is to show only the total numbers entered in Columns C + D + E. Entries in Column E must be explained on attached sheet(s).

Item 12: List by common name all other farm animal species.

Item 13- Other: List, by common name, all other warm-blooded animal species covered by the Regulations. (This will include all wild or exotic species). Use additional sheets if necessary or use APHIS Form 7023A.

****Return Completed Form with an Original Signature of C.E.O., President, or Institutional Official to the Appropriate Office. *****

Annual Report Reminders

September 2016

Only one Annual Report should be submitted per registered facility. Consolidate site numbers onto one report for submission. Site specific numbers should be available to the inspector at each site.

Animals used for research purposes at any time during the reporting year must be reported in Column C, D or E, as appropriate, whether or not they are still being held at the facility.

All animals contained on the facility's inventory on September 30, that are not used in a research project, should be reported in Column B. Animals that were held but died during the year without being used for research purposes should also be reported in Column B. Animals held, but not used for research during the reporting year, that have been moved to another facility and are not present at the facility on September 30 should only be reported by the facility in possession of the animals. Any animals have been transferred to another facility during the fiscal year both facilities are required to report the animals according to the pain category of the work done at the facility.

Registrants with breeding colonies should report their breeding animals and any offspring which are not being used for research purposes in Column B.

Animals present at the facility which were used for research in previous years but were not used in the current year would also be reported in Column B.

Animals used in more than one protocol are counted once in the most painful/distressful category.

Report wild rodents. Do not report the use of laboratory rats, laboratory mice, birds, reptiles, fish or other animals which are exempt from the regulation under the AWA.



Assistance with Accurate Annual Reporting for Research Facilities

September 2016

In order to assist research facilities in accurately reporting animal use on the Annual Report, APHIS Form 7023, Animal Care is providing the following information and examples as guidance only. Research activities are often unique and specific questions not covered by these examples should be directed to the appropriate Regional Office.

Animal Care and Use Review

When an Animal Care and Use Proposal is reviewed, the IACUC must make a determination as to whether the procedure could potentially cause more than slight or momentary pain or distress. If the IACUC determines that the procedures could potentially cause more than slight or momentary pain or distress, the investigator must consider alternatives to all the procedures in that study that may cause pain or distress.

At that time, the IACUC must also review the scientific explanation for justifying the withholding of analgesics, anesthetics or tranquilizing drugs that could be used to relieve the pain or distress animals on the study might experience. If the animals do experience pain which cannot be relieved with appropriate anesthetics, analgesics or tranquilizing drugs, because they would adversely affect the study, those animals are reported in column E with the explanation and reason why pain and distress could not be relieved."

Annual Report of the Research Facility

Occasionally, during the course of a research project unforeseen events involving animals occur, and questions arise as to how best to report these animals on the APHIS Form 7023. Unexpected pain or distress and animal incidents unrelated to ongoing research should be brought to the attention of the IACUC for purposes of adequate protocol and program review but do not need to be included in the annual report.

The following examples are not intended to address protocol review, veterinary care, or training and qualification requirements. Animal Care is providing the following examples as guidance for annual reporting purposes only.

Example 1) An animal experiences pain due to the research procedures, during the course of a study. The pain is recognized, treated with appropriate analgesics, and substantively effective in a timely manner.

Answer: Reported in Column D.



Example 2) An animal experiences pain due to a research procedure but when the pain is recognized, the investigator determines that analgesics, anesthetics or tranquilizers would adversely affect the study.

Answer: Reported in Column E.

Example 3) An animal is unexpectedly found dead in the cage during the course of a study. The animal had been monitored appropriately and there were no pre or post mortem sign of pain or distress. The animal had not experienced pain as part of the study prior to its death.

Answer: Reported in Column C.

Example 4) An animal experiences unexpected pain or distress due to the research procedures during the course of a study. The pain is recognized and the animal is euthanized in a timely manner.

Answer: Reported in Column D.

Example 5) An animal accidentally becomes caught in a cage and experiences pain and distress which is completely unrelated to the study. The injuries are treated and appropriate analgesia is provided.

Answer: This animal should be reported in the pain category appropriate to its experiences in the study. The accident does not affect the reporting category. If the animal did not experience any pain or distress as part of the approved study it would be reported in Column C.

Example 6) An animal develops an ear infection and experiences pain or distress entirely unrelated to the study. Analgesics, anesthetics or tranquilizers would adversely affect the study so the animal is treated with palliative husbandry methods. Husbandry methods assist in controlling, but do not substantively mitigate the pain.

Answer: This is a tough one and does not fit easily into any of the classifications. Because the pain relief must be withheld due to the study, even though the pain is not caused by a research procedure, report this animal in Column E and provide a justification for not providing pain relieving analgesics.

Column E Explanation

This form is intended as an aid to complete the Column E explanation. It is not an official form and its use is voluntary. Annual Reports and explanations should NOT include PII information such as names (principle investigators and research staff), addresses, protocols, meeting notes (either in part or in full), the animals room numbers, grant information, veterinary care programs, and the like. A Column E explanation must be written so as to be understood by lay person as well as scientists.

1. Registration Number: _____
2. Number _____ of animals used in this study.
3. Species (common name) _____ of animals used in this study.
4. Explain the procedure producing pain and/or distress. Explanations should include a brief description of the procedure, but also explain what the animal's experience, examples of which may include, but are not limited to: Neurological signs, seizures, tremors, paralysis, lethargy, inappetance, respiratory signs, GI distress, vomiting, and diarrhea.

5. Attach or include with the reason(s) for why anesthetics, analgesics and tranquilizers could not be used. (For federally mandated testing, see Item 6 below).

6. What, if any, federal regulation require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g. APHIS, 9 CFR 113.102):

Agency _____ CFR _____

Exception/Exemption

The following are guidelines for determining when an Exception/Exemption should or should not be reported on the Annual Report. This information is excerpted from the Animal Care Inspection Guide, Chapter 7, Pages 7-26 -7-27, February 2015 edition.

Exceptions/Exemptions

Exceptions or exemptions to a particular AWA Regulation or Standard **approved by the IACUC must be:**

- For scientific reasons
- Justified in writing

If a regulation or standard also provides specific parameters for an exemption/exception, those parameters must be followed.

Exceptions that **should** be reported on the Annual Report:

- Exceptions approved by the IACUC under 2.38(k) that are **not** provided for under the Regulations and Standards, including but not limited to:
 - Removal of resting platforms from cat enclosures
 - Extension of interval for cleaning/sanitization of enclosures
 - Keeping animals in 24 hour dark cycle.
 - Keeping animals in temperatures outside range described in Part 3-Standards for species
- Exceptions approved by Animal Care, including but not limited to:
 - Approval for use of an animal in more than one major operative procedure from which it is allowed to recover on **more than one protocol** (2.31)(d)(1)(x)(c)
 - Exception to the health certificate requirements (2.38)(h)(2)
 - Temporary tethering of dogs used as the primary enclosure (3.6)(c)(4)

Exceptions that should **not** be reported on the Annual Report:

- Exceptions approved by the JACUC that are provided for under the Regulations and Standards, including but not limited to:
 - Approval for use of an animal in more than one major operative procedure from which it is allowed to recover on **one protocol** (2.31)(d)(1)(x)(a)
 - Short term withholding of food and water from animals (2.38)(f)(2)(ii)
 - Exemption of an individual NHP from some or all of the environmental enhancement plan (3.81)(e)(2)
 - Any deviation from the methods of euthanasia as defined in the AWA regulations which were justified for scientific reasons, in writing, by the investigator (2.31)(d)(1)(xi)
- Exceptions approved by a veterinarian as part of the provision of veterinary care, including but not limited to:
 - Animal is fasted for surgery conducted for husbandry reasons
 - Any major operative procedures for medical or colony management purposes per 2.31(d)(1)(x)(b)
 - Animal is housed in an enclosure that does not meet space requirements for medical reasons while recovering from husbandry or veterinary care related surgery
 - Animal develops vomiting/diarrhea (not study related) and veterinarian prescribes IV fluids and severely restricts food and water intake by mouth for several days



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4700 River Road
Unit 50
Riverdale, MD
20737-1232

September 9, 2016

FY 2016 Annual Report of Research Facility - Column E and Exception Attachments

Dear Registrant:

This letter serves as notice to your organization about an upcoming Freedom of Information Act (FOIA) review of the 2016 Annual Report of Research Facility Column E and Exception Attachments ("AR Attachments"). As a result of the July 1, 2009, Settlement Agreement reached in Humane Society of the United States v. USDA, No. 05-0197 (D.D.C.), APHIS conducted a FOIA review of and subsequently posted to its Animal Care (AC) website all AR Attachments for Fiscal Years 2009 through 2013. Since that time, APHIS has determined that the FOIA Office will continue to review and post the Annual Report of Research Facility report, Column E and Exception Attachments records in accordance with subsection (a)(2) of the FOIA. All previous disclosures of this information can be found on our website at:

<https://acis.aphis.edc.usda.gov/ords/f?p=116:1:0>

NON-FEDERAL RESEARCH FACILITIES

Your 2016 AR Attachments 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.

Whenever APHIS cannot readily determine whether responsive records contain CBI, the agency should obtain and consider the views of the organization that submitted the information. See Executive Order 12,600 (copy enclosed) and 7 C.F.R. § 1.12. In addition, the agency should provide the organization with an opportunity to object to any decision to disclose the information. *Id.*

APHIS requests your views on whether any of the information contained in your 2016 AR Attachments should be considered exempt from disclosure under the FOIA. In reviewing the enclosed records, please highlight information you believe is Del Monte's CBI and prepare a detailed, written justification to support protection of the designated information as CBI. The business submitter must explain fully all grounds upon which disclosure is opposed; specifically, a business submitter must explain item-by-item why disclosure would cause substantial harm to its competitive position. Also, enclosed is a copy of our Instructions for CBI Justification.

Please note that when documents contain information that qualifies as exempt from disclosure as CBI, the entire document is not necessarily exempt. 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.

FEDERAL/VA RESEARCH FACILITIES

The APHIS FOIA office requests your opinion on which, if any, portions of the records should be redacted pursuant to the nine FOIA exemptions. It may be helpful to contact your agency's Freedom of Information office for assistance in processing this consultation as they are responsible for making release determinations on your agency's records. APHIS facilities my contact APHIS FOIA office at (301) 851-4046 for assistance. Please include in your submissions a written justification to support your recommendations.

RESPONDING TO THIS NOTICE

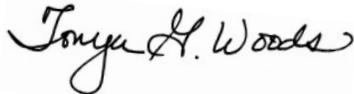
We appreciate receiving your response to this notice no later than **12pm on January 2, 2017**. Please be advised that APHIS will be operating under strict time constraints during this project, and will not be able to grant extensions.

If your organization does not object to disclosure of this information, please notify APHIS of this position in writing using the final page of this letter or send an email to glendora.gilchrist@aphis.usda.gov which states that you have reviewed the material and have no objection to its release pursuant to the FOIA. If you do not respond to this notice, we will assume that you have no objections to the disclosure of the information and will proceed accordingly.

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.

To assist us in reviewing your response, please provide the name and contact information of the individual responsible for reviewing our final determination in your correspondence. To further assist us in our review, include your facility name and registration number on all documents and correspondence. Finally, your response must be sent to the address above as the AC staff will not be responsible for forwarding your responses to the FOIA office. If you have any questions, you may call the APHIS FOIA office at (301) 851-4102 and ask to speak with the 2016 AR Coordinator.

Sincerely,

A handwritten signature in cursive script that reads "Tonya G. Woods".

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

Enclosures:

1. Executive Order (E.O.) 12600
2. Instructions for CBI Justification

To:	2016 AR Coordinator	Facility Contact:
Facility Name:		Facility Reg. No.:
Facility Fax:		No. of Pages:
Facility Phone:		Date:

NO OBJECTIONS RESPONSE

We have no objections to the release of our AR Attachments as received and do not intend to seek judicial review to bar release of these documents.

REDACTIONS PURSUANT TO EXEMPTION 4 REQUESTED

We have objections to the release of our AR Attachments as received and ask that you consider the enclosed justification statement and suggested redactions.

COMMENTS

Signature

Date

Print Name (if different from above)

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.

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The U.S. National Archives and Records Administration

1-86-NARA-NARA or 1-866-272-6272

INSTRUCTIONS FOR CONFIDENTIAL BUSINESS INFORMATION (CBI) JUSTIFICATION

The APHIS FOIA Office will make a decision as to whether information is confidential business information, or “CBI”, protected from public disclosure under Exemption 4 of FOIA. In order to protect information from public disclosure as CBI, 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, Exemption 4 permits APHIS to withhold CBI, the disclosure of which is likely to cause substantial competitive harm.

In conjunction with your review of records for CBI, please designate information you believe is CBI and, in accordance with the instructions below, prepare a detailed written justification to support protection of the designated information. Please explain fully all grounds upon which disclosure is opposed; specifically, a business submitter must explain item-by-item why disclosure would cause substantial harm to its competitive position.

Your written justification should respond to the instructions set forth below and be provided in a format corresponding to each of the below headings.

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 12,600.

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

C. Categorize like pieces of information designated as CBI (gene description, bacterin strain, production/research methods, testing results, financial information, cooperators, etc.).

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; and

3. The specific competitive harm (e.g., financial, research & development, etc.) that could result if the information is released. This is 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. Documents

You must provide APHIS a copy of all pages on which you have identified information as CBI. When records contain information that qualifies as exempt from disclosure as CBI, the entire record is not necessarily exempt. FOIA specifically provides that any reasonably segregable portions of a record must be provided to a requester after deletion of the portions that are exempt. For that reason, please designate the **exact portion** of each page you believe contains CBI.

Information can be designated by drawing a box around it or underlining it if you are sending your submission by facsimile or email. Please use a writing instrument that is capable of drawing a dark heavy line to ensure your redactions can be seen. The underlined/boxed information must be visible through the markings. If sending by mail, you may highlight the information or use one of the methods previously listed.

V. 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.

VI. Additional Help

For assistance in preparing your response or for more information regarding this process, please consult the following resources:

- A. Freedom of Information Act, 5 U.S.C. § 552
- B. Handling Information from a Private Business, 7 C.F.R. 1.12 (copy enclosed)
- C. U.S. Department of Justice's Guide to the FOIA at <http://www.justice.gov/oip/doj-guide-freedom-information-act-0>
- D. Executive Order 12,600- Predisclosure Notification Procedures for Confidential Commercial Information (copy enclosed)

E. Obtain the advice of counsel to ensure you provide the level of detail required to support any Exemption 4 assertions