

Policy Statement on the Protection of Privileged or Confidential Business Information

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Animal and Plant Health Inspection Service
(Docket No. 85-406)

This notice sets forth in full a document establishing the policy of the Animal and Plant Health Inspection Service for protecting certain privileged or confidential business information. This document reads as follows:

APHIS POLICY STATEMENT ON THE PROTECTION OF PRIVILEGED OR CONFIDENTIAL BUSINESS INFORMATION

I. Purpose

The purpose of this policy statement is to establish minimum requirements to control and protect documents received by the Animal and Plant Health Inspection Service (APHIS) that in its judgement contain privileged or confidential business information (CBI), as defined in section IV-E. of this policy statement, concerning biotechnology and the Veterinary Biologics Program..

II. Policy

Title 7, Code of Federal Regulations, sections 1.1-1.16 contain the regulations of the United States Department of Agriculture (USDA) implementing the Freedom of Information Act (FOIA) (5 U.S.C. 552). The FOIA generally provides that federal agencies must make available to the public all records not specifically exempt from disclosure. Section (b) (4) of the FOIA exempts from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. 552(b)(4). This policy statement applies to the disclosure of CBI concerning biotechnology and the Veterinary Biologics Program. APHIS will release such CBI only if disclosure is otherwise required by law, such as a specific statute or court order, by the source of the information, or as provided herein. In addition, APHIS

employees shall take whatever measures are necessary to preclude unauthorized disclosure. APHIS employees who make unauthorized disclosures of information classified as CBI can be subject to prosecution under the Trade Secrets Act, 18 U.S.C. 1905. Under this statute, a federal employee who discloses trade secrets and certain confidential data without authorization shall be fined up to \$1,000 and/or imprisoned for up to one year.

III. Applicable Statutes

Freedom of Information Act Section (b)(4), 5 U.S.C. 552(b)(4) B. Trade Secrets Act, 18 U.S.C. 1905

IV. Definitions

A. Access

The ability and opportunity to gain knowledge of Confidential business Information in any manner.

B. Administrator

The Administrator of the Animal and Plant Health Inspection Service, United States Department of Agriculture, or any other official of the Animal and Plant Health Inspection Service to whom the Administrator has delegated authority to act.

C. Authorized User

An APHIS employee or other person whom the Administrator has certified as requiring access to Confidential Business Information.

D. Biotechnology

Any technique that uses living biological systems to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses.

E. Confidential Business Information (CBI)

Information that would be protected from disclosure under section (b) (4) of the Freedom of Information Act (5 U.S.C. 552(b)(4)) will be classified as Confidential Business Information (CBI). This includes trade secrets and commercial or financial information found to be confidential.

1. Trade Secrets

Documents containing trade secrets and which the person submitting asserts are trade secrets will be deemed CBI. "Trade secrets" means information relating to the production process. This includes production data, formulas, and processes, and quality control tests and data, as well as research methodology and data generated in the development of the production process. Such information must be (1) commercially valuable, (2) used in one's business and (3) maintained in secrecy.

2. Commercial or Financial Information

Documents containing commercial or financial information will be deemed confidential if review establishes that substantial competitive harm would result from disclosure. Information such as safety data, efficacy or potency data, and environmental data may be such confidential information. Persons desiring protection for confidential information must submit a detailed statement containing facts to show that the person faces active competition in the area to which the information relates, and that substantial competitive harm would result from disclosure.

F. Destruction

Pulverization by a paper shredder, burning, or other approved method.

G. Information

Knowledge that can be communicated by any means.

H. Secured Storage Area

A room or equipment that is locked.

I. Staff Office

A staff administering a particular program within the Animal and Plant Health Inspection Service.

J. Unique Identification Number

The number permanently assigned to a document containing CBI when the document is logged in, and which enables the document to be tracked. Each document containing CBI will be assigned a separate number.

V. Identification of Confidential Business Information

A. The applicable staff office shall review documents it receives to determine whether they contain Confidential Business Information.

B. The applicable staff office shall log in Confidential Business Information it receives, and shall assign unique identification numbers to allow for tracking.

C. A red cover sheet printed with the unique identification number shall be attached to the original and each copy of a CBI document.

D. In addition to the cover sheet, each page of each copy of a CBI document shall be stamped "CONFIDENTIAL".

E. A record of each copy of a CBI document and its disposition shall be maintained.

VI. Physical Security of Confidential Business Information

A. Storage of CBI Documents

1. CBI documents are to be stored in secured storage areas when not in use.

2. At the close of a business day, doors in secured work areas shall be locked, alarms activated if appropriate, and documents containing CBI in unsecured work areas shall be placed in secured storage.

B. Access To CBI Documents By Authorized Users

1. The APHIS Administrator's office will maintain a list of persons authorized to have access to Confidential Business Information, and will furnish this list to staff office supervisors.
2. Persons will receive training on safeguarding CBI before obtaining authorized user status.
3. Authorized users shall obtain CBI documents through a person in each applicable staff office designated to be responsible for document control.
4. Requestors must present identification when obtaining CBI material from the applicable staff office. The requestor's name must appear on the authorized user list.
5. For each person on the authorized user list, a charge-out record will be kept. Requestors shall sign the record when receiving and returning CBI documents.
6. Person who terminates USDA employment will not receive exit clearance until all CBI documents that were charged out to the employee have been returned.
7. When an authorized user no longer requires access to CBI, the locks to which the person has had access must be changed.

C. Safeguards During Individual Use of CBI Documents

1. All CBI documents must be handled by authorized personnel only.
2. Authorized users shall not in any manner disclose Confidential Business Information to unauthorized persons. Authorized users shall determine whether persons are authorized to have access to CBI before discussing CBI with them.
3. When unauthorized persons are present, CBI documents must be covered, turned face down, removed from the area, or otherwise protected.
4. All persons are individually responsible for securing any CBI documents in their possession. When persons are reviewing or processing documents containing CBI, the documents are their responsibility until they are returned to the staff person responsible for document control. Persons handling CBI documents must secure them before leaving their work area.
5. Where working areas cannot provide privacy, private meeting areas will be provided

for review of CBI documents.

6. Each person must safeguard keys to files, safes, rooms, etc. Keys to CBI files must be kept in a secured place. Lost keys or suspected breaches of security must be reported immediately to the person responsible for document control, so that changes can be immediately effected.

D. Meetings

Precautions shall be taken so that unauthorized persons are not present at meetings where CBI is discussed.

VII. Copying and Destruction

A. Photocopying

1. Reproduction of documents containing Confidential Business Information shall be kept to a minimum.
2. A record of each copy of a CBI document and its disposition shall be maintained.
3. Bad copies shall be destroyed.

B. Destruction

1. The person responsible for document control in each applicable staff office shall keep records of copies of CBI documents and their disposition.
2. The person responsible for document control shall perform any destruction of documents containing CBI.
3. When users of CBI documents have no further need for them, they shall return CBI documents to the staff office from which they obtained them. Unneeded copies will be destroyed in the staff office.

VIII. Transfer of Confidential Business Information

A. Within APHIS

1. The applicable staff office shall assign unique identification numbers to CBI documents it receives. Copies to be sent to field offices or laboratories shall also be marked with the unique identification number.
2. All transfers of CBI materials within APHIS shall be recorded by the person responsible for document control in each applicable staff office.
3. All CBI documents transferred to field offices, laboratories, or other parts of APHIS

must be logged in and out by a person responsible for document control in that office.

(a) Incoming CBI documents will be entered in the log, using the previously assigned unique identification number printed on the cover sheet. The date of receipt will be recorded.

(b) Documents will then be filed in secured file cabinets.

4. Field offices and laboratories shall maintain security procedures equivalent to those described in this document. Field offices and laboratories shall be responsible for tracking and disposition of the CBI documents in their files.

B. From APHIS to Other Parts of USDA, Other Federal Agencies, and Other Persons

1. Persons from outside of APHIS must show that they need Confidential Business Information for a proper official purpose.

2. Persons from outside of APHIS must maintain security procedures equivalent to those of APHIS before they may receive Confidential Business Information.

3. The person submitting the CBI will be notified of any requests by the public for disclosure and the scope of information to be disclosed, if any.

C. Mail

CBI documents shall be transmitted by registered mail, return receipt requested.

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Dated: September 18, 1985.

Bert W. Hawkins,

Administrator Animal and Plant Health Inspection Service. (FR Doc. 85-22715 Filed 9-20-85; 8:45 am)

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Legal Publications:

Pub. Law 90-23 -- Freedom of Information Act, Amendment (6/5/67)

Pub. Law 80-772 -- Crimes and Criminal Procedure, Title 18 U.S.C., Enactment (Act of 6/25/48); Trade Secrets Act (Act of 6/25/48)

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