Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

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Guide for Claiming Confidential Business Information (CBI) in Submission to APHIS BRS

The information contained in this document is intended solely as guidance. Except where noted, persons may choose to follow APHIS guidance or follow different procedures, practices, or protocols that meet applicable statutes and regulations.

Language implying that guidance is mandatory (e.g., "shall," "must," "required," or "requirement") should not be construed as binding unless the terms are used to refer to a statutory or regulatory requirement.

Following the guidance contained in this document should not be construed as a guarantee of compliance with applicable statutes and regulations.

Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
United States Department of Agriculture

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GUIDE INFORMATION

ISSUING AGENCY/OFFICE:	Animal and Plant Health Inspection Service (APHIS)/ Biotechnology Regulatory Services (BRS)
TITLE OF DOCUMENT:	Guide for Claiming Confidential Business Information (CBI) in Submission to APHIS BRS
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REPLACES:	Guidance for Confidential Business Information Guidance Instructions issued on December 20, 2021
SUMMARY:	This guide assists the public with submitting documents to APHIS BRS by describing formatting and justification procedures for indicating CBI.
DISCLAIMER:	The contents of this document do not have the force and effectof law and are not meant to bind the public in any way. This document isintended only to provide clarity to the public regarding existing requirements under the law or agency regulations.

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INTRODUCTION TO UNDERSTANDING CONFIDENTIAL BUSINESS INFORMATION

All documents submitted to APHIS' Biotechnology Regulatory Services (BRS) are subject to the Freedom of Information Act (FOIA) 5 U.S.C. § 552, which requires federal agencies to provide the public with access to information. BRS provides the public with access to information in response to requests submitted through the APHIS FOIA office and by publishing subsets of information on the BRS website. When providing such access, BRS considers section (b)(4) of the FOIA, which exempts from disclosure certain types of information that are customarily kept as confidential by the business submitter. BRS follows USDA regulations (7 CFR §§ 1.8, 340.7) and Executive Order 12600 in ensuring submitters have the opportunity to claim Confidential Business Information (CBI), consistent with federal law.

Examples of information BRS publishes on the APHIS BRS website include:

- Am I Regulated requests seeking to determine whether a modified organism meets the definition of "regulated article" in 7 CFR part 340.
- Petitions seeking a determination of nonregulated status for a plant developed using genetic engineering.

WHAT IS CBI?

Section (b)(4) of the Freedom of Information Act (also known as Exemption 4) protects (or exempts) from disclosure information that comprises "trade secrets and commercial or financial information obtained from a person and privileged or confidential." BRS refers to this type of information as CBI. BRS follows Department of Justice guidance when analyzing CBI claims.

When a submitter provides BRS with information and seeks to claim some portions of it as CBI, information is deemed CBI if the submitter demonstrates that the information is customarily and actually kept private or closely held, in the context of industry practices concerning the information.[1]

Information that is often justified as CBI in submissions to BRS includes:

- Genotypes, phenotypes (also known as phenotype descriptions), donor organisms, gene or genetic sequence names, gene descriptions, and transformation methods in permits
- Points of origin and destination such as location name and description, and address and contacts (except for County and State names)
- Name, location, and contact information of suppliers or developers of plants or organisms developed using genetic engineering (except for County and State names)
- Detailed descriptions of the country (or countries) and locality (or localities) where the organisms were collected, developed, manufactured, reared, cultivated, and cultured (as applicable)
- Field test location sites such as cities, zip codes, and descriptions (except for County and State names)
- Acreage location (descriptions, drawings, maps, addresses, and GPS coordinates)
- Release site history if it reveals the location (e.g., describing a location as being next to a known landmark) acreage and Material Quantities

[1] See *Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356 (2019).

- Individuals who are connected to a field test site location
- Contractual information between the submitter and a cooperator
- Literature references that describe CBI
- Novel methods, processes, procedures, or safeguards
- Novel design protocols/production design/standard operating procedures
- Novel destruction/devitalization methods
- Novel species names of soil microbial biocontrol agents or pests/diseases

Information that does not typically qualify as CBI in submission to BRS (and, thus, is typically released publicly) includes:

- Information published or otherwise publicly available may not be claimed as confidential or CBI
- Common plant, pest, or pathogen names for which many authorizations have been issued
- Trait (e.g., "Herbicide Resistance," "Product Quality," etc.)
- County and State names found anywhere in documentation
- Field test or other location site codes/coded location identifiers, and other reference numbers not distinguishable outside of the submitter's business
- BRS assigned numbers
- Release site history that does not reveal the location
- Critical habitat specific site locations
- Applicant information submitted to eFile: Applicant's name, position, organization, organization unique identification name or number, full address including number and street, county/providence, township or island, zip codes, country, day telephone, fax, email addresses, and any alternate information. Note that this information is found in Block 1 of an eFile application.*
- Responsible person(s)/entity names
- Signatures of responsible person(s)*
- Document or table headings
- Most literature references
- Commercialized or widely known production methods, processes, or procedures
- Plant names/organism names along with general descriptions of the plant or organism
- Plant traits
- For Petitions and Am I Regulated requests, in addition to the above:
  - General descriptions of the phenotype for plants developed using genetic
  - Identifying line names
  - Submitter's individual names/phone numbers/addresses/email address/fax number(s)

Note that these are not exhaustive lists. BRS will review each claim of confidentiality and will discuss with the submitter any claims that do not meet the criteria for CBI. BRS encourages submitters to release genotypic, phenotypic, and any lab and field data submitted to support the Petition process to facilitate public understanding and comment on APHIS reviews. BRS will not remove redacted areas from submitter documents but will make phenotypic information publicly available in tables that appear on the BRS website.

**Although some information is not eligible for withholding as CBI, it may qualify for protection as Personally Identifiable Information (PII) under FOIA Section 6(b)(6), such as the signatures of responsible persons.*

CBI JUSTIFICATION

All claims of CBI must include a CBI justification, and such claims expire 10 years after the date of the submission unless the submitter requests and provides justification that supports a longer designation period.

CBI justifications must be detailed enough to demonstrate that each piece of information claimed as CBI is customarily kept private or closely held, in the context of industry practices concerning the information. Information is not protected from disclosure simply because the submitter does not want the information to be made public. The language used to prepare your CBI justification should be in non-technical terms when possible and should not reveal any information marked as confidential.

When evaluating CBI claims, BRS considers the factors outlined in the Department of Justice's guidance, the submitter's previous document submissions and CBI claims (if any), and publicly available information. BRS will consult with the APHIS FOIA Office as necessary when considering CBI claims and the release of submitted information.

DOCUMENT PREPARATION AND SUBMISSION

If a document intended for submission to BRS **does not contain CBI**, only submit **one copy**. The document should be **clearly marked "No CBI" in the upper right corner of the first page.**

If a document intended for submission to BRS **contains information the submitter claims as CBI**, the submitter must **submit two versions** of the document along with the justification: a **complete version containing CBI** (the "CBI Copy"), and an **edited version with the CBI redacted** (the "CBI-deleted Copy").

- Each page of a document containing CBI must have "CBI Copy" marked in the upper right corner
- Each page of a CBI-redacted document must have "CBI-deleted Copy" marked in the upper right corner
- In a document containing CBI, mark with square brackets ("[ ]") only the specific words, phrases or sentences claimed as CBI, and in the right margin for each set of brackets write "CBI"
- In the CBI-deleted version, replace with blank spaces the words or phrases marked in the CBI version, mark the spaces with square brackets, and in the right margin for each set of brackets write "CBI-deleted"
- The CBI-deleted version should be identical to the CBI version, except blank spaces surrounded by square brackets occurring in the text where the CBI text has been redacted and "CBI-deleted Copy" should appear in the upper right corner of each page instead of "CBI Copy"
- The CBI-deleted version must be paginated identically to the CBI copy and should be made directly from the same document that originally contained CBI
- Do not insert additional text (transitions, paraphrasing, or generic substitutions, etc.) into the spaces of the CBI-deleted version
- All published references that appear in the reference list of a CBI copy should be included in the reference list of the CBI-deleted copy

VERSION HISTORY

February 7, 2025	Updated version to align with original biotechnology regulations.
December 20, 2021	First published version of Guide for Claiming Confidential Business Information (CBI) in Submission to APHIS BRS.

CBI

Each page should denote that the document contains CBI

SAMPLE LETTER 1: CONTAINS CBI

Company Letterhead

Bernadette Juarez
U.S. Department of Agriculture
APHIS Deputy Administrator
Biotechnology Regulatory Services

Dear Ms. Juarez,

The following example document demonstrates proper formatting and composition of submissions containing Confidential Business Information (CBI) to Biotechnology Regulatory Services (BRS). Arranging content in this way ensures clarity and protection for an institution's CBI data.

This sentence gives background on the purpose of the communication without disclosing novel business methods, practices, or data. This sentence names and describes [specific genotypes, phenotypes, donor organisms, gene names, gene descriptions and transformation methods] to provide BRS with context needed for a decision or response. Square brackets should surround the CBI data to denote its sensitivity. CBI CBI

Publicly available information is not eligible to be claimed as CBI. However, [trade secrets and information that is customarily kept private by the submitter] may be claimed with the proper justification. This justification letter should be submitted along with the request and should detail each category of information that was claimed, without revealing the data itself. A CBI deleted copy of the document should also be provided along with the submission. CBI CBI

For example, if [Gene ABC] is CBI and used in transformation of the organism, [Gene ABC] should be surrounded by brackets and not visible anywhere in the CBI deleted copy of the document. In the justification document, a submitter should explain how the information is customarily kept private by the submitter without revealing the actual information that was enclosed in square brackets. CBI

For proper formatting of CBI Deleted or No CBI materials, please see the following pages.

Sincerely,

Your name
Your title
Your address
Your phone
Your email address

Contact Info is not considered CBI but may be protected as Personally Identifiable Information (PII), if requested

CBI Del

Each page should denote that the document is CBI deleted

SAMPLE LETTER 2: CBI DELETE

Company Letterhead

Bernadette Juarez
U.S. Department of Agriculture
APHIS Deputy Administrator
Biotechnology Regulatory Services

Dear Ms. Juarez,

The following example document demonstrates proper formatting and composition of CBI Deleted documents that must be included with CBI submissions to Biotechnology Regulatory Services (BRS). This document should be identical to the confidential copy, but have all CBI replaced with blank space.

This sentence gives background on the purpose of the communication without disclosing novel business methods, practices, or data. This sentence names and describes [CBI Del
] to provide BRS with context needed for a decision or response. Square brackets should CBI Del
surround the CBI data to denote its sensitivity.

Publicly available information is not eligible to be claimed as CBI. However, [CBI Del
] may be claimed with the proper justification. This justification letter should be submitted along CBI Del
with the request and should detail each category of information that was claimed, without revealing the data itself.
A CBI deleted copy of the document should also be provided along with the submission.

For example, if [ ] is CBI and used in transformation of the organism, [ ] should be surrounded CBI Del
by brackets and not visible anywhere in the CBI deleted copy of the document. In
the justification document, a submitter should explain how the information is customarily kept private by the submitter without revealing the actual information that was enclosed in square brackets.

For proper formatting of CBI documents, please see the previous page. A No CBI example follows.

Sincerely,

Your name
Your title
Your address
Your phone
Your email address

Contact info is not considered CBI but may be protected as Personally Identifiable Information (PII), if requested

No CBI

First page denotes No CBI is contained in the document

SAMPLE LETTER 3: DOES NOT CONTAIN CBI

Company Letterhead

Bernadette Juarez
U.S. Department of Agriculture
APHIS Deputy Administrator
Biotechnology Regulatory Services

Dear Ms. Juarez,

The following example document demonstrates proper formatting and composition of submissions that do not contain Confidential Business Information to Biotechnology Regulatory Services (BRS). Arranging content in this way ensures clarity that the document does not contain sensitive CBI data.

This sentence gives background on the purpose of the communication to provide BRS with context needed for a decision or response. Square brackets should not be included anywhere in the document.

No CBI should be in this document. A justification document is not required with the submission, and no CBI-deleted copy is necessary.

For example, if Gene ABC is not considered to be novel, proprietary, or secret, Gene ABC should not be surrounded by brackets. Regardless of whether a document is marked as containing CBI, BRS and APHIS FOIA routinely allow submitters to conduct a "Requestor CBI" review prior to any public disclosure of the materials. Submitters have a second opportunity to review the document for justifiable claims of CBI at that time.

For proper formatting of CBI and CBI-deleted documents, please see the previous pages.

Sincerely,

Your name
Your title
Your address
Your phone
Your email address

Contact info is not considered CBI but may be protected as Personally Identifiable Information (PII), if requested