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Replaces:	Guidance for CONFIDENTIAL BUSINESS INFORMATION GUIDANCE INSTRUCTIONS issued on August 8, 2019
Summary:	<p>This guidance assists the public with submitting documents to USDA APHIS BRS. It provides the expected formatting and marking procedures for indicating the existence or non-existence of Confidential Business Information in the documents sent to APHIS BRS.</p> <p>https://www.aphis.usda.gov/aphis/ourfocus/biotechnology</p>
Disclaimer:	The contents of this guidance document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency regulations.



USDA-APHIS Biotechnology Regulatory Services

Guidance for Claiming Confidential Business Information (CBI) in Submission to USDA APHIS Biotechnology Regulatory Services (BRS)

v. June 18, 2020

Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
United States Department of Agriculture
4700 River Road
Riverdale, MD 20737

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

Instructions for Claiming Confidential Business Information (CBI) in Submission to USDA APHIS Biotechnology Regulatory Services (BRS)

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Introduction to Understanding Confidential Business Information

All documents are subject to the Freedom of Information Act (FOIA) 5 U.S.C. § 552, which requires that records submitted to federal agencies be made available to the public. BRS provides the public with documents it receives when formally requested through the APHIS FOIA office. Additionally, BRS publishes subsets of submitted documents online as described in this guidance.

For example:

Confirmation requests that seek to confirm regulatory status under 7 CFR part 340 will be published on our APHIS SECURE webpage in the near future.

Regulatory Status Review requests for evaluation of a plant developed using genetic engineering to determine its regulated status under 7 CFR part 340 will be published on our APHIS SECURE webpage in the near future.

Am I Regulated Letters that seek to confirm regulatory status under 7 CFR part 340 are published at: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated/regulated_article_letters_of_inquiry/regulated_article_letters_of_inquiry

Petitions for determination of non-regulated status are also posted online at: <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status>

Section (b)(4) of the FOIA, however, exempts from disclosure certain types of information related to trade secrets and commercial or financial information, collectively referred to as confidential business information (CBI). Documents submitted to BRS that contain CBI require special handling.

What is CBI?

Information that would be protected from disclosure under section (b)(4) of the FOIA is classified as CBI. This includes trade secrets and commercial or financial information found to be confidential.

A trade secret is information relating to the production process, including 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.

Commercial or financial information may be deemed confidential if review establishes that the applicant/developer faces active competition in the area to which the information relates and 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.

Information that is published or otherwise publicly available may not be claimed as CBI. BRS will review each claim of CBI and will discuss with the requestor any claims that do not meet the criteria for CBI.

If an applicant, developer, or other business submitter (collectively referred to hereafter as "submitter") believes a document to be submitted to BRS contains confidential business information, the submitter must include three documents in his/her submission:

- 1) A CBI Justification – A detailed letter justifying any CBI claims found in the document.
- 2) A CBI Copy – The document containing the CBI.
- 3) A CBI-Deleted Copy – A CBI document with all CBI deleted.

If a submitter does not intend to claim confidential business information in a document to be submitted to BRS, the submitter is only required to provide one copy of the material. These documents should be clearly marked "No CBI" in the upper right corner of the page.

CBI Justification

If a submitter believes that a document to be submitted to BRS contains confidential business information, the submitter must include a CBI Justification document justifying all claims of CBI. The CBI Justification must be detailed enough to demonstrate that each piece of information claimed as CBI meets the definitions of trade secret or commercial or financial information, as described above. Claims of CBI must be justified in terms related to competitive harm due to its release. Information is not protected from disclosure simply because the submitter does not want the information to be made public.

BRS will consult with the APHIS FOIA Office, if necessary, to make a final decision as to whether the information qualifies for protection under FOIA.

The following are examples of information often reasonably justified as CBI in submissions to BRS:

- Field Test Location Sites such as cities, zip codes and descriptions (this does not include County and State Names)
- Acreage Location (descriptions, drawings, maps, addresses and GPS coordinates)
- Acreage and Material Quantities
- Literature references that describe gene, genotype, or other area of the submission that are claimed as CBI
- Contractual information between the submitter and a cooperator
- Individuals who are connected to a field test site location
- Name, location, and contact information of suppliers or developers of plants or organisms developed using genetic engineering (except for State and County names)
- Genotypes, phenotypes, donor organisms, gene names, gene descriptions and transformation method
- Points of Origin and Destination such as location name and description, and address and contacts (except for State and County Names)
- Release Site History if it reveals a description of the location
- Detailed descriptions of locations where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced
- Novel methods, processes, procedures or safeguards
 - Novel design protocols/production design
 - Novel destruction/devitalization methods
 - Novel species names of soil microbial biocontrol agents or pests/diseases

The following kinds of information are not typically considered CBI:

- Field Test Location Site Company Codes, Reference Numbers and BRS assigned numbers
- County and State Names found anywhere in documentation
- Most literature references
- Petitions and Compliance Submissions:
 - Submitter's individual names/phone numbers/addresses/email address/fax number(s)
 - Phenotypic category (such as identifying Herbicide Resistance, Product Quality, etc.)
 - Identifying line names

- ANY information found on Block 1 of ePermits permit/notification applications
- Responsible person(s)/entity names
- Signatures of responsible person(s) names
- Critical Habitat specific site locations
- Location Site Codes/Coded location identifiers (not distinguishable outside of the submitter's business)
- Common pests and pathogens for which many permits have been issued
- Document or table headings

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

Preparation of Documents Containing CBI

If a document to be submitted 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").

- Submit Petition Documents to: BRS.Petitions@usda.gov
- Submit Confirmation Requests Documents to: ConfirmationRequests@usda.gov
- Submit Regulatory Status Review Documents to: **To be determined**
- Submit Permit and Compliance Documents within USDA APHIS online ePermits system: <https://epermits.aphis.usda.gov/epermits>
 - Note Compliance Documents may also be submitted via: BRSCompliance@usda.gov

Guidelines for Preparing CBI and CBI-Deleted Document Versions

- 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 or phrases 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 1) blank spaces surrounded by square brackets occurring in the text where the CBI text has been redacted and 2) "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. The CBI-deleted version should be made directly from the same document which 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 CBI copy should be included in the reference list of the CBI-deleted copy.

Preparation of Documents that DO NOT Contain CBI

If a document to be submitted to BRS does not contain CBI, only submit one copy. These documents should be clearly marked “No CBI” in the upper right corner of the page.

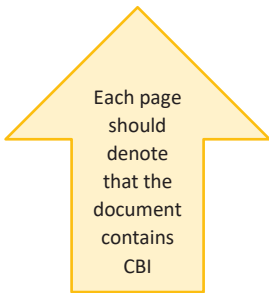
Example CBI, CBI-Deleted, and No CBI Document Formats

See Sample Letters on following pages.

Company Letterhead

CBI Copy

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



Each page
should
denote
that the
document
contains
CBI

Contains Confidential Business Information

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 commercially valuable] 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

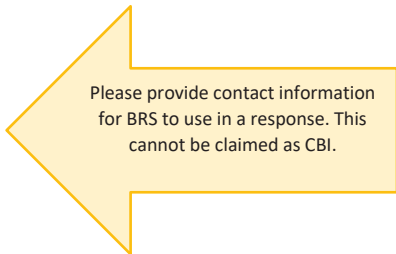
For example, if [Gene ABC] is CBI and used in transformation of the organism, [Gene ABC] should be surrounded by brackets and not visible anywhere in the CBI deleted copy of the document. In the justification document, a submitter may describe why disclosure of genomic information is competitively or financially harmful without revealing the actual information that was enclosed in square brackets.

CBI, 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

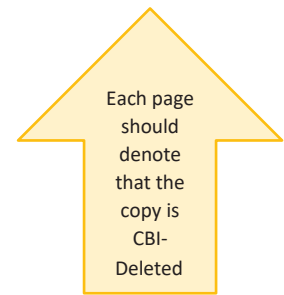


Please provide contact information
for BRS to use in a response. This
cannot be claimed as CBI.

Company Letterhead

CBI Deleted Copy

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



Confidential Business Information Deleted

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 [] to provide BRS with context needed for a decision or response. Square brackets should surround the CBI data to denote its sensitivity.

CBI-Deleted
CBI-Deleted

Publicly available information is not eligible to be claimed as CBI. However, [] 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-Deleted
CBI-Deleted

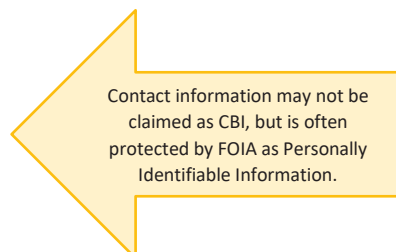
For example, if [] is CBI and used in transformation of the organism, [] should be surrounded by brackets and not visible anywhere in the CBI deleted copy of the document. In the justification document, a submitter may describe why disclosure of genomic information is competitively or financially harmful without revealing the actual information that was enclosed in square brackets.

CBI-Deleted,
CBI-Deleted

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

Sincerely,

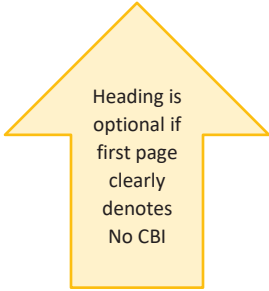
Your Name
Your Title
Your Address
Your Phone
Your Email



Company Letterhead

No CBI

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



Heading is optional if first page clearly denotes No CBI

Does Not Contain Confidential Business Information

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 without disclosing novel business methods, practices, or data. This sentence names and describes information (that the institution does not consider financially harmful) to provide BRS with context needed for a decision or response. Square brackets should not be included anywhere in the document.

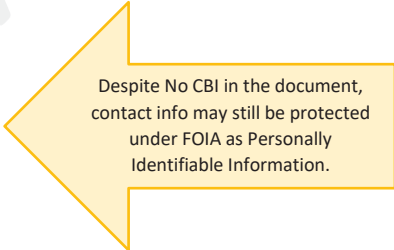
No information in this document should be considered CBI. A justification document is not required with the submission, and no CBI-deleted copy is necessary.

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 “Second Bite of the Apple” 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



Despite No CBI in the document, contact info may still be protected under FOIA as Personally Identifiable Information.