



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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Investigation and Processing of Alleged Violations of the Virus-Serum-Toxin Act

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Notes:

Investigation Methods and Processing of Alleged Violations of the Virus-Serum-Toxin Act

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1. Purpose and Scope

This document describes the responsibilities, duties and associated methods to conduct and process a Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) Veterinary Biologics Investigation (VBI). Veterinary Services Memorandum 800.1 (*Responsibilities and Authorities for the Veterinary Biologics Program*) delegates authority to the IC Director to direct investigations of the Virus-Serum-Toxin Act (VSTA) and regulations (title 9, Code of Federal Regulations [9 CFR], parts 101-121).

2. Investigative Responsibilities

2.1 Center for Veterinary Biologics-Inspection and Compliance

Inspection and Compliance (IC) is responsible for investigating alleged violations of the VSTA or the 9 CFR regulations. In addition, the IC Director may request the assistance of the Regional Director, Investigative and Enforcement Services, Animal and Plant Health Inspection Service (APHIS), in the investigation of alleged violations of the VSTA and regulations. For investigations of violations of the VSTA or regulations by unlicensed entities, IC is responsible for monitoring and coordinating these investigations.

2.2 The Regional Director/Investigation and Enforcement Services (RD/IES)

IC may request support from the RD/IES where the alleged violation occurred to support or conduct investigations of unlicensed or licensed manufacturers. IC will provide technical and investigative support to IES as appropriate. In addition, IC may request RD/IES assistance for investigations involving a licensed product that has allegedly been illegally handled by an unlicensed person or business. All IES interaction will be discussed with the IC Director for prior to any action taken.

2.3 Center for Veterinary Biologics-Policy, Evaluation, and Licensing

CVB-Policy, Evaluation, and Licensing (PEL) may assist IC and IES in investigations. All PEL interactions with IES need to go through IC.

3. Violations

Investigation of alleged violations of the VSTA involving veterinary biologics can be divided into two categories.

3.1 Violation of the VSTA by an unlicensed entity

This is the preparation, selling, bartering, exchanging or shipping of a product portrayed as a veterinary biologic that has not been federally licensed or approved by the Administrator. The violation also includes the importation of an unlicensed product portrayed as a veterinary biologic, or the adulteration of licensed product.

3.2 Violation of the VSTA or the promulgated regulations by a licensed entity

This is the act of a person, firm or corporation that violates the VSTA or the promulgated regulations in the 9 CFR, parts 101 through 118.

The following are examples of some typical, but not all, violations which may require investigation:

- Distribution of known defective product
- Shipment or advertising of an unlicensed veterinary biologic
- Importation of any biological product without a permit
- Use of an unauthorized premises for any step in production of a licensed product
- Falsification of production or test records of a licensed product
- False or misleading advertising for a veterinary biological product
- False labeling or adulteration of labels
- Lack of protection after Rabies Vaccine administration

4. Procedures

When aware of a violation, IC is responsible for initiating the process, and when necessary, involving IES.

4.1 IC Director Responsibilities

The IC Director has delegated responsibilities associated with investigations of alleged violations of the VSTA to the Compliance Section Leader.

The IC Director:

- Assures that proper disposition of all investigations are accomplished.
- Will maintain a current list of all CVB personnel trained in the affidavit process.
- May sign or delegate signing of an APHIS Form 7060, *Official Warning, Violation of Federal Regulations*.

4.2 Compliance Section Leader Responsibilities

The Compliance Section Leader:

- Reviews all investigations when opened and when closed for completeness.
- Reviews all proposed regulatory actions to assure that actions taken are appropriate and in accord with all applicable regulations.
- Coordinates all investigations and recommends cases for prosecution.
- Acts as a liaison with the IES, the Office of General Counsel (OGC) and the Department of Justice (DOJ) on case development and litigation.
- Provides assistance and guidance to IES personnel and assigned investigation lead.
- Provides summary reports on all investigations to the IC Director as required.
- Authorize “Controlled Buy” to obtain evidence

4.3 Investigation Manager Responsibilities

The Investigation Manager:

- Assists the Compliance Section Leader and Investigation lead in investigations.
- Provides assistance and guidance to IES personnel and assigned investigation lead.
- Provides summary reports on all investigations to the IC Director or Compliance Section Leader as required.
- Serves role as a delegated authority.

4.4 Investigation and Compliance Specialist (ICS) Responsibilities

The ICS:

- Sets up the investigation case files.
- Administrative support for the investigation database (LSRTIS).
- Assists in investigations as requested.
- Administrative support for physical evidence Chain of Custody
- Executes record retention on physical investigation files according to Disposal Authority NC1-310-77-2
- Conducts administrative reviews of investigations to ensure completeness and proper disposition.

4.5 Assigned Investigation Lead Responsibilities

The assigned Investigation Lead:

- May be a Biologics Specialist, Manager, Epidemiologist or Section Leader
- Maintains a current investigation file within a Chain of Custody.
- Forwards information to PEL on alleged violations of advertising or labels for PEL advice and consultation.
- Reviews the evidence and reports submitted concerning the investigation.
- Consults with PEL and other Veterinary Services personnel and requests CVB testing as required.
- Prepares investigation summaries.
- Prepares the closing memorandum and submits with recommended disposition to the IC Director after review by the Compliance Section Leader.
- Only discusses information regarding the investigation with those individuals on a need to know basis.

5. Processing an Investigation

Upon receipt of the alleged violation, the information is given to the Compliance Section Leader, or the Investigation Manager, who:

- Reviews the violation for validity.
- Assigns a unique number to the investigation.
- Assigns the VBI to an Investigation Lead.
- Sends notification that a VBI was opened to CVB Directors, Compliance Section Leader, Investigation Lead and ICS.

Special Considerations for Anonymity

When IC receives information on a possible violation from a second party (i.e., whistle blower, competitor, etc.) the following steps are taken:

- The Compliance Section Leader or Investigation Manager is notified as soon as possible.
- An acknowledgement letter, drafted by the Investigation Lead, is sent to the person who reported the alleged violation, expressing acknowledgement of report and our intent to investigate the matter.
- If the person requests anonymity, advise them that we have procedures to protect anonymity, but cannot guarantee anonymity.
- Such as, if the investigation develops into a court case, names cannot be withheld.
- Plainly note in the VBI folder that the person wishes to remain anonymous. This is to alert the FOIA office in the event the closed VBI is provided through a FOIA request.
- If it cannot be determined who submitted the information, and there is enough information to follow through with an investigation, the process of initiating an investigation is still performed.

6. Veterinary Biological Investigations Scope

The scope of a veterinary biological investigation is to investigate and prove or disprove a violation of the VSTA or its promulgated regulations, such as:

- Prove the product being investigated is portrayed as a veterinary biological product.

- Prove whether the product being investigated is federally licensed.
- Prove production or distribution of an unlicensed product has taken place.
- Prove importation of veterinary biological products or components thereof has taken place without prior approval and appropriate permit(s) having been issued.
- Prove a website or webpage or other advertising was used to make unlicensed or unpermitted veterinary biological products available to the United States or territories.
- Prove that unknown master seed or seed virus has been stored or used within a federally licensed facility without prior approval or authorization to do same.
- Prove that falsification of production or related records associated with a licensed product has taken place.
- Prove that a defective product produced by a licensed firm has been distributed to users.

7. Investigation Methods

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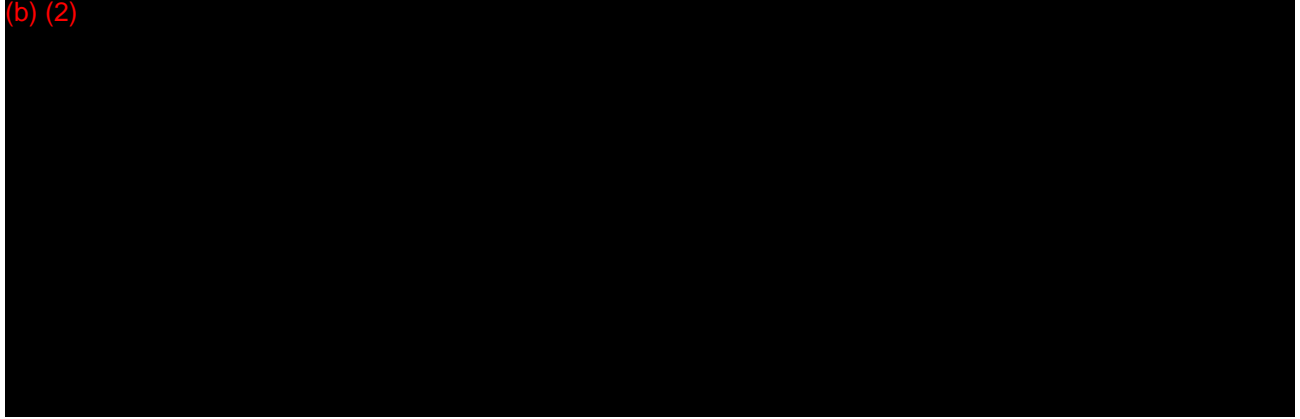


7.1 Evidence Chain of Custody

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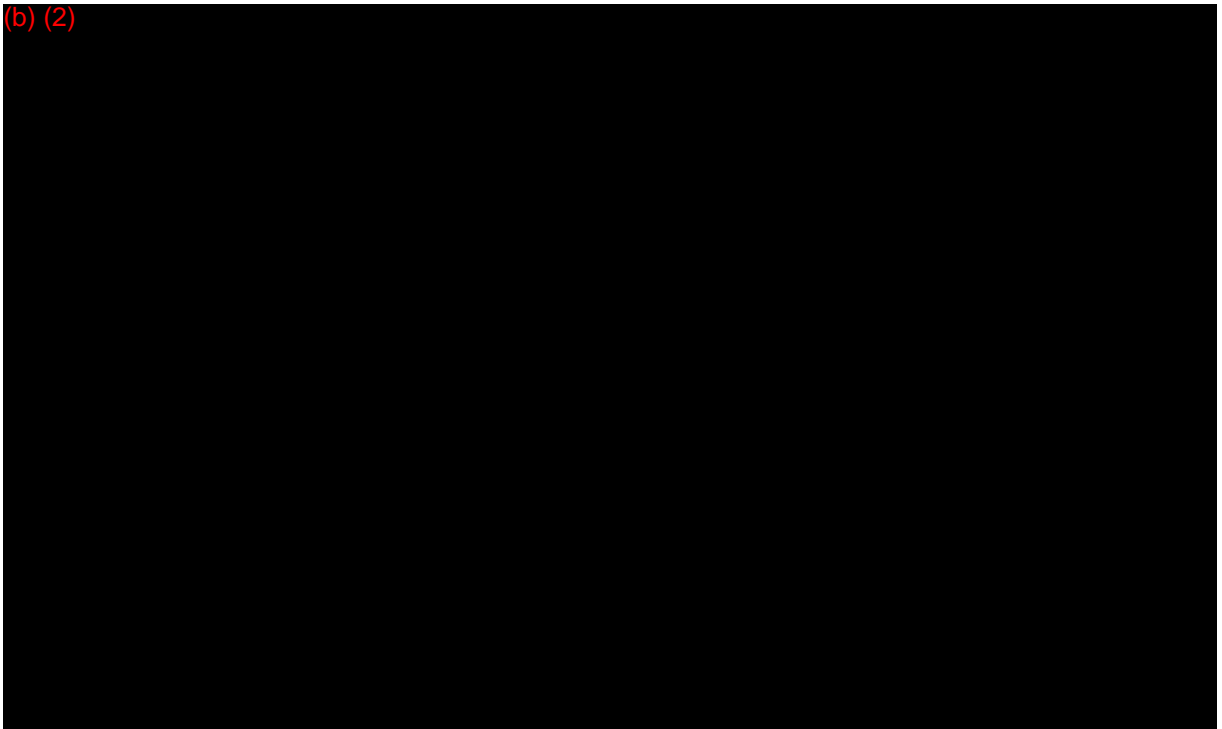
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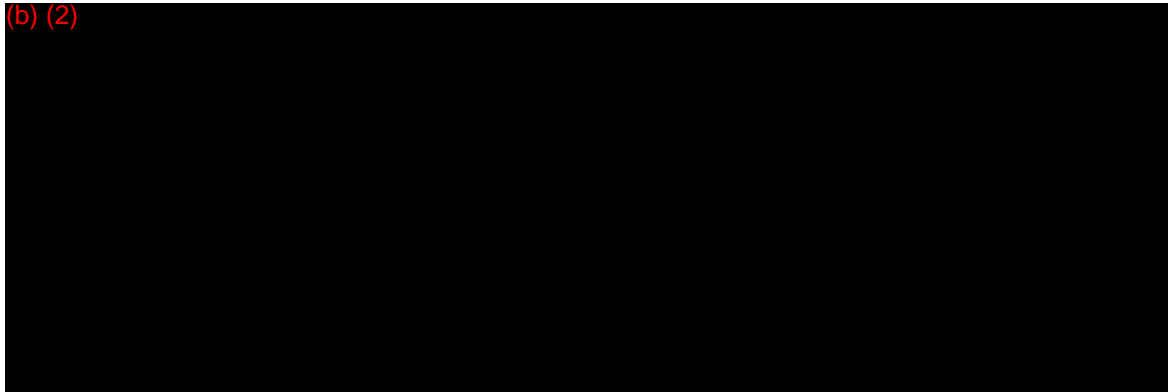
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7.2 Documentary Evidence

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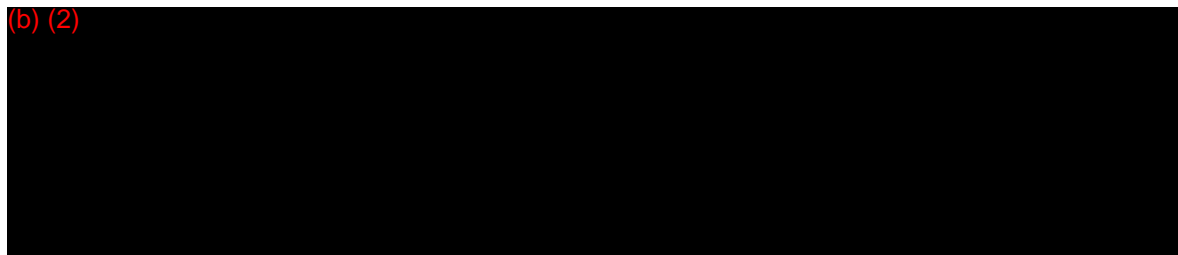
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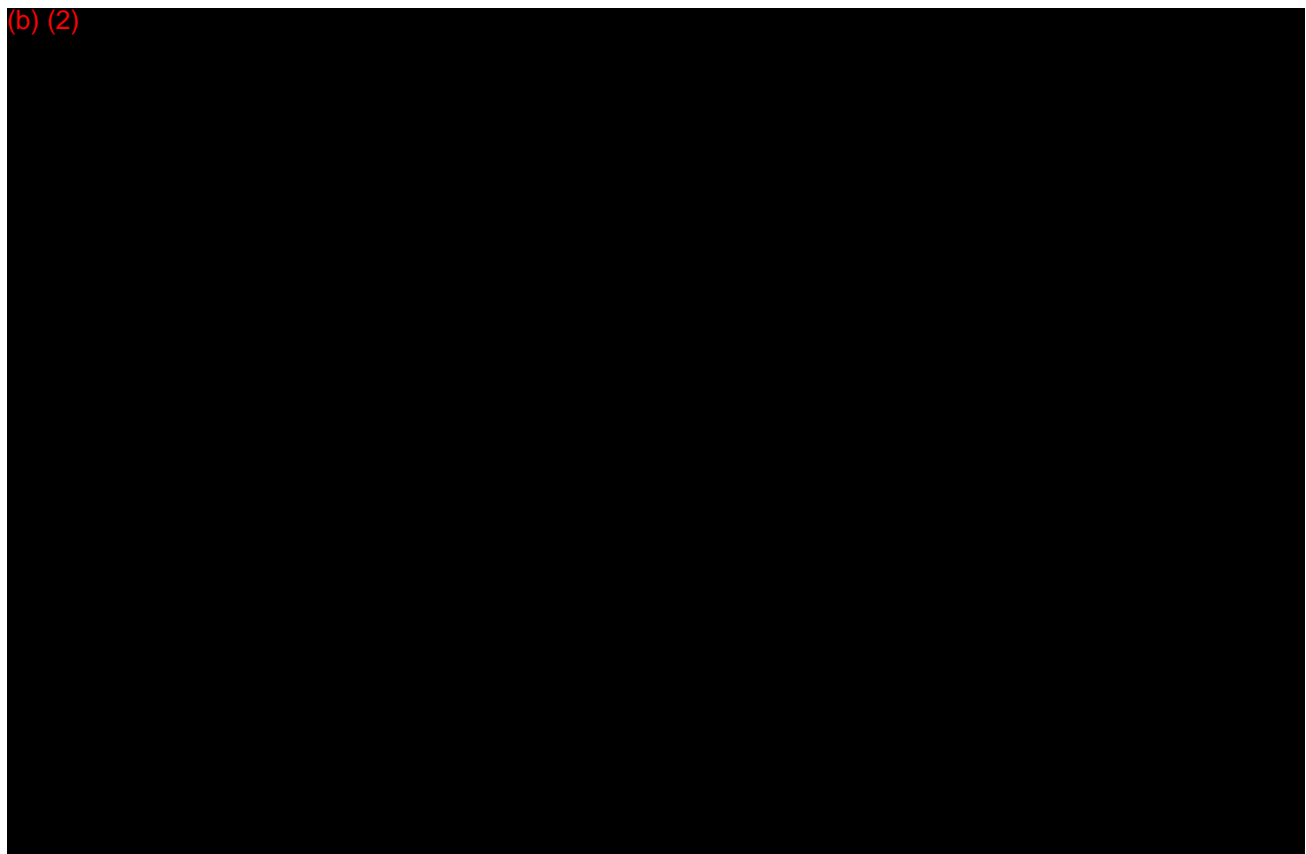
7.3 Purpose of the Investigation

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7.4 Building Evidence

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7.5 Rules of Evidence

7.5.1 Evaluating the evidence

If the results of an investigation appear to sustain the Allegation, the evidence must be obtained and presented in a manner that will stand up under the Federal Rules of Evidence (88 Stat pages 1926-1949, Public Law 93-595, 28 USC App).

7.5.2 Relevance

The evidence must relate to the matter at issue and tend to prove the alleged violation. Irrelevant facts and those that are not essential to the issue should be omitted.

7.5.3 Hearsay

"Hearsay" is secondhand information or knowledge. Hearsay testimony is usually not allowed as evidence.

7.5.4 Original Document

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7.5.5 Exclusionary Rule

In criminal proceedings, all evidence secured in violation of the U.S. Constitution is inadmissible.

7.6 Statements

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Three Divisions of a Statement

1. Introduction

Be sure the following information is given:

- The name and identity of the interviewee
- The name and identity of the interviewer
- The date and place of the interview
- That the statements are voluntary.

2. The Statement Proper

Present the facts, circumstances, or events concisely in chronological order whenever possible. Preserve the actual words the interviewee uses. The words of the interviewer may be more accurate and correct, but they may not say what the interviewee wants to say. Stress interviewee's personal knowledge of material facts.

3. Conclusion

Indicate that the interviewee has a clear understanding of the contents of the statement and of the truth and correctness of what is in the statement. Ask them to sign the statement in the presence of the interviewer. Ask for initials if they are unwilling to sign their full name. If they are unwilling to sign or initial, add a paragraph to the effect that the interviewee has read the statement and is unwilling to sign. Ask for that to be initialed.

7.7 Affidavits

An affidavit is a written statement made under oath or affirmation before a person specifically authorized to take affidavits or before a notary public. Only a person trained and authorized to obtain affidavits can perform this function.

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Warn the person making the false statements that knowingly giving false information under oath can be a commission of Section 1001 of Title 18 of the United States Code.

7.8 The Interview

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7.9 Miranda Rule

Keep in mind that the Supreme Court has indicated that a person must be informed of their constitutional rights at the point when the questioning shifts from the interrogatory to the accusatory, that is, shifts from finding facts to that of alleging a violation occurred. Investigators should have a copy of the "Statement of Rights" available for this purpose at all times. The recent interpretation indicates that the Miranda Rule applies only to the person in custody or that believes they are in custody.

"**MIRANDA RIGHTS**": "Before I ask you questions, you must understand your rights, which are: You have the right to remain silent. Anything you say can be used against you in court. You have the right to talk to a lawyer for advice before I ask you any questions, and to have him with you during questioning. If you decide to answer questions with or without a lawyer present, you will have the right to stop answering at any time."

8. Reporting the Investigation

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8.1 Common Errors

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8.2 Analysis of the Case

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8.3 The Veterinary Biologics Investigation (VBI) Report

A separate report may be required when investigators visit sites or personnel to obtain information regarding a VBI. The Report of Investigation (ROI) is filed as part of the VBI.

The ROI requires concurrence of the Compliance Section Leader and the IC Director to be finalized

The Compliance Section Leader or the IC Director may:

- Refer the case to the CVB Directors for OGC review and recommendations.
- Weigh the evidence. If insufficient, the IC Director may close the case or ask for further information and continue the investigation.
- If an apparent violation is proved, the IC Director may recommend further actions be taken by the CVB Directors, VS Deputy Administrator, APHIS Administrator, OGC, or U.S. District Court.

The ROI should minimally contain the following:

- Purpose of the investigation and the member of IC Management who authorized the investigation
- A summary of the background information
- Categories or observations
- A summary, and if applicable, recommendation

9. Options to Address Violations

Depending on the violation, several avenues may be pursued to either bring the entity into compliance with the regulations or initiate prosecution.

In any instance, the intent is to protect American Agriculture, domestic animals, the consumer and public health from any possible harm.

When reasonable, attempt to educate and work with violators so that they become compliant with the VSTA.

Actions are taken based on a preponderance of evidence, potential risk carried by the violation, demonstrated willingness of the subject to reach or maintain compliance, historical response, and regulatory flexibility.

9.1 Infraction Notice

This type of letter is used to notify a firm that holds a U.S. Veterinary Biologics Establishment License or Permit that we have evidence to support a violation of the VSTA or promulgated regulations. We inform the firm that subsequent violations of a similar nature could result in further actions by this Agency. See 9 CFR 105.2

9.2 Warning Letter

This type of letter is used when it has been determined that an entity may be producing and distributing a veterinary biologics without holding a U.S. Veterinary Biologics Establishment or Veterinary Product License. The letter's purpose is to warn the entity that it is unlawful under the VSTA for any firm to ship a veterinary biological product without have a U.S Veterinary Biologics Establishment or Veterinary Product License. The entity is directed to cease the violation and respond.

9.3 APHIS Mandated Stop Distribution and Sale

See 9 CFR 105.3 and 115.2

9.4 APHIS Form 7060, Official Warning, Violation of Federal Regulations.

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9.5 Detention, Seizure and Condemnation

See 9 CFR 118

9.6 Formal Administrative Procedures without a hearing

See 9 CFR 105.1 (b), 105.3 (a)

See 9 CFR 122.4 (b)

9.7 Formal Administrative Procedures with a hearing

See 9 CFR 105.1 (a)

See 9 CFR 114.8 (f)

See 9 CFR 122.4 (a)

9.8 Prosecuting Apparent Violations

There are two avenues of prosecution for apparent violations:

- Criminal prosecution in U.S. District Courts, as recommended by OGC.
- Formal administrative hearings before USDA Administrative Law Judges.
See 9 CFR part 123.

9.9 Criminal Proceedings

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9.9.1 Courtroom Testimony

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9.2 Courtroom Etiquette

In the courtroom or during the trial, the witness should show proper respect by dressing conservatively and behaving appropriately. The witness shall refrain from reading newspapers or files, talking or whispering to neighbors, and visiting around or changing seats. Also needs to avoid fraternization with defendant, defense attorney or defense witnesses, and be available to take witness stand when called.

When on the witness stand, it is necessary to be confident. When taking an oath, the witness shall stand erect with hand at shoulder height or placed on Bible--let clerk guide--reply to clerk in firm, clear voice, and sit erect but comfortably in witness chair.

When testifying, the witness shall:

- Give first name, middle initial and last name;
- Identify himself (herself) when asked by stating the title and full name of the Agency;
- Be truthful;
 - Do not avoid or conceal facts in answering questions which may pertain to omissions, oversights, deficiencies or failure to develop facts in investigations
 - Do not hesitate to correct mistakes

- Keep voice loud enough so judge and jury can hear, and avoid repeating questions.

The witness should ask for clarification if the questioning is not understood. Notes may be used to refresh recollection. However, once a visual display is made during testimony, defense counsel is permitted to examine such material. The investigation report should not be carried to the witness stand except after a plea of guilty or *nolo contendere*; court merely wishes to be informed.

When testifying, the witness shall be responsive, clear, and concise and shall not answer more than was called for by the question; however, the witness may ask for clarification of long questions that may actually represent several questions. The witness shall:

- avoid unnecessary minute details, and never offer OPINIONS;
- be an unprejudiced, unbiased fact finder, avoiding overemphatic statements; and
- never indicate by attitude or words any eagerness to convict the defendant.

He or she shall wait to answer the question until the court has ruled when either counsel enters an objection, and in general, shall be courteous and respectful to court, counsel and jury.

10. Closure of VBI

Official closure of an investigation is approved by the IC Director demonstrating concurrence by signing the final Report of Investigation. The date of closure will be that signature date.

11. Summary of Revisions

Version CVB-SOP-0037.02

- Alphanumeric number has changed from ICSOP0016.02 to CVB-SOP-0037.02.
- Add word “Methods” to Title name
- Remove items covered by Work Instructions
- Update and clarify roles and responsibilities
- Address use of electronic documents
- Remove references and appendixes

- Clarified sections

Version ICSOP0016.02

- The Contact information has been updated.
- 7.2: Clarification of document identification has been added.
- 9: The location of template letters has been updated.
- Appendix I: The Chronology of Events has been updated.