US Environmental Protection Agency
Office of Pesticide Programs

Office of Pesticide Programs
Microbiology Laboratory
Environmental Science Center, Ft. Meade, MD

Standard Operating Procedure for
Chain of Custody Procedures for
Antimicrobial Samples

SOP Number: COC-01-08

Date Revised: 09-19-18

SOP Number	COC-01-08
Title	Chain of Custody Procedures for Antimicrobial Samples
Scope	This SOP describes procedures used by the Microbiology Laboratory Branch for the login, storage, tracking, and disposal of antimicrobial product samples.
Application	This SOP applies to only those product samples requiring chain of custody (COC) documentation.

	Approval Date
SOP Developer:	_____ Print Name: _____
SOP Reviewer	_____ Print Name: _____
Quality Assurance Unit	_____ Print Name: _____
Branch Chief	_____ Print Name: _____
Safety, Health, and Environmental Management Office	_____ Print Name: _____

Date SOP issued:	
Controlled copy number:	
Date SOP withdrawn:	

TABLE OF CONTENTS

Contents	Page Number
1. DEFINITIONS	3
2. HEALTH AND SAFETY	3
3. PERSONNEL QUALIFICATIONS AND TRAINING	3
4. INSTRUMENT CALIBRATION	3
5. SAMPLE HANDLING AND STORAGE	3
6. QUALITY CONTROL	3
7. INTERFERENCES	3
8. NON-CONFORMING DATA	4
9. DATA MANAGEMENT	4
10. CAUTIONS	4
11. SPECIAL APPARATUS AND MATERIALS	4
12. PROCEDURE AND ANALYSIS	4
13. DATA ANALYSIS/CALCULATIONS	8
14. FORMS AND DATA SHEETS	8
15. REFERENCES	9

1. Definitions	1. Chain of Custody (COC): Formal documentation showing the full process of receipt, transfer, handling, storage, disposition, and disposal of specific antimicrobial samples. 2. Sample custodian: Trained personnel authorized to open shipping containers containing samples (including official samples and samples from sources other than official [inspector] collection, see 12.1), inspect a sample, place in and remove samples from the sample storage area, record chain-of-custody information, and return samples to the storage area. 3. Date of sample disposal: Date that the sample is removed from COC and declared as waste.
2. Health and Safety	1. The Study Director and/or lead analyst should consult the Safety Data Sheet for specific hazards associated with products. 2. Use secondary containment while storing, transporting, and handling product samples.
3. Personnel Qualifications and Training	The COC sample custodians are MLB scientists who are listed on the COC Sample Custodian Form (see Section 14, Form 8).
4. Instrument Calibration	N/A
5. Sample Handling and Storage	1. Rooms B204 and D204 at EPA's Environmental Science Center have been designated as the secured storage sites for product samples. 2. Flammable samples are stored in the locked flammable storage cabinet in room B204. All other samples are stored in room D204. 3. The temperature and relative humidity of sample storage rooms are monitored by the computer-based Environmental Monitoring and Alarm System (see SOP QC-05, Monitoring Environmental Parameters.)
6. Quality Control	1. Timely, accurate, and legible sample information recorded in ink is required on all chain-of-custody documentation.
7. Interferences	1. Insufficient COC documentation, illegible entries by the inspectors, or incorrect entries of sample identity by the inspectors may interfere with completion of the sample login process. 2. Address illegible, missing, or incorrect entries that may interfere with the completion of the sample login process by contacting the inspector for clarification. Document deficiencies. A written explanation by the inspector may be required. 3. Do not accept samples which arrive in poor condition (e.g., leaking) for analysis, and if requested, dispose of the sample following the specified

	procedures and notify the sender. Notify the Office of Enforcement and Compliance Assurance (OECA) as appropriate. 4. COC seals may become detached from samples over time due to dehydration. Inspect seal integrity quarterly (see 12.1 q).
8. Non-conforming Data	Manage non-conforming data consistent with SOP ADM-07, Non-Conformance Reports.
9. Data Management	1. Archive data consistent with SOP ADM-03, Records and Archives.
10. Cautions	1. Sample custodians must log in samples and transfer them to the storage facility in a timely manner.
11. Special Apparatus and Materials	N/A
12. Procedure and Analysis	
12.1 Sample Receipt and Log-in	a. Product samples may originate from a variety of sources (e.g., officially collected by inspector, purchased from the marketplace). Samples typically are delivered by USPS or courier to the Environmental Science Center. However, they may also be hand carried to the facility. MLB will initiate and complete COC forms for product samples as necessary. The forms will accurately reflect the sample collection and delivery scenario. See also section 12.1.j. b. For samples delivered by USPS, courier, or other delivery service, ESC loading dock personnel deliver the sample to MLB; however, only an MLB sample custodian may open the box, inspect contents, and initiate chain of custody forms. c. Loading dock personnel are required to date and initial the Shipping and Receiving Record for Disinfectant Products (see Section 14). d. Upon receipt, sample custodians inspect each shipping container for external structural damage, tampering, and evidence of leaks or spills. Document any sign of damage, tampering, leaks, or spills on the Shipping and Receiving Record for Disinfectant Products (see Section 14) and any chain-of-custody forms provided by the inspector. e. Take photographs of the shipping container, label, and contents as necessary to further document their condition.

	f. Open the shipping container to inspect the contents for leakage or damage. g. Review any COC documentation sent by an inspector, and if necessary apply signature and date of receipt. h. Review all paperwork sent by the inspector or vendor to identify any pertinent information such as lot number (see 12.2, a, xi), sample expiration date, storage conditions, etc. i. Save any packing slips as part of the official record. i. Initiate a History of Official Sample Form (EPA Form 3540-17 – see Section 14). j. For product samples hand carried into the facility, initiate chain of custody documentation beginning with the Shipping and Receiving Record for Disinfectant Products and the History of Official Sample Form. Fill out the appropriate sections of the form. i. The assumption is that the sample containers are loose and not packed in a sealed box. If they are packed in a sealed box, follow sections 12.1.d through 12.1.f. ii. Examine the individual sample containers for damage or leakage. iii. Make any relevant notations on the forms to clearly indicate that the sample was hand carried to the facility and was not shipped. iv. Save any purchase receipts, if relevant, as part of the official record. k. Place the sample container in a plastic bag, and seal. Fill out the official seal and affix to the plastic bag. l. Maintain sample collection and chain-of-custody information in the Disinfectant Product Field Chain-of-Custody Documentation from Inspector notebook. Document deficiencies in paperwork accompanying the shipment (i.e. lack of field chain-of-custody papers). m. Complete the Comprehensive Sample Log form (see Section 14). This log is stored in a notebook in room D217. Place the sample in the designated sample storage area. All samples must be stored in secondary containment. n. Prior to testing, initiate a Laboratory Chain-of-Custody Form (see

	Section 14) and a Chain-of Custody Seal Log (see Section 14). o. Fill out the Laboratory Chain-of-Custody Form whenever a product sample is removed from storage and the seal broken (also see SOP MB-22: Disinfectant Product Preparation and Sampling, section 12). Affix broken chain-of-custody seals in the Chain-of-Custody Seal Log (see Section 14). A new chain-of-custody seal is established on the sample as per the directions in the Pesticides Inspection Manual (see Section 15). p. When applicable, MLB will submit form COC-01-08_F7 to the registrant/manufacturer to document the efficacy test conditions; retain this form in the COC folder for the product. q. Inspect product samples under COC quarterly to determine the integrity of the COC seals, to inspect the sample containers for leakage, and assess samples for further retention. Replace any COC seal if it becomes compromised (e.g., torn or lack of adhesiveness) – archive the original COC seal in the seal log. Document the date of inspection, location of samples, the name of the person inspecting the samples, and findings/action items on the inspection log (see Section 14).
12.2 Filling out the History of Official Sample Form	a. Complete one form per product sample number. Follow the guidance for data entry for the specified fields listed below; fields #1-#4 are self-explanatory: i. <u>#5. DATE RECEIVED</u>: Enter the date the shipment was received by the laboratory. This date is the same as the date entered on the Shipping and Receiving Record for Disinfectant Products. ii. <u>#6. RECEIVED BY</u>: The signature of the MLB personnel responsible for receiving the shipment from the loading dock personnel is required; date of signature is also required. The individual who receives the sample may not necessarily be a sample custodian; however, a sample custodian is responsible for completing the History of Official Sample Form. Transfer of the sample from the MLB receiver to an MLB sample custodian must be documented. iii. <u>#7. RECEIVED FROM</u>: Record the name of the ESC loading dock personnel and the person who actually shipped the package to the ESC (inspector, administrative assistant).

	iv. #8. SENT VIA: Enter the name of the shipping company and type of delivery. v. #9. SAMPLE CONDITION: Record as Good or Poor; if Poor, describe the condition in detail in #15 REMARKS. vi. #10. CONDITION OF SEALS: Record as Good, Poor, or No Seals (products from sources other than official collection); if Poor, describe the condition in detail in #15 REMARKS. vii. #11. SEALED BY: Enter the name which appears on the seals (the name should also appear on inspector's chain-of-custody paperwork). viii. #12. DATE SEALED: Enter the date taken from the seals. The seal date must be the date of collection specified on the inspector's chain-of-custody paperwork. If a sample was sealed on a date other than the date of collection, contact OECA for guidance. ix. #13. PIECES RECEIVED: Enter the number of seals and the number and type of product containers per seal. x. #14. PLACE STORED: Enter the official sample storage room (B204 flammable cabinet for flammable samples or D204 for all others). xi. #15. REMARKS: Record notable items such as damaged samples, labeling clarification, special sample storage requirements, name of the sample custodian completing the History of Official Sample Form (if different from the individual in #6), and lot number. For official samples, record lot number on the History of Official Sample Form only if the inspector has recorded a lot number on his paperwork. Do not assume that codes imprinted on containers are lot numbers. If the inspector failed to record a lot number on his paperwork, the sample lot number is considered to be unknown. The inspector may be contacted for verification. For samples received from sources other than official inspector collection, the lot number may be extrapolated from the labeling, paperwork accompanying the sample, sticker affixed to bottle, etc. as long as the number recorded is clearly a lot number.
12.3 Sample Disposal	a. Consult with MLB management prior to sample disposal to ensure that all testing and client needs have been met. Process and dispose

	samples that have expired, are leaking, or are no longer required to be maintained, according to the ESC's waste disposal practices. b. For products to be disposed, remove the COC seal from the product, initial and date in the appropriate box, and affix the seal in the Chain-of-Custody Seal Log. c. Complete the "Product Disposal Information" section on the Laboratory Chain-of-Custody Form. Make an entry on the form to indicate that the sample was removed from storage room but note in the "Purpose of Removal" block that the sample was removed for disposal. d. Note the date of disposal on the Comprehensive Sample Log. e. If the sample is in a plastic bag, remove the sample and discard the bag, if not compromised. f. Once the COC paperwork is completed and the seal removed, place the sample in secondary containment in the B209 fume hood, declare it as "waste", and contact the ESC Safety, Health and Environmental Management (SHEM) manager (x52681) or facility waste contractor (x52857) to request and arrange for a waste pick up and disposal.
13. Data Analysis/ Calculations	None.
14. Forms and Data Sheets	Forms are stored separately from the SOP under the following file names: 1. Shipping and Receiving Record for Disinfectant Product Samples Form COC-01-08_F1.doc 2. History of Official Sample Form (EPA Form 3540-17) COC-01-08_F2.doc 3. Laboratory Chain-of-Custody Form COC-01-08_F3.doc 4. Chain-of-Custody Seal Log COC-01-08_F4.doc 5. Comprehensive Sample Log COC-01-08_F5.doc 6. Sample Inspection Log COC-01-08_F6.docx 7. Efficacy Test Conditions Form COC-01-08_F7.docx 8. Sample Custodians for the Laboratory COC-01-08_F8.docx

15. References	1. Pesticides Inspection Manual 2013. Electronic Link: 2013 Manual