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-01-07

Date Revised: 05-27-15

SOP Number	COC-01-07
Title	Chain of Custody Procedures for Antimicrobial Samples
Scope	This SOP describes procedures used by the Microbiology Laboratory Branch for the login, 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Date SOP withdrawn:	

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1. Definitions	1. Chain of Custody (COC): Formal documentation showing the full process of receipt, transfer, handling, disposition, and disposal of specific antimicrobial samples. 2. Product sample Custodian: Product sample custodians are authorized through training to open shipping containers containing samples (including official samples and samples from sources other than official [inspector] collection, see 10.6), inspect a sample, place and remove samples from the sample storage area, record chain-of-custody information, prepare product dilutions, and return samples to the storage area. 3. Date of sample disposal = Date that the sample is removed from chain of custody and declared as waste.
2. Health and Safety	Follow procedures specified in SOP MB-01, Laboratory Biosafety. The Study Director and/or lead analyst should consult the Material Safety Data Sheet for specific hazards associated with products.
3. Personnel Qualifications and Training	The COC sample custodians are MLB scientists, who are qualified by training to be sample custodians, and are listed on the COC Sample Custodian Form (see Section 14, Form 8). Each custodian must be trained on current COC procedures and documentation must be maintained and updated regularly.
4. Instrument Calibration	N/A
5. Sample Handling and Storage	N/A
6. Quality Control	1. Timely, accurate, and legible sample information recorded in ink is required on all chain-of-custody documentation. 2. For quality control purposes, the required information is documented on the appropriate forms.
7. Interferences	1. Insufficient chain-of-custody 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. Illegible, missing, or incorrect entries that may interfere with the completion of the sample login process are addressed by contacting the inspector for clarification. Deficiencies must be documented. A written explanation by the inspector may be required. 3. Samples which arrive in poor condition (e.g., leaking) will not be accepted for analysis. The sample is disposed of following the specified procedures

	and the sender notified. For officially-collected samples, the inspector and the Office of Enforcement and Compliance Assurance (OECA) are notified to send replacement samples. 4. COC seals may become detached over time due to dehydration and must be checked periodically to inspect their integrity.
8. Non-conforming Data	Management of non-conforming data/information will be specified in the study protocol; procedures will be consistent with SOP ADM-07, Non-Conformance Reports.
9. Data Management	1. Data will be archived consistent with SOP ADM-03, Records and Archives. 2. For a current list of sample custodians for the laboratory, see Section 14. After each addition to or deletion from the list, an updated electronic copy of the list is be filed in the shared directory with the other forms associated with this SOP.
10. Cautions	1. Condition of the primary shipping container, the product sample, and the chain-of-custody seal must be noted on the appropriate form. 2. Samples should be logged in and transferred to the storage facility as soon as possible by an official OPP Microbiology Laboratory sample custodian. 3. Sample custodians are responsible for signing out samples for testing and returning the samples to the storage area following procedures outlined in this SOP.
11. Special Apparatus and Materials	Rooms B204 and D204 at EPA's Environmental Science Center have been designated as the secured storage sites for product samples. Flammable samples are stored in the locked flammable storage cabinet in room B204. All other samples are stored in room D204. 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.)
12. Procedure and Analysis	
12.1 Sample Receipt and Log-in	a. Product samples should be shipped to the Microbiology Laboratory to the attention of Michele Cottrill, US EPA, Environmental Science Center (ESC), 701 Mapes Road, Ft. Meade, MD 20755-5350 or her delegate. b. When applicable (e.g., voluntary product submission for ATP testing), MLB will submit form COC-01-07_F7 to the registrant/manufacturer to document the efficacy test conditions; this

	form should be retained in the COC folder for the product. c. Upon delivery of the sample and receipt by ESC loading dock personnel, the sample is delivered to MLB; however, only an MLB sample custodian may open the box, inspect contents, and initiate chain of custody forms. d. Loading dock personnel are required to date and initial the Shipping and Receiving Record for Disinfectant Products (see Section 14). e. Upon receipt, inspect each shipping container for external structural damage, tampering, and evidence of leaks or spills. Any sign of damage, tampering, or leaks or spills must be documented on the Shipping and Receiving Record for Disinfectant Products (see Section 14) and any chain-of-custody forms provided by the inspector. f. Take photographs of the shipping container, label, and contents as necessary to further document their condition. g. Open the shipping container to inspect the contents for leakage or damage. h. Review the chain-of-custody documentation sent by the inspector, and if necessary apply signature and date of receipt. i. Review all paperwork sent by the inspector to identify any pertinent information such as lot number (see 12.2, a, xi), sample expiration date, storage conditions, etc. j. Initiate a History of Official Sample Form (EPA Form 3540-17 – see Section 14) if not included with sample. k. For product samples from sources other than official inspector collection (e.g., products purchased from the marketplace which require COC documentation), 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. l. Place the sample container in a plastic bag, and seal. Fill out the official seal and affix to the plastic bag. m. Sample collection and chain-of-custody information is maintained in the Disinfectant Product Field Chain-of-Custody Documentation from Inspector notebook. Deficiencies in paperwork accompanying the shipment (i.e. lack of field chain-of-custody papers) are

	documented. n. 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 in secondary containment. o. Prior to testing, initiate a Laboratory Chain-of-Custody Form (see Section 14) and a Chain-of Custody Seal Log (see Section 14). p. 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). Place 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). 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.	#7. RECEIVED FROM: 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 of 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 place 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 as in Section 12.1, k 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, 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-01-07_F1.doc 2. History of Official Sample Form (EPA Form 3540-17) COC-01-07_F2.doc 3. Laboratory Chain-of-Custody Form COC-01-07_F3.doc 4. Chain-of-Custody Seal Log COC-01-07_F4.doc 5. Comprehensive Sample Log COC-01-07_F5.doc 6. Sample Inspection Log COC-01-07_F6.docx

	7. Efficacy Test Conditions Form COC-01-07_F7.docx 8. Sample Custodians for the Laboratory COC-01-07_F8.docx
15. References	1. Pesticides Inspection Manual (Chapter 9) 2002. Link: Pesticide Inspection Manual