January 11, 2021

Michele Cottrill
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Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460

RE: HCPA Comments on EPA Interim Guidance for Products Adding Residual Efficacy Claims - EPA-HQ-OPP-2020-0529.

Ms. Cottrill:

The Household & Commercial Products Association (HCPA) thanks the U.S. Environmental Protection Agency (EPA) for soliciting comments on the Agency's Interim Guidance for Products Adding Residual Efficacy Claims. HCPA is the premier trade association representing the interests of companies engaged in the manufacture, formulation, distribution, and sale of more than $180 billion annually in the U.S. of familiar and trusted consumer products that help household and institutional customers create cleaner and healthier environments. Our members have extensive experience with efficacy testing and specifically residual test methods as well as extensive viral testing knowledge and BSL-3 safety experience and we appreciate the opportunity to submit comments on the interim guidance.

The challenges faced by the United States in controlling the COVID-19 pandemic have led to the emergence or re-emergence of products and technologies that claim to have long-lasting antiviral efficacy. Unfortunately, some of the information currently available on long-lasting products may be misleading or confusing. HCPA would like to acknowledge the importance of EPA's guidance as well as its role in providing clarity on products and technologies that may be unfamiliar to the public but may potentially have benefits to public health.

If you have questions on any information submitted in our comments, please feel free to reach out to me at amojica@thehcpa.org.

Sincerely:

Andrea Mojica
Vice President, Regulatory Affairs

HCPA COMMENTS

The HCPA comments are organized in 3 different sections. The first section provides HCPA's general comments on the interim guidance. The second section focuses on supplemental residual antimicrobial products while the third section provides detailed technical comments for all three methods referenced in the interim guidance.

1. GENERAL COMMENTS

Economic Impact of EPA's Approach for Supplemental Residual Antimicrobial Products Testing

HCPA strongly recommends that the Agency commit to a thorough cost evaluation of running the testing laid out in this guidance document. This evaluation must include third-party labs that can confirm their ability and resources to perform such specialized testing. The prerequisite disinfection testing, long-lasting bacterial testing in addition to viral testing creates both a time-consuming and costly list of tests to be performed before any data can be submitted and reviewed. HCPA has determined that the supplemental antimicrobial surface coating method and the modified copper method and residual long-lasting methods will be the most expensive antimicrobial test methods ever seen in the antimicrobial industry. This becomes a 'barrier to entry' for many companies, especially smaller businesses and in essence defeats the purpose or advantage of any expedited registration path the Agency can offer. The overarching goal laid out in the press release that announced the guidance was as follows:

"EPA is providing an expedited path for our nation's manufacturers and innovators to get cutting-edge, long-lasting disinfecting products into the marketplace as safely and quickly as possible," ***said EPA Administrator Andrew Wheeler****. "As we continue to re-open our schools, workplaces, and other public spaces, it is important Americans have as many tools as possible to slow the spread of COVID-19."*

While there may be an expedited review and registration path, the road to generating data is long and expensive. HCPA believes that certain aspects of the testing regimen could be streamlined without jeopardizing the integrity of the data. Areas to streamline testing could include reductions in carrier replication (reduce to 3 carriers which still retains statistical rigor), lot replication, spread plating and reductions in overburdensome and unnecessary prerequisites. These changes could dramatically reduce the cost and make the test method more accessible to companies and enable effective products to get to market.

Anti-viral Claims for Non-Disinfectant Products – A New Precedent

HCPA applauds the Agency's break in precedent, allowing viral claims to be added to non-disinfectant products, i.e., viral claim allowance on long-lasting supplemental products. This decision was clearly not taken lightly and was based on the public health need. HCPA urges the Agency to follow this precedent by allowing viral claims on other products of importance to public health without having to prove bacterial disinfection or long-lasting bacterial disinfection. There are likely a range of products that could provide effective anti-viral efficacy at reasonable contact times and concentrations. By introducing prerequisite testing/claims (not required for supplemental products) the complexity, cost and efficacy hurdles becomes higher for these products. In addition, HCPA recommends that viral claims (e.g., SARS-CoV-2) should be an

option for any product bearing public health claims (sanitizer, disinfectant) without overburdensome prerequisites. As long as product data can prove efficacy, clear use directions and claims language could then be used. In April 2020 HCPA commented on this topic in the context of EPA's Scientific Advisory Board COVID-19 Review Panel.

The Categorization of Long-Lasting Coatings, Surfaces or Paints

HCPA generally agrees with splitting long-lasting claims between two major sub-groups – Residual Disinfectants and Supplemental Residual Antimicrobial Products. However, we believe the sub-categorization of the Supplemental Residual Antimicrobial Products should be broken down into three additional sub-categorizations: 1. Temporary Coatings & Films, 2. Solids and 3. Paints. The test method for residual claims for the newly proposed stand-alone sub-category of Paints should follow the previously EPA-approved protocol for paints – *Test Method for Determining the Efficacy of Antimicrobial Coated Surfaces as Residual Self Sanitizers*. Please refer to Table 1 below to distinguish between the recommended requirements for each of the Supplemental Residual Antimicrobial Product claims.

Proposed Additions to Guidance Table

HCPA appreciates the use of a table format to summarize the categories outlined in the guidance. Our members propose that the guidance could be further enhanced with additional detail in the summary table or utilizing individual quick reference tables for each type of claim. These tables are extremely useful to registrants and testing labs. HCPA proposes the additions captured in Table 1.

When listing the performance standards for each product category/claim we propose that the Agency tie together the three aspects (log reduction, contact time AND duration/durability) of each category. This gives a holistic view of each category and will help to avoid misleading or misrepresented claims.

Bridging of Claims

HCPA appreciates the allowance for the bridging of claims from traditional disinfection (UDM/GST claims) to residual disinfection. It is important that a conservative stance on contact time and concentration is taken in bridging strategies to maintain trust in the data. This bridge from traditional disinfection to residual method moves claims from less stringent to more stringent testing. It therefore makes sense that the claims being bridged follow the most conservative contact times or concentrations tested under residual conditions.

HCPA requests that EPA adds a description of the allowed bridging of Additional Bacteria from the non-residual, non-food contact sanitization testing (AOAC GDSAN, AOAC Available Chlorine) to the residual self-sanitization (RSS) claim after the required bacteria have been tested in the RSS testing. Please describe how contact times and dilutions will be bridged where the residual testing finds the same, shorter, or longer contact times or higher/lower dilutions than the standard sanitization claim.

HCPA also requests the Agency add a description of the allowed bridging of Additional Bacteria and Viruses from the non-residual, disinfection testing (AOAC GST/UDM/GST-TOW/ASTM E2362) to the residual self-disinfection (RSD) claim after the required bacteria have been tested

in the RSD testing. Please describe how contact times and dilutions will be bridged where the residual testing finds the same, shorter, or longer contact times or higher/lower dilutions than the standard disinfection claim.

SARS-CoV-2 Test Requirements
HCPA would like to understand the requirements for adding a SARS-CoV-2 residual claim. Please confirm for all residual testing categories that SARS-CoV-2 testing may be conducted on 2 lots. For the RSD claims, these lots would be at or below nominal. For the Supplemental Long-lasting Residual products, these lots would follow the LCL Policy stated in 810.2000.

Revision of Guidance and Changes to Requirements
HCPA requests that once a final guidance is issued, registrants be given a 12-month implementation period. As outlined in the EPA's 810 FAQs studies that were initiated (date the study director signs the protocol) prior to the implementation date but submitted to the Agency for review after the implementation date may use either the previous version of the guideline or the revised version. It is our understanding that no additional data or studies would be required for products registered under the interim guidance if changes are made or a final guidance is released, except through the Data Call In (DCI) process.

Additionally, HCPA requests that any technical changes made to the methods referenced in the guidance following the review of public comments will be communicated to industry stakeholders in a transparent and timely manner. Changes to methods can greatly disrupt in-flight innovation and the generation of data if enough flexibility or time is not built into the implementation of changes.

Required Organisms
HCPA recommends the Agency allow *Salmonella enterica* (ATCC 10708) to be used as an alternative required organism (in place of *Pseudomonas aeruginosa* (ATCC 15442) to support broad-spectrum residual disinfection (as described by OCSPP 810.2200) and supplemental residual antimicrobial product claims for temporary coatings & films. HCPA further recommends that EPA allow viral residual claims to be added to this broad-spectrum residual disinfection product. This creates a suitable level of efficacy for non-hospital settings – e.g., public transit and other large public areas).

Furthermore, to align with the required organisms, HCPA recommends the Agency allow *Salmonella enterica* (ATCC 10708) to be used as an alternative required organism - in place of *Pseudomonas aeruginosa* (ATCC 15442) - to support supplemental residual antimicrobial claims for either fixed solids or paints. HCPA also recommends that the EPA allow *Klebsiella aerogenes* to be used as an alternative required organism - in place of *Pseudomonas aeruginosa* (ATCC 15442) - to support supplemental residual antimicrobial claims for either fixed solids or paints as described by the *Test Method for Determining the Efficacy of Antimicrobial Coated Surfaces as Residual Self Sanitizers*.

Germs Claim
HCPA requests that EPA allow the 'Germs claim' to be added to qualifying residual disinfectant products. HCPA recommends adoption of similar efficacy and labeling as described in the current 'Germs' guidance, per the EPA letter to CSPA, January 5, 2005.[1]

Non-GLP Allowance
HCPA appreciates the allowance to generate Non-GLP data provided by this interim guidance. As stewards of antimicrobial products, our members believe it is important for the Agency to emphasize the studies substantiating long-lasting efficacy should be carried out with faithful adherence to OCSPP 810.2000. It should also be noted that the studies are subject to audit by the EPA.

2. SUPPLEMENTAL RESIDUAL ANTIMICROBIAL PRODUCTS

HCPA Proposed Edits to Labeling for Supplemental Residual Antimicrobial Products:
Products should carry the following prominent labeling to indicate that it is a supplement to standard disinfection and cleaning. The statement should not be prescribed as long as it addresses the specific effectiveness of the product.

- Example statement: "*This product is effective by providing additional protection against [insert microorganism(s)] for up to X days.**" Other statements to be acceptable pending review by EPA.
    - Qualifying statement should further describe how the product is to be used with an EPA registered disinfectant. Example: "**When used with an EPA registered disinfectant, this product provides supplemental protection*." Other qualifying statements to be acceptable pending review by EPA.

HCPA Proposed Edits to List N Appendix:
HCPA recommends the following edits (in red).

What you need to know
- All products on this list are EPA-registered for supplemental disinfection use. These products are not disinfectants (*Note to EPA: we may see dual purpose products in the future, and this will need to be updated).*
- These products work in two hours or less (refer to label) ~~within two hours of~~ when a virus comes ~~coming~~ into contact with a surface. These products ~~and~~ can remain effective for weeks or ~~to~~ years. Refer to each product labeling for proper use.
- All products on this list ~~are supplemental residual antimicrobial products. This means they~~ can supplement, but do not replace, routine cleaning and disinfection.
- ~~Products on this list are not disinfectants, which must meet a higher standard of efficacy.~~ To find residual disinfectants that can be used against SARS-CoV-2 (COVID-19), look for products on List N with the formulation type "residual."

[1] https://www.epa.gov/pesticide-labels/use-term-germs-antimicrobial-labels

Stewardship Program
HCPA urges the Agency to participate in additional stewardship and education on these new product categories to further the legitimacy and effectiveness of any industry-led stewardship work.

The Agency should ensure that there is an allowance for a collective (multiple suppliers/manufactures) stewardship program to ease the burden and cost of developing and maintaining such a program. It is also important to build in an ability to sunset such a program as appropriate.

Existing Product Exemptions
HCPA would like EPA to confirm that existing products are exempted from the stewardship program and clarify that there are no new requirements for existing products unless a new claim is being added.

3. METHOD COMMENTS

HCPA members have created two tables of comments, recommendations and requests for clarity on a range of technical items for methods referenced in the interim guidance (Table 2 and 3). HCPA respectfully requests that all comments be addressed to facilitate consistent testing of these product categories. Some of the larger themes are also captured below.

a). General Comments

Consistency Across Methods
HCPA urges the Agency to make the methods referenced in the guidance more consistent, including but not limited to soil, culture media, plating and enumeration, carrier specifications, and neutralization confirmation. Many aspects of the recent guidance documents do not line up with each other or the existing methods that have been used to support antimicrobial products on the market today. Consistency across the methodologies will greatly enhance efficiencies in third-party laboratories already stretched to their limits because of pandemic related testing.

Calculations
HCPA requests clarity on calculating the performance criteria. HCPA suggests the acceptance criteria is based on the mean of the test carriers, and not each individual carrier tested.

It is of the utmost importance that the handling of outlier data be addressed in this and other quantitative methods. The sheer size and complexity of these methods mean that an outlier (coming from carrier variability or other source) could be detrimental and costly to product development efforts.

Electrostatic Spraying (ESS) Application Method
HCPA recommends that if ESS is used as an application method only maximum distance (worst case scenario) is required for testing. Doubling the testing is unreasonable, not supported by science and extremely costly.

Reference to 229E
HCPA has noted references to 229E are different throughout the guidance and requests that the references to 229E are made consistent.

b). Residual Disinfectants

Relevancy of Testing Parameters
HCPA seeks clarity and transparency on the scientific evidence used to determine the abrasion and reinoculation parameters of the methods cited in the guidance. Of most importance to the registrant community is an understanding of the origins of the 'wear regimens' chosen, the reasons behind the differences across methods (weights and abrasion material choices) and any relevancy to 'real world scenarios.' Information on these aspects of the method will be of great benefit in inspiring confidence in the use of these products.

c). Supplemental Residual Antimicrobial Product

Incompatibility of Products to Chemical Wears
If a registrant determines that a product is incompatible with one of the standard 'chemical wear' products, can such incompatibility be accounted for by substitution of said material in testing and label use directions alerting the end-user to avoid use of certain cleaning agents e.g., Allied BioScience incompatibility with ethanol? HCPA would like to see a standard process or recommendations for substitutions when incompatibility issues arise.

Method Execution and Timing
HCPA has concerns about the size and complexity of the testing outlined in this guidance. Our members have a keen interest in helping to streamline the testing regimens without losing the scientific rigor of the methods. Currently the methods have timing limitations and excessive numbers of carriers/repetitions which make execution extremely cumbersome. It will likely require unique scheduling and/or multiple analysts to perform testing. For example, due to the high demand on the contract laboratories for efficacy testing, the chemical wearing may need to be performed by another lab and carriers then shipped to another lab for the efficacy testing. The use of the carriers within 7 days from the last chemical wear may create undue stressors on the scheduling and testing process since the use of carriers after a longer time-period would suggest a worst-case scenario and therefore an added challenge to the product. HCPA recommends that the 7-days be increased to 30-days.

Alignment of Cleaning Materials and Chemical Disinfectant
Specific to the method for Evaluating the Efficacy of Antimicrobial Surface Coatings (for coatings and films), the Agency should strongly consider allowing alternate cleaning materials aside from the sponge. The prescribed sponge does not reflect realistic materials used by end users. Using a cloth, similar to the one used in the RSS method can be appropriate (TexWipe Clean Cotton Wipers) and should be adopted. Additionally, the volume of chemical disinfectant used should be reconsidered as 20 mL of chemical disinfectant used in a petri dish for laboratory purposes provides overly saturated and unrealistic conditions for cleaning. Alternate volumes should be allowed based on calculations which reflect actual cleaning scenarios.

These alternate cleaning proposals only apply to the coatings & films, and fixed solids, and not the proposed method for paint. For scenarios that involve cleaning painted materials, use of a sponge is appropriate.

Contamination Risks
The length of time it takes to perform long-lasting testing provides ample opportunity for airborne contamination of the instrument which could introduce contamination into the test system and in turn into the testing results. At the conclusion of the durability testing HCPA asks for allowance of sterilization, e.g., UV, gamma irradiation, of the carriers prior to running the efficacy test, where needed.

Contact Time for Residual Coating
HCPA requests that the Agency acknowledges the possibility that contact times shorter than 1 hour may be achievable for residual coating products. The test method has been designed to accommodate such efficacy determinations through the inclusion of parallel controls. Any perceived 'natural die off' of bacteria or virus will be accounted for using such controls and therefore shorter contact times can be reliably proven utilizing the current method. Registrants should be allowed to claim contact times that are demonstratable using sound science.

Batch Replication
The interim guidance for supplemental residual products states 3 test lots are required for bacteria testing whereas the BEAD SOP's for coatings and solid surfaces only describe 2 lots. Please confirm only 2 lots are required for bacterial claim support due to the extensive number of arms in the study.

Neutralization
To avoid adding unnecessary size and cost (see examples below) to the interim supplemental residual testing and to align with current practices, HCPA requests consideration that the Neutralization Assay be reduced to a single replicate for each organism dilution tested. Where possible, please include a Neutralization Assay diagram in the Interim Surface Coating guidance, as was listed in the Interim Fixed/Solid-Copper surface guidance. The performance of filtration for the surface treatment testing is also a large hindrance to the timing of execution. In lieu of filtration, HCPA recommends that the Agency add alternative plating method options including spiral and spread plating.

Examples:

- *For Surface treatment*: Triplicate carriers x 2 test lots x 3 dilutions = 18 coated carriers. If the other portions are in triplicate as well, there are 9 vessels of "neutralizer only", and 9 more of a PBS treatment. That is 36 total enumerations with filtering per organism (72 enumerations for both organisms). 18 more if we have 3 test lots. Testing all portions in triplicate with filtering likely adds thousands of dollars to the test cost and may not be necessary scientifically speaking. It is not clear if EPA means to have all of portions done in triplicate, a diagram as is listed below for the draft copper protocol would be very helpful.
- *For Fixed/Solid surface - Copper*: Triplicate carriers x 2 test lots x 3 dilutions = 18 coated carriers. Triplicate SS carriers x 3 dilutions = 9 control carriers. Also, per the diagram below, there would be 9 more neutralizer vessels and 3 PBS. This is 39 total enumerations per organism (78 total). 18 more if we have 3 test lots. The Stainless-Steel carrier control should be removed, or the neutralizer alone should be removed as both should not be needed.

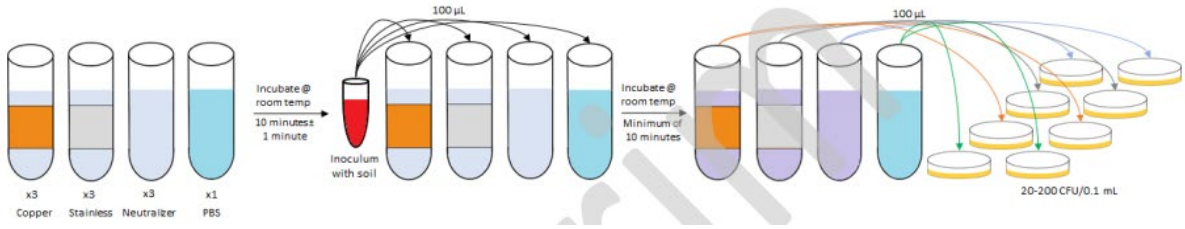

Table 1. Proposed Modifications to Guidance Table

	Claim			
	Residual Disinfectants	**Supplemental Residual Antimicrobial Products**		
		Temporary (Coatings & Films)	**Fixed Solids**	**Paint**
Required to Meet EPA's standard for disinfection efficacy, per 810.2200	Optional	No	No	No
Eligible to make standard disinfection efficacy claims, per 810.2200	Optional	Optional	No	No
Duration of residual claim	≤ 24 hours	≤ 4 Weeks (product efficacy determines duration) Long durations via Agency consultation	Years	Years
Durability assessment	Abrasion	Abrasion & Chemical	Abrasion & Chemical	Abrasion & Chemical
Test method for residual claims (bacteria)	Residual Self-Sanitization Protocol with the following modifications: • *Staphylococcus aureus* ATCC 6538 • *Pseudomonas aeruginosa* ATCC 15442 Or • *Salmonella enterica* ATCC 10708 • 4 passes/cycle • Increase bacterial load	Performance of Antimicrobial Surface Coatings on Hard Non-porous Surfaces • *Staphylococcus aureus* ATCC 6538 • *Pseudomonas aeruginosa* ATCC 15442 Or • *Salmonella enterica* ATCC 10708 Or • *Klebsiella aerogenes* ATCC 13048	Draft Copper Surface Protocol • *Staphylococcus aureus* ATCC 6538 • *Pseudomonas aeruginosa* ATCC 15442 Or • *Salmonella enterica* ATCC 10708 Or • *Klebsiella aerogenes* ATCC 13048	Test Method for Determining the Efficacy of Antimicrobial Coated Surfaces as Residual Self Sanitizers • *Staphylococcus aureus* ATCC 6538 • *Pseudomonas aeruginosa* ATCC 15442 Or • *Salmonella enterica* ATCC 10708 Or • *Klebsiella aerogenes* ATCC 13048

	Claim			
	Residual Disinfectants	**Supplemental Residual Antimicrobial Products**		
		Temporary (Coatings & Films)	**Fixed Solids**	**Paint**
Batch Requirements (required bacteria)	• 3 lots • LCL	• 2 lots • LCL	• 2 lots • LCL	• 2 lots • LCL
Additional bacterial residual claims	Based on the above organisms, other vegetative bacteria may be bridged without further review of efficacy data	Test each strain using the same method • 2 lots • Nominal	Test each strain using the same method • 2 lots • Nominal	Test each strain using the same method • 2 lots • Nominal
Performance standard for bacteria for residual claim	5-log reduction within 10 min to support a residual claim for up to 24 hours	3-log reduction within 2 hours to support a residual claim for multiple weeks	3-log reduction within 2 hours to support a residual claim for multiple years	3-log reduction within 2 hours to support a residual claim for multiple years
Test method for residual claims (virucidal)	Residual Self-Sanitization Protocol modified for viruses: • Most difficult to kill virus intended for residual claims • 4 passes per cycle	Performance of Antimicrobial Surface Coatings on Hard Non-porous Surfaces modified for viruses • Test each desired virus • Durability assessment conducted for the most difficult to kill virus	Draft Copper Surface Protocol modified for viruses • Test each desired virus • Durability assessment conducted for the most difficult to kill virus	*Test Method for Determining the Efficacy of Antimicrobial Coated Surfaces as Residual Self Sanitizers* modified for viruses • Test each desired virus • Durability assessment conducted for the most difficult to kill virus
Residual Efficacy test conditions (virucidal)	• 2 lots for all viruses • LCL	• 2 lots • LCL	• 2 lots • LCL	• 2 lots • LCL
Additional virucidal claims	Based on the above virus, other viruses may be bridged without further review of efficacy data	Test using coated carriers that were not subjected to the durability procedure • 2 lots • Nominal	Test using carriers that were not subjected to the durability procedure • 2 lots • Nominal	Test using carriers that were not subjected to the durability procedure • 2 lots • Nominal
Performance standard for	3-log-reduction within 10 min to	3-log reduction	3-log reduction within 2 hours to	3-log reduction within 2 hours to

	Claim			
	Residual Disinfectants	**Supplemental Residual Antimicrobial Products**		
		Temporary (Coatings & Films)	**Fixed Solids**	**Paint**
viruses* for residual claim	support a residual claim for up to 24 hours	within 2 hours to support a residual claim for up to four weeks	support a residual claim for years	support a residual claim for years
List N qualification for residual use	Non-enveloped virus or a human coronavirus (SARS-CoV-2 or human coronavirus 229E)	Supplemental use (List N Appendix only): non-enveloped virus or a human coronavirus (SARS-CoV-2 or human coronavirus 229E)	Supplemental use (List N Appendix only)	Supplemental use (List N Appendix only)
Supplemental Labeling	Not Applicable	Required	Required	Required
Stewardship Program	Not Applicable	Required	Required	Required

Table 2.

Interim Method for Evaluating the Efficacy of Antimicrobial Surface Coatings	
Location	**COMMENT**
Guide/Method	The Guide states 3 test lots are required for bacteria. The BEAD Method only describes 2 lots. Please confirm only 2 lots are required for bacterial claim support due to the extensive number of arms in the study.
Line 31	Revise to read "...the unexposed control carriers held in parallel to the test carriers."
Line 33 / Guide Addition	Will claims be allowed on "untouched surfaces" as EPA has allowed before by omitting the wear cycles? If so, please include testing and labeling instructions.
Line 50	HCPA recommends alternative culture broths are listed, (e.g., Synthetic broth and Nutrient Broth). OECD work has demonstrated good consistency in numbers grown in Synthetic broth so it should be added as an option.
Line 77	Please include option to utilize 5% FBS soil load or 3-part soil. FBS soil load is the current standard soil for disinfectants. The OECD equivalency workgroup has found that filter sterilizing mucin is an important preparation step for consistency. Please clarify this sterilization step and incorporate specific instructions for proper dilution and filtration of mucin.
Line 81	If the labels of the products state they are effective in hard water, must they be made in that hard water level?
Line 86	The chemical exposure Solution A for the copper method is identified as 3000 ppm NaOCl where the film method has it identified as 2000 ppm NaOCl. Is this discrepancy supported?
Line 86 & 93	Solution B is defined as an EPA registered pesticide product allowable for hard, non-porous spray applications containing 3-6% hydrogen peroxide and peracetic acid. Will the Agency allow substitutions if these products are unavailable?
Line 94	Repeat the sentence from Lines 89-90 "The solution concentration for the quaternary ammonium compound is not limited to a defined range."
Line 98	References of reputable suppliers of carriers would be appreciated.
Line 99	Follow Appendix B Carrier Specifications outlined for all methods where stainless-steel carriers are specified.
Line 109	HCPA would like clarity on the reuse limitations of sponges.
Line 142-143	Why has EPA elected to use 25% less weight for these products as compared with RSS/RSD and less weight for the dry abrasion?

Line 146	Please include an option for manual titration of total Chlorine as an alternative for Hach.
Line 146	Please confirm that sponsor can coat carriers and provide to a 3rd party lab to test efficacy. Please offer considerations (e.g., documentation, storage and transport, sterility, EPA audit) for such carrier treatment.
Line 154	Please confirm that there is an error in the text of the interim guidance and that registrants should follow the requirement listed here as 2 lots.
Line 161-162	Due to the extensive nature of this testing, will EPA allow a decontamination step after wear and before efficacy testing that would not remove or interfere with the residual testing (e.g., irradiation)?
Line 170-171	Recommend alignment with OECD C. diff carrier preparation (Liquinox 1% solution or equivalent)
Line 173	The description here is very prescriptive. Please alter language to allow flexibility for large batch sterilization (important for workflow and throughput) and the ability to use sterile plastic petri dishes for transfer.
Line 173	May dry heat be used as an alternative to steam sterilization to avoid rusting?
Line 187-191	Please provide flexibility to allow carrier drying at "ambient" conditions inside of an environmental chamber and/or BSC. Define ambient if a chamber or BSC is allowed i.e., 18-25°C, <55% RH
Line 187	The RSS and RSD methods require an initial inoculation of bacteria and soil. Why has this method omitted that step? Will all use directions require pre-cleaning before application of this residual product? If that is not preferred, may a 5% soil step be included initially to support use directions which only require pre-cleaning of heavy soil?
Line 193	The Agency may want to suggest coating additional carriers to avoid having under-treated carriers.
Line 228	Based on the weighted arm, will sponge edges be pushed below the carrier edges thus causing the film to peel along the edges? Would it be better to cut the sponge the width of the carriers to avoid artificially damaging the film?
Line 238	HCPA recommends reducing replicates from 5 to 4 and performing the testing similar to the method 01-1A orientation to increase efficiency and consistency across methods. This new arrangement doubles the time it takes to perform abrasion cycles.
Line 275	Please confirm that this indicates that you would have to rewet the sponge Cycles 1-5 are not completed in an hour.
Line 279	Since 1 week of wear is defined as 10 abrasion cycles of wet / dry wear, is it possible (perhaps running 3 lab shifts) to consolidate all wear for 2 or 4 weeks into a single 5-day period?
Line 304	Should the control carriers (Control Set #2 Carriers 4-12 in Figure 1) also be rinsed to simulate this step in the test carriers? This would allow an understanding of the potential source of contamination or a neutralization problem to be confirmed.

Line 304-307	Should this be done horizontally in a Gram stain type-rack to avoid damaging the film?
Line 315 & 404	Logistics of 7-day restriction is unreasonable, allowing more time to initiate the test should not alter the assessment of the coating, it would be considered more stringent. HCPA recommends up to 30 days to initiate testing. Lab resources and logistics will dictate completion time. Reductions in carrier repetition would also reduce this time.
Line 353-358	Please include option to utilize 5% FBS soil load or 3-part soil. FBS soil load is the current standard soil for disinfectants. The OECD equivalency workgroup has found that filter sterilizing mucin is an important preparation step for consistency. Please clarify this sterilization step and incorporate specific instructions for proper dilution and filtration of mucin.
Line 359	It will be difficult to achieve final inoculation within allowed 30 minutes without multiple analysts to inoculate, dry and recover. HCPA recommends extending to 60 minutes. Reductions in carrier repetition would also reduce timing issues.
Line 367	Add "e.g.," to allow for other absorbance values to be used.
Line 380 & Line 386 & Line 391	If the inoculum only has 20-200 CFU in 0.1mL (Line 380-381) and this is added to 20mL of recovery media/neutralizer, then the final concentration in the tube will be 0.1-1 CFU/mL. (Line 386 suggests it will be 20-200 CFU though no units are provided.) 810.2000 suggests that neutralization be proven at ≤100CFU/mL of the final solution. To align with this level, Line 380 should change to 4000 - 40,000 CFU/0.1mL, to achieve the correct final dose of 20-200 CFU/mL neutralization recovery fluid. Once this is adjusted, then Line 391 will need to be adjusted as if the full volume is filtered the plates will be overgrown - plating 1 mL will achieve countable plates.
Line 383	Triplicate is not explained well here. Please confirm the intention. HCPA recommends that the method aligns with other standard methods and 3 dilutions are used rather than 3 separate replicates for each dilution.
Line 391	Please make allowance for spread plating to be in alignment with the copper method and allow spiral plating.
Line 419	Due to the number of carriers needed for inoculation (81 per organism), please consider an extension of the inoculum/soil expiration beyond 30 minutes (e.g., 60 minutes requested previously).
Line 432	Due to the difficulty in meeting the tight 30-minute time frame and possible delays with the filtering steps, HCPA recommends longer 1-hour time frames or an allowance to refrigerate neutralized samples for up to 1 hour before the 30 minutes apply (as long as controls are treated the same).

Line 437	Filtering the serial dilutions adds time and cost to this method. Standard duplicate spread plating of the serial dilutions would speed up the recovery timing and you could still filter the remaining neutralizer. One would count up to 300 CFU for spread plates. Note that current RSS guidance has pour-plating. HCPA recommends that the Agency add alternative plating method options.
Line 463	Insert instructions on how contamination will be handled for single plates, single colonies, partial plate spreading or fungal contamination. May partial unobscured plates still be counted?
Line 465	Add a soil sterility control.
Line 494	If filters allowing up to 250 CFU counts are used, please confirm this is acceptable and the calculations may change to align with the vendor.
Line 497	Please describe, with an example, the neutralization confirmation calculation and how triplicates are incorporated.
Line 498	Add a section on possible outlier calculation methods to support repeat testing where a carrier is shown to be an outlier.
Table 4, page 16, Line 499	Please confirm that the log differences in counts are for bacteria and not viruses.
Table 4, page 16, Line 499	If testing passes the LR criteria of greater than or equal to 3.0 log, but fails the variation criteria of less than or equal to 0.5 log for controls or the 1.0 log for coated sets - does the testing need to be repeated? Is there any case where a passing test with variation outside these criteria is acceptable?

Table 3.

Interim Method for the Evaluation of Bactericidal Activity of Hard, Non-porous Copper-Containing Surface Products	
Location	**COMMENT**
Guide Section III(A)	To address potential incompatibility issues of coating with wet wear chemistries, HCPA recommends the Agency add some additional options for these wet wear standard chemistries. Label language could help to reflect any incompatibility.
Line 22-22	Please clarify why the abrasion regime is six weeks for copper and four weeks for coatings?
Line 63	HCPA recommends alternative culture broths are listed, e.g., Synthetic broth and Nutrient Broth. OECD work has demonstrated good consistency in numbers grown in Synthetic broth so it should be added as an option.
Line 90	The OECD equivalency workgroup has found that filter sterilized mucin provides consistency to the method where autoclaved mucin may be altering the protein content. Please clarify this sterilization step.
Line 97	The chemical exposure Solution A for the copper method is identified as 3000 ppm NaOCl where the film method has it identified as 2000 ppm NaOCl. Is this discrepancy supported by data?
Line 122	HCPA requests allowances for alternative carriers e.g., glass, Leneta plastic.
Line 131	Please include a picture of pads and spacers. HCPA recommends that square pads be used to aid cutting and fitting. Please also describe reuse limitations of sponges.
Line 154	Please include an option for manual titration of total Chlorine as an alternative for Hach.
Line 171 Table 1	Please confirm that there is an error in the text of the interim guidance and that registrants should follow the requirement listed here as 2 lots.
Line 171 Table 1	Please confirm that “Exposed” refers to carriers subjected to the physical abrasion and chemical treatment, while “unexposed” refers to those carriers not subjected to the physical abrasion and chemical treatment.
Line 215	Please confirm whether this is the sponge attachment or the 01-1A RSS weigh boat? The weight range suggests the sponge attachment. The interim surface coating guidance lists 454 g.
Line 217	Are two attachments needed to use separate abrasion pads and run these carriers simultaneously?
Line 221-222	Does this mean a separate abrasion if you do not use two attachments? HCPA recommends the Agency states “or abraded separately” rather than 'back-to-back.'

Line 230 Table 2	Solution C is not described consistently (Reagents Section - EPA registered Quat, Table 2 - EDTA/phosphoric acid).
Line 234	Please remove reference to 'mist'. Product should be applied as intended on label.
Line 243	Please clarify that this should read 'paper' not 'papers.'
Line 299	Please add “e.g.,” to allow for other absorbance values to be used.
Line 308-309	HCPA proposes that this method align with the coatings method for neutralization control.
Line 327	HCPA recommends that monitoring be made optional.
Line 336	Please remove reference to 'production lot' regarding carriers
Line ~355 under Efficacy Test Procedure	If 38 carriers (total for one organism) are inoculated at 20 second intervals, the inoculation takes 12 minutes 20 seconds (outside of this 10-minute window). The inoculation can be staggered; however, you would then be coming close to the inoculum/soil expiring within 30 minutes of preparation. HCPA recommends allowing an extension of the inoculum/soil expiration to 1 hour to aid in timing.
Line 371	HCPA recommends spread plating for a portion of the dilution to streamline and reduce cost of testing.
Line 470	Please describe the neutralization control calculation. Should recoveries at the appropriate dilution be averaged before the 50% comparison?