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Via Electronic Submission

Subject: HCPA Comments on the Draft Guidance for the Evaluation of Products for Claims Against Viruses; Docket No. EPA-HQ-OPP-2023-0288

The Household & Commercial Products Association[1] (HCPA) thanks the U.S. Environmental Protection Agency (EPA) for the opportunity to provide comments on the *Draft Guidance for the Evaluation of Products for Claims Against Viruses*.

HCPA acknowledges the importance of EPA guidance and appreciates the Agency's work to provide the regulated community with critical direction on evaluating products to ensure consistent and measurable evaluation of their benefits to public health. HCPA is supportive of the development of this guidance to expand the availability of virucidal claims for antimicrobial pesticides and provide a framework for registrants to make such claims. Our comments identify areas of ambiguity that should be considered and addressed by EPA prior to finalizing the guidance. We also identify areas of opportunity for potential expansion of the guidance in the future after the first implementation period ends.

Comments for Immediate Consideration

HCPA offers the following specific comments for immediate consideration by the Agency.

Product Eligibility and Test Criteria

The draft guidance references OCSPP 810.2000[2], 810.2200[3], and 810.2300[4] guidance documents. *HCPA requests that EPA include a reference in the draft guidance to Series 810 FAQ[5] document as it also provides useful information for registrants making relevant efficacy claims.*

[1] The Household & Commercial Products Association (HCPA) is the premier trade association representing companies that manufacture and sell $180 billion annually of trusted and familiar products used for cleaning, protecting, maintaining, and disinfecting homes and commercial environments. HCPA member companies employ 200,000 people in the U.S. whose work helps consumers and workers to create cleaner, healthier and more productive lives.
[2] General Considerations for Testing Public Health Antimicrobial Pesticides, Guide for Efficacy Testing.
[3] Disinfectants for Use on Environmental Surfaces, Guide for Efficacy Testing.
[4] Sanitizers for Use on Hard Surfaces – Efficacy Data Recommendations.
[5] Frequent Questions for the 2018 Series 810 – Product Performance Test Guidelines: Antimicrobial Efficacy Test Guidelines.

Additionally, the draft guidance states: "As specified in 810.2200, two batches of product at the Lower Certified Limit (LCL) should be tested for the hardest-to-kill virus strain on the product label. For all additional viruses, two batches of product at the nominal concentration should be tested. Testing can be conducted on virus surrogates and non-surrogates as specified in the 810.2200 guidance. For non-surrogate viruses, one surface per batch should be tested, and for surrogates, two surfaces per batch."

While the number of batches (two) is consistent with OCSPP 810.2200, testing for SARS-CoV-2 has been historically performed using three batches. *To avoid undue confusion, HCPA requests that EPA clarify in the guidance whether a two-batch analysis is acceptable for SARS-CoV-2 moving forward.*

Table 1

HCPA proposes the following edits to Table 1 for additional clarity (see in red below).

Claim	Sub-category	Organism	Method*	Performance standard**	Test Contact time
Bacterial Disinfectant	Hospital	*Staphylococcus aureus* (ATCC 6538) & *Pseudomonas aeruginosa* (ATCC 15442)	AOAC UDM, GST or modified GST depending on product form and use (liquid; spray; towelette)	~~Complete kill on number of carriers prescribed in~~ See 810.2200- *varies by organism and method. For Salmonella enterica UDM* see EPA BEAD SOP MB-05.	≤ 10 minutes
	Broad Spectrum	*Staphylococcus aureus* (ATCC 6538) & *Salmonella enterica* (ATCC 10708) or *Pseudomonas aeruginosa* (ATCC 15442)			
Bacterial Sanitizer	Non-food contact Hard - surface	*Staphylococcus aureus* (ATCC 6538) & *Klebsiella pneumoniae* (ATCC 4352) or ~~*E. aerogenes*~~ *Klebsiella aerogenes* (ATCC 13048)	ASTM E1153	≥ 99.9% (3-log)	≤ 5 minutes

	Food-contact Hard surface - Halide actives	*Salmonella enterica* (ATCC 6539) *or* *Staphylococcus aureus* (ATCC 6538)	AOAC 955.16 International Chlorine (Available) in Disinfectants Germicidal Equivalent Concentration	Test results should demonstrate product concentrations equivalent in activity to 50, 100, ~~and~~ **or** 200 ppm of available chlorine.	≤ ~~30~~60 seconds (label states 1 minute)
	Food-contact Hard surface - Non-halide actives	*Escherichia coli* (ATCC 11229) & *Staphylococcus aureus* (ATCC 6538)	AOAC 960.09 International Germicidal and Detergent Sanitizing Action of Disinfectants	≥ 99.999% (5- log)	≤ 30 seconds (label states 1 minute)
	Food-contact Hard Surface Sanitizer Towelette	*Escherichia coli* (ATCC 11229) & *Staphylococcus aureus* (ATCC 6538)	Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes***	≥ 99.999% (5- log)	≤ 30 seconds (label states 1 minute)
NEW: Virucidal	**NEW:** Virucidal claims may be added to products with the above disinfectant or sanitizer claims	**Virus claimed on the label or approved surrogate**	**ASTM E1053**	**≥ 99.9% (3-log)**	≤ 10 minutes for disinfectants; ~~and~~ ≤ 5 minutes for non-food contact surface sanitizers; and ≤ 1 minute for food contact surface sanitizers

*AOAC = AOAC International (formerly Association of Official Analytical Chemists)/ASTM = ASTM International (formerly American Society for Testing and Materials).

**See EPA Series 810 – Product Performance Test Guidelines and Antimicrobial Testing Methods & Procedures Developed by EPA's Microbiology Laboratory for recommended and updated methods and performance standards or alternative EPA approved test method.

***Draft guidance; contact EPA for method updates.

HCPA recommends that EPA explicitly state that the first two rows of Table 1 reflect performance standards within bacterial methods to prevent confusion.

Additionally, to avoid bacteria strain confusion, HCPA recommends that EPA include the ATCC numbers for each strain as outlined in red above. HCPA also requests that EPA update E. aerogenes to K. aerogenes to align with the latest nomenclature change. Similarly, HCPA recommends that EPA include the AOAC method numbers for ease of identification.

The Performance Standard for a bacterial disinfectant in Table 1 states: "Complete kill on number of carriers prescribed in See 810.2200- varies by organism and method." HCPA notes that the current "complete kill" statement does not align with the test criteria identified in OCSPP 810.2200. *To ensure alignment with OCSPP 810.2200 and reflect the most up-to-date testing requirements, HCPA requests that the current text be replaced with "See 810.2200 – varies by organism and method. For Salmonella enterica UDM see EPA BEAD SOP MB-05." We also request that the Agency update the Series 810 FAQ and OCSPP 810.220 to reflect the requirements for Salmonella enterica per EPA BEAD's SOP MB-05 to reduce confusion and the availability of conflicting product performance criteria to registrants.*

HCPA also notes that the performance standard and contact time for food-contact hard surface - halide actives under the bacterial sanitizer claim in Table 1 include statements that are inconsistent with AOAC 955.16 International Chlorine (Available) in Disinfectants Germicidal Equivalent Concentration test method. The performance standard reads "[t]est results should demonstrate product concentrations equivalent in activity to 50, 100, and 200 ppm of available chlorine." It should read: "[t]est results should demonstrate product concentrations equivalent in activity to 50, 100, **or** 200 ppm of available chlorine." The contact time reads "≤ 30 seconds (label states 1 minute);" but it should read "≤ 60 seconds (label states 1 minute)." *HCPA requests that the Agency make these corrections for clarity and consistency.*

Furthermore, it is unclear why food contact towelettes are excluded from this policy. *HCPA requests that EPA allow virucidal claims for food contact towelettes, given that such claims can be tested using ASTM International's E1053 (see proposed edits in red incorporated into Table 1).*[6] EPA currently registers soft, porous sanitization claims with these products[7] and this exclusion is particularly restrictive given the number of towelette products already registered for use as sanitizers.

Contact Time for Virucidal Sanitizer Claims

As written, there are ambiguities within the draft guidance as it relates to the contact time proposed for virucidal claims. The document includes a statement that "[t]his draft guidance proposes no change to the test methods or performance standards recommended for a product to meet any of the antimicrobial pesticide product definitions or fall under the categories of claims on such products (see section II)." The test method cited for virucidal claims (ASTM E1053), however, includes a test contact time of ≤ 10 minutes, which is inconsistent with a later statement in the guidance that "[t]he maximum contact time to achieve the performance standard for viruses should be consistent with the maximum contact time for the bactericidal claim (see Table 1)."

Based on the Series 810 guidelines, the contact time would equate disinfection to ≤ 10 minutes, non-food contact surface sanitization to ≤ 5 minutes, and food contact surface sanitization to ≤ 1 minute. Table 1, however, states "≤ 10 minutes for disinfectants and ≤ 5 minutes for sanitizers." Additionally, Table 1 does not differentiate between the contact times for virucidal claims for food and non-food contact.

[6] Standard Practice to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces.
[7] Disinfectants and Sanitizers for Use on Fabrics and Textiles—Efficacy Data Recommendations.

HCPA agrees with EPA's approach to align the new policy with the performance standard consistent with the maximum label contact time for bactericidal claims and requests that the Agency update the draft guidance by addressing these ambiguities. *We request that the Agency update the Table 1 virucidal sanitizer claim to state: "≤ 10 minutes for disinfectants; ≤ 5 minutes for non-food contact surface sanitizers; and ≤ 1 minute for food contact surface sanitizers."* This change will ensure that the guidance is used accurately and is reflective of EPA's intent to align the policy with the performance standard contact time for bactericidal claims.

Furthermore, HCPA requests the following edits (in red) to the sentence that precedes Table 1: "The maximum contact time to achieve the performance standard for viruses should be consistent with the maximum label contact time for the bactericidal claim (see virucidal claims in Table 1)." HCPA also requests that EPA revise the Table 1 header "Contact time" to read "Test contact time." These revisions will clarify that viruses can be tested and claimed at ≤ 1 minute for all food contact sanitizers.

Regulatory Submission Process – Registration Process

HCPA notes that the link to the Pesticide Registration Manual[8] contains outdated Pesticide Registration Improvement Act (PRIA) information and needs to be updated to ensure that registrants have accurate and consistent information on the regulatory and submission process for registration of antimicrobial products. For example, when accessing Chapter 5: Registration Fees through the link provided, the Chapter 5 webpage includes an outdated link[9] to the PRIA determination decision tree. The PRIA determination decision tree still reflects PRIA 4 fees and information. *Therefore, HCPA requests that EPA update the Pesticide Registration Manual webpage and associated links to reflect PRIA 5 information.*

Implementation – Label Changes

HCPA requests that EPA provide additional information on the pathway for submission of virucidal claim additions to product labels. Considering the time-limited policy implementation period, it will be critical for registrants to have clear instructions on how to submit label changes through existing PRIA codes to ensure any necessary new registrations and/or amendments are approved in a meaningful time frame to allow maximal use of the policy.

Specifically, details are needed on claim additions to existing products for which data is already on file with the Agency. For example, if a registrant with an existing registered product wishes to add a virucidal sanitizer claim to a product for which EPA has previously reviewed and accepted virucidal disinfection data, the microorganism qualifiers on the label will need to be separated into disinfection and sanitizer sections. As written, it is unclear whether such a request would be categorized as a PRIA action or as a fast-track amendment. *Given that no new data would need to be reviewed under this circumstance for products with existing registrations where viral data that were previously accepted are simply being cited by MRID number, HCPA requests that the Agency clearly outline the pathway for changing the label in a timely manner for registrants without overly burdening the Agency.*

Implementation – Time Limited Policy

The draft guidance states that EPA intends to grant the addition of virucidal claims to products that are only sanitizers for a limited period of a maximum of seven years, starting from the date the guidance is finalized for use. While HCPA understands that the expansion of virucidal claims for sanitizers represents

[8] https://www.epa.gov/pesticide-registration/pesticide-registration-manual
[9] https://www.epa.gov/pria-fees/pria-4-fee-determination-decision-tree

a significant policy shift for the Agency, we are concerned that seven years is not sufficient for new sanitizer products to enter the market. Many companies have existing sanitizers that will qualify for virucidal claim additions; however, the seven-year limitation to the policy leaves little room for the development of novel products.

Bringing a new product to market consists of a highly involved process that can take years to complete. Considering the amount of time and resources that a company invests in developing a new product, the seven-year time limit effectively disincentivizes innovation. We believe that for EPA to gain a full understanding of the effects of this policy shift, it will be important that companies feel that they have an opportunity to innovate and utilize the policy to its full potential. *Therefore, HCPA requests that the Agency extend the time-limited period to a minimum of 15 years.*

Furthermore, the draft guidance states that "[a] year prior to expiration of the time-limited registration, the Agency will analyze the products registered under this guidance. Comments provided by industry and registrants as well as product users would be considered to determine if a revision to the guidance is necessary or if the guidance can be re-issued without a time-limitation. Prior to the end of the seven-year period, the Agency will review the record and may make suggestions for changes to the policy, as necessary or decide to make the policy permanent."

HCPA has concerns that the policy impact analysis could take longer than a year and recommends that, instead, the Agency begins its evaluation two years prior to the expiration of the policy. We also request that EPA explicitly state in the guidance that products can remain on the market until EPA's analysis is complete and a decision has been made on revising/repealing the policy.

Upon its evaluation, should the Agency determine that the guidance will be terminated, it is essential that registrants have a clear understanding of the appropriate pathway to remove virucidal claims from sanitizer products. As written, the guidance states that the registrants will engage with EPA on an appropriate pathway for such an action, however it does not provide clear instructions on whether label changes will need to be done via PRIA or non-PRIA actions. *HCPA requests that EPA determine what this pathway will be ahead of time to ensure consistent and timely removal of claims. We also request that that changes to the policy, including termination, are clearly and widely communicated to the registrant community and the public.*

<u>Label Guidance</u>

The guidance states: "For products that only have sanitizer claims seeking a virucidal claim, this language should be present on the label to indicate the product should not be used in patient care areas of healthcare settings, for example – 'Not for use in patient care areas of hospital/healthcare facilities.'"

HCPA requests that EPA further explain the sample language to clarify the difference between acceptable and unacceptable hospital/healthcare claims. We recommend that EPA allow use of sanitizer-only products in non-patient care areas of health care facilities. For example, it would be acceptable to have a specified claim stating "for use in non-patient hospital areas," but unacceptable to make a general statement such as "for use in hospital or healthcare settings."

Furthermore, HCPA requests that EPA confirm that combination disinfectant/sanitizer products can continue to indicate that the product can be "for use in [patient care areas of] hospital/healthcare facilities" where virucidal claims are linked to disinfection use patterns even when those virucidal claims are also linked to sanitization use patterns.

Additionally, HCPA requests that EPA fix a typo in the following sentence: "Claim language such as the following may be added to the label to emphasize where the product is intended to be used."

Lastly, under the examples of claims that would generally not be acceptable on the label of a product containing sanitizer only claims seeking addition of virucidal claims (Page 7), HCPA requests that EPA separates the "Kills germs" provision from the "Unqualified virus claims" provision to avoid user confusion.

Label Guidance – Sample Claim Language

We appreciate the sample claim language provided in the draft guidance. However, it is important that registrants know that flexibility is allowed in claim language given the large variety of pesticide products that exist and may enter the market. *Therefore, HCPA requests that EPA explicitly state that the Agency will allow flexibility on language depending on the type of product.*

EVP

In alignment with the EPA Pesticide Program Dialogue Committee's (PPDC) Emerging Pathogens Implementation Committee (EPIC) recommendations, HCPA supports the inclusion of viral sanitizer claims in the future Emerging Pathogen Policy and inclusion of viral sanitizer products on a list similar to List Q. *As such, HCPA requests that EPA include language in the guidance addressing the development of such a list.*

Comments for Future Consideration

HCPA appreciates EPA's diligent efforts in developing guidance for evaluating products for claims against viruses. We understand that the expansion of the availability of virucidal claims represents a significant policy shift for the Agency, and that further expansion of the guidance currently are not feasible. Therefore, we offer the following specific comments for consideration by the Agency after the initial time-limited implementation period.

Background and Purpose

The draft guidance currently "reiterates recommended test methods and regulatory guidance for the addition of virucidal claims to products that meet the criteria for hard surface disinfection claims consistent with the 810.2200 test guidelines." *HCPA understands this limitation is necessary for the initial implementation period of the guidance, but requests that, in the future, the Agency consider expanding the guidance to cover soft surface, porous surface, and residual (long-lasting) sanitizer claims in accordance with existing EPA guidance and test methods. We also request that the Agency consider expanding the guidance to allow for laundry sanitization as an appropriate prerequisite claim for adding laundry virucidal claims in the future.*

Definitions

HCPA requests that, when EPA revises OCSPP 810.2000 guidance,[10] it includes a definition for food contact and non-food contact sanitization which states the allowed voluntary addition of viral claims

[10] General Considerations for Testing Public Health Antimicrobial Pesticides, Guide for Efficacy Testing.

when desired. Updating 810.2000 as such, would ensure consistency across EPA guidance documents and avoid undue confusion for the registrant community.

Implementation – Registration Tracking and Collection of Input

The draft guidance states that products registered under the time limited policy will receive registrations with terms and conditions that will be tracked by EPA internally to capture all products under this policy and communicate with the registrants as necessary. *HCPA requests additional details about how the Agency intends to track these registrations and requests that EPA allow tracking to be visible to the registrant for ease of access to the information.*

EPA notes in the draft guidance that the purpose of a time-limited registration is to allow registrants to come forth and use the guidance for registration, and for the Agency to evaluate the benefits, concerns, and related experience to inform its decision on making the guidance permanent. How does EPA intend to collect this feedback from stakeholders, including the registrant community (*e.g.,* an EPA mailbox specifically dedicated to this effort, an existing mailbox (AD Ombudsman), a docket)? *HCPA requests that the Agency specify how this information will be collected by the Agency for evaluation and encourages EPA to make this information publicly available to increase transparency and avoid increased Agency workload if stakeholders submit multiple Freedom of Information Act (FOIA) requests.*

HCPA thanks EPA in advance for its consideration of these comments. Please do not hesitate to contact us if you wish to discuss further.

Sincerely,

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