OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

October 10, 2024

Agency Response to Public Comments for the Evaluation of Products for Claims Against Viruses Guidance

On July 17, 2023, EPA posted draft guidance describing how registrants of antimicrobial products with sanitizing claims could add claims that these products are effective against viruses. The purpose of this guidance is to expand the universe and availability of antimicrobial products that are effective against viruses. The comment period closed on September 15, 2023.

EPA received comments from five entities and sincerely appreciates the valuable feedback from these organizations and individuals. The attached table is a compilation of the comments received, grouped by topic area, and the Agency's response to those comments. A key at the end of this document correlates the comment numbers to the source of the comments that were posted on regulations.gov for docket EPA-HQ-OPP-2023-0288.

The primary areas of comment included the following:

- The allowance for virucidal sanitizer claims on soft surfaces/textiles/porous surfaces
- Implementation
- Concerns about the time limited registration/policy
- Edits/recommendations for Table 1. Product Eligibility and Test Criteria
- Testing parameters
- Residual Claims
- Contact Time(s) for Food Contact Sanitizers
- Emerging Viral Pathogen (EVP) inclusion
- Label language concerns/recommendations

After considering the public comments received, the Agency revised and finalized the guidance document. The revised guidance document and the associated test methods can be found in EPA-HQ-OPP-2023-0288.

Public Comment Key:

Commenter	**Comment numbers**
Center for Biocide Chemistries	1-17
ISSA	18
Clorox	19-25
HCPA	26-51
IRG	52-56

Comments Received

Comment Category	Specific Comment	Comment #	Agency Response
Soft surface/textiles/porous surfaces	CBC encourages EPA to consider expansion of the viral sanitizer policy to include soft and porous surfaces.	15	The Agency acknowledges the interest in including other surface types and claims in this new guidance. However, the initial implementation of this guidance will concentrate on hard non-porous surfaces. The Agency may consider expansion in the future.
	As EPA evaluates comments on its porous surface guidance and viral sanitizer policy, CBC encourages EPA to prioritize expansion of both policies to allow consumers and residential users access to appropriate products to disinfect and sanitize the variety of frequently touched surfaces where viruses can survive.	16	
	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.	48	
	The IRG strongly supports expansion of the viral sanitizer policy to include soft and porous surfaces. Quantitative Efficacy Methods for residential soft surface sanitization claims are well established under OCSPP Test Guidelines 810.2400 to allow consumers access to appropriate products to sanitize hard and soft surfaces. These are the same surface materials where viruses can survive. Soft surface sanitizers should also be able to utilize those methods to demonstrate efficacy against viruses to make virucidal claims.	53	

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	HCPA would like clarification as to why at this time the guidance does not address food contact towelette testing considering ASTM E 1053 is available for use and given the number of towelette products that are registered already as sanitizers.	31	No specific application methods were mentioned nor excluded with respect to the addition of virucidal claims. The guidance is not intended to exclude towelettes. Table 1 in the guidance has been revised to clarify that the ASTM E1053 method should be modified appropriately for each formulation type.
Implementation	CBC encourages EPA to further expand the guidance or provide additional clarification for registrants as to how label changes under the new policy should be submitted for various types of products.	6	Thank you for your comment. If no new data are being submitted, this type of submission would be considered a non-coded PRIA action. This is consistent with how the agency processes emerging viral pathogen (EVP) claims with no new data. The Agency is providing additional clarity on this topic in the final guidance. You may also reference the link below for additional details. https://www.epa.gov/pria-fees/actions-not-covered-pria-registration-service-fees
	CBC requests a clear understanding of how to submit label changes through the existing Pesticide Registration Improvement Act (PRIA) codes, even when new data does not necessarily have to be submitted and reviewed by EPA to add the virucidal claim.	7	
	CBC is concerned that if submissions are not able to be submitted through the PRIA pathway, many products will not have necessary amendments approved in a meaningful time frame to utilize the policy before its proposed expiration.	8	Thank you for your comment. The Agency has been working to implement process efficiencies to reduce the non-PRIA backlog and review new non-PRIA actions more expeditiously.
	In many cases existing label qualifiers are tied to disinfection, which require changes to allow for the creation of the sanitizer only product as there are distinct contact times for disinfection and sanitization.	9	Thank you for your comment. If no new data are being submitted, this type of submission would be considered a non-coded PRIA action.

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	Clarity is needed on how EPA would request such changes be submitted either through PRIA or non-PRIA submissions.		This is consistent with how the agency processes EVP claims with no new data. The Agency is providing additional clarity on this topic in the final guidance.
	HCPA Requests EPA provides details on claim additions to existing products for which virucidal data is already on file with the Agency. Would these actions be under PRIA or fast track amendments.	36	Thank you for your comment. If no new data are being submitted, this type of submission would fall under the non-coded PRIA pathway for fast-track amendments.
	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.	50	Thank you for your comment. We will track addition of these claims at the product level using our pesticide registration workflow. As the Agency develops external facing tracking tools, which are not currently available, we will consider addition of external tracking for these claims.
	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.	51	Thank you for your comment. The Agency will establish an open docket for stakeholders to provide any comments, issues, or concerns. The Agency intends to address items within a reasonable time frame based on Agency resources at that time.
	HCPA requests EPA to provide additional information on the pathway for submission of virucidal claims additions to product labels. Clear	35	Thank you for your comment. If no new data are being submitted, this type of submission would fall under the non-coded PRIA pathway for fast-

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	instructions on how to submit these additions would be helpful to the registrants.		track amendments. If new data are being submitted, the submission would fall under the normal PRIA pathway. There is no submission process specifically for these new clams. However, when submitting a new product registration and/or a label amendment, the Agency requests that the accompanying cover letter includes the intent to submit under this time limited guidance.
	IRG encourages EPA to provide clear guidance for registrants as to how label changes under the new policy should be submitted for various types of products. This is particularly important in any time-limited program. Given the historical difficulties with non-PRIA actions, these Sanitizer viral label changes must be accomplished through the existing Pesticide Registration Improvement Act (PRIA) codes, even when new data does not necessarily have to be submitted and reviewed by EPA to add the virucidal claim. IRG is concerned that if submissions are not able to be submitted through the PRIA pathway, the effectiveness of the new policy will be damaged, and registrants will be deterred from using it. For example, many existing product master labels are set up for both a disinfectant and a sanitizer. Adding the virucidal claims for sanitizer only products may require separating aspects of the disinfection and sanitizer sections on the master label. Label sections which are tied to disinfection may require changes for a new sanitizer only product since there are different contact times for disinfection and sanitization. EPA should consider clarifying how such changes should be submitted through PRIA. One possibility is to consider a registrant-submitted "Discussion Volume" that would accompany the label amendment. The volume could provide helpful details to aid the Agency review of the label under the new Guidance for the Evaluation of Products for Claims Against Viruses, particularly if	54	Thank you for your comment. If no new data are being submitted, this type of submission would fall under the non-coded PRIA pathway for fast-track amendments. If new data are being submitted, the submission would fall under the normal PRIA pathway. There is no submission process specifically for these new claims. The Agency will continue to review claims in the context in which they are used in the product label to ensure they are supported by efficacy data, and not misleading to the end user. The example details that you would put in the proposed discussion volume may be included in the supplemental cover letter provided with your submission along with the accompanying cover letter that includes the intent to submit under this time limited guidance.

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	the Efficacy team will be involved in the review. For example, the volume could include a summary of the qualifying viruses that can accompany sanitizer-only products and the relevant contact times. Submitting this volume as a new MRID may enable submission under PRIA.		
Time limited registration/policy	CBC is concerned that the seven-year time limit will deter registrants from utilizing the new policy and registering new sanitizers with viricidal claims.	1	The Agency has revised the guidance to provide a 10-year time limit. This timeframe will better allow the agency to determine if allowance of new virucidal claims aligns with the Agency's goals. The Agency expects to begin evaluation of the policy two years before the expiration date. This is reflected in the revised guidance. The Agency is committed to making a determination within the 10 years regarding impact of the guidance and next steps for the pilot.
	It is also unclear whether, under the current seven-year expiration proposal, there is an opportunity for the guidance to be re-issued in time for those sanitizer-only virucidal products to remain on the market without interruption.	2	
	In the event that EPA's analysis of the policy and feedback received takes longer than one year, the final guidance should make clear that products can remain on the market until EPA issues a final decision whether the policy should be altered, made permanent, or sunset is issued.	3	
	To balance the EPA's goal of evaluating the policy after an appropriate time interval and the need to incentivize registrants to utilize the new policy, CBC recommends extending the timeframe to a minimum of 15 years.	4	
	CBC also recommends starting the evaluation of the policy two years before the expiration date to ensure enough time for EPA to evaluate and propose any changes to the policy.	5	
	HCPA expresses concerns that a 7 year limited registration is not sufficient for new sanitizer products to enter the market. Seven years may be ok for existing sanitizers that may qualify for the new virucidal claim, but novel products require more time for development.	37	

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	HCPA expresses concerns regarding the Agency's policy impact analysis - which indicates that a year prior to the completion of the 7 year registration period the Agency will gather information to make a final determination on said guidance. HCPA suggest a period of 2 years.	38	
	HCPA requests that products registered under this Guidance remain on the market until EPA's analysis is complete and a final decision is made.	39	
	The IRG companies feel strongly that the seven-year time limit will deter registrants from utilizing the new policy and registering new sanitizers with viricidal claims. The IRG member companies have extensive experience with these regulatory timelines; we strongly recommend that EPA extend the new policy's lifetime to a minimum of 15 years. This extension will strongly incentivize registrant participation while yielding data and experience to better inform the Agency on a decision regarding the policy's future. Given the OCSPP/OPP/AD leadership's confidence in this policy's success, the IRG also suggests the addition of language that would permit the OPP Office Director, after periodic review of sufficient data and experience, to make a decision at any time that this Interim Guidance should be made a permanent policy.	52	
	HCPA requests that EPA determine what is the pathway to ensure consistent and timely removal of claims if the Guidance is to be terminated. Additionally, HCPA requests this information is clearly and widely communicated to the registrant community.	40	The Agency will consider this request when feedback and comments are evaluated, and clear next steps will be communicated if the path forward is to terminate the guidance.
Table 1. Product Eligibility and Test Criteria	CBC notes that for the guidance to be used accurately for food contact sanitizers with virucidal claims, Table 1 should be edited to clarify a 1 minute maximum contact time for food contact sanitizers making virucidal claims.	10	Thank you for your comment. The table has been edited to remove a required contact time for efficacy testing of food contact sanitizer Halide

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	CBC highlights that he contact time listed in Table 1 incorrectly shows the contact times for the bactericidal sanitizing methods. The AOAC Available Chlorine (halide method) uses a 60 second contact time, not a 30 second contact time as reflected in Table 1. This should be corrected in the final guidance document.	13	products due to the nature of the method. The table now aligns with the associated test method and the Agency's 810.2300 guidance. The label contact time should reflect 1 minute.
	HCPA requests corrections regarding food contact hard surfaces halide testing - regarding contact time and chlorine concentrations.	30	
	HCPA requests revisions to Table 1 to ensure contact times are defined by the maximum contact time to achieve the performance standard for viruses.	33	
	HCPA suggest edits to Table 1 - these edits include: Update organism name and ATCC No., update on contact times for both sanitization categories, update on contact time under the NEW virucidal category.	28	Thank you for your comment. The suggested edits have been incorporated in the final version of the guidance.
Testing Parameters	CBC requests clarity as to whether under this guidance, EPA will allow viricidal claims on food contact sanitizers below one minute (e.g., a food contact sanitizer could have a one minute bacterial claim and a 15 second viral claim).	11	Thank you for your comment. Food contact sanitizers historically have always had a label contact time of 1 minute through consultation with FDA for food establishments. For consistency, a 1-minute contact time should be utilized for all virucidal claims on food contact sanitizers.
	CBC would also like to clarify that registrants can utilize different dilutable concentrate dosing instructions depending on the virus and claims.	14	Thank you for your comment. The Agency will continue to review claims in the context in which they are used based on the product label (to include various dilutions), to ensure they are supported by efficacy data.
	HCPA suggest adding clarification regarding testing 2 or 3 lots of product against SARS CoV-2.	27	Thank you for your comment. SARS CoV-2 should be tested using 3 lots for the first strain on the label. The

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			guidance has been updated to reflect these specifications.
	HCPA requests to add SOP MB-05 as the Use Dilution Method (UDM) method reference for testing against *Salmonella enterica*. Additionally, HCPA requests an update on the Series 810 FAQ and 810.2200 to reflect the requirements for testing against *Salmonella enterica*.	29	Thank you for your comment. SOP MB-05 may be utilized for *S. enterica* for disinfection claims and the guidance has been updated to reflect this. Additionally, the Agency will consider the request to add SOP MB-05 to the 810 FAQ and 810.2200 the next time these documents are updated.
Residual Claims	EPA could also consider expansion to residual hard surface sanitization claims in a future guidance.	17	The Agency acknowledges the interest in including residual claims in this new guidance. However, at this time the initial implementation of the guidance does not include residual claims. The Agency may consider expansion in the future.
Food Contact Sanitizers Contact Time	If EPA confirms the 1 minute maximum labeled contact time for viral claims for food contact sanitizers, CBC requests that EPA establish a standard testing contact time of one minute for viruses to support the one minute labeled time.	12	Thank you for your comment. The final guidance has been revised to include an updated version of the table. The maximum contact time for food contact sanitizers (FCS) is 1 minute and the maximum contact time for non-food contact sanitizers (NFCS) is 5 minutes, to include claims against viruses.
	Requests clarification on contact times. Based on 810 guidelines the CT for disinfection is <10 minutes, NFCS <5 min and FCS <1 minute.	32	

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	Table 1 should be updated to reflect the different CTs and differentiate between CTs for NFCS and FCS.		
	IRG recommends clarification/edits to the guidance on contact time requirements between non-food contact and food contact sanitizer products. The Draft Guidance currently states that a five-minute maximum contact time applies to all sanitizers; however, page 4 of the guidance says, "the maximum contact time to achieve the performance standard time for viruses should be consistent with the maximum contact time for bactericidal claims." Thus, for food-contact sanitizers with bactericidal claims, one minute is the correct maximum contact time. Table 1 should be edited to clarify a 1-minute maximum contact time for food contact sanitizers making virucidal claims.	55	
	Clorox recommends that for non-food contact settings, the contact time for virucidal claims should be allowed to extend beyond the bacterial sanitization claim (i.e. up to 10 minutes).	20	Thank you for your comment. As described in this guidance, the maximum contact time for FCS is 1 minute and the maximum contact time for NFCS is 5 minutes, to include claims against viruses. Anything beyond those limitations falls outside of the agency's historical acceptance criteria for sanitizers. Registrants may consult with EPA regarding virucidal claims associated with other contact times on a case-by-case basis prior to data generation and submission as they may cause confusion for end-users regarding how the agency defines sanitizers vs disinfectants.
Emerging Viral Pathogens	Products that are sanitizers (without disinfecting claims) that bear labeling for virucidal use should be eligible under the process for making Emerging Viral Pathogen (EVP) claims.	19	Thank you for your recommendation. The Agency has determined that as currently written, the EVP guidance does not support the addition of EVP

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	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.	47	claims to products with only sanitizer claims. The EVP guidance specifies that certain **EPA-registered disinfectant** products are eligible for emerging viral pathogens claims. Products with sanitizer only claims, do not meet the criteria outlined in the guidance. The Agency will consider this suggestion for any future revisions to the EVP guidance.
	Products that are sanitizers only with virucidal claims should be eligible for making claims against Emerging Viral Pathogens (EVP). Currently, the guidance to registrants for EVP claims are limited to products that are EPA-registered disinfectants. Because this guidance for virucidal claims does not propose any change to microbiology methodologies or performance criteria, efficacy against viral pathogens is the same regardless of a product being a bacterial disinfectant or sanitizer. As this guidance becomes final, the EVP policy should immediately make any antimicrobial disinfectant or sanitizer eligible to make claims against emerging viral pathogens.	56	
Label language	"Claim language for Virucide use directions should follow a header such as, "USE DIRECTIONS for VIRUCIDES ONLY". Clorox supports this labeling aspect and encourages the Agency to accept other label headers with similar language.	21	Thank you for your comment, the feedback is appreciated.
	Labeling guidance and claims should be carefully considered as to promote the appropriate use of sanitizing products that bear virucidal claims, in comparison to disinfecting products.	22	Thank you for your comment. The Agency has expanded the definition of patient care areas by adding a list of non-patient care areas for additional reference.
	Clorox recommends that the EPA define "patient care areas" and that labeling under this guidance should indicate that use is not appropriate for any patient care areas, regardless of site.	24	
	Under "Product Eligibility and Test Criteria", the draft guidance states that "it may be appropriate to consider labeling these products to indicate "Not for use in patient care areas of hospital/healthcare facilities". Clorox encourages this statement (or language similar) to be required on labeling as to prevent sanitizer products from being used	23	Thank you for your comment. The Agency will review product label language on a case-by-case basis to ensure that all label claims are

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	in place of a disinfecting product in patient care settings. To indicate that it “may be appropriate” to include these types of statements suggests that the language is optional.		supported by efficacy data and clarity is provided for the end user.
	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.	41	
	It is critical to inform users about a product’s efficacy performance. There should be ways to inform clear differences between a disinfecting product and sanitizing product, when virucidal claims are present on labels. The Agency may want to consider a statement such as “Not for use as a disinfectant” when products are labeled under this guidance. This may help differentiate product performance and allow users to make informed decisions when choosing to use an antimicrobial product.	25	Thank you for your comment. The Agency will continue to review claims in the context in which they are used based on the product label to ensure they are supported by efficacy data, and not misleading to the end user. Additionally, the label suggestion provided has been included in the final guidance under the label section as suggested language.
	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.	42	Thank you for your comment. The Agency will continue to review claims in the context in which they are used based on the product label to ensure they are supported by efficacy data, and not misleading to the end user. In the scenario presented, the Agency anticipates requiring that the label qualify the claim, “for use in [patient care areas of] hospital/healthcare facilities” with “when used according to disinfection instructions” for clarity.

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	HCPA requests that 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), that EPA separates the "Kills germs" provision from the "Unqualified virus claims" provision to avoid user confusion.	44	Thank you for your comment. The Guidance has been updated to reflect the edit you have requested.
	HCPA requests flexibility on the sample claims language provided in the guidance. Therefore, HCPA requests that EPA explicitly state that the Agency will allow flexibility on language depending on the type of product.	45	Thank you for your comment. The Agency will continue to review all label language and ensure that it is appropriate based on the context and efficacy data provided. The agency is not requiring registrants to use the sample language.
Miscellaneous	Add reference to Series 810 FAQ document since it provides useful information for registrants	26	Thank you for your comment. This edit has been incorporated in the final version of the guidance.
	HCPA requests that EPA update the Pesticide Registration Manual webpage and associated links to reflect PRIA 5 information.	34	This request is outside of the scope of this guidance. However, the Agency commits to coordinating with the appropriate parties to see that appropriate updates are made.
	Fix typo on 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."	43	Thank you for your comment. This edit has been incorporated in the final version of the guidance.
	HCPA requests that, when EPA revises OCSPP 810.2000 guidance, it includes a definition for food contact and non-food contact sanitization which states the allowed voluntary addition of viral claims when desired. Updating 810.2000 as such, would ensure consistency across EPA guidance documents and avoid undue confusion for the registrant community.	49	This request is outside of the scope of this guidance. However, the Agency acknowledges your request and will consider it the next time the 810 guidelines are updated.