Report of the Emerging Pathogens Implementation Committee to EPA's Pesticide Program Dialogue Committee (PPDC)

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Executive Summary

The Emerging Pathogens Implementation Committee (EPIC) was established by the Pesticide Program Dialogue Committee (PPDC) at its May 2022 meeting. This effort builds on the work of the PPDC's Emerging Pathogens Work Group (EPWG), proposed in Fall 2020, to conduct a retrospective analysis of the U.S. Environmental Protection Agency (EPA) Emerging Viral Pathogen (EVP) Policy and EPA's antimicrobial response to the COVID-19 pandemic. EPWG first met in January 2021, comprised of more than 20 members from regulated industry, academia, trade associations, regulatory/technical consultants, transportation industry, and U.S. Centers for Disease Control and Prevention (CDC).

After two years of meetings and work, EPWG proposed more than 85 recommendations to EPA at the May 2022 meeting. The EPA Antimicrobials Division (AD) reviewed each recommendation and prioritized the recommendations for consideration during the implementation phase.

After the sunsetting of the EPWG, the PPDC charged the newly-formed EPIC with:

- Refining and implementing the EPWG's recommendations, and
- Examining how to expand the EVP Policy to other types of antimicrobial pathogens.

Functionally, the EPIC split its work into three main work groups: Technical Work Group, Policy Work Group, and Communications and Education Work Group (**Figure 1**).

Figure 1. Emerging Pathogen Implementation Committee (EPIC) Work Groups

Each Work Group met on a biweekly to monthly basis to develop final recommendations for the PPDC's consideration. These recommendations are summarized below and discussed in further detail in subsequent sections of the report.

Policy Recommendations:

- **Recommendation 1**: EPA should develop a pathway for registrants to communicate EVP activation on-packaging, with a preference for use of a multi-use QR Code option.

- **Recommendation 2**: EPA should update the Section 18 checklist with an addendum of additional information that supports antimicrobial-related public health submissions.

- **Recommendation 3**: EPA should develop new modules for the Section 18 training that focus on antimicrobial-related public health emergencies and submissions.

Technical Recommendations:

- **Recommendation 4:** EPA should consider the PPDC Committee's proposed revisions to the EVP Policy and publish an updated policy as quickly as possible to assure readiness for the next viral emerging pathogen. The revised EVP should be published for immediate implementation during the public comment period.

- **Recommendation 5:** EPA should consider the PPDC Committee's proposed drafts of Emerging Pathogen policies for Bacterial Sporeformers, Mycobacteria, Fungi/Yeast, and Bacteria Policy and publish policies as quickly as possible to assure readiness for future emerging pathogens. These policies should be published as draft documents for public comment prior to implementation.

- **Recommendation 6:** PPDC should request annual updates from EPA on the progress in developing, reviewing, and publishing all 5 Emerging Pathogen Policies.

- **Recommendation 7:** EPA should create a process to periodically reassess the published emerging pathogen policies to assimilate or make changes based on new research and experience with emerging pathogens. This may include PPDC initiating future work groups similar to the current group to aid EPA in this endeavor.

Education and Communications Recommendations:

- **Recommendation 8:** EPA should partner with stakeholders, including user groups, to co-develop infographics targeting proper antimicrobial pesticide use prioritizing a clear distinction between disinfectants and sanitizers. Additional infographics/pictograms or fact sheets of immediate interest should include: (1) when and how to effectively use antimicrobial pesticides and (2) frequency of reapplication based on use sector and conditions.

- **Recommendation 9:** EPA should develop useful tools, potentially online training modules and videos for how to use, read, and interpret the interactive EPA Lists, more specifically Lists N and Q. These videos and training modules should provide easy to follow instructions for successfully accessing and navigating through the sites to select a desired product. These could include an assessment tool to demonstrate proficiency.

- **Recommendation 10:** EPA should compile training, education, and communication documents for antimicrobial pesticide use into a centralized location on an EPA landing page. For example, the "How to Read a Label" document generated in collaboration with CDC, Project Firstline, and EPA can be housed in a central location on an EPA antimicrobial pesticide webpage along with other sector centric documents for ease of locating. This webpage should also be linked on the EVP landing page and offered with a Spanish translation.

- **Recommendation 11:** EPA should develop and include on its EVP website infographics or pictograms to provide clear differentiation between Tier 1, Tier 2, and Tier 3 viral descriptions for List Q product selection.

- **Recommendation 12:** EPA should provide additional context for users as to what types of surfaces are considered porous and non-porous. The use surfaces defined in List N and List Q, or on any lists where the surfaces are defined as porous and non-porous are not intuitive. More information is needed to better understand the actual use surfaces where the product is compatible. Frequently these use sites defined as porous or non-porous are inherently difficult to understand but are more nuanced in scenarios where a surface/item is portable or flexible and can be located indoors or outdoors.

- **Recommendation 13:** Provide clear instructions or potential hyperlink to address frequency of use based on sector and use sites within sector. In lieu of or in the interim, consider developing general training curricula to (1) Distinguish between routine disinfection based on sector/versus outbreak situations; and (2) Provide distinctions between primary (master) label and actual product label and circumstances where they can differ.

- **Recommendation 14:** EPA should develop joint messaging with FDA, where applicable, on several topics where federal agency jurisdictional oversight is frequently unclear. Consider prioritizing hand hygiene/antiseptics/sanitizers/disinfectants clarification as the initial deliverable.

- **Recommendation 15:** With the development and diversity of the QR codes, EPA could consider guidance for how registrants can provide links to EPA training and educational tools at point of sale for informed product selection.

- **Recommendation 16**: EPA should expand translations to several EVP related resources beyond Spanish.

I. Policy Recommendations

A. Point-of-Sale Identification of EVP-eligible products for purchasers

The PPDC Emerging Pathogen Work Group (EPWG) recommended that further work be undertaken to explore on-package information to convey when a product can be used to address an emerging pathogen. EPA has a clear policy outlining how registrants can add claims to a product for Emerging Viral Pathogens (see discussion of updates to EVP policy in the Technical Recommendations). However, the current policy does not allow for any on-package communication to purchasers that the product would be effective against a currently activated emerging viral pathogen. Registrants can currently only communicate this information in limited off-label locations (e.g., websites, sales sheets, technical hotlines).

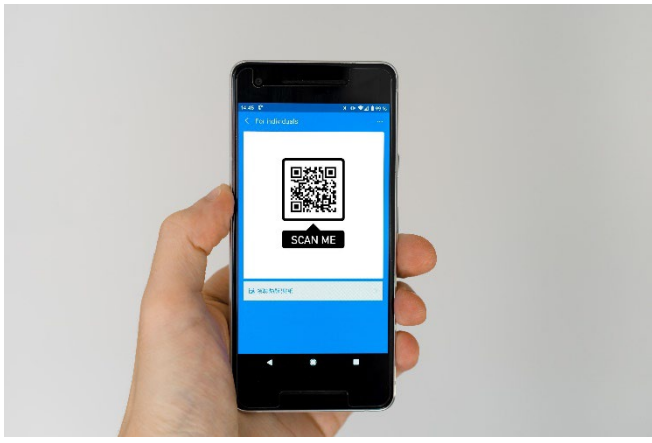
While the PPDC EPWG suggested an on-label icon to deliver this information, EPA feedback was that this is resource and time intensive to develop. EPIC recommends that EPA explore the use of a QR code on label to deliver this information to purchasers.

A QR Code could work as follows:

1. A registrant adds a QR code to a pesticide product label. (*Example to right is not a FIFRA-regulated product*.)

Consideration: Allow text next to the QR code that indicates what the QR code will contain "pointer text." The QR code could be used for multiple purposes (e.g., emerging pathogen labeling, bilingual labeling, Safety Data Sheets (SDS)) depending on EPA policy allowances and registrant preference.

2. A consumer accesses the QR code using a smart phone camera. The QR code contains a link to a registrant-supported website, taking the consumer directly to that website. The current EVP policy allows registrants to make EVP statements on company websites, though they must be non-label related. The proposed revised EVP policy will allow QR codes on labels to link to the EPA-approved EVP language.



Considerations: Can QR codes offer options of different websites for different information? QR codes may start to be used for more information on pesticides—with the passage of PRIA V, it is likely many products will use this to provide the required Spanish language information. QR codes, therefore, may not be exclusively used for EVP information and registrants are unlikely to place more than 1 QR code on a label, which may be confusing for consumers. Adding pointer language above the QR code may resolve consumer confusion (e.g., Click to see SDS, Spanish labeling, and Emerging Pathogen list.)

3. The content on the registrant's website would contain pre-approved EVP language, with potential links to the EPA EVP policy, relevant lists of products, and more information at the CDC or World Organisation for Animal Health (WOAH) pathogen-specific website address, as determined by the EVP policy.

   Considerations: One advantage of a QR code is that the language on a linked website through a QR code can be quickly changed in response to an outbreak or end of an outbreak.

An additional consideration for conveying key information to consumers during an EVP outbreak could be aisle signage with a QR code conveying EVP information.

B. Expanding Section 18 Submission and Training Tools to Target Public Health Emergencies

During the COVID-19 pandemic, there were a significant number of Section 18 applications for new products to address the declared public health emergency. The Section 18 process has historically been used to address localized pest emergencies, typically involving agricultural-use pesticides. EPA has a robust online Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 18 Emergency Exemption Information and Training Resource, developed in 2012 by university of California- Davis Extension through the Pesticide Regulatory Education Program (PREP) Cooperative Agreement funded by the U.S. EPA. The course was reformatted under the PREP Cooperative Agreement in 2023 managed by Colorado State University (CSU). While this course is a very helpful tool, it is not geared toward the unique, national circumstances of an antimicrobial public health emergency like the COVID-19 pandemic rather it is more targeted to agricultural emerging pests.

To increase the quality of Section 18 applications submitted in future public health emergencies, the EPIC Policy Work Group examined the current Section 18 checklist and discussed the information that would be most helpful to EPA in determining whether an application met the Section 18 criteria. While EPA cannot change the Section 18 requirements, as these are established by FIFRA, EPA can guide applicants on the types of information that should be submitted to increase the quality of an application during a public health emergency.

Specifically, EPIC recommends that EPA provide an addendum to the Section 18 checklist to assist applicants during public health emergencies. This addendum could include more information as to:

- Why is this product/treatment needed?
  - Why currently registered pesticides are not available, adequate, or effective to control the public health emergency.
  - For applications to address a public health pest that is a virus (or other microbes once the proposed emerging pathogen policies are published – **See Technical Recommendations**), this section should also explain why pesticides eligible for use against the public health threat if the EPA's Emerging Pathogen Policy has been activated for the pest are not available, adequate, or effective to control the emergency.
- Ensuring the quality and usability of efficacy data

- Efficacy data should be submitted following general data expectations and should support all pesticidal label claims. Testing should be done on the target pest, or an acceptable surrogate organism. Efficacy testing should address factors or conditions that would normally be encountered with the use pattern(s) intended for the product.
- Data must be credible, independently collected, reproducible, and repeatable.
- Applicants should review and utilize EPA's OCSPP 810.2000 and/or other relevant EPA 810 testing guidelines/guidance when developing and submitting efficacy data.
- To assist in the proper review and evaluation of product performance, complete descriptions of the test employed, and the results obtained should be submitted to the agency. The applicant is encouraged to use the EPA's Standardized Efficacy Study Report and Efficacy Study Summary as a template for the study report and to include all the reporting elements listed in 810.2000.

Should EPA resources and grants allow, PPDC EPIC also recommends updating the existing FIFRA Section 18 Emergency Exemption training modules with a module specifically on public health emergencies.

II. Technical Recommendations

The Technical Work Group is a robust and diverse work group of registrants, academicians, user groups, trade associations, the U.S. Centers for Disease Control and Prevention (CDC) and Agency staff to review the published literature, collect the laboratory experiences and recommendations to prepare this guidance and the underlying processes. The proactive registration process for viral emerging pathogens began with the 2009 guidance which was subsequently updated in 2016 (https://www.epa.gov/sites/default/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf).

This policy allows registrants to proactively obtain or pre-register for future emerging viruses based on viral structure which imparts a well published hierarchy of inactivation. The registration is reviewed by EPA to assure existing scientific studies have met EPA requirements, Good Laboratory Practices (GLP), and will support the emerging type of virus structure (small, non-enveloped, large, non-enveloped, or enveloped virus). The label claims are also pre-reviewed by EPA for use in off-label communications and may only be used once EPA triggers on its website that the specific conditions have been met under the policy to allow registrants to immediately begin making off-label instructions and claims to users in need of products to combat the pathogen. As the current timeline to register a new microbe claim may take 3-4 years to achieve, this pre-registration tool allows the EPA and registrants to instruct users on the best available products to combat an emerging pathogen within hours to days. The attached policies describe the registration process and how products will qualify for these claims in detail (**Appendices 1-5**).

The Work Group began its effort by revising the 2016 Emerging Viral Policy (EVP) based on the recommendations of the earlier EPWG which collected learnings and suggestions from users across many sectors, registrants, Agency staff, etc., from the COVID-19 experience. This retrospective analysis was performed to improve the efficiency and breadth of the policy to assure the US was better prepared for the next viral pandemic. The proposed revisions of the policy found in Appendix 1 include:

- Expanded surface types including hard and soft porous and fabric surfaces for non-residual and residual uses,
- Expanded uses beyond hard surface disinfection including laundry, food contact and non-food contact sanitization, and sterilant/sporicides,
- Provided EPA with flexibility to add more uses as the need arises or to maintain supply chain,
- Expanded the eligibility criteria to include more ways to qualify for the claim (e.g., sporicidal data; animal/human viruses may support each other),
- Expanded allowable EVP communication language including table formats and use directions,
- Expanded options for where EVP communication may be used,
- Established the EPA Web landing page as the communication hub to trigger/close out the use of emerging pathogen claims
- Added allowance for a QR code or other equivalent “on label” link to EVP communications,

- Expanded to allow EPA to trigger the policy for outbreaks outside the US where potential exists to impact the US to allow for preparedness,
- Expanded the Regulatory Agencies the EPA may rely upon to identify outbreaks, viral structure, and transmission (e.g., United States Department of Agriculture (USDA), Health Alert Network (HAN)), and
- Added/Updated registration process and templates (e.g., cover letter, "terms", Master Label) for registrant use and to standardize the registrant process.

We are recommending that EPA publish this revised EVP policy as soon as possible for interim use while taking public comments due to the extensive and successful use of the historical policy and the many critical improvements added by the Technical Work Group.

Upon completion of the EVP revisions, per PPDC request and using the same pre-registration process used for EVP, the group reviewed the published literature, scientific test methods, registered products/volumes, and unpublished work among the public health agencies, contract labs, EPA laboratory, and registrant labs. This information was used to prepare the proposed policies for the remaining microbes including Bacterial Sporeformers (e.g., *Clostridium, Clostridioides, Bacillus*), Mycobacteria (e.g., *M. tuberculosis, M. lepra*), Filamentous Fungi and Yeast (e.g., *Aspergillus, Candida, Stachybotrys*), and vegetative Bacteria (e.g., *Staphylococcus, Escherichia, Pseudomonas*). Appendices 2-5 provide a draft policy modeled after the EVP with the relevant information for each microbe type. We are recommending that EPA move to publish these drafts for public comment as soon as possible so they may be finalized and published for use before the next emergency arises.

In many cases, data was not available that directly evaluates whether indicated research categories are predictive for a microbe. As such, recommendations provided are based on the collective expert opinion of the PPDC EPIC whose input is based on published literature, and the research and testing experience of the assembled experts. In general, the Work Group took a conservative approach requiring evidence of performance on microbes of much stringency where the emerging pathogen may need. EPA may also consider other existing claims or microbial strains to support use of a product during an outbreak to assure sufficient supply of appropriately registered products to meet the public health need. As this field continues to evolve while the US will continue to experience various emerging pathogens, the Work Group is recommending the establishing a battle rhythm of reviewing the current literature and the response to various outbreaks to revise and amend the current and proposed policies periodically.

While discussing the current testing requirements, the Work Group also made several recommendations on future changes to test methods, required test strains, test carriers, test conditions, etc.; those have been captured in **Appendix 6** for EPA consideration for future research and development. While the Work Group has made recommendations in each of the policies intended for publication on the testing that will support an emerging pathogen claim, the group also made recommendations to EPA for internal use where the data and experiences trended toward supporting emerging pathogen claims but perhaps just fell short of sufficient information to make a full public recommendation in the policy. In this case, the Work Group documented their recommendations to EPA for internal use should the supply chain be insufficient or other

emergency conditions arise that required more products than the published policy allows (**Appendix 6**).

III. Education/ Communication Processes and Recommendations

The initial Emerging Pathogen Work Group's (EPWG) Charge Question #3 was "What education is needed during a pandemic or other emergency for the public, end users, and other regulating authorities?" (**Figure 2**). This charge question and subsequent recommendations were taskers for the current Emerging Pathogen Implementation Committee (EPIC) through the Communication and Education Work Group (**Figure 2**).

During the last 2.5 years, the Communication and Education Work Group, focused on the following target areas:

- Translating several Emerging Viral Pathogen (EVP) documents into Spanish and making the resources publicly available on the EVP landing page.
- Conducting outreach to several sectors to better understand the gaps in education and communication regarding proper antimicrobial pesticide use.
- Proposing and/or developing sector targeted-centric education and communication tools to facilitate proper use of antimicrobial pesticides.

Translated Documents

During the Spring 2021 PPDC meeting, following the EPWG meeting report, a PPDC member stressed the need for EVP-related documents to be translated. This request was initiated during the former EPWG tenure, however the action was delayed and subsequently forwarded to EPIC completion. As the first action, the current PPDC EPIC identified and prioritized which EVP-resources would be targeted for Spanish translation and eventual web posting and EVP landing page. Since the currently posted EVP guidance will be revised soon, EPIC decided to limit Spanish translations to the following documents: (1) Overview of the Emerging Viral Pathogen Guidance and Status for Antimicrobial Pesticides website, and (2) Disinfectants for Emerging Viral Pathogens (EVPs): List Q webpage instructions. The Overview for the webpage is static and represents useful information for end users. The other portions of the webpage are either dynamic or include dedicated information for registrants. Future opportunities to translate other resources will occur with the proposed EVP guidance revisions. Currently, other dynamic sections of EVP webpages (i.e., Lists, etc.) create significant hurdles for timely translations and postings.

In May of 2024, weeks prior to the Spring PPDC meeting, the two translated resources previously identified were provided on the public facing EPA EVP landing page.

Sector Outreach and Identified Communication/Education Gaps

During year 1 of EPIC's operation, the Education and Communication Work Group's goal was to gather information from different sectors as captured in the EPWGs tables (**Figure 2**). The targeted sectors included healthcare, transportation (ground, air, and cruise), schools/daycare/institutions,

farmers, food establishments (retail and processing), hospitality/hotels, senior facilities/nursing homes/assisted living facilities, and general industries. Initially, the Work Group proposed to conduct interviews using questions developed explicitly for this purpose by the Association for Professionals in Infection Control and Epidemiology (APIC) (**Figure 3**). The proposed questions represented specific information that the Education and Communication Work Group wanted to access from each sector; however, the group realized early in the information gathering phase that several sectors were completely survey-fatigued following the endless, never-ending questionnaires conducted during the pandemic. To lessen the added burden of tasking the individualized sectors with completing another survey/questionnaire, the Work Group decided to abbreviate the information gathering phase to informal phone calls utilizing only a subset of the questions through conversations. This strategy proved efficacious for the Migrant Clinicians Network (MCN), CDC's Vessel Sanitation Program (VSP), the National Center for Farmworkers (NCFH), and an individual from a large, national hotel chain. Other sector information gathering was limited to specific emails, published literature from user group surveys and interviews, sector-specific user group publications and websites, and informal interagency meetings and conversations.

<u>Proposed education and communication tools to facilitate proper use of antimicrobial pesticide use and Final Recommendations</u>

Following the sector analyses from each referenced source, the EPIC Education and Communication Work Group consistently observed four (4) recurring concerns regardless of end user:

- Lack of guidance on product over use, exposure, and worker protection standard (WPS) for antimicrobial products
- Confusion over when to use a "disinfectant" or a "sanitizer", and how to distinguish between them
- Language barriers and literacy challenges with labels and use directions
- Incompatibility issues with products and exposed/treated surfaces

The Education and Communication Work Group prioritized the four (4) identified concerns to initiate the education and communication resource development phase. Distinguishing the difference between disinfectants and sanitizers represented the concern of highest prioritization. While brainstorming on sufficient tools for addressing this item, the Work Group wanted to leverage the knowledge obtained from conversations regarding the lack of comprehension of previously developed tools compounded by frequent overall incomprehension of antimicrobial labels and use directions.

The Work Group decided, as identified in bullet #4 above, language barriers and overall literacy challenges should influence the development of any resource. To that end, Infographics/pictograms were the suggested communication/educational tool to provide immediate resolution for distinguishing between disinfectants and sanitizers. Several regulated and user groups have developed effective infographics to facilitate education and communication for antimicrobial pesticides use. Leveraging the existence of infographic tools, the Work Group contemplated using and/or co-branding with existing infographics to make these resources readily

available on the Agency's website. These recommendations at their core may be cross sectional, however, the group reached a hard pause with navigating through the EPA legal ramifications of co-branding. Since education and communication deficiencies are recurring, chronic issues regardless of pesticide type (i.e., conventional, antimicrobial), the EPIC Education and Communication Work Group provided the cited recommendations included in the Executive Summary.

Figure 2. EPWG Synopsis.

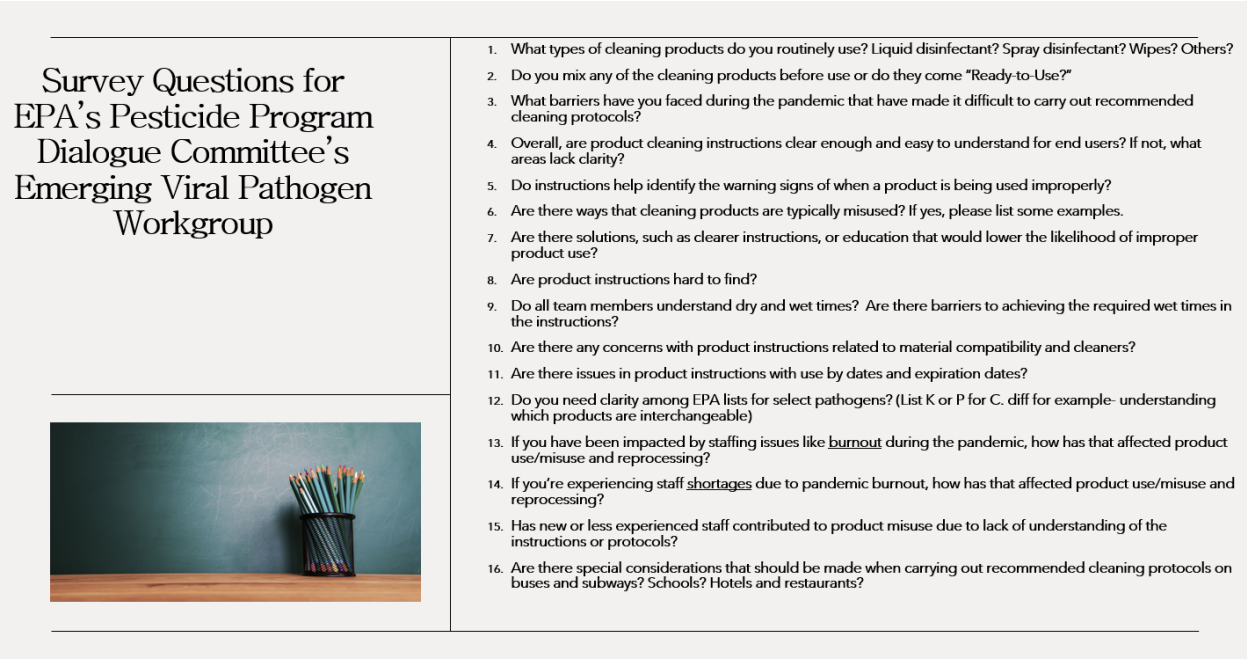
Charge Question 3: What education is needed during a pandemic or other emergency for the public, end users, and other regulating authorities?
Issue: There was ineffective messaging across several sectors due to information and education gaps.
Response: Develop targeted resources and references for general and specialized messaging for key sectors at different stages of a pandemic/emergency gathered through planned outreach tools (surveys, etc.) and lessons learned
Recommendation
3.1.1. Conduct surveys at each phase of the pandemic or emergency to determine how to communicate and what could have been done better
3.1.2. Communicate survey results to appropriate stakeholders
General Messaging Across All Sectors
Recommendation
3.1.3. Provide all documents in English and Spanish, at a minimum
3.1.4. Identify the audience and develop documents that best speak to that specific audience
3.1.5. Establish a clear dissemination process for documents (mainstream media channels, press, consumer unions for education/reports)
3.1.6. Continue to educate through every phase
3.1.7. Collaborate with other regulatory bodies and associations because of their sector expertise and inherent expertise to develop materials, respectively
3.1.8. Develop Webex/Webinars from EPA and other trade organizations and make these educational resources available in a centralized location. This can occur with greater frequency in a virtual space across many sectors
3.1.9. Leverage trade organizations and other groups to better understand the challenges and best practices in a collaborative space
Pre-Pandemic
Recommendation
3.1.10. Provide information on effective products
3.1.11. Provide information on when and how to use products based on sector
3.1.12. Correct any misinformation
During the Pandemic

Recommendation
3.1.13. Provide information on effective products for the pathogen at issue if known
3.1.14. Provide information on when and how to use products based on sector for the pathogen at issue
3.1.15. Identify examples of frequent/high touch areas of concern/how they evolve
3.1.16. Adjust product recommendations based on transmission routes /better clarification of products for use
3.1.17. Consider consumer products that can be used at homes/effectively disinfectant the spectrum of fomites, etc.
3.1.18. Reassure products are suitable for use when used as directed
3.1.19. Correct any misinformation
Post Pandemic
Recommendation
3.1.20. If enhanced or elevated disinfection practices are being used during pandemic, communicate to sectors when they can go back to normal
3.1.21. Correct any misinformation
Specialized Messaging for Identified Sectors
Aircrafts/Facilities
Pre-Pandemic
Recommendation
3.1.22. Test and qualify as many products as possible through the airline testing/qualification program
3.1.23. Leverage other testing/certification programs
3.1.24. Identify if there is an international entity list of approved disinfectants for international use
During Pandemic
Recommendation
3.1.25. Identify products that may be incompatible with aircraft surfaces
Cruise Industry
Pre-Pandemic/During Pandemic
Recommendation
3.1.26. Identify if there is an international list of approved disinfectants for international use
Post-Pandemic
Recommendation
3.1.27. Research what practices the cruise industry has employed to taper infectious cases since cruise industry has had a history of incidents related to illnesses in enclosed space/people in close proximity to each other
3.1.28. Research what this industry has done to improve air system ventilation/filtration
3.1.29. Identify the targeted high touch areas in this industry
3.1.30. Identify what lessons can be learned from this industry
Federal/State/Local Government
Pre-Pandemic
Recommendation

3.1.31. Share insights on EPA policies and practices related to pandemic/emergency responses to prevent divergence
3.1.32. Assess regulations and identify where there are conflicting and synergistic messaging related to the use of disinfectants
3.1.33. Communicate with various regulatory agencies that oversee pandemic responses and solutions (CDC, EPA, FDA, etc.) to find common avenues for consistent messaging and leveraging of resources
During Pandemic
Recommendation
3.1.34. Ensure extra communication for parties driving the messaging for the emergency event
3.1.35. Continue to communicate with various regulatory agencies that oversee pandemic responses and solutions (CDC, EPA, FDA, etc.) to find common avenues for consistent messaging and leveraging of resources
3.1.36. Communicate directly with the public (e.g., webinars)
Post Pandemic
Recommendation
3.1.37. Continue to communicate/dialogue with various regulatory agencies that oversee pandemic responses and solutions (CDC, EPA, FDA, etc.) to find common avenues for consistent messaging, leveraging of resources and lessons learned
Food Processing
Recommendation
3.1.38. Leverage relationship with FDA and USDA and organizations such as Institute for Food Safety and Health (IFSH) to better understand the challenges and best practices in a collaborative space
Pre-/During/Post-Pandemic
Recommendation
3.1.39. Establish emergency procedures and product types (disinfectants) compatible with Food Safety Modernization Act and other ordinances (PMO, etc.) to avoid confusion and misinformation, misuse of products, etc. in collaboration with FDA and USDA
Food Service/Food Retail
Recommendation
3.1.40. Leverage trade organizations, such as Association of Food and Drug Officials and the National Restaurant Association, and other groups to better understand the challenges and best practices in a collaborative space
Pre-/During/Post-Pandemic
Recommendation
3.1.41. Establish emergency procedures and product types (disinfectants) compatible with Food Code to avoid confusion and misinformation, misuse of products, etc. with collaboration with FDA
Hotel/Hospitality
General
Recommendation
3.1.42. Leverage trade organizations, such as the American Hotel and Lodging Association, and other groups to better understand the challenges and best practices in a collaborative space
Pre-/During/Post-Pandemic
Recommendation

3.1.43. Research who is the appropriate voice for this sector since this sector was hit hard and was also a big target for false claims and 'silver bullet'.
3.1.44. Educate on what this sector should be wary of could be useful
Package Delivery Services
Pre-/During/ -Pandemic
Recommendation
3.1.45. Identify consumer products that can be used at home
3.1.46. Identify effective disinfectants for use on package deliveries
Schools/Education Institutions
Pre-/During/ -Pandemic
Recommendation
3.1.47. Leverage teacher unions and other groups to better understand the challenges and best practices in a collaborative space
3.1.48. Use Social Media Outlets to reach certain age groups

Figure 3. Sector Survey Questions for PPDC EPIC Education and Communication Work Group



APPENDIX 1: Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens

GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING VIRAL PATHOGENS

DRAFT 5-11-23

In this document:

I. Background and Purpose

This policy is a revision of the August 19, 2016, guidance. The additions and changes to the document are based upon the many learnings from the SARS-CoV-2 and variants pandemic that began in March 2020. Under the Environmental Protection Agency (EPA) Pesticide Program Dialogue Committee (PPDC), EPA assembled a robust and diverse work group of registrants, user groups, trade associations, and Agency staff to collect the experiences and recommendations from diverse groups to amend this guidance and the underlying processes.[1,2] Subsequently, PPDC formed the Emerging Pathogen Implementation Committee (EPIC), to carry out those recommendations which include the revision of this policy.

Emerging pathogens are an increasing public health concern in the United States as well as globally. Many of the emerging pathogens of greatest concern are pathogenic viruses, and the ability of some of these viruses to persist on environmental surfaces (hard/soft, porous or non-porous surfaces) can play a role in human disease transmission. Because viral pathogens are novel as they initially emerge, few, if any, EPA-registered product labels may specify use against these emerging viral pathogens ("EVP"). Also, these pathogens are likely unavailable commercially and/or they may not be adaptable to standard methods for laboratory testing. Thus, it may be difficult to assess the efficacy of new or existing EPA-registered disinfectants and sanitizers against such pathogens and have them added to product labels in a timely manner to respond to a public health threat. (References made throughout the document to "sanitizers" are intended to mean non-food contact and food contact sanitizers as defined in 810.2000[3] for treatment of hard, non-porous surfaces for use in non-patient care areas.) As a result, the Agency is providing a voluntary, two-step process to enable use of certain EPA-registered products against emerging viral pathogens not identified on the product label. Registrants are encouraged to proactively register their products for Emerging Viral Pathogen claims to be ready for future outbreaks:

1) In the first preparedness step, registrants with an eligible disinfectant or other allowed product types may submit a request, via label amendment or during the registration of a new product, to signify control of an emerging viral pathogen group(s) to proactively add a designated statement to the master label (See Attachment 3). If the product meets the eligibility criteria outlined in this Guidance, the agency generally will approve the label language and add the product to List Q, an EPA online tool for users to search for products pre-registered for EVP claims (https://www.epa.gov/pesticide-registration/disinfectants-emerging-viral-pathogens-evps-list-q). Approval of the language includes additional terms and conditions of registration regarding how the designated statement may be published and communicated (Attachment 1). This option

allows for registered products to be prepared for future outbreaks. This action must be carried out on the Basic Registration before a Supplemental Registration will be eligible to make claims. The Supplemental registrant must adhere to the same Terms (Attachment 1), EPA stamped label language found on the Basic Registration, and all aspects of this policy.

2) The second execution step of this process occurs during a human or animal disease outbreak caused by an emerging virus. In this step, EPA identifies the emerging pathogen(s) eligible for this policy and notifies Registrants at the "*Emerging Viral Pathogen Guidance and Status for Antimicrobial Pesticides*" webpage[4] that the preapproved communications may be initiated. Registrants of products with previously accepted emerging viral pathogen label language and terms of registration (Attachment 1) would be allowed to use the designated statement in off-label communications intended to inform the user community and general public that the registered product(s) may be used against the specific emerging viral pathogen. These off-label statements will inform the public about the utility of these products against the emerging pathogen in the most expeditious manner and can be more easily removed once the outbreak has ended than statements on a label. Also, a QR Code or other approved equivalent indicator on the label may direct the user to the approved language. If a particular product was not yet approved for use of emerging viral pathogen language, the first step above may be initiated.

Note that this document provides general guidance to EPA, pesticide registrants, applicants for pesticide registrations, and the public. This guidance is not binding on EPA or any outside parties, and EPA may depart from the guidance where circumstances warrant and without prior notice.

II. Viral Subgroup Classification

EPA and the Centers for Disease Control and Prevention (CDC) recognize that certain microorganisms can be ranked with respect to their tolerance to chemical disinfectants and sanitizers. Whereas the Spaulding[5] Classification model focuses on medical devices, the Klein-DeForest[6-8] model, used by CDC and other public health agencies, tiers microorganisms in accordance with the level of tolerance to being killed (inactivated) by typical disinfectant or sanitizer products. The Klein-DeForest model expands the tiers to include all microorganisms. With this approach, viruses are divided into three viral subgroups (small non-enveloped, large non-enveloped, and enveloped) based on their relative tolerance to inactivation (see below). According to this hierarchy, if an antimicrobial product can kill a small, non-enveloped virus it should be able to kill any large, non-enveloped virus or any enveloped virus. Similarly, a product that can kill a large, non-enveloped virus should be able to kill any enveloped virus. Additionally, if an antimicrobial product can kill the required spore-forming bacteria stated in 810.2100 Guidelines[3] , it should be able to kill any virus in any viral subgroup.[6-8]

Small, Non-Enveloped Viruses (<50 nm): These small, non-enveloped viruses can be highly resistant to inactivation. Despite the lack of a lipid envelope, these organisms have a very resistant protein capsid. The following are viral families in the small non-enveloped subgroup: (1) Picornaviridae (e.g., Hepatitis A, Coxsackievirus, Enterovirus, Poliovirus, Rhinovirus), (2) Parvoviridae (e.g., Canine Parvovirus), (3) Caliciviridae (e.g., Feline Calicivirus), (4) Astroviridae, and (5) Polyomaviridae (e.g., SV 40).

Large, Non-Enveloped Viruses: Compared to small, non-enveloped viruses, these viruses are less resistant to inactivation. Although they have a resistant protein capsid, their larger size (50-100nm) makes them more vulnerable than their smaller viral counterparts. The following are viral families in the large non-enveloped subgroup: (1) Adenoviridae (e.g., Adenovirus type 5), (2) Reoviridae (e.g., Rotavirus), and (3) Papillomaviridae.

Enveloped Viruses: Enveloped viruses are the least resistant to inactivation. The structure of these viruses includes a lipid envelope, which is easily compromised. Once the lipid envelope is damaged, the integrity of the virus is compromised, thereby neutralizing its infectivity. The following are viral families in the enveloped subgroup: (1) Arenaviridae, (2) Bornaviridae, (3) Bunyaviridae (e.g., Hantavirus), (4) Coronaviridae (e.g., human Coronavirus strain 229E, SARS-CoV-2), (5) Filoviridae (e.g., Ebola virus), (6) Flaviviridae (e.g., Zika virus), (7) Hepadnaviridae (e.g., Duck Hepatitis B virus), (8) Herpesviridae (e.g., Herpes Simplex virus type 1), (9) Orthomyxoviridae (e.g., Influenza viruses), (10) Paramyxoviridae (e.g., Parainfluenza viruses, Mumps, Respiratory Syncytial Virus (RSV), Measles), (11) Poxviridae (e.g., Mpox virus, Vaccinia virus), (12) Retroviridae (e.g., Human Immunodeficiency Virus, HIV), (13) Rhabdoviridae (e.g., Rabies virus), and (14) Togaviridae (e.g., Rubella virus).

Under the criteria outlined in Section III of this Guidance, this hierarchy is used to determine a product's anticipated efficacy against an emerging viral pathogen. Animal viruses may be used to support human EVP virus communications and vice versa.

III. Product Eligibility Criteria

Registrants should use the following criteria to determine if a new or existing EPA-registered product is eligible to use the process described in this Guidance. An eligible product should meet both of the following criteria:

1. The product is a new or existing EPA-registered in at least one of the following categories:
    a. Hospital/healthcare or broad-spectrum disinfectant
    b. Food or non-food contact sanitizer
    c. Residual disinfectant
    d. Laundry disinfectant
    e. Sterilant or sporicide
    f. Or other EPA approved prerequisite claim as allowed by EPA.[3,10, 11, 12]

    with directions for use on hard porous, hard non-porous, soft porous, and/or soft non-porous surfaces per the applicable EPA guidance for registration.

2. The currently accepted product label (from a new or existing EPA registered product as described above in III.1 should have efficacy claims against at least one of the following viral pathogen groupings:

a) A product should be approved by EPA to inactivate at least one large or one small non-enveloped virus or have a sporicidal/sterilant/*C. difficile* disinfectant with sporicidal activity claim **to be eligible for use against an enveloped emerging viral pathogen.**

b) A product should be approved by EPA to inactivate at least one small, non-enveloped virus or have a sporicidal/sterilant/*C. difficile* disinfectant with sporicidal activity claim **to be eligible for use against a large, non-enveloped emerging viral pathogen.**

c) A product should be approved by EPA to inactivate at least two small, non-enveloped viruses with each from a different viral family or have a sporicidal/sterilant/*C. difficile* disinfectant with sporicidal activity claim **to be eligible for use against a small, non-enveloped emerging viral pathogen.**

Where eligible products registered for use against pathogens in one category of the Spaulding Classification model or have an alternative prerequisite claim, the product can be presumed effective against pathogens in less-resistant categories. This hierarchy is intended to serve as a conservative approach to identifying products likely to be effective against emerging pathogens. However, since there is no viral subgroup known to be more resistant than small, non-enveloped viral pathogens, a product must be proven to be efficacious against at least two small,

non-enveloped viral pathogens from different viral families or have sporicidal activity in order to be eligible for emerging pathogen claims pursuant to this guidance in regard to an outbreak of an emerging small, non-enveloped viral pathogen.

EPA may also consider other existing claims or microbial strains to support use of a product during an outbreak to assure sufficient supply of appropriate registered products to meet the public health need.

IV. Instructions for Using the Process

The following are instructions for registrants (with a product eligible under Section III above) who wish to make claims against emerging viral pathogens. Emerging viral pathogens are defined by the National Institute of Allergy and Infectious Diseases as viruses "that have newly appeared in a population or have existed but are rapidly increasing in incidence or geographic range." The Stage 2 process of communication may only be actioned if the EPA, through the **Emerging Viral Pathogen Guidance and Status for Antimicrobial Pesticides webpage**[4] has identified the emerging viral pathogen and initiated the policy. This will not occur until EPA, or other national or global public health authority has determined surface disinfection/sanitization may help control its spread. The expiration date for use of the emerging viral pathogen communication will also be detailed on the EPA Emerging Viral Pathogen Guidance and Status for Antimicrobial Pesticides **webpage**[4].

Registrants may follow a two-stage process to identify effective disinfectant and sanitizer products for use against viral pathogens. To permit registrants to make limited off label claims of their product's efficacy against such pathogens, a registrant may either; 1) make a product label amendment with modified terms of registration through a Food Quality Protection Act (FQPA) (fast-track, non-PRIA), or a Pesticide Registration Improvement Act (PRIA) label amendment, or 2) add emerging viral pathogens language as part of a PRIA registration filing for a new product registration. During either process, the registrant will explain why the product meets the criteria for use against one or more categories of emerging [enveloped / large non-enveloped / small non-enveloped] viral pathogens.

To ensure the efficient processing of the application the registrant should include the following:

- A detailed cover letter to EPA (See Example in Attachment 2) including:
  - A subject line that clearly indicates "Emerging Viral Pathogen Claim";
  - A request to make emerging viral pathogen claims;
  - A description of how the product meets the eligibility criteria for use against one or more categories of viral pathogens consistent with the guidance;
  - An identification of the virus(es) or spore from the product label being used to support the emerging viral pathogen claims and the study ID number (MRID) that supports the claim;
  - A request to be added to EPA List Q for EVP claims.
- A pesticide application for registration (Form 8570-1);
- An up-to-date data matrix (Form 8570-35);
- A signed Terms of Registration form (See Attachment 1); and
- A Master Label amended to include the emerging viral pathogen generic text (See Attachment 3). **Note**: The container label in market must include the strains used to support the EVP claim.

The application should be submitted via the EPA Central Data Exchange (CDX) portal.

V. Outbreak Criteria Associated with Emerging Pathogens Process

As stated above, the process described in this Guidance is for use with emerging pathogens associated with certain human or animal disease outbreaks in the US or found internationally with potential to impact the US. Thus, registrants whose registered master labels include the approved statements, either via label amendment or during the new registration process as described in Section IV above, may publish the approved statements only upon EPA announcement at the **Emerging Viral Pathogen Guidance and Status for Antimicrobial Pesticides webpage**[4]. For a disease outbreak, EPA will assure the following criteria:

1. The causative organism should be a virus that causes an infectious disease that has appeared in a human or animal population for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range ("emerging viral pathogen").[9] It includes both new and re-emerging viral pathogens listed by either the CDC, World Organization for Animal Health (WOAH, formerly OIE), US Department of Agriculture (USDA), or other equivalent global or national organizations.

   For example, this information may be found in one of the publications below:

   a. For human disease, the outbreak may be listed in one of the following CDC publications:
      i. CDC Current Outbreak List for "U.S. based outbreaks" (www.cdc.gov/outbreaks),
      ii. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process to federal, state, territorial, tribal, and local public health practitioners; clinicians; public health laboratories, and to those who subscribe to receive HAN-alerts.
      iii. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
   b. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the United States of America on the WOAH Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI) or international outbreaks that have the potential to impact the US.

2. The CDC, WOAH, or other equivalent global or national organization has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. (For example, see WOAH technical disease cards (https://www.woah.org/en/what-we-do/animal-health-and-welfare/animal-diseases/). Based on the taxonomy of the outbreak pathogen, the pathogen's viral structure (small non-enveloped, large non-enveloped, enveloped) should be determined and compared to the hierarchy described in Section III necessary to support an emerging viral pathogen claim.
3. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection/sanitization has been recommended by the CDC, WOAH, EPA or other equivalent global/national organization to control the spread of the pathogen. This may include hard and/or soft, porous and/or non-porous surfaces.

VI. References

[1] US EPA, Pesticide Program dialogue Committee Meeting, October 27-28, 2021. Presentation – Emerging Viral Pathogens Workgroup Report and Recommendations: *https://www.epa.gov/system/files/documents/2021-10/presentation-emerging-viral-pathogens-workgroup-report-recommendations.pdf*.

[2] US EPA, Pesticide Program Dialogue Committee Meeting, May 25-26, 2022. Emerging Viral Pathogens Workgroup Update: *https://www.epa.gov/system/files/documents/2022-05/PPDC-Emerging-Pathogens-Workgroup-Update.pdf*.

[3] Product Performance Test Guidelines: OCSPP 810.2100 Disinfectants for Use on Hard Surfaces – Efficacy Data Recommendations (current version). *https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-810-product-performance-test-guidelines*.

[4] US Environmental Protection Agency. Emerging Viral Pathogen Guidance and Status for Antimicrobial Pesticides webpage. *https://www.epa.gov/pesticide-registration/emerging-viral-pathogen-guidance-and-status-antimicrobial-pesticides*.

[5] Spaulding E.H. 1968. Chemical disinfection of medical and surgical materials. Disinfection, Sterilization, & Preservation, 3rd Edition, Block S (Ed), (Lea & Febiger, Philadelphia, PA).

[6] Klein and DeForest. 1963. The chemical inactivation of viruses. In Proceedings of the Chemical Specialty Manufacturing Association, Chicago, 49th Midyear Meetings, pages 116-118.

[7] Klein and DeForest. 1965. Chemical inactivation of viruses. Fed. Proc., 24 319 (Abstract 1052).

[8] Klein and DeForest. 1983. Principles of viral inactivity. In Disinfection, Sterilization, and Preservation. 3rd Edition. Edited by S. Block. Philadelphia, Lea & Febiger, pages 422-434.

[9] World Health Organization (WHO). 2015. Emerging Diseases. Available from: *http://www.who.int/topics/emerging_diseases/en/*

[10] Product Performance Test Guidelines: OCSPP 810.2200 Disinfectants for Use on Hard Surfaces – Efficacy Data Recommendations (current version). *https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-810-product-performance-test-guidelines*.

[11] Product Performance Test Guidelines: OCSPP 810.2300 Disinfectants for Use on Hard Surfaces – Efficacy Data Recommendations (current version). *https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-810-product-performance-test-guidelines*.

[12] Product Performance Test Guidelines: OCSPP 810.2400 Disinfectants for Use on Hard Surfaces – Efficacy Data Recommendations (current version). *https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-810-product-performance-test-guidelines*.

Attachment 1

Example Terms of Registration

Instructions: The following are the Terms of Registration required to support the inclusion of Emerging Viral Pathogen claims associated with an eligible EPA registration. These options may be used at the registrant's discretion. All options will rely on the EPA pre-approved language and be based on the EPA defined provisions as found in the **EPA Emerging Viral Pathogen Guidance and Status for Antimicrobial Pesticides landing page[4]**. In all cases, Federal pre-approval of the eligibility for EVP language would occur in the registration process. No State/Federal outreach is necessary when EVP claims are pre-registered and the Emerging Viral Pathogens allowance is triggered on the EPA webpage[4] based on the EPA Emerging Viral Pathogen Guidance and Status for Antimicrobial Pesticides.

This template is included in the initial submission requesting the Emerging Pathogen claims or when the claims are changed or updated in subsequent filings. Where changes are being made to a label that is not related to the EVP language, it is not necessary to resubmit the Terms document.

Template

Terms of Registration for EMERGING VIRAL PATHOGENS CLAIMS

This product qualifies for emerging viral pathogen claims as outlined in the GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING VIRAL PATHOGENS when used in accordance with the appropriate use directions. This product meets the criteria to make claims against certain emerging viral pathogens based on the viral structure outlined in the Table(s) below:

For [Insert surface type (e.g., soft, porous surfaces); Repeat table as needed to cover all uses/surfaces]]:	
For an emerging viral pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	Insert virus/bacterial spore former
Large, non-enveloped virus	Insert virus/bacterial spore former
Small, non-enveloped virus	Insert virus/bacterial spore former

The use of the Emerging Viral Pathogen statements shall be based on the following Terms of Registration.

1. The Emerging Viral Pathogen statements are allowed to appear as:
    a. Distributed Literature: Anywhere consumers/users/purchasers of the product may be located (e.g., technical literature distributed to health care facilities, physicians, nurses, and public health officials, "1-800" consumer information services, social media sites, company/distributor websites (non-label related, distributor catalogs, magazine ads, newspapers, etc.).

    b. QR Code or equivalent: On label or found in distributed literature. The QR Code may be activated when the Emerging Viral Pathogen is added to the EPA website[4] triggering the Policy, and the Code would be deactivated when the EVP allowance expires or sunsets.

    c. Hang Tag / Sticker(s): On product container.

2. Statements shall adhere to one the following formats. Minor adjustments may be made at the approval of the EPA:

   [Product name] has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard, **[porous and/or non-porous surfaces]**. Therefore, **[product name]** can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting organism (virus(es), bacteria (spore former)]** on **[hard, porous/non-porous surfaces]**. Refer to the **[CDC or OIE or EPA Emerging Viral Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[pathogen-specific website address]** for additional information.

   [Name of illness/outbreak] is caused by **[name of emerging virus]. [Product name]** kills similar viruses and therefore can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting virus(es), bacteria (spore former)]** on **[hard, porous/non-porous surfaces].** Refer to the **[CDC or OIE or EPA Emerging Viral Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[website address]** for additional information.

   [Product name] can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting organism (virus(es), bacteria (spore former)]** on **[hard/soft, porous/non-porous surfaces]**.

   See Attachment 4 in the EVP Policy which shows several table-based methods of communication.

3. Provided the registration is approved for making Emerging Viral Pathogen claims, the registrant may begin communicating these statement(s) upon notification of the outbreak of an emerging viral pathogen on the **EPA Emerging Viral Pathogen Guidance and Status for Antimicrobial Pesticides landing page.** The registrant shall cease and remove all such non-label communications intended for consumers upon expiration of the emerging viral pathogen emergency as defined on the **EPA Emerging Viral Pathogen Guidance and Status for Antimicrobial Pesticides landing page.** The emerging pathogen claim language may remain on the master label.

4. The registrant agrees that paragraphs 1 through 3 above shall become immediately void and ineffective if registration for use against **[name of supporting virus(es)]** is suspended or cancelled or no longer meets the criteria for a sporicide, disinfectant or sanitizer claim (see EPA Product Performance Test 810 Guidelines[3,4,10-12]). In addition, evidence of ineffectiveness against any labeled pathogen in a less-resistant Spaulding category would also be grounds for voiding paragraphs 1 through 3.

[*Insert Registrant/Agent Signature*]

Insert Registrant/Agent Name & Title **Signature Date**

Attachment 2: Example Sample Cover Letter

Date:

Name (insert name of EPA contact)
Antimicrobials Division (7510P)
U.S. Environmental Protection Agency
Office of Pesticide Programs, Mail Code 7506C
1200 Pennsylvania Ave. NW
Washington, DC 20460

Subject: Emerging Viral Pathogens Claims

Dear Name:

Company Name (Company Name, Address, EPA Company Number), is submitting a terms of registration letter to add Emerging Viral Pathogens Claims to product EPA Registration Number XXXX-XXX.

Briefly, this (insert registration action type, e.g., FQPA, Fast Track Amendment, New Registration, etc.) is being submitted to include language to allow for claims to be made for emerging viral pathogens. Volume 1 includes the Terms of Registration template found in GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING VIRAL PATHOGENS. As outlined in the Table(s) below, this product is eligible to make claims against emerging viral pathogens per the EPA Policy on the surfaces noted:

For [Insert surface type (e.g., soft, porous surfaces); Repeat table as needed to cover all surfaces]]:		
For an emerging viral pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*	*MRID Numbers*
Enveloped virus	Insert non-enveloped virus/bacterial sporeformer name	Insert number supporting strain cited in column 2
Large, non-enveloped virus	Insert small non-enveloped virus/bacterial sporeformer name	Insert number supporting strain cited in column 2
Small, non-enveloped virus	Insert 2 small non-enveloped virus/bacterial sporeformer name	Insert number(s) supporting strain(s) cited in column 2

The Master Label includes the required text per EPA Guidance.

Sincerely,

Registrant

Attachment 3: Example Master Label Template

Instructions:

The following language must be inserted into the Master Label for review and approval by EPA prior to any Basic or Supplemental registrant making any emerging viral pathogen claims. The Table below may be replicated as needed for each surface type (e.g., hard/soft, porous and non-porous). In the Table, Registrants may list different virus or bacterial spore formers for each structural type as long as the listed item meets the stringency requirements outlined in Section III. Different viruses or spores may be listed on each row of the table and multiple viruses or spores may be listed in single row.

TEMPLATE

EMERGING VIRAL PATHOGENS CLAIMS

This product qualifies for emerging viral pathogen claims as outlined in the GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING VIRAL PATHOGENS when used in accordance with the appropriate use directions. This product meets the criteria to make claims against certain emerging viral pathogens based on the viral structure outlined in the Table(s) below:

For [Insert surface type (e.g., soft, porous surfaces); Repeat table as needed to cover all surfaces]]:	
For an emerging viral pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	Insert virus/bacterial spore former
Large, non-enveloped virus	Insert virus/bacterial spore former
Small, non-enveloped virus	Insert virus/bacterial spore former

[Product name] has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on **[hard and/or soft, porous and/or non-porous surfaces]**. Therefore, **[product name]** can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting organism (virus(es) or bacterial spore former)]** on **[hard/soft, porous/non-porous surfaces]**. Refer to the **[CDC, WOAH, EPA[4], or other]** website at **[website address]** for additional information.

[Name of illness/outbreak] is caused by **[name of emerging virus]. [Product name]** kills similar viruses and therefore, can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting virus(es) or bacterial spore former]** on **[hard/soft, porous/non-porous surfaces].** Refer to the **[CDC, WOAH, EPA[4] or other]** website at **[website address]** for additional information.

[Product name] can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting organism (virus(es), bacteria (spore former)]** on **[hard/soft, porous/non-porous surfaces]**.

See Attachment 4 of the EPA Policy which shows several table-based methods of communications.

Attachment 4: Alternate Example Table Formats for EVP Communications

Instructions: The following tables provide possible format examples to illustrate how a registrant may configure the EPA stamped label EVP claim(s) and registered directions for use of the EVP cited strain into a table format to communicate with Registrants. The tables may include multiple approved EVP uses (e.g., hard surface disinfection, soft surface disinfection) as well as multiple approved products.

Example Template #1 (Pathogen-specific EVP List):

Product Name	EPA Reg. No.	SKUs and/or Package Size	Product Use Category and Concentration/ Form	Application and Surface Type	Approved for use with Direct [Viral Pathogen] Claim	Approved for use with the Emerging Viral Pathogen Claim	Approved for use with [Related Pathogen] Claim (Optional)
[Insert EPA Approved Brand Name(s)]	[EPA Reg. No.]	[SKU] [Package Volume]	[Product category] [Product Form]	[Application and surface type]	Where a direct claim for the EVP exists on the label, insert [Contact time] at [concentration]	Where an EVP claim for the EVP exists, insert [Contact time] at [concentration] (Follow [EVP Pathogen] directions)	Where EPA has allowed special additional EVP allowances, insert [Contact time] at [concentration] (Follow [Related Pathogen] directions)

Example of Completed Table Using Template 1 (Pathogen-specific EVP List):

Product Name	EPA Reg. No.	SKUs	Product Category	Application and Surface Type	Approved for use with Direct SARS-CoV-2 Claim	Approved for use with the Emerging Viral Pathogen Claim	Approved for use with Human Coronavirus Claim
Product 111	1111-11	11111 (1 gallon)	Disinfectant (RTU)	Spray on hard, non-porous surfaces[1]	5 minutes at RTU (Follow SARS-CoV-2 directions)	10 minutes at RTU (Follow Norovirus directions)	7 minutes at RTU (Follow Human Coronavirus directions)
Product 222	2222-22	22222 (1 gallon)	Disinfectant (Concentrate)	Spray or soak on hard, non-porous surfaces[1]	5 minutes at 5 oz/gal (Follow SARS-CoV-2 directions)	10 minutes at 5 oz/gal 5 minutes at 10 oz/gal (Follow Norovirus directions)	7 minutes at 5 oz/gal (Follow Human Coronavirus directions)

Product 222	2222-22	22222 (1 gallon)	Disinfectant (Concentrate)	Spray on soft, porous surfaces[2]	7 minutes at 5 oz/gal (Follow SARS-CoV-2 directions)	7 minutes at 10 oz/gal (Follow Norovirus directions)	10 minutes at 5 oz/gal (Follow Human Coronavirus directions)

[1] Refer to EPA Master Label for list of approved hard, non-porous surfaces

[2] Refer to EPA Master Label for list of approved soft, porous surfaces

Example Template #2 (Pathogen-specific EVP List):

EVP	Product Name	EPA Reg. No.	SKUs and/or Package Volume	Product Category	Application and Surface Type	Pathogen Supporting EVP Claim	Use Instructions
[Insert EVP]	[Insert EPA Approved Brand Name(s)]	[EPA Reg. No.]	[SKU][Package Volume]	[Product category]	[Application and surface type]	[Insert virus or spore name(s)]	[Insert abbrev. Use Directions for the Pathogen supporting the EVP Claim]

Example of Template #3 (Pathogen-specific EVP List):

EVP	Product Name	EPA Reg. No.	SKUs and/or Package Volume	Product Category	Application and Surface Type	Pathogen Supporting EVP Claim	Use Instructions
[Insert EVP]	[Insert EPA Approved Brand Name]	[EPA Reg. No.]	[SKU][Package Volume]	[Product category]	[Application and surface type]	[Insert virus or spore name(s)]	[Insert abbrev. Use Directions for the Pathogen supporting the EVP Claim]
				[Product category]	[Application and surface type]	[Insert virus or spore name(s)]	[Insert abbrev. Use Directions for the Pathogen supporting the EVP Claim]

Example of Completed Table Using Template 2 (Pathogen-specific EVP List):

EVP	Product Name	EPA Reg. No.	SKUs and/or Package Volume	Product Category	Application and Surface Type	Pathogen Supporting EVP Claim	Use Instructions
SARS-CoV-2 and variants	Disinfectant ABC	#####-##	24oz Trigger	Disinfectant	Hard, Non-Porous Surfaces	Rotavirus	Hold treated surfaces for 10mins.
Rabbit Hemorrhagic Fever Virus			24oz Trigger	Disinfectant	Hard, Non-Porous Surfaces	Canine Parvovirus, Rhinovirus	Hold treated surfaces for 10mins.

APPENDIX 2: Guidance to Registrants: Process for Making Claims Against Emerging Bacterial Sporeforming Pathogens

GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING BACTERIAL SPOREFORMING PATHOGENS

DRAFT 12-21-23

In this document:

I. Background and Purpose

This policy builds upon and expands the emerging pathogen response outlined in the Guidance To Registrants: Process for Making Claims Against Emerging Viral Pathogens (August 19, 2016) to create a similar process for addressing bacterial sporeforming pathogens.[1] Under the Environmental Protection Agency (EPA) Pesticide Program Dialogue Committee (PPDC), EPA assembled a robust and diverse work group of registrants, academicians, user groups, trade associations, and Agency staff to review the published literature[2-11], collect the experiences and recommendations to prepare this guidance and the underlying processes.[13,14] Subsequently, PPDC formed the Emerging Pathogen Implementation Committee (EPIC), to carry out those recommendations which include the preparation of this policy.

Emerging pathogens ("EP") are an increasing public health concern in the United States as well as globally. Some of these emerging pathogens may have the ability to persist on environmental surfaces (hard/soft, porous or non-porous surfaces) that can play a role in human disease transmission. Here we are proposing an emerging spore forming pathogen policy. Because the occurrence of emerging sporeforming pathogens is less common and predictable than established pathogens, few, if any, EPA-registered product labels specify use against this category of infectious agents. By their very nature, bacterial sporeformers are more stable in the environment. Also, depending on the testing scheme, these pathogens may be unavailable commercially and standard methods for laboratory testing may not have been developed. Thus, it may be difficult to assess the efficacy of EPA-registered products against such pathogens in a timely manner and to add these sporeformers to existing product registrations, which requires the submission of efficacy data for Agency review to respond to a public health threat. As a result, the Agency is providing a voluntary, two-step process to enable use of certain EPA-registered products against emerging sporeforming pathogens not identified on the product label. Registrants are encouraged to proactively register their products for Emerging Sporeforming Bacterial Pathogen claims to be ready for future outbreaks:

1) In the first stage, which may be performed prior to any outbreak, registrants with an eligible disinfectant may submit a request, via label amendment or during the registration of a new product, to control an emerging sporeforming bacterial pathogen to proactively add a designated statement to the master label (See Attachment 1). If the product meets the eligibility criteria suggested in this Guidance, the Agency generally will approve the label language and, where available, add the product to an online list for users to search for products pre-registered for these claims. Approval of the language includes additional terms and conditions of registration regarding how the designated statement may be published and communicated

(Attachment 1). This option allows for registered products to be prepared for future outbreaks. This action must be carried out on the Basic Registration before a Supplemental Registration will be eligible to make claims. The Supplemental registrant must adhere to the same Terms (Attachment 1), EPA stamped label language found on the Basic Registration, and all aspects of this policy.

2) The second stage of this process occurs during a human or animal disease outbreak caused by an emerging sporeformer. In this stage, EPA identifies the emerging pathogen(s) eligible for this policy and notifies Registrants at the "*Emerging Bacterial Sporeforming Pathogens Guidance and Status for Antimicrobial Pesticides*" webpage[1] that the preapproved communications may be initiated. Registrants of products with previously accepted emerging pathogen label language and terms of registration (Attachment 1) would be allowed to use the designated statement in off-label communications intended to inform the user community and general public that the registered product(s) may be used against the specific emerging pathogen. These off-label statements will inform the public about the utility of these products against the emerging pathogen in the most expeditious manner and can be more easily removed once the outbreak has ended than statements on a label. Also, a QR Code or other approved equivalent indicator on the label may direct the user to the approved language. If a particular product was not yet approved for use of emerging pathogen language, the first step above may be initiated.

Note that this document provides general guidance to EPA, pesticide registrants, applicants for pesticide registrations, and the public. This guidance is not binding on EPA or any outside parties, and EPA may depart from the guidance where circumstances warrant and without prior notice.

II. Bacterial Sporeformer Classification and Other Microorganisms

EPA and the Centers for Disease Control and Prevention (CDC) recognize that certain microorganisms can be ranked with respect to their tolerance to chemical disinfectants. Whereas the Spaulding[15] Classification model focuses on medical devices, the Klein-DeForest[12,16-18] model, used by CDC and other public health agencies, tiers microorganisms in accordance with the level of tolerance to being killed (inactivated) by typical antimicrobial products.

Certain Gram-positive species of bacteria will develop spores when stressed by developing an outer shell as protection. While there are many genera that form spores due to recent reclassification efforts[19], the most commonly tested spore-forming bacteria belong to two genera of the *Firmicutes* phylum, the aerobic or facultative anaerobic *Bacilli* and the strictly anaerobic *Clostridia/Clostrioides*.

The structure of the bacterial spore (the spore cost and cortex) protects it from environmental conditions which makes it extremely difficult to kill. Bacterial endospores can survive temperatures up to 150°C and as low as absolute zero. Endospores are resistant to chemical agents (including alcohol), ultraviolet radiation, extreme pH gradients, drought, and nutrition depletion.

Testing for sporicidal efficacy is outlined in United States Environmental Protection Agency "Product Performance Test Guidelines OCSPP 810.2100: Testing for Sterilants, Sporicides, and Decontaminants Guidance for Efficacy Testing".[20] Current requirements for testing are based on label claims for Sterilant, Sporicide, *Clostridium difficile*, *Bacillus anthracis* and additional sporeformers outlined in the table below and follow various standard methods. Within these testing requirements, EPA has a variety of test carrier types that are used to represent hard non-porous (stainless steel penicylinders/discs), hard porous (porcelain penicylinders), and soft surfaces (suture loops). Based on the availability of testing on a variety of test carriers, the emerging pathogen claims may be expanded to this array of surfaces.

In addition to the required testing strains identified in 810.2100, based on published research and US/UK government research, the work group has identified several additional sporeformer strains that could be utilized as a prerequisite for emerging sporeformer claims as described in Section III (e.g., *B. thuringiensis Al Hakam, B. thuringiensis kurstaki HD-1 cry).*[10] To obtain these claims, EPA may require a PRIA New Protocol (A521/A522) review (*https://www.epa.gov/pria-fees/pria-antimicrobial-other-actions-protocol-review*). Registrants interested in adding these" Additional Sporeformer" strains should contact EPA for further instructions and confirmation of required prerequisites.

Sporeformer Registration Category	Strains	Carrier types
Sterilant	Bacillus subtilis (ATCC 19659) and Clostridium sporogenes (ATCC 3584)	Porcelain penicylinders and suture loops
Sporicide	*Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584)	Porcelain penicylinders, stainless steel penicylinders, or suture loops
Clostridioides (formerly *Clostridium) difficile* Disinfectant	*Clostridioides difficile* (ATCC 43598)	Brushed Stainless Steel disc
Bacillus anthracis Decontaminant	*Bacillus anthracis* virulent strain or acceptable surrogate species	Porcelain penicylinder and suture loops; or testing materials representative of use site(s) for quantitative testing
Additional sporeformer microorganisms	*B. thuringiensis Al Hakam, B. thuringiensis kurstaki HD-1 cry, B. anthracis* Sterne*, or B. anthracis* ΔSterne	Carrier type(s) depending on label claim

Prions are infectious agents that are found in the nervous system and are comprised of abnormal forms of the prion protein (PrP). They are very resistant to heat and chemical agents[8,9,12]. Testing for Prions is outlined in United States Environmental Protection Agency "Product Performance Test Guidelines OCSPP 810.2700: Products with Prion Related Claims".[21] Prions are recommended to be used as a prerequisite for emerging pathogen claims supporting bacterial sporeformers for hard, non-porous surface products using pre-cleaning of all environmental surfaces.

Protozoa are single celled eukaryotes, either parasitic or free-living which may be transmitted from person to person.[15] They can cause diseases such as malaria, giardia, and toxoplasmosis. Protozoa cysts and oocysts have a high resistance to chemical germicides[15] but relatively susceptible to drying; however, efficacy against protozoa is not recommended as prerequisite for an emerging pathogen claim as there are no current registration guidelines or test methods available.

Under the criteria outlined in Section III of this Guidance, these prerequisites may be used to determine a product's anticipated efficacy against an emerging sporeforming pathogen.

III. Product Eligibility Criteria

Registrants should use the following criteria to determine if a new or existing EPA-registered product is eligible to use the process described in this Guidance. An eligible product should meet the following criteria:

1. The product is a new or existing EPA-registered product with claims on the label in at least one of the following Registration Categories (Table column 1) with directions for use on hard porous, hard non-porous, and/or soft porous surfaces per the applicable EPA guidance for registration[20,21]:

2. The above EPA registered product as described would be eligible for emerging bacterial sporeformer claims as shown in Columns 2-4 of the Table below when tested using the appropriate test carrier for the surface type. In addition, due to the stringency of the spore form, the emerging pathogen claims must require pre-cleaning of all surfaces to assure effectiveness.

Registration Categories[20,21]	**Supports Emerging Pathogen Claims for:**		
	Hard, Non-Porous Surfaces when tested on hard, non-porous carrier (stainless steel)	**Hard, Porous Surfaces** when tested on hard, porous carrier (porcelain penicylinder)	**Soft Surfaces** when tested on soft carrier (suture loop)
Prions[21]	Bacillus/ Clostridia/Clostridioides spp.	None	None
Sterilant[20]	Clostridia/Clostridioides spp.	Clostridia/Clostridioides spp.	Clostridia/Clostridioides spp.
Sporicidal[20]	Clostridia/Clostridioides spp.	Clostridia/Clostridioides spp.	Clostridia/Clostridioides spp.
***Clostridioides* (formerly *Clostridium) difficile* Disinfectant**[20]	None	None	None
B. anthracis Decontaminant[20]	Bacillus/ Clostridia/Clostridioides spp.	Bacillus/ Clostridia/Clostridioides spp.	None
***B. thuringiensis Al Hakam, B. thuringiensis kurstaki HD-1 cry-, B. anthracis Sterne, or B. anthracis ΔSterne*[10]**	Bacillus/ Clostridia/Clostridioides spp.	Bacillus/ Clostridia/Clostridioides spp.	Bacillus/ Clostridia/Clostridioides spp.

As the Table above illustrates, we are acknowledging a difference in difficulty of kill between the required sporicidal test strains.[3] Thus, we have recommended above in some cases that the required *B. subtillus* and *C. sporogenes* strains are limited to supporting emerging pathogens in only the *Clostridia* and *Clostrioides* species.

EPA may also consider other existing claims or microbial strains to support use of a product during an outbreak to assure sufficient supply of appropriate registered products to meet the public health need.

IV. Instructions for Using the Process

The following are instructions for registrants (with a product eligible under Section III above) who wish to make claims against emerging sporeforming pathogens. Emerging pathogens are defined by the National Institute of Allergy and Infectious Diseases as those "that have newly appeared in a population or have existed but are rapidly increasing in incidence or geographic range." The Stage 2 process of communication may only be actioned if the EPA, through the **Emerging Sporeforming Pathogen Guidance and Status for Antimicrobial Pesticides webpage**[1] has identified the emerging pathogen and initiated the policy. This will not occur until EPA, or other national or global public health authority has determined surface disinfection may help control its spread. The expiration date for use of the emerging sporeforming pathogen communication will also be detailed on the EPA Emerging Sporeforming Pathogen Guidance and Status for Antimicrobial Pesticides **webpage**[1].

Registrants may follow a two-stage process to identify effective disinfectant products for use against emerging pathogens. To permit registrants to make limited off label claims of their product's efficacy against such pathogens, a registrant may either; 1) make a product label amendment with modified terms of registration through a Food Quality Protection Act (FQPA) (fast-track, non-PRIA), or a Pesticide Registration Improvement Act (PRIA) label amendment, or 2) add emerging pathogen language as part of a PRIA registration filing for a new product registration. During either process, the registrant will explain why the product meets the criteria for use against one or more categories of emerging sporeforming bacterial pathogens.

To ensure the efficient processing of the application the registrant should include the following:

- A detailed cover letter to EPA (See Example in Attachment 2) including:
  - A subject line that clearly indicates "Emerging Sporeforming Pathogen Claim";
  - A request to make emerging sporeforming pathogen claims;
  - A description of how the product meets the eligibility criteria for use consistent with the guidance;
  - An identification of the spore(s) from the product label being used to support the emerging sporeformer pathogen claims and the study ID number (MRID) that supports the claim;
  - A request to be added to EPA List for emerging sporeformer claims.
- A pesticide application for registration (Form 8570-1);
- An up-to-date data matrix (Form 8570-35);
- A signed Terms of Registration form (See Attachment 1); and
- A Master Label amended to include the emerging sporeformer pathogen generic text (See Attachment 3). **Note**: The container label in market must include the strains used to support the emerging pathogen claim.

The application should be submitted via the EPA Central Data Exchange (CDX) portal.

V. Outbreak Criteria Associated with Emerging Pathogens Process

As stated above, the process described in this Guidance is for use with emerging pathogens associated with certain human or animal disease outbreaks in the US or found internationally with potential to impact the US. Thus, registrants whose registered master labels include the approved statements, either via label amendment or during the new registration process as described in Section IV above, may publish the approved statements only upon EPA announcement at the **Emerging Bacterial Sporeformer Pathogen Guidance and Status for Antimicrobial Pesticides webpage**[1]. For a disease outbreak, EPA will assure the following criteria:

1. The causative organism should be a bacterial sporeformer that causes an infectious disease that has appeared in a human or animal population for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range ("emerging bacterial sporeforming pathogen").[22] It includes both new and re-emerging sporeforming pathogens listed by the CDC, World Organization for Animal Health (WOAH, formerly OIE), US Department of Agriculture (USDA), or other equivalent global or national organizations.

   For example, this information may be found in one of the publications below:

   a. For human disease, the outbreak may be listed in one of the following CDC publications:
      i. CDC Current Outbreak List for "U.S. based outbreaks" (www.cdc.gov/outbreaks),
      ii. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process to federal, state, territorial, tribal, and local public health practitioners; clinicians; public health laboratories, and to those who subscribe to receive HAN-alerts.
      iii. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
   b. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the United States of America on the WOAH Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI) or international outbreaks that have the potential to impact the US.

2. The CDC, WOAH, or other equivalent global or national organization has identified the taxonomy, including the bacterial sporeformer genus of the pathogen and provides notice to the public of the identity of the emerging strain that is responsible for an infectious disease outbreak. (For example, see WOAH technical disease cards (https://www.woah.org/en/what-we-do/animal-health-and-welfare/animal-diseases/). Based on the taxonomy of the outbreak pathogen, the bacteria's ability to form spores should be confirmed and compared to the hierarchy described in Section III necessary to support an emerging sporeforming pathogen claim.
3. The bacterial sporeformer can be transmitted via environmental surfaces (non-vector transmission), and environmental surface treatment has been recommended by the CDC, WOAH, EPA or other equivalent global/national organization to control the spread of the pathogen. This may include hard and/or soft, porous and/or non-porous surfaces.

VI. References

[1] US Environmental Protection Agency. Emerging Viral Pathogen Guidance and Status for Antimicrobial Pesticides webpage. *https://www.epa.gov/pesticide-registration/emerging-viral-pathogen-guidance-and-status-antimicrobial-pesticides*.

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[13] US EPA, Pesticide Program dialogue Committee Meeting, October 27-28, 2021. Presentation – Emerging Viral Pathogens Workgroup Report and Recommendations:

https://www.epa.gov/system/files/documents/2021-10/presentation-emerging-viral-pathogens-workgroup-report-recommendations.pdf.

[14] US EPA, Pesticide Program Dialogue Committee Meeting, May 25-26, 2022. Emerging Viral Pathogens Workgroup Update: https://www.epa.gov/system/files/documents/2022-05/PPDC-Emerging-Pathogens-Workgroup-Update.pdf.

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[21] Product Performance Test Guidelines: OCSPP 810.2700 Products with Prion-Related Claims (current version). https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-810-product-performance-test-guidelines.

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Attachment 1

Example Terms of Registration

Instructions: The following are the Terms of Registration required to support the inclusion of Emerging Sporeformer Pathogen claims associated with an eligible EPA registration. These options may be used at the registrant's discretion. All options will rely on the EPA pre-approved language and be based on the EPA defined provisions as found in the **EPA Emerging Sporeformer Pathogen Guidance and Status for Antimicrobial Pesticides landing page**[1]. In all cases, Federal pre-approval of the eligibility for EP language would occur in the registration process. No State/Federal outreach is necessary when EP claims are pre-registered and the Emerging Sporeforming Pathogens allowance is triggered on the EPA webpage[1] based on the EPA Emerging Sporeforming Pathogen Guidance and Status for Antimicrobial Pesticides.

This template is included in the initial submission requesting the Emerging Pathogen claims or when the claims are changed or updated in subsequent filings. Where changes are being made to a label that is not related to the EP language, it is not necessary to resubmit the Terms document.

Template

Terms of Registration for EMERGING BACTERIAL SPOREFORMING PATHOGENS CLAIMS

This product qualifies for emerging sporeformer pathogen claims as outlined in the GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING BACTERIAL SPOREFORMING PATHOGENS when used in accordance with the appropriate use directions including the required pre-cleaning use directions for all surfaces. This product meets the criteria to make claims against certain emerging sporeforming pathogens based on the structure outlined in the Table(s) below and aligned with Section III of the guidance:

For [Insert surface type (e.g., soft, porous surfaces); Repeat table as needed to cover all uses/surfaces and other EP microorganism claims]]:	
For an emerging bacterial sporeforming pathogen that is a…	*…follow the directions for use for the following organisms on the label with the added pre-cleaning instructions:*
Bacterial Sporeformer	Insert bacterial spore former(s)/prion name
Bacterial Sporeformer	Insert bacterial spore former(s)/prion name

The use of the Emerging Sporeforming Pathogen statements shall be based on the following Terms of Registration.

1. The Emerging Pathogen statements are allowed to appear as:
    a. Distributed Literature: Anywhere consumers/users/purchasers of the product may be located (e.g., technical literature distributed to health care facilities, physicians, nurses, and public health officials, "1-800" consumer information services, social media sites, company/distributor websites (non-label related, distributor catalogs, magazine ads, newspapers, etc.).

    b. QR Code or equivalent: On label or found in distributed literature. The QR Code may be activated when the Emerging Pathogen is added to the EPA website[4] triggering the Policy, and the Code would be deactivated when the EP allowance expires or sunsets.

    c. Hang Tag / Sticker(s): On product container.

2. Statements shall adhere to one the following formats. Minor adjustments may be made at the approval of the EPA:

   [Product name] has demonstrated effectiveness against sporeformers[prions] similar to **[name of emerging bacterial sporeformer]** on hard, **[porous and/or non-porous and/or soft surfaces]**. Therefore, following precleaning of all visible soil, **[product name]** can be used against **[name of emerging bacterial sporeformer]** when used in accordance with the directions for use against **[name of supporting bacterial sporeformer/prion]** on **[hard, porous/non-porous/soft surfaces]**. Refer to the **[CDC or OIE or EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[pathogen-specific website address]** for additional information.

   [Name of illness/outbreak] is caused by **[name of emerging bacterial sporeformer]. [Product name]** kills similar sporeformer [prion] and therefore following precleaning of all visible soil can be used against **[name of emerging bacterial sporeformer]** when used in accordance with the directions for use against **[name of supporting bacterial sporeformer/prion]** on **[hard, porous/non-porous/soft surfaces].** Refer to the **[CDC or OIE or EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[website address]** for additional information.

   Following precleaning of all visible soil, **[Product name]** can be used against **[name of emerging bacterial sporeformer]** when used in accordance with the directions for use against **[name of supporting bacteria sporeformer/prion]** on **[hard/soft, porous/non-porous surfaces]**.

   See Attachment 4 in the EP Policy which shows several table-based methods of communication.

3. Provided the registration is approved for making Emerging Bacterial Sporeforming Pathogen claims, the registrant may begin communicating these statement(s) upon notification of the outbreak of an emerging sporeforming pathogen on the **EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page.** The registrant shall cease and remove all such non-label communications intended for consumers upon expiration of the emerging bacterial sporeforming pathogen emergency as defined on the **EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page.** The emerging pathogen claim language may remain on the master label.

4. The registrant agrees that paragraphs 1 through 3 above shall become immediately void and ineffective if registration for use against **[name of supporting bacterial sporeformer/prion** is suspended or cancelled or no longer meets the criteria in EPA Performance Test 810 Guidelines[3,10]. In addition, evidence of ineffectiveness against any labeled pathogen in a less-resistant Spaulding category would also be grounds for voiding paragraphs 1 through 3.

[*Insert Registrant/Agent Signature*]

Insert Registrant/Agent Name & Title **Signature Date**

Attachment 2: Example Sample Cover Letter

Date:

Name (insert name of EPA contact)
Antimicrobials Division (7510P)
U.S. Environmental Protection Agency
Office of Pesticide Programs, Mail Code 7506C
1200 Pennsylvania Ave. NW
Washington, DC 20460

Subject: Emerging Bacterial Sporeforming Pathogen Claims

Dear Name:

Company Name (Company Name, Address, EPA Company Number), is submitting a terms of registration letter to add Emerging Bacterial Sporeforming Pathogen Claims to product EPA Registration Number XXXX-XXX.

Briefly, this (insert registration action type, e.g., FQPA, Fast Track Amendment, New Registration, etc.) is being submitted to include language to allow for claims to be made for emerging bacterial sporeforming pathogens. The submission includes the Terms of Registration template found in GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING BACTERIAL SPOREFORMING PATHOGENS. As outlined in the Table(s) below, this product is eligible to make claims against emerging pathogens per the EPA Policy on the surfaces noted:

For [Insert surface type (e.g., soft, porous surfaces); Repeat table as needed to cover all surfaces and other EP microorganism claims]]:		
For an emerging bacterial sporeformer pathogen that is a/an…	*…follow the directions for use for the following organisms on the label with the added pre-cleaning instructions:*	*MRID Numbers*
Bacterial Sporeformer	Insert bacterial sporeformer/prion name	Insert number supporting strain cited in column 2
Bacterial Sporeformer	Insert bacterial sporeformer/prion name	Insert number supporting strain cited in column 2

The Master Label includes the required text per EPA Guidance.

Sincerely,

Registrant

Attachment 3: Example Master Label Template

Instructions:

The following language must be inserted into the Master Label for review and approval by EPA prior to any Basic or Supplemental registrant making any emerging pathogen claims. The Table below may be replicated as needed for each surface type (e.g., hard/soft, porous and non-porous) or emerging pathogen type. In the Table, Registrants may list different bacterial spore formers or prions for the emerging sporeforming claim as outlined in Section III. Different spores/prions may be listed in each row of the table and multiple strains may be listed in a single row.

TEMPLATE

EMERGING VIRAL BACTERIAL SPOREFORMING CLAIMS

This product qualifies for emerging bacterial sporeforming pathogen claims as outlined in the GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING BACTERIAL SPOREFORMING PATHOGENS when used in accordance with the appropriate use directions following precleaning of all surfaces. This product meets the criteria to make claims against certain emerging bacterial sporeforming pathogens based on the prerequisites listed in the Table(s) below:

For [Insert surface type (e.g., soft, porous surfaces); Repeat table as needed to cover all surfaces and other EP microorganism claim]]:	
For an emerging bacterial sporeforming pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Bacterial Sporeformer	Insert bacterial spore former/prion name
Bacterial Sporeformer	Insert bacterial spore former/prion name

[Product name] has demonstrated effectiveness against sporeformers[prions] similar to **[name of emerging bacterial sporeformer]** on hard, **[porous and/or non-porous and/or soft surfaces]**. Therefore, following precleaning of all visible soil, **[product name]** can be used against **[name of emerging bacterial sporeformer]** when used in accordance with the directions for use against **[name of supporting bacterial sporeformer/prion]** on **[hard, porous/non-porous/soft surfaces]**. Refer to the **[CDC or OIE or EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[pathogen-specific website address]** for additional information.

[Name of illness/outbreak] is caused by **[name of emerging bacterial sporeformer]. [Product name]** kills similar sporeformer [prion] and therefore following precleaning of all visible soil can be used against **[name of emerging bacterial sporeformer]** when used in accordance with the directions for use against **[name of supporting bacterial sporeformer/prion]** on **[hard, porous/non-porous/soft surfaces].** Refer to the **[CDC or OIE or EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[website address]** for additional information.

Following precleaning of all visible soil, **[Product name]** can be used against **[name of emerging bacterial sporeformer]** when used in accordance with the directions for use against **[name of supporting bacteria sporeformer/prion]** on **[hard/soft, porous/non-porous surfaces]**.

See Attachment 4 of the EPA Policy which shows several table-based methods of communications.

Attachment 4: Alternate Example Table Formats for EP Communications

Instructions: The following tables provide possible format examples to illustrate how a registrant may configure the EPA stamped label EP claim(s) and registered directions for use of the EP cited strain coupled with the precleaning requirements into a table format to communicate with Registrants. The tables may include multiple approved EP uses (e.g., EVP hard surface disinfection, EVP soft surface disinfection, Emerging Sporeformers hard surface sporicide) as well as multiple approved products.

Example Template #1 (Pathogen-specific EP List):

Product Name	**EPA Reg. No.**	**SKUs and/or Package Size**	**Product Use Category and Concentration/ Form**	**Application and Surface Type**	**Approved for use with Direct [Bacterial Sporeforming Pathogen] Claim**	**Approved for use with the Emerging Sporeforming Pathogen Claim**	**Approved for use with [Related Pathogen] Claim (Optional)**
[Insert EPA Approved Brand Name(s)]	[EPA Reg. No.]	[SKU] [Package Volume]	[Product category] [Product Form]	Insert requirement to preclean all surfaces. [Insert Application and surface type]	Where a direct claim for the EP exists on the label, insert [Contact time] at [concentration]	Where an EP claim for the EP exists, insert [Contact time] at [concentration] (Follow [EP Pathogen] directions)	Where EPA has allowed special additional EP allowances, insert [Contact time] at [concentration] (Follow [Related Pathogen] directions)

Example of Completed Table Using Template 1 (Pathogen-specific EP List):

Product Name	**EPA Reg. No.**	**SKUs**	**Product Category**	**Application and Surface Type**	**Approved for use with Direct Claim**	**Approved for use with the Emerging Viral Pathogen Claim**	**Approved for use with *C. difficile* Claim**
Product 111	1111-11	11111 (1 gallon)	Sporicide (RTU)	Spray on pre-cleaned hard, non-porous surfaces[1]	5 minutes at RTU (Follow [insert strain name] directions)	10 minutes at RTU (Follow Sporicide directions)	7 minutes at RTU (Follow C. difficile directions)
Product 222	2222-22	22222 (1 gallon)	Sporicide (Concentrate)	Preclean surfaces. Spray or soak on hard, non-porous surfaces[1]	5 minutes at 5 oz/gal [insert strain name]	10 minutes at 5 oz/gal 5 minutes at 10 oz/gal (Follow Sporicide directions)	7 minutes at 5 oz/gal (Follow C. difficile directions)

Product 222	2222-22	22222 (1 gallon)	Sporicide (Concentrate)	Preclean surfaces. Spray on soft, porous surfaces[2]	7 minutes at 5 oz/gal (Follow [insert strain] directions)	7 minutes at 10 oz/gal (Follow Sporicide directions)	10 minutes at 5 oz/gal (Follow *C. difficile* directions)

[1] Refer to EPA Master Label for list of approved hard, non-porous surfaces.

[2] Refer to EPA Master Label for list of approved soft, porous surfaces.

Example Template #2 (Pathogen-specific EP List):

EP	Product Name	EPA Reg. No.	SKUs and/or Package Volume	Product Category	Application and Surface Type	Pathogen Supporting EVP Claim	Use Instructions
[Insert EP]	[Insert EPA Approved Brand Name(s)]	[EPA Reg. No.]	[SKU][Package Volume]	[Product category]	Insert requirement to preclean all surfaces. [Insert Application and surface type]	[Insert bacterial sporeformer or prion name(s)]	Insert requirement to preclean all surfaces [Insert abbrev. Use Directions for the Pathogen supporting the EP Claim]

Example of Template #3 (Pathogen-specific EP List):

EP	Product Name	EPA Reg. No.	SKUs and/or Package Volume	Product Category	Application and Surface Type	Pathogen Supporting EP Claim	Use Instructions
[Insert EP]	[Insert EPA Approved Brand Name]	[EPA Reg. No.]	[SKU][Package Volume]	[Product category]	Insert requirement to preclean all surfaces. [Insert Application and surface type]	[Insert spore/prion name(s)]	Insert requirement to preclean all surfaces. [Insert abbrev. Use Directions for the Pathogen supporting the EVP Claim]
				[Product category]	Insert requirement to preclean all surfaces. [Insert Application and surface type]	[Insert spore/prion name(s)]	Insert requirement to preclean all surfaces. [Insert abbrev. Use Directions for the Pathogen supporting the EVP Claim]

Example of Completed Table Using Template 2 (Pathogen-specific EVP List):

EP	Product Name	EPA Reg. No.	SKUs and/or Package Volume	Product Category	Application and Surface Type	Pathogen Supporting EP Claim	Use Instructions
Clostridioides difficile Strain R20291	Sporicide ABC	#####-##	24oz Trigger	Sporicide	Precleaned Hard, Non-Porous Surfaces	*Bacillus subtillus*; *Clostridium sporogenes*	Apply to precleaned surfaces and hold treated for 10mins.
Bacillus anthracis Strain 34F2			24oz Trigger	Prion	Precleaned Hard, Non-Porous Surfaces	Scrapie Prion	Apply to precleaned and hold treated surfaces for 10mins.

APPENDIX 3: Guidance to Registrants: Process for Making Claims Against Emerging Mycobacterial Pathogens

GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING MYCOBACTERIAL PATHOGENS

4/10/2024 DRAFT

In this document:

I. Background and Purpose

This policy builds upon and expands the emerging pathogen response outlined in the Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens (August 19, 2016) to create a similar process for addressing pathogenic mycobacteria.[1] Under the Environmental Protection Agency (EPA) Pesticide Program Dialogue Committee (PPDC), EPA assembled a robust and diverse work group of registrants, academicians, user groups, trade associations, the U.S. Centers for Disease Control and Prevention (CDC) and Agency staff to review the published literature[2-25], collect the experiences and recommendations to prepare this guidance and the underlying processes.[26,27] Subsequently, PPDC formed the Emerging Pathogen Implementation Committee (EPIC), to carry out those recommendations which include the preparation of this policy.

Emerging pathogens ("EP") are an increasing public health concern in the United States as well as globally. Some of these emerging pathogens may have the ability to persist on environmental surfaces (hard/soft, porous or non-porous) that can play a role in human disease transmission. Here we are proposing an emerging mycobacterial pathogen policy. Because the occurrence of emerging pathogenic mycobacteria is less common than established pathogens, few, if any, EPA-registered product labels specify use against this category of infectious agents. Also, depending on the testing scheme, these pathogens may be unavailable commercially and standard methods for laboratory testing may not have been developed and deposited with culture collection repositories. Thus, it may be difficult to assess the efficacy of EPA-registered products against such pathogens in a timely manner and to add these mycobacteria to existing product registrations, which requires the submission of efficacy data for Agency review to respond to a public health threat. As a result, the Agency is providing a voluntary, two-step process to enable use of certain EPA-registered products against emerging mycobacterial pathogens not identified on the product label. Registrants are encouraged to proactively register their products for Emerging Mycobacterial Pathogen claims to be ready for future outbreaks:

1) In the first stage, which may be performed prior to any outbreak, registrants with an eligible disinfectant may submit a request, via label amendment or during the registration of a new product, to control an emerging mycobacterial pathogen to proactively add a designated statement to the master label (See Attachment 1). If the product meets the eligibility criteria suggested in this Guidance, the Agency generally will approve the label language and, where available, add the product to an online list for users to search for products pre-registered for these claims. Approval of the language includes additional terms and conditions of registration regarding how the designated statement may be published and communicated (Attachment 1). This option allows for registered products to be prepared for future outbreaks. This action must be carried

out on the Basic Registration before a Supplemental Registration will be eligible to make claims. The Supplemental registrant must adhere to the same Terms (Attachment 1), EPA stamped label language found on the Basic Registration, and all aspects of this policy.

2) The second stage of this process occurs during a human or animal disease outbreak caused by an emerging type of pathogenic mycobacterium. In this stage, EPA identifies the emerging pathogen(s) eligible for this policy and notifies Registrants at the "*Emerging Pathogenic Mycobacteria Guidance and Status for Antimicrobial Pesticides*" webpage[1] that the preapproved communications may be initiated. Registrants of products with previously accepted emerging pathogen label language and terms of registration (Attachment 1) would be allowed to use the designated statement in off-label communications intended to inform the user community and general public that the registered product(s) may be used against the specific emerging pathogen. These off-label statements will inform the public about the utility of these products against the emerging pathogen in the most expeditious manner and can be more easily removed once the outbreak has ended than statements on a label. Also, a QR Code or other approved equivalent indicator on the label may direct the user to the approved language. If a particular product has not yet been approved for use of emerging pathogen language, the first step above may be initiated.

Many user facilities may have internal policies that prohibit off-label usage of disinfectants. In order to allow these facilities to use appropriately registered products against the specific emerging pathogen, the following statement may be included within internal policies, "The use of the EPA's GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING MYCOBACTERIAL PATHOGENS as applied to currently EPA registered disinfectants does not constitute off-label usage or a violation of FIFRA for users of these products. Users of germicides/disinfectant products should carefully follow all manufacturer's instructions for use and label instructions."

Note that this document provides general guidance to EPA, pesticide registrants, applicants for pesticide registrations, and the public. This guidance is not binding on EPA or any outside parties, and EPA may depart from the guidance where circumstances warrant and without prior notice.

II. *Mycobacterium* Classification and Other Microorganisms

EPA and the CDC recognize that certain microorganisms can be ranked with respect to their tolerance to chemical disinfectants. Whereas the Spaulding[28] Classification model focuses on medical devices, the Klein-DeForest[12,29-31] model, used by CDC and other public health agencies, tiers microorganisms in accordance with the level of tolerance to being killed (inactivated) by typical antimicrobial products.

Mycobacterium is a genus of Gram positive, acid fast bacteria which include *M. tuberculosis* and *M. leprae* causing the human diseases tuberculosis and leprosy, respectively. Additionally, the genus includes several human and animal pathogens which are termed as non-tuberculous mycobacteria or environmental mycobacteria. Mycobacteria in general are characterized by a cell well containing a complex of peptidoglycan and arabinogalactan, which is surrounded by a hydrophobic, lipid-rich outer membrane made of mycolic acid. This unique outer membrane creates a waxy coating on the mycobacteria making them more difficult to inactivate as compared to other types of vegetative bacteria.

Testing for mycobacterial efficacy is outlined in United States Environmental Protection Agency "Product Performance Test Guidelines OCSPP 810.2200: Disinfectants for Use on Environmental Surfaces Guidance for Efficacy Testing".[33] Current requirements for testing are based on tuberculocidal label claims outlined in the table below and follow various standard methods. Within these testing requirements, EPA has a variety of test carrier types that are used to represent hard non-porous (glass slides), and hard porous (porcelain penicylinders) surfaces.

While the title of the EPA registration category has historically been "Tuberculocidal Disinfectants", the genus *Mycobacterium* contains well-known human pathogens such as *M. tuberculosis* (tubercle bacillus) and *M. leprae* (Hanson's bacillus) as well as nearly 190 other species variously termed as nontuberculous mycobacteria (NTM), environmental mycobacteria (EM), atypical mycobacteria or mycobacteria other than tuberculosis' (MOTT). While *M. tuberculosis* and *M. leprae* are not known to grow in the environment and can spread primarily by air and via close person-to-person contact, NTM in general are opportunistic pathogens and are being incriminated in an increasing variety of human infections. They have a waxy coating and can readily form biofilms, thus making them more refractory to disinfection. Considering the continuing increase in the number of NTM and their emerging importance as environment-based human pathogens, the policy has aligned with the broader "Mycobacteria" term to better reflect and cover the full genus.

Based on the availability of testing on a variety of test carriers, the emerging pathogen claims may be expanded to this array of surfaces.

Registration Category	Strain	Product type	Carrier types
Tuberculocidal	*Mycobacterium bovis* (BCG) ATCC 35743	Glutaraldehyde-based	Not Applicable - Suspension test – Claims supported by suspension tests are not eligible to support Emerging Pathogen claims
		Non-Glutaraldehyde liquid	Porcelain penicylinders
		Non-Glutaraldehyde spray	Glass slides
		Non-Glutaraldehyde towelette	

Under the criteria outlined in Section III of this Guidance, these prerequisites may be used to determine a product's anticipated efficacy against an emerging mycobacterial pathogen along with the additional registration categories described below.

III. Product Eligibility Criteria

Registrants should use the following criteria to determine if a new or existing EPA-registered product is eligible to use the process described in this Guidance. An eligible product should meet the following criteria:

1. The product is a new or existing EPA-registered product with claims on the label in at least one of the following Registration Categories (Table column 1) with directions for use on hard porous, hard non-porous, and/or soft porous surfaces per the applicable EPA guidance for registration[32,33]:

2. The above EPA registered product, as described, would be eligible for emerging mycobacterial claims as shown in Columns 2-4 of the Table below when tested using the appropriate test carrier for the surface type.

Registration Categories[32,33]	Supports Emerging Pathogen Claims[a] for:		
	Hard, Non-Porous Surfaces when tested on hard, non-porous carrier (stainless steel, glass slide)	**Hard, Porous Surfaces** when tested on hard, porous carrier (porcelain penicylinder)	**Soft Surfaces** when tested on soft carrier (suture loop)
Sterilant[32]	*Mycobacterium spp.*	*Mycobacterium spp.*	*Mycobacterium spp.*
Sporicidal[b,32]	*Mycobacterium spp.*	*Mycobacterium spp.*	*Mycobacterium spp.*
***Clostridioides* (formerly *Clostridium) difficile* Disinfectant**[32]	*Mycobacterium spp.*	None	None
***Bacillus anthracis* Decontaminant**[32]	*Mycobacterium spp.*	*Mycobacterium spp.*	*Mycobacterium* spp.
***Tuberculocide*[c,33]**	*Mycobacterium spp.*	*Mycobacterium spp.*	None
***Candida auris* Disinfectant**[d,33]	*Mycobacterium spp.*	None	None
Small Non-Enveloped Virucidal Disinfectant (Two viruses from List Below)[e,33]	*Mycobacterium spp.*	None	None

[a] In many cases, data is not available that directly evaluates whether indicated research categories are predictive for *Mycobacterium sp*. As such, recommendations provided are based on the collective expert opinion of the PPDC Emerging Pathogen Implementation Committee whose input is based on published literature, and the research and testing experience of the assembled experts.

[b] The working group has also recommended that products with claims for the following bacterial sporeformers also be used to support emerging pathogenic mycobacteria: *B. thuringiensis Al Hakam, B. thuringiensis kurstaki* HD-1 cry-*, B. anthracis* Sterne*, or B. anthracis Δ*Sterne[8]. The type of test carrier used will determine the appropriate surface for the claim. EPA does not currently have products with these spore claims. EPA may require a new PRIA protocol review to add such claims. Please contact EPA prior to initiation of testing.

[c] Tuberculocidal claims supported by suspension testing described in 810.2200, Section I(1) will not be eligible to use this testing to support an emerging pathogen claim due to the Expert working group's concern of potentially reduced stringency associated with suspension methods and their lack of simulation of product use. These products may use other testing relying on dried test carriers as noted in the table to support an emerging pathogen claim. In a public health crisis, EPA may reconsider this stance on a case-by-case basis to address supply chain shortages.

[d] This recommendation is not proposed based organism structural hierarchy but based on CDC and EPA testing experience with registered tuberculocides demonstrating the stringency of the *M. bovis* test strain.[20-22]

[e] The registration must include at least two of the following viral stains, each from a different family, to make emerging mycobacterial pathogen claims: Parvovirus (canine, porcine, etc.), Hepatitis A virus, Feline Calicivirus, Murine Norovirus, Rhinovirus, and Poliovirus. The option to utilize Polioviruses to support emerging mycobacterial claims is not intended to encourage new testing but rather to utilize existing claims based on previously submitted and accepted data. We are aware and support efforts to contain polioviruses in the U.S. (U.S. National Authority for Containment of Poliovirus CDC (https://www.cdc.gov/orr/polioviruscontainment/index.htm).

EPA may also consider other existing claims or microbial strains to support use of a product during an outbreak to assure sufficient supply of appropriate registered products to meet the public health need.

IV. Instructions for Using the Process

The following are instructions for registrants (with a product eligible under Section III above) who wish to make claims against emerging mycobacterial pathogens. Emerging pathogens are defined by the National Institute of Allergy and Infectious Diseases as those "that have newly appeared in a population or have existed but are rapidly increasing in incidence or geographic range." The Stage 2 process of communication may only be actioned if the EPA, through the **Emerging Pathogenic Mycobacteria Guidance and Status for Antimicrobial Pesticides webpage**[1] has identified the emerging pathogen and initiated the policy. This will not occur until EPA, or other national or global public health authority has determined surface disinfection may help control its spread. The expiration date for use of the emerging mycobacterial pathogen communication will also be detailed on the EPA Emerging Mycobacterial Pathogen Guidance and Status for Antimicrobial Pesticides **webpage**[1].

Registrants may follow a two-stage process to identify effective disinfectant products for use against emerging pathogens. To permit registrants in compliance with FIFRA to make limited off label claims of their product's efficacy against such pathogens, a registrant may either; 1) make a product label amendment with modified terms of registration through a Food Quality Protection Act (FQPA) (fast-track, non-PRIA), or a Pesticide Registration Improvement Act (PRIA) label amendment, or 2) add emerging pathogen language as part of a PRIA registration filing for a new product registration. During either process, the registrant will explain why the product meets the criteria for use against one or more categories of emerging mycobacterial pathogens.

To ensure the efficient processing of the application the registrant should include the following:

- A detailed cover letter to EPA (See Example in Attachment 2) including:
    - A subject line that clearly indicates "Emerging Mycobacterial Pathogen Claim";
    - A request to make emerging mycobacterial pathogen claims;
    - A description of how the product meets the eligibility criteria for use consistent with the guidance;
    - An identification of the registration category from the product label being used to support the emerging mycobacterial pathogen claims and the study ID number (MRID) that supports the claim;
    - A request to be added to EPA List for emerging mycobacterial claims.
- A pesticide application for registration (Form 8570-1);
- An up-to-date data matrix (Form 8570-35);
- A signed Terms of Registration form (See Attachment 1); and
- A Master Label amended to include the emerging mycobacterial pathogen generic text (See Attachment 3). **Note**: The container label in market must include the strains used to support the emerging pathogen claim.

The application should be submitted via the EPA Central Data Exchange (CDX) portal.

V. Outbreak Criteria Associated with Emerging Pathogens Process

As stated above, the process described in this Guidance is for use with emerging pathogens associated with certain human or animal disease outbreaks in the US or found internationally with potential to impact the US. Thus, registrants whose registered master labels include the approved statements, either via label amendment or during the new registration process as described in Section IV above, may publish the approved statements only upon EPA announcement at the **Emerging Pathogenic Mycobacteria Guidance and Status for Antimicrobial Pesticides webpage**[4]. For a disease outbreak, EPA will assure the following criteria:

1. The causative organism should be a mycobacterium that causes an infectious disease that has appeared in a human or animal population for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range ("emerging mycobacterium pathogen").[9] It includes both new and re-emerging mycobacterial pathogens listed by the CDC, World Organization for Animal Health (WOAH, formerly OIE), US Department of Agriculture (USDA), WHO (https://www.who.int/emergencies/disease-outbreak-news) or other equivalent global or national organizations.

   For example, this information may be found in one of the publications below:

   a. For human disease, the outbreak may be listed in one of the following CDC publications:
      i. CDC Current Outbreak List for "U.S. based outbreaks" (www.cdc.gov/outbreaks),
      ii. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process to federal, state, territorial, tribal, and local public health practitioners; clinicians; public health laboratories, and to those who subscribe to receive HAN-alerts.
      iii. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
   b. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the United States of America on the WOAH Weekly Disease Information page (https://wahis.woah.org/#/home) or international outbreaks that have the potential to impact the US.

2. The CDC, WOAH, or other equivalent global or national organization has identified the taxonomy, including the mycobacterium species, of the pathogen and provides notice to the public of the identity of the emerging pathogen that is responsible for an infectious disease outbreak. (For example, see WOAH technical disease cards (https://www.woah.org/en/what-we-do/animal-health-and-welfare/animal-diseases/). Based on the taxonomy of the outbreak pathogen, the *Mycobacterium* species should be confirmed and compared to the hierarchy described in Section III necessary to support an emerging mycobacterium pathogen claim.
3. The mycobacterium can be transmitted via environmental surfaces (non-insect-vector transmission), and environmental surface disinfection/sanitization has been recommended by the CDC, WOAH, EPA or other equivalent global/national organization to control the spread of the pathogen. This may include hard and/or soft, porous and/or non-porous surfaces for non-residual and/or residual uses.

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[31] Klein and DeForest. 1983. Principles of viral inactivity. In Disinfection, Sterilization, and Preservation. 3rd Edition. Edited by S. Block. Philadelphia, Lea & Febiger, pages 422-434.

[32] Product Performance Test Guidelines: OCSPP 810.2100 Disinfectants for Use on Hard Surfaces – Efficacy Data Recommendations (current version). *https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-810-product-performance-test-guidelines*.

[33] Product Performance Test Guidelines: OCSPP 810.2200 Disinfectants for Use on Environmental Surfaces; Guidance for Efficacy Testing (current version). *https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-810-product-performance-test-guidelines*.

[34] World Health Organization (WHO). 2015. Emerging Diseases. Available from: *http://www.who.int/topics/emerging_diseases/en*

Attachment 1

Example Terms of Registration

Instructions: The following are the Terms of Registration required to support the inclusion of Emerging Mycobacterial Pathogen claims associated with an eligible EPA registration. These options may be used at the registrant's discretion. All options will rely on the EPA pre-approved language and be based on the EPA defined provisions as found in the **EPA Emerging Pathogenic Mycobacteria Guidance and Status for Antimicrobial Pesticides landing page**[1]. In all cases, Federal pre-approval of the eligibility for EP language would occur in the registration process. No State/Federal outreach is necessary when EP claims are pre-registered and the Emerging Mycobacterial Pathogens allowance is triggered on the EPA webpage[1] based on the EPA Emerging Mycobacterial Pathogen Guidance and Status for Antimicrobial Pesticides.

This template is included in the initial submission requesting the Emerging Pathogen claims or when the claims are changed or updated in subsequent filings. Where changes are being made to a label that is not related to the EP language, it is not necessary to resubmit the Terms document.

Template

Terms of Registration for EMERGING MYCOBACTERIAL PATHOGENS CLAIMS

This product qualifies for emerging mycobacterial pathogen claims as outlined in the GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING MYCOBACTERIAL PATHOGENS when used in accordance with the appropriate use directions. This product meets the criteria to make claims against certain emerging mycobacterial pathogens based on the structure outlined in the Table(s) below and aligned with Section III of the guidance:

For [Insert surface type (e.g., soft, porous surfaces); Repeat table as needed to cover all uses/surfaces and other EP microorganism claims]]:	
For an emerging mycobacterial pathogen that is a…	*…follow the directions for use for the following organisms on the label*
Mycobacterium	Insert bacterial spore former(s)/*M. bovis*/ *C. auris*/ virus(es) name(s)

The use of the Emerging Mycobacterial Pathogen statements shall be based on the following Terms of Registration.

1. The Emerging Pathogen statements are allowed to appear as:
    a. Distributed Literature: Anywhere consumers/users/purchasers of the product may be located (e.g., technical literature distributed to health care facilities, physicians, nurses, and public health officials, "1-800" consumer information services, social media sites, company/distributor websites (non-label related, distributor catalogs, magazine ads, newspapers, etc.).

    b. QR Code or equivalent: On label or found in distributed literature. The QR Code may be activated when the Emerging Pathogen is added to the EPA website[1] triggering the Policy, and the Code would be deactivated when the EP allowance expires or sunsets.

    c. Hang Tag / Sticker(s): On product container.

2. Statements shall adhere to one the following formats. Minor adjustments may be made at the approval of the EPA:

   [Product name] has demonstrated effectiveness against [sporeformers)/ *M. bovis*/ *C. auris*/ virus names] similar to **[name of emerging Mycobacterium]** on hard, **[porous and/or non-porous and/or soft surfaces]**. Therefore, **[product name]** can be used against **[name of emerging Mycobacterium]** when used in accordance with the directions for use against **[name of supporting bacterial sporeformer**/ *M. bovis*/ *C. auris*/ virus names**]** on **[hard, porous/non-porous/soft surfaces]**. Refer to the **[CDC or OIE or EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[pathogen-specific website address]** for additional information.

   [Name of illness/outbreak] is caused by **[name of emerging Mycobacterium]. [Product name]** kills similar [sporeformer/ *M. bovis*/ *C. auris*/ virus names] and therefore can be used against **[name of emerging Mycobacterium]** when used in accordance with the directions for use against **[name of supporting bacterial sporeformer/***M. bovis*/ *C. auris*/ virus names) **]** on **[hard, porous/non-porous/soft surfaces].** Refer to the **[CDC or OIE or EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[website address]** for additional information.

   [Product name] can be used against **[name of emerging Mycobacterium]** when used in accordance with the directions for use against **[name of supporting bacteria sporeformer/**M. bovis/ C. auris/ virus names**]** on **[hard/soft, porous/non-porous surfaces]**.

   See Attachment 4 in the EP Policy which shows several table-based methods of communication.

3. Provided the registration is approved for making Emerging Mycobacterial Pathogen claims, the registrant may begin communicating these statement(s) upon notification of the outbreak of an emerging mycobacterial pathogen on the **EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page.** The registrant shall cease and remove all such non-label communications intended for consumers upon expiration of the emerging mycobacterial pathogen emergency as defined on the **EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page.** The emerging pathogen claim language may remain on the master label.

4. The registrant agrees that paragraphs 1 through 3 above shall become immediately void and ineffective if registration for use against **the supporting claim (e.g., bacterial sporeformer, M. bovis, C. auris, or named viruses)** is suspended or cancelled or no longer meets the criteria in EPA Performance Test 810 Guidelines[35,36]. In addition, evidence of ineffectiveness against any labeled pathogen in a less-resistant Spaulding category would also be grounds for voiding paragraphs 1 through 3.

[*Insert Registrant/Agent Signature*]

Insert Registrant/Agent Name & Title **Signature Date**

Attachment 2: Example Sample Cover Letter

Date:

Name (insert name of EPA contact)
Antimicrobials Division (7510P)
U.S. Environmental Protection Agency
Office of Pesticide Programs, Mail Code 7506C
1200 Pennsylvania Ave. NW
Washington, DC 20460

Subject: Emerging Mycobacterial Pathogen Claims

Dear Name:

Company Name (Company Name, Address, EPA Company Number), is submitting a terms of registration letter to add Emerging Mycobacterial Pathogen Claims to product EPA Registration Number XXXX-XXX.

Briefly, this (insert registration action type, e.g., FQPA, Fast Track Amendment, New Registration, etc.) is being submitted to include language to allow for claims to be made for emerging mycobacterial pathogens. The submission includes the Terms of Registration template found in GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING MYCOBACTERIAL PATHOGENS. As outlined in the Table(s) below, this product is eligible to make claims against emerging pathogens per the EPA Policy on the surfaces noted:

For [Insert surface type (e.g., soft, porous surfaces); Repeat table as needed to cover all surfaces and other EP microorganism claims]]:		
For an emerging mycobacterial pathogen that is a/an…	*…follow the directions for use for the following organisms on the label*	*MRID Numbers*
Mycobacterium spp.	Insert bacterial sporeformer/*M. bovis*/ *C. auris*/ virus names	Insert number supporting strain cited in column 2

The Master Label includes the required text per EPA Guidance.

Sincerely,

Registrant

Attachment 3: Example Master Label Template

Instructions:

The following language must be inserted into the Master Label for review and approval by EPA prior to any Basic or Supplemental registrant making any emerging pathogen claims. The Table below may be replicated as needed for each surface type (e.g., hard/soft, porous and non-porous) or emerging pathogen type. In the Table, Registrants may list different bacterial spore formers/*M. bovis*/ *C. auris*/ virus names for the emerging mycobacterial claim as outlined in Section III. Different spores/*M. bovis*/ *C. auris*/ virus names may be listed in each row of the table and multiple strains may be listed in a single row.

TEMPLATE

EMERGING MYCOBACTERIAL CLAIMS

This product qualifies for emerging mycobacterial pathogen claims as outlined in the GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING MYCOBACTERIAL PATHOGENS when used in accordance with the appropriate use directions. This product meets the criteria to make claims against certain emerging mycobacterial pathogens based on the prerequisites listed in the Table(s) below:

For [Insert surface type (e.g., soft, porous surfaces); Repeat table as needed to cover all surfaces and other EP microorganism claim]]:	
For an emerging mycobacterial pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Mycobacterium spp.	Insert bacterial spore former/*M. bovis*/ *C. auris*/ virus names

[Product name] has demonstrated effectiveness against [sporeformers/ *M. bovis*/ *C. auris*/ virus names] similar to **[name of emerging Mycobacterium]** on hard, **[porous and/or non-porous and/or soft surfaces]**. Therefore, **[product name]** can be used against **[name of emerging Mycobacterium]** when used in accordance with the directions for use against **[name of supporting bacterial sporeformer/**M. bovis/ C. auris/ virus names**]** on **[hard, porous/non-porous/soft surfaces]**. Refer to the **[CDC or OIE or EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[pathogen-specific website address]** for additional information.

[Name of illness/outbreak] is caused by **[name of emerging Mycobacterium]. [Product name]** kills similar [sporeformer/*M. bovis*/ *C. auris*/ virus names] and can be used against **[name of emerging Mycobacterium]** when used in accordance with the directions for use against **[name of supporting bacterial sporeformer/***M. bovis*/ *C. auris*/ virus names**]** on **[hard, porous/non-porous/soft surfaces].** Refer to the **[CDC or OIE or EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[website address]** for additional information.

[Product name] can be used against **[name of emerging Mycobacterium]** when used in accordance with the directions for use against **[name of supporting bacteria sporeformer/***M. bovis*/ *C. auris*/ virus names**]** on **[hard/soft, porous/non-porous surfaces]**.

See Attachment 4 of the EPA Policy which shows several table-based methods of communications.

Attachment 4: Alternate Example Table Formats for EP Communications

Instructions: The following tables provide possible format examples to illustrate how a registrant may configure the EPA stamped label EP claim(s) and registered directions for use of the EP cited strain into a table format to communicate with Registrants. The tables may include multiple approved EP uses (e.g., EVP hard surface disinfection, EVP soft surface disinfection, Emerging Sporeformers hard surface sporicide, Emerging Mycobacterial hard surface disinfection) as well as multiple approved products.

Example Template #1 (Pathogen-specific EP List):

Product Name	**EPA Reg. No.**	**SKUs and/or Package Size**	**Product Use Category and Concentration/ Form**	**Application and Surface Type**	**Approved for use with Direct [Mycobacterial Pathogen] Claim**	**Approved for use with the Emerging Mycobacterial Pathogen Claim**	**Approved for use with [Related Pathogen] Claim (Optional)**
[Insert EPA Approved Brand Name(s)]	[EPA Reg. No.]	[SKU] [Package Volume]	[Product category] [Product Form]	[Insert Application and surface type]	Where a direct claim for the EP exists on the label, insert [Contact time] at [concentration]	Where an EP claim for the EP exists, insert [Contact time] at [concentration] (Follow [EP Pathogen] directions)	Where EPA has allowed special additional EP allowances, insert [Contact time] at [concentration] (Follow [Related Pathogen] directions)

Example of Completed Table Using Template 1 (Pathogen-specific EP List):

Product Name	**EPA Reg. No.**	**SKUs**	**Product Category**	**Application and Surface Type**	**Approved for use with Direct Claim**	**Approved for use with the Emerging Pathogen Claim**	**Approved for use with *C. difficile* Claim**
Product 313	1111-11	11111 (1 gallon)	Tuberculocide (RTU)	Spray on hard, non-porous surfaces[1]	5 minutes at RTU (Follow Tuberculocide directions)	10 minutes at RTU (Follow Sporicide directions)	7 minutes at RTU (Follow *C. difficile* directions)
Product 314	2222-22	22222 (1 gallon)	Tuberculocide (Concentrate)	Spray or soak on hard, non-porous surfaces[1]	5 minutes at 5 oz/gal (Follow Tuberculocide directions)	10 minutes at 5 oz/gal 5 minutes at 10 oz/gal (Follow Sporicide directions)	7 minutes at 5 oz/gal (Follow *C. difficile* directions)

Product 315	2222-22	22222 (1 gallon)	Tuberculocide (Concentrate)	Spray on soft, porous surfaces[2]	7 minutes at 5 oz/gal (Follow Tuberculocide directions)	7 minutes at 10 oz/gal (Follow Sporicide directions)	10 minutes at 5 oz/gal (Follow *C. difficile* directions)

476 [1] Refer to EPA Master Label for list of approved hard, non-porous surfaces.

477 [2] Refer to EPA Master Label for list of approved soft, porous surfaces.

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479 **Example Template #2 (Pathogen-specific EP List):**

EP	Product Name	EPA Reg. No.	SKUs and/or Package Volume	Product Category	Application and Surface Type	Pathogen Supporting EP Claim	Use Instructions
[Insert EP]	[Insert EPA Approved Brand Name(s)]	[EPA Reg. No.]	[SKU][Package Volume]	[Product category]	[Insert Application and surface type]	[Insert bacterial sporeformer/ *M. bovis*, *C. auris*, or virus names]	[Insert abbrev. Use Directions for the Pathogen supporting the EP Claim]

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481 **Example of Template #3 (Pathogen-specific EP List):**

EP	Product Name	EPA Reg. No.	SKUs and/or Package Volume	Product Category	Application and Surface Type	Pathogen Supporting EP Claim	Use Instructions
[Insert EP]	[Insert EPA Approved Brand Name]	[EPA Reg. No.]	[SKU][Package Volume]	[Product category]	. [Insert Application and surface type]	[Insert bacterial sporeformer/ *M. bovis*, *C. auris*, or virus names]	[Insert abbrev. Use Directions for the Pathogen supporting the EP Claim]
				[Product category]	. [Insert Application and surface type]	[Insert bacterial sporeformer/ *M. bovis*, *C. auris*, or virus names]	[Insert abbrev. Use Directions for the Pathogen supporting the EP Claim]

482 **Example of Completed Table Using Template 2 (Pathogen-specific EVP List):**

EP	Product Name	EPA Reg. No.	SKUs and/or Package Volume	Product Category	Application and Surface Type	Pathogen Supporting EP Claim	Use Instructions
Clostridioides difficile Strain R20291	Sporicide ABC	#####-##	24oz Trigger	Sporicide	Hard, Non-Porous Surfaces	*Bacillus subtillus*; *Clostridium sporogenes*	Apply to precleaned surfaces and

							hold treated for 10mins.
Mycobacterium abscessus Strain T36			24oz Trigger	Disinfectant	Hard, Non-Porous Surfaces	*Mycobacterium bovis*	Apply to surfaces and hold treated for 10 mins.

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APPENDIX 4: Guidance to Registrants: Process for Making Claims Against Emerging Fungal Pathogens

GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING FUNGAL PATHOGENS

DRAFT

In this document:

I. Background and Purpose

This policy builds upon and expands the emerging pathogen response outlined in the Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens (August 19, 2016) to create a similar process for addressing pathogenic fungi including yeast.[1] Under the Environmental Protection Agency (EPA) Pesticide Program Dialogue Committee (PPDC), EPA assembled a robust and diverse work group of registrants, academicians, user groups, trade associations, the U.S. Centers for Disease Control and Prevention (CDC) and Agency staff to review the published literature[2-16], collect the experiences and recommendations to prepare this guidance and the underlying processes.[17,18] Subsequently, PPDC formed the Emerging Pathogen Implementation Committee (EPIC), to carry out those recommendations which include the preparation of this policy.

Emerging pathogens ("EP") are an increasing public health concern in the United States as well as globally. Some of these emerging pathogens may have the ability to persist on environmental surfaces (hard/soft, porous or non-porous) that can play a role in human disease transmission. Here we are proposing an emerging fungal pathogen policy. Because the emergence of fungal pathogens is less well recognized and common, few, if any, EPA-registered product labels are likely to specify use against this category of infectious agents. Also, depending on the testing scheme, representative and well-characterized strains of human pathogenic fungi may be unavailable at culture collections along with a paucity of standard methods for testing microbicides against them. Thus, it is difficult to assess such products for EPA registrations in a timely manner to respond to a public health threat. As a result, the Agency is providing a voluntary, two-step process to enable use of certain EPA-registered products against emerging fungal pathogens not identified on the product label. Registrants are encouraged to proactively register their products for Emerging Fungal Pathogen claims to be ready for future outbreaks:

1) In the first stage, which may be performed prior to any outbreak, registrants with an eligible disinfectant may submit a request, via label amendment or during the registration of a new product, to control an emerging fungal pathogen to proactively add a designated statement to the master label (See Attachment 1). If the product meets the eligibility criteria suggested in this Guidance, the Agency generally will approve the label language and, where available, add the product to an online list for users to search for products pre-registered for these claims. Approval of the language includes additional terms and conditions of registration regarding how the designated statement may be published and communicated (Attachment 1). This option allows for registered products to be prepared for future outbreaks. This action must be carried out on the Basic Registration before a Supplemental Registration will be eligible to make claims. The Supplemental registrant must adhere to the same Terms (Attachment 1), EPA stamped label language found on the Basic Registration, and all aspects of this policy.

2) The second stage of this process occurs during a human or animal disease outbreak caused by an emerging type of pathogenic fungus. In this stage, EPA identifies the emerging pathogen(s) eligible for this policy and notifies Registrants at the "*Emerging Pathogenic Fungal Guidance and Status for Antimicrobial Pesticides*" webpage[1] that the preapproved communications may be initiated. Registrants of products with previously accepted emerging pathogen label language and terms of registration (Attachment 1) would be allowed to use the designated statement in off-label communications intended to inform the user community and general public that the registered product(s) may be used against the specific emerging pathogen. These off-label statements will inform the public about the utility of these products against the emerging pathogen in the most expeditious manner and can be more easily removed once the outbreak has ended than statements on a label. Also, a QR Code or other approved equivalent indicator on the label may direct the user to the approved language. If a particular product has not yet been approved for use of emerging pathogen language, the first step above may be initiated.

Many user facilities may have internal policies that prohibit off-label usage of disinfectants. To allow these facilities to use appropriately registered products against the specific emerging pathogen, the following statement may be included within internal policies, "The use of the EPA's GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING FUNGAL PATHOGENS as applied to currently EPA registered disinfectants does not constitute off-label usage or a violation of FIFRA for users of these products. Users of germicides/disinfectant products should carefully follow all manufacturer's instructions for use and label instructions."

Note that this document provides general guidance to EPA, pesticide registrants, applicants for pesticide registrations, and the public. This guidance is not binding on EPA or any outside parties, and EPA may depart from the guidance where circumstances warrant and without prior notice.

II. Fungal Classification and Other Microorganisms

EPA and the CDC recognize that certain microorganisms can be ranked with respect to their tolerance to chemical disinfectants. Whereas the Spaulding[19] Classification model focuses on medical devices, the Klein-DeForest[20-22] model, used by CDC and other public health agencies, tiers microorganisms in accordance with the level of tolerance to being killed (inactivated) by typical antimicrobial products.

Fungi represent a diverse kingdom of eukaryotic organisms, four of the classes (Basidiomycetes, Ascomycetes, Zygomycetes, and Deuteromycetes) are characterized by the presence of a cell wall often containing chitin and/or chitosan.[29] While most fungi do not pose a risk to human health, some fungi are medically relevant and can cause

serious infections. Common modes of clinical exposure to pathogenic fungi can include inhalation, traumatic inoculation or through fomite mediated transmission.

Historically, fungi have been classified based on key morphological and reproductive structures.[30] Many fungi produce "spores", a catch-all term for a wide variety of specialized structures that can enhance persistence, support reproduction, or aid dispersal. Spore structures and features can vary significantly based on factors such as the producing species, whether the spore is formed through sexual or asexual processes, and whether the spore is produced through a reproductive process or by reprogramming of a previously existing vegetative cell. Some fungi produce larger structures that encase multiple individual spores such as "Macroconidia" or "Sporangia", and some fungi may produce multiple spore types simultaneously. In contrast, some fungi do not produce spores at all. Fungal taxonomy is complex and nomenclature changes are ongoing. There are substantial data gaps in the literature regarding how the many types of fungi and spore structures respond to disinfectants, particularly with standardized methodologies.

For the purposes of this guidance, fungal pathogens will be represented by two categories: filamentous fungi or yeast. Filamentous fungi are characterized by branching filaments called hyphae which form a network structure known as the mycelium. Notably, for the purpose of this guidance, filamentous fungi are assumed in this document to produce some type of spore which is the subject of disinfectant testing and the basis of associated guidance, such as the macroconidia of *Trichophyton* species, or the enteroblastic conidia of *Aspergillus sp*. In contrast, "yeast" in this document are understood to be non-spore forming, where vegetative cells are the subject of disinfectant testing and basis of associated guidance, such as *Candida auris* or *C. albicans*.

It is worth noting some fungi are dimorphic and alternate between yeast and filamentous states, including the medically relevant BSL-3 pathogens *Blastomyces*, *Histoplasma,* and *Coccidioides species*. This guidance does not address these organisms.

Testing for fungal disinfectant efficacy is outlined in United States Environmental Protection Agency "Product Performance Test Guidelines OCSPP 810.2200: Disinfectants for Use on Environmental Surfaces Guidance for Efficacy Testing", EPA Pesticide Assessment Guidelines: Subdivision G, and the EPA Guidance for the Efficacy Evaluation of Products for Claims against Drug-Resistant Candida auris.[24, 27, 28] Current requirements for testing are based on label claims for fungicidal disinfectants including *Trichophyton*, *Aspergillus*, *C. auris*, and other fungal strains are outlined in the table below and follow various standard methods. Within these testing requirements, EPA has a variety of test carrier types that are used to represent hard non-porous (stainless steel penicylinders, brushed stainless steel discs, glass slides) surfaces.

Registration Category	Strain	Test Method	Carrier Type
Fungicidal Disinfectant[24]	*T. interdigitale* ATCC 9533	AOAC 964.02/955.14/955.15 Use-Dilution Method (modified for Fungi)	Stainless Steel Penicylinders
		AOAC 961.02 Germicidal Spray Products as Disinfectants	Glass slides
		AOAC 955.17 Fungicidal Activity of Disinfectants	Not Applicable, Suspension Test - Claims supported by suspension tests are not eligible to support Emerging Pathogen claims
C. auris Disinfectant[28]Disinfectant[28]	*C. auris* CDC AR Bank #0385	EPA BEAD SOP MB35/MB37	Stainless Steel Disc
Mildewcidal Disinfectant[24,27]	*A. niger* ATCC 6275, or *A. brasilensis ATCC* 16404	AOAC 964.02/955.14/955.15 Use-Dilution Method (modified for Fungi)	Stainless Steel Penicylinders
		AOAC 961.02 Germicidal Spray Products as Disinfectants	Glass slides
		AOAC 955.17 Fungicidal Activity of Disinfectants	Not Applicable, Suspension Test - Claims supported by suspension tests are not eligible to support Emerging Pathogen claims
Fungicidal Yeast Disinfectant[24]	*Candida* spp.	AOAC 964.02/955.14/955.15 Use-Dilution Method (modified for Fungi)	Stainless Steel Penicylinders
		AOAC 961.02 Germicidal Spray Products as Disinfectants	Glass slides

Under the criteria outlined in Section III of this Guidance, prerequisite strains of greater difficulty to inactivate may be used to determine a product's anticipated efficacy against an emerging fungal pathogen from the additional registration categories described below.

The EPA product performance guidelines also include other fungistatic and mildewstatic test guidelines[27]. These inhibitory fungal test methods will not be used to support emerging pathogen claims.

III. Product Eligibility Criteria

Registrants should use the following criteria to determine if a new or existing EPA-registered product is eligible to use the process described in this Guidance. An eligible product should meet the following criteria:

1. The product is a new or existing EPA-registered product with claims on the label in at least one of the following Registration Categories (Table column 1) with directions for use on hard porous, hard non-porous, and/or soft, porous surfaces per the applicable EPA guidance for registration[23-2424]:

2. The above EPA registered product, as described, would be eligible for emerging fungal claims as shown in Columns 2-4 of the Table below when tested using the appropriate test carrier for the surface type.

Registration Categories[23,2424]	**Supports Emerging Pathogen Claims[a] for:**		
	Hard, Non-Porous Surfaces when tested on hard, non-porous carrier (stainless steel, glass slide)	**Hard, Porous Surfaces** when tested on hard, porous carrier (porcelain penicylinder)	**Soft Surfaces** when tested on soft carrier (suture loop)
Sterilant[23]	*Filamentous fungi and Yeast*	*Filamentous fungi and Yeast*	*Filamentous fungi and Yeast*
Sporicidal[b][,23]	*Filamentous fungi and Yeast*	*Filamentous fungi and Yeast*	*Filamentous fungi and Yeast*
***Clostridioides difficile* Disinfectant**[23]	*Filamentous fungi and Yeast*	None	None
***Bacillus anthracis* Decontaminant**[23]	*Filamentous fungi and Yeast*	*Filamentous fungi and Yeast*	*Filamentous fungi and Yeast*
***B. thuringiensis, etc.*[b]**	*Filamentous fungi and Yeast*	*Filamentous fungi and Yeast*	*Filamentous fungi and Yeast*
***Fungicidal Disinfectant (T. interdigitale)*[c, 24]**	*Trichophyton spp.* (Testing conducted by AOAC 955.17 suspension method is not eligible.)[c]	*None*	None
***Mildewcidal Disinfectant (A. niger or A. brasiliensis)*[27]**	*Trichophyton and Aspergillus spp.* (Testing conducted by AOAC 955.17 suspension method is not eligible.)[c]	*None*	None
***Candida auris* Disinfectant**[24]	*Yeast*	None	None
Small Non-Enveloped Virucidal Disinfectant (Two viruses from List Below)[d,24]	*Filamentous Fungi*	None	None

[a] In many cases, data is not available that directly evaluates whether indicated research categories are predictive of activity against fungi. As such, recommendations provided are based on the collective expert opinion of the PPDC Emerging Pathogen Implementation Committee whose input is based on published literature, and the research and testing experience of the assembled experts.

[b] The working group recommended that products with claims for the following bacterial sporeformers also be used to support emerging pathogenic fungi: *B. thuringiensis Al Hakam, B. thuringiensis kurstaki* HD-1 cry-*, B. anthracis* Sterne*, or B. anthracis Δ*Sterne[25]. The type of test carrier used will determine the appropriate surface for the claim. EPA does not currently have products with these spore claims. EPA may require a new PRIA protocol review to add such claims. Please contact EPA prior to initiation of testing.

[c] Fungal claims supported by AOAC 955.17 suspension testing described in 810.2200, Section H(1)[24] will not be eligible to support an emerging pathogen claim due to the Expert working group's concern of potentially reduced stringency associated with suspension methods and their lack of simulation of product use. These products may use other testing relying on dried test carriers as noted in the table to support an emerging pathogen claim. In a public health crisis, EPA may reconsider this stance on a case-by-case basis to address supply chain issues.

[d] The registration must include at least two of the following viral strains, each from a different family, to make emerging fungal pathogen claims: Parvovirus (canine, porcine, etc.), Hepatitis A virus, Feline Calicivirus, Murine Norovirus, Rhinovirus, and Poliovirus. The option to utilize Polioviruses to support emerging fungal claims is not intended to encourage new testing but rather to utilize existing claims based on previously submitted and accepted data. We are aware and support efforts to contain polioviruses in the U.S. (U.S. National Authority for Containment of Poliovirus CDC (https://www.cdc.gov/orr/polioviruscontainment/index.htm).

EPA may also consider other existing claims or microbial strains to support use of a product during an outbreak to assure sufficient supply of appropriate registered products to meet the public health need.

IV. Instructions for Using the Process

The following are instructions for registrants (with a product eligible under Section III above) who wish to make claims against emerging fungal pathogens. Emerging pathogens are defined by the National Institute of Allergy and Infectious Diseases as those "that have newly appeared in a population or have existed but are rapidly increasing in incidence or geographic range." The Stage 2 process of communication may only be actioned if the EPA, through the **Emerging Pathogenic Fungal Guidance and Status for Antimicrobial Pesticides webpage**[1] has identified the emerging pathogen and initiated the policy. This will not occur until EPA, or other national or global public health authority has determined surface disinfection may help control its spread. The expiration date for use of the emerging fungal pathogen communication will also be detailed on the EPA Emerging Fungal Pathogen Guidance and Status for Antimicrobial Pesticides **webpage**[1].

Registrants may follow a two-stage process to identify effective disinfectant products for use against emerging pathogens. To permit registrants in compliance with FIFRA to make limited off label claims of their product's efficacy against such pathogens, a registrant may either; 1) make a product label amendment with modified terms of registration through a Food Quality Protection Act (FQPA) (fast-track, non-PRIA), or a Pesticide Registration Improvement Act (PRIA) label amendment, or 2) add emerging pathogen language as part of a PRIA registration filing for a new product registration. During either process, the registrant will explain why the product meets the criteria for use against one or more categories of emerging fungal pathogens.

To ensure the efficient processing of the application the registrant should include the following:

- A detailed cover letter to EPA (See Example in Attachment 2) including:
    - A subject line that clearly indicates "Emerging Fungal Pathogen Claim";
    - A request to make emerging fungal pathogen claims;
    - A description of how the product meets the eligibility criteria for use consistent with the guidance;

- An identification of the registration category from the product label being used to support the emerging fungal pathogen claims and the study ID number (MRID) that supports the claim;
- A request to be added to EPA List for emerging fungal claims.

- A pesticide application for registration (Form 8570-1);
- An up-to-date data matrix (Form 8570-35);
- A signed Terms of Registration form (See Attachment 1); and
- A Master Label amended to include the emerging fungal pathogen generic text (See Attachment 3). **Note**: The container label in market must include the strains used to support the emerging pathogen claim.

The application should be submitted via the EPA Central Data Exchange (CDX) portal.

V. Outbreak Criteria Associated with Emerging Pathogens Process

As stated above, the process described in this Guidance is for use with emerging pathogens associated with certain human or animal disease outbreaks in the US or found internationally with potential to impact the US. Thus, registrants whose registered master labels include the approved statements, either via label amendment or during the new registration process as described in Section IV above, may publish the approved statements only upon EPA announcement at the **Emerging Pathogenic Fungal Guidance and Status for Antimicrobial Pesticides webpage**[11] For a disease outbreak, EPA will assure the following criteria:

1. The causative organism should be a fungus that causes an infection that has appeared in a human or animal population for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range ("emerging fungal pathogen").[2626] It includes both new and re-emerging fungal pathogens listed by the CDC, World Organization for Animal Health (WOAH, formerly OIE), US Department of Agriculture (USDA), WHO (https://www.who.int/emergencies/disease-outbreak-news) or other equivalent global or national organizations.

   For example, this information may be found in one of the publications below:

   a. For human disease, the outbreak may be listed in one of the following CDC publications:
      i. CDC Current Outbreak List for "U.S. based outbreaks" (www.cdc.gov/outbreaks),
      ii. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process to federal, state, territorial, tribal, and local public health practitioners; clinicians; public health laboratories, and to those who subscribe to receive HAN-alerts.
      iii. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
   b. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the United States of America on the WOAH Weekly Disease Information page (https://wahis.woah.org/#/home) or international outbreaks that have the potential to impact the US.

2. The CDC, WOAH, or other equivalent global or national organization has identified the taxonomy, including the fungal species, of the pathogen and provides notice to the public of the identity of the emerging pathogen that is responsible for an infectious disease outbreak. (For example, see WOAH

technical disease cards (https://www.woah.org/en/what-we-do/animal-health-and-welfare/animal-diseases/). Based on the taxonomy of the outbreak pathogen, the Fungal species should be confirmed and compared to the hierarchy described in Section III necessary to support an emerging fungal pathogen claim.

3. The fungus can be transmitted via environmental surfaces (non-insect-vector transmission), and environmental surface disinfection/sanitization has been recommended by the CDC, WOAH, EPA or other equivalent global/national organization to control the spread of the pathogen. This may include hard and/or soft, porous and/or non-porous surfaces for non-residual and/or residual uses.

VI. References

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Attachment 1

Example Terms of Registration

Instructions: The following are the Terms of Registration required to support the inclusion of Emerging Fungal Pathogen claims associated with an eligible EPA registration. These options may be used at the registrant's discretion. All options will rely on the EPA pre-approved language and be based on the EPA defined provisions as found in the **EPA Emerging Pathogenic Fungal Guidance and Status for Antimicrobial Pesticides landing page**[1]. In all cases, Federal pre-approval of the eligibility for EP language would occur in the registration process. No State/Federal outreach is necessary when EP claims are pre-registered and the Emerging Fungal Pathogens allowance is triggered on the EPA webpage[1] based on the EPA Emerging Fungal Pathogen Guidance and Status for Antimicrobial Pesticides.

This template is included in the initial submission requesting the Emerging Pathogen claims or when the claims are changed or updated in subsequent filings. Where changes are being made to a label that is not related to the EP language, it is not necessary to resubmit the Terms document.

Template

Terms of Registration for EMERGING FUNGAL PATHOGENS CLAIMS

This product qualifies for emerging fungal pathogen claims as outlined in the GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING FUNGAL PATHOGENS when used in accordance with the appropriate use directions. This product meets the criteria to make claims against certain emerging fungal pathogens based on the structure outlined in the Table(s) below and aligned with Section III of the guidance:

For [Insert surface type (e.g., soft, porous surfaces); Repeat table as needed to cover all uses/surfaces and other EP microorganism claims]]:	
For an emerging fungal pathogen that is a…	*…follow the directions for use for the following organisms on the label*
Filamentous Fungi	Insert bacterial spore former/Fungi/*C. auris*/Viral names
Yeast	Insert bacterial spore former/ *C. auris* name(s)

The use of the Emerging Fungal Pathogen statements shall be based on the following Terms of Registration.

1. The Emerging Pathogen statements are allowed to appear as:
    a. Distributed Literature: Anywhere consumers/users/purchasers of the product may be located (e.g., technical literature distributed to health care facilities, physicians, nurses, and public health officials, "1-800" consumer information services, social media sites, company/distributor websites (non-label related, distributor catalogs, magazine ads, newspapers, etc.).

    b. QR Code or equivalent: On label or found in distributed literature. The QR Code may be activated when the Emerging Pathogen is added to the EPA website[1] triggering the Policy, and the Code would be deactivated when the EP allowance expires or sunsets.

    c. Hang Tag / Sticker(s): On product container.

2. Statements shall adhere to one the following formats. Minor adjustments may be made at the approval of the EPA:

   [Product name] has demonstrated effectiveness against [bacterial sporeformers/Fungi/C. auris/ virus names] similar to **[name of emerging Fungi]** on hard, **[porous and/or non-porous and/or soft surfaces]**. Therefore, **[product name]** can be used against **[name of emerging Fungi]** when used in accordance with the directions for use against **[name of supporting bacterial sporeformer**/Fungi/C. auris/virus names**]** on **[hard, porous/non-porous/soft surfaces]**. Refer to the **[CDC or OIE or EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[pathogen-specific website address]** for additional information.

   [Name of illness/outbreak] is caused by **[name of emerging Fungi]. [Product name]** kills similar [sporeformer/Fungi/C. auris/ virus names] and therefore can be used against **[name of emerging Fungi]** when used in accordance with the directions for use against **[name of supporting bacterial sporeformer/**Fungi/C. auris/ virus names) **]** on **[hard, porous/non-porous/soft surfaces].** Refer to the **[CDC or OIE or EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[website address]** for additional information.

   [Product name] can be used against **[name of emerging Fungi]** when used in accordance with the directions for use against **[name of supporting bacteria sporeformer/**Fungi/C. auris/ virus names**]** on **[hard/soft, porous/non-porous surfaces]**.

   See Attachment 4 in the EP Policy which shows several table-based methods of communication.

3. Provided the registration is approved for making Emerging Fungal Pathogen claims, the registrant may begin communicating these statement(s) upon notification of the outbreak of an emerging fungal pathogen on the **EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page.** The registrant shall cease and remove all such non-label communications intended for consumers upon expiration of the emerging fungal pathogen emergency as defined on the **EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page.** The emerging pathogen claim language may remain on the master label.

4. The registrant agrees that paragraphs 1 through 3 above shall become immediately void and ineffective if registration for use against **the supporting claim (e.g., bacterial sporeformer, Fungi , C. auris, or named viruses)** is suspended or cancelled or no longer meets the criteria in EPA Performance Test 810 Guidelines[23,24]. In addition, evidence of ineffectiveness against any labeled pathogen in a less-resistant Spaulding category would also be grounds for voiding paragraphs 1 through 3.

[*Insert Registrant/Agent Signature*]

Insert Registrant/Agent Name & Title **Signature Date**

Attachment 2: Example Sample Cover Letter

Date:

Name (insert name of EPA contact)
Antimicrobials Division (7510P)
U.S. Environmental Protection Agency
Office of Pesticide Programs, Mail Code 7506C
1200 Pennsylvania Ave. NW
Washington, DC 20460

Subject: Emerging Fungal Pathogen Claims

Dear Name:

Company Name (Company Name, Address, EPA Company Number), is submitting a terms of registration letter to add Emerging Fungal Pathogen Claims to product EPA Registration Number XXXX-XXX.

Briefly, this (insert registration action type, e.g., FQPA, Fast Track Amendment, New Registration, etc.) is being submitted to include language to allow for claims to be made for emerging fungal pathogens. The submission includes the Terms of Registration template found in GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING FUNGAL PATHOGENS. As outlined in the Table(s) below, this product is eligible to make claims against emerging pathogens per the EPA Policy on the surfaces noted:

For [Insert surface type (e.g., soft, porous surfaces); Repeat table as needed to cover all surfaces and other EP microorganism claims]]:		
For an emerging fungal pathogen that is a/an…	*…follow the directions for use for the following organisms on the label*	*MRID Numbers*
. Filamentous fungi	Insert bacterial sporeformer/Fungi/*C. auris*/Virus names	Insert number supporting strain cited in column 2
Yeast	Insert bacterial sporeformer/C. auris	Insert number supporting strain cited in column 2

The Master Label includes the required text per EPA Guidance.

Sincerely,

Registrant

Attachment 3: Example Master Label Template

Instructions:

The following language must be inserted into the Master Label for review and approval by EPA prior to any Basic or Supplemental registrant making any emerging pathogen claims. The Table below may be replicated as needed for each surface type (e.g., hard/soft, porous and non-porous) or emerging pathogen type. In the Table, Registrants may list different bacterial spore formers/Fungi/*C. auris*/ virus names for the emerging fungal claim as outlined in Section III. Different spores/Fungi/*C. auris*/ virus names may be listed in each row of the table and multiple strains may be listed in a single row.

TEMPLATE

EMERGING FUNGAL CLAIMS

This product qualifies for emerging fungal pathogen claims as outlined in the GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING FUNGAL PATHOGENS when used in accordance with the appropriate use directions. This product meets the criteria to make claims against certain emerging fungal pathogens based on the prerequisites listed in the Table(s) below:

For [Insert surface type (e.g., soft, porous surfaces); Repeat table as needed to cover all surfaces and other EP microorganism claim]]:	
For an emerging fungal pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Filamentous fungi	Insert bacterial spore former/Fungi//*C. auris*/Virus name(s)
Yeast	Insert bacterial spore former/*C. auris* name(s)

[Product name] has demonstrated effectiveness against [**sporeformers Fungi/*C. auris*/ virus names**] similar to **[name of emerging Fungi]** on hard, **[porous and/or non-porous and/or soft surfaces]**. Therefore, **[product name]** can be used against **[name of emerging Fungi]** when used in accordance with the directions for use against **[name of supporting bacterial sporeformer/**Fungi/*C. auris*/ virus names**]** on **[hard, porous/non-porous/soft surfaces]**. Refer to the **[CDC or OIE or EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[pathogen-specific website address]** for additional information.

[Name of illness/outbreak] is caused by **[name of emerging Fungi]. [Product name]** kills similar [sporeformer/Fungi/ *C. auris*/ virus names] and can be used against **[name of emerging Fungi]** when used in accordance with the directions for use against **[name of supporting bacterial sporeformer/**Fungi/ *C. auris*/ virus names**]** on **[hard, porous/non-porous/soft surfaces].** Refer to the **[CDC or OIE or EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[website address]** for additional information.

[Product name] can be used against **[name of emerging Fungi]** when used in accordance with the directions for use against **[name of supporting bacteria sporeformer/Fungi/*C. auris*/virus names]** on **[hard/soft, porous/non-porous surfaces]**.

See Attachment 4 of the EPA Policy which shows several table-based methods of communications.

Attachment 4: Alternate Example Table Formats for EP Communications

Instructions: The following tables provide possible format examples to illustrate how a registrant may configure the EPA stamped label EP claim(s) and registered directions for use of the EP cited strain into a table format to communicate with Registrants. The tables may include multiple approved EP uses (e.g., EVP hard surface disinfection, EVP soft surface disinfection, Emerging Sporeformers hard surface sporicide, Emerging Fungal hard surface disinfection) as well as multiple approved products.

Example Template #1 (Pathogen-specific EP List):

Product Name	EPA Reg. No.	SKUs and/or Package Size	Product Use Category and Concentration/ Form	Application and Surface Type	Approved for use with Direct [Fungal Pathogen] Claim	Approved for use with the Emerging Fungal Pathogen Claim	Approved for use with [Related Pathogen] Claim (Optional)
[Insert EPA Approved Brand Name(s)]	[EPA Reg. No.]	[SKU] [Package Volume]	[Product category] [Product Form]	[Insert Application and surface type]	Where a direct claim for the EP exists on the label, insert [Contact time] at [concentration]	Where an EP claim for the EP exists, insert [Contact time] at [concentration] (Follow [EP Pathogen] directions)	Where EPA has allowed special additional EP allowances, insert [Contact time] at [concentration] (Follow [Related Pathogen] directions)

Example of Completed Table Using Template 1 (Pathogen-specific EP List):

Product Name	EPA Reg. No.	SKUs	Product Category	Application and Surface Type	Approved for use with Direct Claim	Approved for use with the Emerging Pathogen Claim	Approved for use with C. difficile Claim
Product 313	1111-11	11111 (1 gallon)	Fungicide (RTU)	Spray on hard, non-porous surfaces[1]	5 minutes at RTU (Follow [insert strain name]directions)	10 minutes at RTU (Follow Sporicide directions)	7 minutes at RTU (Follow C. difficile directions)
Product 314	2222-22	22222 (1 gallon)	Fungicide (Concentrate)	Spray or soak on hard, non-porous surfaces[1]	5 minutes at 5 oz/gal (Follow [insert strain name]directions)	10 minutes at 5 oz/gal 5 minutes at 10 oz/gal (Follow Sporicide directions)	7 minutes at 5 oz/gal (Follow C. difficile directions)
Product 315	2222-22	22222 (1 gallon)	Fungicide (Concentrate)	Spray on soft, porous surfaces[2]	7 minutes at 5 oz/gal (Follow [insert strain name]directions)	7 minutes at 10 oz/gal (Follow Sporicide directions)	10 minutes at 5 oz/gal (Follow C. difficile directions)

[1] Refer to EPA Master Label for list of approved hard, non-porous surfaces.

[2] Refer to EPA Master Label for list of approved soft, porous surfaces.

Example Template #2 (Pathogen-specific EP List):

EP	Product Name	EPA Reg. No.	SKUs and/or Package Volume	Product Category	Application and Surface Type	Pathogen Supporting EP Claim	Use Instructions
[Insert EP]	[Insert EPA Approved Brand Name(s)]	[EPA Reg. No.]	[SKU][Package Volume]	[Product category]	[Insert Application and surface type]	[Insert bacterial sporeformer/Fungi/ *C. auris*, or virus names]	[Insert abbrev. Use Directions for the Pathogen supporting the EP Claim]

Example of Template #3 (Pathogen-specific EP List):

EP	Product Name	EPA Reg. No.	SKUs and/or Package Volume	Product Category	Application and Surface Type	Pathogen Supporting EP Claim	Use Instructions
[Insert EP]	[Insert EPA Approved Brand Name]	[EPA Reg. No.]	[SKU][Package Volume]	[Product category]	. [Insert Application and surface type]	[Insert bacterial sporeformer/ Fungi/ *C. auris*, or virus names]	[Insert abbrev. Use Directions for the Pathogen supporting the EP Claim]
				[Product category]	. [Insert Application and surface type]	[Insert bacterial sporeformer/Fungi/ *C. auris*, or virus names]	[Insert abbrev. Use Directions for the Pathogen supporting the EP Claim]

Example of Completed Table Using Template 2 (Pathogen-specific EVP List):

EP	Product Name	EPA Reg. No.	SKUs and/or Package Volume	Product Category	Application and Surface Type	Pathogen Supporting EP Claim	Use Instructions
Clostridioides difficile Strain R20291	Sporicide ABC	#####-##	24oz Trigger	Sporicide	Hard, Non-Porous Surfaces	Bacillus subtillus; Clostridium sporogenes	Apply to precleaned surfaces and hold treated for 10mins.
Aspergillus fumigatus			24oz Trigger	Sporicide	Hard, Non-Porous Porous, and Soft Surfaces	B. subtillus and C. sporogenes	Apply to surfaces and hold treated for 10mins.
Cryptococcus neoformans			24 oz Trigger	Disinfectant	Hard Non-Porous Surfaces	C. auris AR Bank #0385	Apply to surfaces and hold treated for 10mins.

APPENDIX 5: Guidance to Registrants: Process for Making Claims Against Emerging Bacterial Pathogens

GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING BACTERIAL PATHOGENS

DRAFT

In this document:

I. Background and Purpose

This policy builds upon and expands the emerging pathogen response outlined in the Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens (August 19, 2016) to create a similar process for addressing pathogenic bacteria.[1] Under the Environmental Protection Agency (EPA) Pesticide Program Dialogue Committee (PPDC), EPA assembled a robust and diverse work group of registrants, academicians, user groups, trade associations, the U.S. Centers for Disease Control and Prevention (CDC) and Agency staff to review the published literature[2-16], collect the experiences and recommendations to prepare this guidance and the underlying processes.[17-18] Subsequently, PPDC formed the Emerging Pathogen Implementation Committee (EPIC), to carry out those recommendations which include the preparation of this policy.

Emerging pathogens ("EP") are an increasing public health concern in the United States as well as globally. Some of these emerging pathogens may have the ability to persist on environmental surfaces (hard/soft, porous or non-porous) that can play a role in human disease transmission. Here we are proposing an emerging bacterial pathogen policy. Because the occurrence of emerging pathogenic bacteria is less common than established pathogens, few, if any, EPA-registered product labels specify use against this category of infectious agents. Also, depending on the testing scheme, these pathogens may be unavailable commercially and standard methods for laboratory testing may not have been developed and deposited with culture collection repositories. Thus, it may be difficult to assess the efficacy of EPA-registered products against such pathogens in a timely manner and to add these bacteria to existing product registrations, which requires the submission of efficacy data for Agency review to respond to a public health threat. As a result, the Agency is providing a voluntary, two-step process to enable use of certain EPA-registered products against emerging bacterial pathogens not identified on the product label. Registrants are encouraged to proactively register their products for Emerging Bacterial Pathogen claims to be ready for future outbreaks:

1) In the first stage, which may be performed prior to any outbreak, registrants with an eligible disinfectant may submit a request, via label amendment or during the registration of a new product, to control an emerging bacterial pathogen to proactively add a designated statement to the master label (See Attachment 1). If the product meets the eligibility criteria suggested in this Guidance, the Agency generally will approve the label language and, where available, add the product to an online list for users to search for products pre-registered for these claims. Approval of the language includes additional terms and conditions of registration regarding how the designated statement may be published and communicated (Attachment 1). This option allows for registered products to be prepared for future outbreaks. This action must be carried

out on the Basic Registration before a Supplemental Registration will be eligible to make claims. The Supplemental registrant must adhere to the same Terms (Attachment 1), EPA stamped label language found on the Basic Registration, and all aspects of this policy.

2) The second stage of this process occurs during a human or animal disease outbreak caused by an emerging type of pathogenic bacteria. In this stage, EPA identifies the emerging pathogen(s) eligible for this policy and notifies Registrants at the "*Emerging Pathogenic Bacteria Guidance and Status for Antimicrobial Pesticides*" webpage[1] that the preapproved communications may be initiated. Registrants of products with previously accepted emerging pathogen label language and terms of registration (Attachment 1) would be allowed to use the designated statement in off-label communications intended to inform the user community and general public that the registered product(s) may be used against the specific emerging pathogen. These off-label statements will inform the public about the utility of these products against the emerging pathogen in the most expeditious manner and can be more easily removed once the outbreak has ended than statements on a label. Also, a QR Code or other approved equivalent indicator on the label may direct the user to the approved language. If a particular product has not yet been approved for use of emerging pathogen language, the first step above may be initiated.

Many user facilities may have internal policies that prohibit off-label usage of disinfectants. In order to allow these facilities to use appropriately registered products against the specific emerging pathogen, the following statement may be included within internal policies, "The use of the EPA's GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING BACTERIAL PATHOGENS as applied to currently EPA registered disinfectants does not constitute off-label usage or a violation of FIFRA for users of these products. Users of germicides/disinfectant products should carefully follow all manufacturer's instructions for use and label instructions."

Note that this document provides general guidance to EPA, pesticide registrants, applicants for pesticide registrations, and the public. This guidance is not binding on EPA or any outside parties, and EPA may depart from the guidance where circumstances warrant and without prior notice.

II. Bacterial Classification and Other Microorganisms

EPA and the CDC recognize that certain microorganisms can be ranked with respect to their tolerance to chemical disinfectants. Whereas the Spaulding[19] Classification model focuses on medical devices, the Klein-DeForest[20-22] model, used by CDC and other public health agencies, tiers microorganisms in accordance with the level of tolerance to being killed (inactivated) by typical antimicrobial products.

Bacteria represent a vast group of prokaryotic organisms, that include a diverse range of sizes and shapes. Typically, bacteria are larger than viruses but smaller than eukaryotic cells, with an average length of 0.4 to 3.0 micrometers.[26] Peptidoglycan content in the cell wall structure can be used to categorize bacteria as gram-positive or gram-negative. Gram-structure combined with bacterial shape (cocci, bacilli, vibrio, spirochetes, etc.) and grouping patterns can be used to define bacterial morphology.[27]

Bacteria are ubiquitous in the environment and within most living organisms. While many bacteria are harmless or even beneficial for human health, others may be pathogenic, leading to illness and infection in humans or animals. As a result of the large scope of the bacterial domain, clinical presentations from bacterial infection are equally broad, ranging from minor skin irritation to severe systemic infection.

Testing for bacterial disinfection efficacy is outlined in United States Environmental Protection Agency "Product Performance Test Guidelines OCSPP 810.2200: Disinfectants for Use on Environmental Surfaces Guidance for Efficacy Testing".[24] Current requirements for testing are based on label claims outlined in the table below and

follow various standard methods. Within these testing requirements, EPA has a variety of test carrier types that are used to represent hard non-porous (glass slides, stainless steel penicylinders or disks), and hard porous (porcelain penicylinders) surfaces.

Based on the availability of testing on a variety of test carriers, the emerging pathogen claims may be expanded to this array of surfaces.

Registration Category	Strain	Test Method	Carrier Type
Hospital Disinfectant	*S. aureus* ATCC 6538 And *P. aeruginosa* ATCC 15442	AOAC Use Dilution Method	Stainless Steel Penicylinders
		AOAC Germicidal Spray Method	Glass Slides
General / Broad Spectrum Disinfectant	*S. aureus* ATCC 6538 And *P. aeruginosa* ATCC 15442 Or *S. enterica* ATCC	AOAC Use Dilution Method	Stainless Steel Penicylinders
		AOAC Germicidal Spray Method	Glass Slides
Limited Disinfectant	*S. aureus* ATCC 6538 or *P. aeruginosa* ATCC 15442 Or *S. enterica* ATCC	AOAC Use Dilution Method	Stainless Steel Penicylinders
		AOAC Germicidal Spray Method	Glass Slides

Under the criteria outlined in Section III of this Guidance, these prerequisites may be used to determine a product's anticipated efficacy against an emerging bacterial pathogen along with the additional registration categories described below.

III. Product Eligibility Criteria

Registrants should use the following criteria to determine if a new or existing EPA-registered product is eligible to use the process described in this Guidance. An eligible product should meet the following criteria:

1. The product is a new or existing EPA-registered product with claims on the label in at least one of the following Registration Categories (Table column 1) with directions for use on hard porous, hard non-porous, and/or soft porous surfaces per the applicable EPA guidance for registration[23,24]:

2. The above EPA registered product, as described, would be eligible for emerging bacterial claims as shown in Columns 2-4 of the Table below when tested using the appropriate test carrier for the surface type.

Registration Categories[23,24]	Supports Emerging Pathogen Claims[a] for:		
	Hard, Non-Porous Surfaces when tested on hard, non-porous carrier (stainless steel, glass slide)	**Hard, Porous Surfaces** when tested on hard, porous carrier (porcelain penicylinder)	**Soft Surfaces** when tested on soft carrier (suture loop)
Sterilant[23]	*Bacterial spp.*	*Bacterial spp.*	*Bacterial spp.*
Sporicidal[b,23]	*Bacterial spp.*	*Bacterial spp.*	*Bacterial spp.*
Clostridioides **(formerly *Clostridium) difficile)* Disinfectant**[23]	*Bacterial spp.*	None	None
Bacillus anthracis **Decontaminant**[23]	*Bacterial spp.*	*Bacterial spp.*	*Bacterial* spp.
Mycobactericide[c,24]	*Bacterial spp.*	*None*	None
A. niger / A. brasiliensis disinfectant[c, 24]	*Bacterial spp.*	None	None
T. interdigitales disinfectant[c, 24]	*Bacterial spp.*	None	None
Candida auris **Disinfectant**[24]	*Bacterial spp.*	None	None

[a] In many cases, data is not available that directly evaluates whether indicated research categories are predictive for a *bacterial sp*. As such, recommendations provided are based on the collective expert opinion of the PPDC Emerging Pathogen Implementation Committee whose input is based on published literature, and the research and testing experience of the assembled experts.

[b] The working group has also recommended that products with claims for the following bacterial sporeformers also be used to support emerging pathogenic bacteria: *B. thuringiensis Al Hakam, B. thuringiensis kurstaki* HD-1 cry-*, B. anthracis* Sterne*, or B. anthracis Δ*Sterne. The type of test carrier used will determine the appropriate surface for the claim. EPA does not currently have products with these spore claims. EPA may require a new PRIA protocol review to add such claims. Please contact EPA prior to initiation of testing.

[c] Claims supported by suspension testing described in 810.2200, will not be eligible to use this testing to support an emerging pathogen claim due to the Expert working group's concern of potentially reduced stringency associated with suspension methods and their lack of simulation of product use. These products may use other testing relying on dried test carriers as noted in the table to support an emerging pathogen claim. In a public health crisis, EPA may reconsider this stance on a case-by-case basis to address supply chain shortages.

EPA may also consider other existing claims or microbial strains to support use of a product during an outbreak to assure sufficient supply of appropriate registered products to meet the public health need.

IV. Instructions for Using the Process

The following are instructions for registrants (with a product eligible under Section III above) who wish to make claims against emerging bacterial pathogens. Emerging pathogens are defined by the National Institute of Allergy and Infectious Diseases as those "that have newly appeared in a population or have existed but are rapidly increasing in incidence or geographic range." The Stage 2 process of communication may only be actioned if the EPA, through the **Emerging Pathogenic Bacteria Guidance and Status for Antimicrobial Pesticides webpage**[1] has identified the emerging pathogen and initiated the policy. This will not occur until EPA, or another national or global public health authority has determined surface disinfection may help control its spread. The expiration date for use of the emerging bacterial pathogen communication will also be detailed on the EPA Emerging Bacterial Pathogen Guidance and Status for Antimicrobial Pesticides webpage[1].

Registrants may follow a two-stage process to identify effective disinfectant products for use against emerging pathogens. To permit registrants in compliance with FIFRA to make limited off label claims of their product's efficacy against such pathogens, a registrant may either; 1) make a product label amendment with modified terms of registration through a Food Quality Protection Act (FQPA) (fast-track, non-PRIA), or a Pesticide Registration Improvement Act (PRIA) label amendment, or 2) add emerging pathogen language as part of a PRIA registration filing for a new product registration. During either process, the registrant will explain why the product meets the criteria for use against one or more categories of emerging bacterial pathogens.

To ensure the efficient processing of the application the registrant should include the following:

- A detailed cover letter to EPA (See Example in Attachment 2) including:
  - A subject line that clearly indicates "Emerging Bacterial Pathogen Claim";
  - A request to make emerging bacterial pathogen claims;
  - A description of how the product meets the eligibility criteria for use consistent with the guidance;
  - An identification of the registration category from the product label being used to support the emerging bacterial pathogen claims and the study ID number (MRID) that supports the claim;
  - A request to be added to EPA List for emerging bacterial claims.
- A pesticide application for registration (Form 8570-1);
- An up-to-date data matrix (Form 8570-35);
- A signed Terms of Registration form (See Attachment 1); and
- A Master Label amended to include the emerging bacterial pathogen generic text (See Attachment 3). **Note**: The container label in market must include the strains used to support the emerging pathogen claim.

The application should be submitted via the EPA Central Data Exchange (CDX) portal.

V. Outbreak Criteria Associated with Emerging Pathogens Process

As stated above, the process described in this Guidance is for use with emerging pathogens associated with certain human or animal disease outbreaks in the US or found internationally with potential to impact the US. Thus, registrants whose registered master labels include the approved statements, either via label amendment or during the new registration process as described in Section IV above, may publish the approved statements only upon EPA announcement at the **Emerging Pathogenic Bacteria Guidance and Status for Antimicrobial Pesticides webpage1** For a disease outbreak, EPA will assure the following criteria:

1. The causative organism should be a bacterium that causes an infectious disease that has appeared in a human or animal population for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range ("emerging bacterial pathogen"). It includes both new and re-emerging bacterial pathogens listed by the CDC, World Organization for Animal Health (WOAH, formerly OIE), US Department of Agriculture (USDA), WHO (https://www.who.int/emergencies/disease-outbreak-news) or other equivalent global or national organizations.

   For example, this information may be found in one of the publications below:

   a. For human disease, the outbreak may be listed in one of the following CDC publications:
      i. CDC Current Outbreak List for "U.S. based outbreaks" (www.cdc.gov/outbreaks),
      ii. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process to federal, state, territorial, tribal, and local public health practitioners; clinicians; public health laboratories, and to those who subscribe to receive HAN-alerts.
      iii. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
   b. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the United States of America on the WOAH Weekly Disease Information page (https://wahis.woah.org/#/home) or international outbreaks that have the potential to impact the US.

2. The CDC, WOAH, or other equivalent global or national organization has identified the taxonomy, including the bacterium species, of the pathogen and provides notice to the public of the identity of the emerging pathogen that is responsible for an infectious disease outbreak. (For example, see WOAH technical disease cards (https://www.woah.org/en/what-we-do/animal-health-and-welfare/animal-diseases/). Based on the taxonomy of the outbreak pathogen, the bacterium species should be confirmed and compared to the hierarchy described in Section III necessary to support an emerging bacterium pathogen claim.
3. The bacterium can be transmitted via environmental surfaces (non-insect-vector transmission), and environmental surface disinfection/sanitization has been recommended by the CDC, WOAH, EPA or other equivalent global/national organization to control the spread of the pathogen. This may include hard and/or soft, porous and/or non-porous surfaces for non-residual and/or residual uses.

VI. References

[1] US Environmental Protection Agency. Emerging Viral Pathogen Guidance and Status for Antimicrobial Pesticides webpage. *https://www.epa.gov/pesticide-registration/emerging-viral-pathogen-guidance-and-status-antimicrobial-pesticides*.

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Attachment 1

Example Terms of Registration

Instructions: The following are the Terms of Registration required to support the inclusion of Emerging Bacterial Pathogen claims associated with an eligible EPA registration. These options may be used at the registrant's discretion. All options will rely on the EPA pre-approved language and be based on the EPA defined provisions as found in the **EPA Emerging Pathogenic Bacteria Guidance and Status for Antimicrobial Pesticides landing page**[1]. In all cases, Federal pre-approval of the eligibility for EP language would occur in the registration process. No State/Federal outreach is necessary when EP claims are pre-registered and the Emerging Bacterial Pathogens allowance is triggered on the EPA webpage[1] based on the EPA Emerging Bacterial Pathogen Guidance and Status for Antimicrobial Pesticides.

This template is included in the initial submission requesting the Emerging Pathogen claims or when the claims are changed or updated in subsequent filings. Where changes are being made to a label that is not related to the EP language, it is not necessary to resubmit the Terms document.

Template

Terms of Registration for EMERGING BACTERIAL PATHOGENS CLAIMS

This product qualifies for emerging bacterial pathogen claims as outlined in the GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING BACTERIAL PATHOGENS when used in accordance with the appropriate use directions. This product meets the criteria to make claims against certain emerging bacterial pathogens based on the structure outlined in the Table(s) below and aligned with Section III of the guidance:

For [Insert surface type (e.g., soft, porous surfaces); Repeat table as needed to cover all uses/surfaces and other EP microorganism claims]]:	
For an emerging bacterial pathogen that is a…	*…follow the directions for use for the following organisms on the label*
bacterium	Insert bacterial spore former(s)/M. bovis/ Fungi name(s)

The use of the Emerging bacterial Pathogen statements shall be based on the following Terms of Registration.

1. The Emerging Pathogen statements are allowed to appear as:
    a. Distributed Literature: Anywhere consumers/users/purchasers of the product may be located (e.g., technical literature distributed to health care facilities, physicians, nurses, and public health officials, "1-800" consumer information services, social media sites, company/distributor websites (non-label related, distributor catalogs, magazine ads, newspapers, etc.).

    b. QR Code or equivalent: On label or found in distributed literature. The QR Code may be activated when the Emerging Pathogen is added to the EPA website[1] triggering the Policy, and the Code would be deactivated when the EP allowance expires or sunsets.

    c. Hang Tag / Sticker(s): On product container.

2. Statements shall adhere to one the following formats. Minor adjustments may be made at the approval of the EPA:

[Product name] has demonstrated effectiveness against [sporeformers/ M. bovis/ Fungi names] similar to **[name of emerging bacterium]** on hard, **[porous and/or non-porous and/or soft surfaces]**. Therefore, **[product name]** can be used against **[name of emerging bacterium]** when used in accordance with the directions for use against **[name of supporting bacterial sporeformer**/ M. bovis/ Fungi names**]** on **[hard, porous/non-porous/soft surfaces]**. Refer to the **[CDC or OIE or EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[pathogen-specific website address]** for additional information.

[Name of illness/outbreak] is caused by **[name of emerging bacterium]. [Product name]** kills similar [sporeformer/ M. bovis/ Fungi names] and therefore can be used against **[name of emerging bacterium]** when used in accordance with the directions for use against **[name of supporting sporeformer/**M. bovis/ Fungi names) **]** on **[hard, porous/non-porous/soft surfaces].** Refer to the **[CDC or OIE or EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[website address]** for additional information.

[Product name] can be used against **[name of emerging bacterium]** when used in accordance with the directions for use against **[name of supporting sporeformer/**M. bovis/ Fungi names**]** on **[hard/soft, porous/non-porous surfaces]**.

See Attachment 4 in the EP Policy which shows several table-based methods of communication.

3. Provided the registration is approved for making Emerging Bacterial Pathogen claims, the registrant may begin communicating these statement(s) upon notification of the outbreak of an emerging bacterial pathogen on the **EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page.** The registrant shall cease and remove all such non-label communications intended for consumers upon expiration of the emerging bacterial pathogen emergency as defined on the **EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page.** The emerging pathogen claim language may remain on the master label.

4. The registrant agrees that paragraphs 1 through 3 above shall become immediately void and ineffective if registration for use against **the supporting claim (e.g., bacterial sporeformer, M. bovis, or Fungi)** is suspended or cancelled or no longer meets the criteria in EPA Performance Test 810 Guidelines[23,24]. In addition, evidence of ineffectiveness against any labeled pathogen in a less-resistant Spaulding category would also be grounds for voiding paragraphs 1 through 3.

[*Insert Registrant/Agent Signature*]

Insert Registrant/Agent Name & Title **Signature Date**

Attachment 2: Example Sample Cover Letter

Date:

Name (insert name of EPA contact)
Antimicrobials Division (7510P)
U.S. Environmental Protection Agency
Office of Pesticide Programs, Mail Code 7506C
1200 Pennsylvania Ave. NW
Washington, DC 20460

Subject: Emerging Bacterial Pathogen Claims

Dear Name:

Company Name (Company Name, Address, EPA Company Number), is submitting a terms of registration letter to add Emerging Bacterial Pathogen Claims to product EPA Registration Number XXXX-XXX.

Briefly, this (insert registration action type, e.g., FQPA, Fast Track Amendment, New Registration, etc.) is being submitted to include language to allow for claims to be made for emerging bacterial pathogens. The submission includes the Terms of Registration template found in GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING BACTERIAL PATHOGENS. As outlined in the Table(s) below, this product is eligible to make claims against emerging pathogens per the EPA Policy on the surfaces noted:

For [Insert surface type (e.g., soft, porous surfaces); Repeat table as needed to cover all surfaces and other EP microorganism claims]]:		
For an emerging bacterial pathogen that is a/an…	*…follow the directions for use for the following organisms on the label*	*MRID Numbers*
bacterium *spp.*	Insert bacterial sporeformer/*M. bovis*/ Fungi names	Insert number supporting strain cited in column 2

The Master Label includes the required text per EPA Guidance.

Sincerely,

Registrant

Attachment 3: Example Master Label Template

Instructions:

The following language must be inserted into the Master Label for review and approval by EPA prior to any Basic or Supplemental registrant making any emerging pathogen claims. The Table below may be replicated as needed for each surface type (e.g., hard/soft, porous and non-porous) or emerging pathogen type. In the Table, Registrants may list different bacterial spore formers/*M. bovis*/ Fungi names for the emerging bacterial claim as outlined in Section III. Different spores/*M. bovis*/ Fungi names may be listed in each row of the table and multiple strains may be listed in a single row.

TEMPLATE

EMERGING BACTERIAL CLAIMS

This product qualifies for emerging bacterial pathogen claims as outlined in the GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING BACTERIAL PATHOGENS when used in accordance with the appropriate use directions. This product meets the criteria to make claims against certain emerging bacterial pathogens based on the prerequisites listed in the Table(s) below:

For [Insert surface type (e.g., soft, porous surfaces); Repeat table as needed to cover all surfaces and other EP microorganism claim]]:	
For an emerging bacterial pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
bacterial *spp*.	Insert bacterial spore former/M. bovis/ Fungi names

[Product name] has demonstrated effectiveness against [sporeformers/ M. bovis/ Fungi names] similar to **[name of emerging bacterium]** on hard, **[porous and/or non-porous and/or soft surfaces]**. Therefore, **[product name]** can be used against **[name of emerging bacterium]** when used in accordance with the directions for use against **[name of supporting bacterial sporeformer/**M. bovis/ Fungi names**]** on **[hard, porous/non-porous/soft surfaces]**. Refer to the **[CDC or OIE or EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[pathogen-specific website address]** for additional information.

[Name of illness/outbreak] is caused by **[name of emerging bacterium]. [Product name]** kills similar [sporeformer/M. bovis/ Fungi names] and can be used against **[name of emerging bacterium]** when used in accordance with the directions for use against **[name of supporting bacterial sporeformer/**M. bovis/ Fungi names**]** on **[hard, porous/non-porous/soft surfaces].** Refer to the **[CDC or OIE or EPA Emerging Pathogen Guidance and Status for Antimicrobial Pesticides landing page]** website at **[website address]** for additional information.

[Product name] can be used against **[name of emerging bacterium]** when used in accordance with the directions for use against **[name of supporting bacteria sporeformer/**M. bovis/ Fungi names**]** on **[hard/soft, porous/non-porous surfaces]**.

See Attachment 4 of the EPA Policy which shows several table-based methods of communications.

Attachment 4: Alternate Example Table Formats for EP Communications

Instructions: The following tables provide possible format examples to illustrate how a registrant may configure the EPA stamped label EP claim(s) and registered directions for use of the EP cited strain into a table format to communicate with Registrants. The tables may include multiple approved EP uses (e.g., EVP hard surface disinfection, EVP soft surface disinfection, Emerging Sporeformers hard surface sporicide, Emerging bacterial hard surface disinfection) as well as multiple approved products.

Example Template #1 (Pathogen-specific EP List):

Product Name	**EPA Reg. No.**	**SKUs and/or Package Size**	**Product Use Category and Concentration/ Form**	**Application and Surface Type**	**Approved for use with Direct [Bacterial Pathogen] Claim**	**Approved for use with the Emerging Bacterial Pathogen Claim**	**Approved for use with [Related Pathogen] Claim (Optional)**
[Insert EPA Approved Brand Name(s)]	[EPA Reg. No.]	[SKU] [Package Volume]	[Product category] [Product Form]	[Insert Application and surface type]	Where a direct claim for the EP exists on the label, insert [Contact time] at [concentration]	Where an EP claim for the EP exists, insert [Contact time] at [concentration] (Follow [EP Pathogen] directions)	Where EPA has allowed special additional EP allowances, insert [Contact time] at [concentration] (Follow [Related Pathogen] directions)

Example of Completed Table Using Template 1 (Pathogen-specific EP List):

Product Name	**EPA Reg. No.**	**SKUs**	**Product Category**	**Application and Surface Type**	**Approved for use with Direct Claim**	**Approved for use with the Emerging Pathogen Claim**	**Approved for use with C. difficile Claim**
Product 313	1111-11	11111 (1 gallon)	Disinfectant (RTU)	Spray on hard, non-porous surfaces[1]	5 minutes at RTU (Follow disinfection directions)	10 minutes at RTU (Follow Sporicide directions)	7 minutes at RTU (Follow C. difficile directions)
Product 314	2222-22	22222 (1 gallon)	Disinfectant (Concentrate)	Spray or soak on hard, non-porous surfaces[1]	5 minutes at 5 oz/gal (Follow disinfection directions)	10 minutes at 5 oz/gal 5 minutes at 10 oz/gal (Follow Sporicide directions)	7 minutes at 5 oz/gal (Follow *C. difficile* directions)

Product 315	2222-22	22222 (1 gallon)	Disinfectant (Concentrate)	Spray on soft, porous surfaces[2]	7 minutes at 5 oz/gal (Follow disinfection directions)	7 minutes at 10 oz/gal (Follow Sporicide directions)	10 minutes at 5 oz/gal (Follow *C. difficile* directions)

[1] Refer to EPA Master Label for list of approved hard, non-porous surfaces.

[2] Refer to EPA Master Label for list of approved soft, porous surfaces.

Example Template #2 (Pathogen-specific EP List):

EP	Product Name	EPA Reg. No.	SKUs and/or Package Volume	Product Category	Application and Surface Type	Pathogen Supporting EP Claim	Use Instructions
[Insert EP]	[Insert EPA Approved Brand Name(s)]	[EPA Reg. No.]	[SKU][Package Volume]	[Product category]	[Insert Application and surface type]	[Insert bacterial sporeformer/ *M. bovis*, Fungi names]	[Insert abbrev. Use Directions for the Pathogen supporting the EP Claim]

Example of Template #3 (Pathogen-specific EP List):

EP	Product Name	EPA Reg. No.	SKUs and/or Package Volume	Product Category	Application and Surface Type	Pathogen Supporting EP Claim	Use Instructions
[Insert EP]	[Insert EPA Approved Brand Name]	[EPA Reg. No.]	[SKU][Package Volume]	[Product category]	. [Insert Application and surface type]	[Insert bacterial sporeformer/ *M. bovis*, Fungi names]	[Insert abbrev. Use Directions for the Pathogen supporting the EP Claim]
				[Product category]	. [Insert Application and surface type]	[Insert bacterial sporeformer/ *M. bovis*, Fungi names]	[Insert abbrev. Use Directions for the Pathogen supporting the EP Claim]

Example of Completed Table Using Template 2 (Pathogen-specific EVP List):

EP	Product Name	EPA Reg. No.	SKUs and/or Package Volume	Product Category	Application and Surface Type	Pathogen Supporting EP Claim	Use Instructions
Clostridioides difficile Strain R20291	Sporicide ABC	#####-##	24oz Trigger	Sporicide	Hard, Non-Porous Surfaces	*Bacillus subtillus*; *Clostridium sporogenes*	Apply to precleaned surfaces and

							hold treated for 10mins.
P. aeruginosa Strain X			24oz Trigger	Disinfectant	Hard, Non-Porous Surfaces	*Mycobacterium bovis*	Apply to surfaces and hold treated for 10mins.

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APPENDIX 6: General Efficacy Testing Recommendations for Emerging Pathogens Policies

GENERAL EFFICACY TESTING RECOMENDATIONS FOR EMERGING PATHOGENS POLICIES

Background and Purpose

Under the Environmental Protection Agency (EPA) Pesticide Program Dialogue Committee (PPDC), EPA assembled a diverse work group of registrants, academicians, user groups, trade associations, the U.S. Centers for Disease Control and Prevention (CDC) and Agency staff to build upon and expand the emerging pathogen policy outlined in the Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens (August 19, 2016). The workgroup known as Emerging Pathogen Implementation Committee (EPIC) Technical Committee (heretofore "Committee") also had recommendations related to efficacy testing methods, test strains, guidance, etc. The following is a list of recommendations or considerations for EPA and PPDC to consider as they review and modernize efficacy guidance and methods.

Summary of "Case-by-Case" Recommendations for EPA Internal Use Where Supply Chain Issues Arise

The draft emerging pathogen policies for each microbe convey the Committee recommendation consensus for the efficacy prerequisite claims that should support proactive registration of emerging pathogen claims. However, the Committee made tentative recommendations for internal EPA use on a case-by-case basis in a public health crisis where the supply chain was not sufficient to meet the public health need to respond to an emerging pathogen. Each recommendation is stated below under the specific microbe type and Figures 1-5 summarize those stances.

Recommendations by Microbe

<u>Bacterial Sporeformers:</u>

- *Emerging Sporeformer Draft Policy*: In this policy, the Committee recommended against the broad use of the *C. difficile* spore disinfection claim (810.2100) on hard, non-porous surfaces as a prerequisite for all bacterial sporeformers due to the ease of inactivation of the spores for this species as compared to the range of potential sporeformers that could be encountered. However, the group did recommend that EPA could on a case-by-case basis consider utilization of this claim for hard, non-porous surface application as a prerequisite for emerging pathogen claims for sporeformers per the proposed policy based on the emerging species, relative spore resistance to disinfection, and potential supply chain issues in a public health crisis.

- *Emerging Sporeformer Draft Policy*: For this policy, the Committee recommended against reliance on sporicidal claims that are based upon suspension test methods (e.g., D-value testing, ASTM E1891) as compared to the methods which utilize a test carrier with dried test organism (e.g., AOAC 966.04 Sporicidal Activity of Disinfectants, ASTM E2197, ASTM E3218) in order to better simulate product use and due to the higher stringency found with test carrier based methods. However, the group did recommend

that EPA could on a case-by-case basis reconsider utilization of this claim for hard, non-porous surface application as a prerequisite for emerging pathogen claims where supply chain issues arise during in a public health crisis.

- *Porous Test Carriers*: The Committee recommends that EPA fund a technical assessment of various soft, porous materials to establish a stronger justification for selecting a specific type(s) of soft, porous material for antimicrobial testing than the current silk/polyester suture loop. Natural and synthetic materials, and materials that range in water-absorbing capabilities from high water absorption to low water absorption should be selected for consideration. Cotton, silk, nylon, and polyester are common examples. Additionally, the Committee recommends work be undertaken to develop a variety of hard porous carriers that are good simulants of the range of hard, porous surfaces that may be present in the typical residential, I&I, and healthcare use sites to replace or use in addition to the porcelain penicylinder currently used in testing. All carriers should be inert, commercially available, sterilizable, and readily immersible in the product.

Mycobacteria:

- *Test Strain*: The Work Group recommends EPA research a replacement strain for *M. bovis* (ATCC 35743) that is easier to work with in the lab and has shorter growth/incubation time while preserving the disinfection stringency of the current test (e.g., *M. terrae*). EPA may consider selecting a resistant strain though the practicality of maintaining resistance and a consistent challenge over time should be confirmed.

- *Claim Category Name*: The Work group recommends renaming the "Tuberculocidal" category and claim to "Mycobactericidal" in all EPA guidance (e.g., 810.2000, 810.2200) to recognize the public health importance of entire genus. The genus *Mycobacterium* contains well-known human pathogens such as *M. tuberculosis* (tubercle bacillus) and *M. leprae* *(*https://www.cdc.gov/leprosy/index.html#:~:text=Hansen's%20disease%20(also%20known%20as,the%20disease%20can%20be%20cured) as well as nearly 190 other species variously termed as nontuberculous mycobacteria (NTM), environmental mycobacteria (EM), atypical mycobacteria or mycobacteria other than tuberculosis' (MOTT). While *M. tuberculosis* and *M. leprae* are not known to grow in the environment and can spread primarily by air and via close person-to-person contact, NTM in general are opportunistic pathogens and are being incriminated in an increasing variety of human infections. They have a waxy coating and can readily form biofilms, thus making them more refractory to disinfection. This will require an accompanying user education component to support such a change. Considering the continuing increase in the number of NTM and their emerging importance as environment-based human pathogens, it is suggested that the term "tuberculocides" be replaced with "mycobactericide" to better reflect the current state of science.

- *Emerging Mycobacteria Draft Policy*: For this policy, the Committee recommended against reliance on "sporicidal" claims that are based upon suspension test methods (e.g., D-value testing, ASTM E1891) as compared to the methods which utilize a test carrier with dried test organism (e.g., AOAC 966.04 Sporicidal Activity of Disinfectants, ASTM E2197, ASTM E3218) to support emerging Mycobacterial claims in order to better simulate product use and due to the higher stringency found with test carrier based methods. However, the group did recommend that EPA could on a case-by-case basis reconsider utilization of this claim for hard, non-porous surface application as a prerequisite for emerging pathogen claims where supply chain issues arise during in a public health crisis.

- *Emerging Mycobacteria Draft Policy*: For this policy, the Committee recommended against reliance on "mycobactericidal or tuberculocidal" claims that are based upon suspension test methods (e.g., EPA BEAD SOP M16 Quantitative Suspension Test (Ascenzi Method)) as compared to the methods which utilize a test carrier with dried test organism (e.g., AOAC 965.12 Tuberculocidal Activity of Disinfectants, AOAC 961.02 Germicidal Spray Test) to support emerging Mycobacterial claims in order to better simulate product use and due to the higher stringency found with test carrier based methods. However, the group did recommend that EPA could on a case-by-case basis reconsider utilization of this claim for hard, non-porous surface application as a prerequisite for emerging mycobacterial claims where supply chain issues arise during in a public health crisis.

- *Mycobactericidal Suspension Test Methods*: EPA currently allows tuberculocidal claims for glutaraldehyde-based disinfectants only (810.2200) based upon suspension test methods (e.g., EPA BEAD SOP M16 Quantitative Suspension Test (Ascenzi Method)). The Committee request EPA revisit the use of suspension methods to support these claims as the stringency of this testing may not be on par with the stringency found in the carrier-based methods and the methods do not simulate use.

- <u>Filamentous Fungi and Yeast</u>

  - *Emerging Fungal/Yeast Draft Policy*: For this policy, the Committee recommended against reliance on "sporicidal" claims that are based upon suspension test methods (e.g., D-value testing, ASTM E1891) as compared to the methods which utilize a test carrier with dried test organism (e.g., AOAC 966.04 Sporicidal Activity of Disinfectants, ASTM E2197, ASTM E3218) to support emerging fungal claims in order to better simulate product use and due to the higher stringency found with carrier-based methods. However, the group did recommend that EPA could on a case-by-case basis reconsider utilization of this claim for hard, non-porous surface application as a prerequisite for emerging pathogen claims where supply chain issues arise during in a public health crisis.

- *Emerging Fungal/Yeast Draft Policy*: For this policy, the Committee recommended against reliance on "mycobactericidal or tuberculocidal" claims that are based upon suspension test methods (e.g., EPA BEAD SOP M16 Quantitative Suspension Test (Ascenzi Method)) as compared to the methods which utilize a test carrier with dried test organism (e.g., AOAC 965.12 Tuberculocidal Activity of Disinfectants, AOAC 961.02 Germicidal Spray Test) to support emerging Fungal/Yeast claims in order to better simulate product use and due to the higher stringency found with carrier-based methods. However, the group did recommend that EPA could on a case-by-case basis reconsider utilization of this claim for hard, non-porous surface application as a prerequisite for emerging mycobacterial claims where supply chain issues arise during in a public health crisis.

- *Emerging Fungal/Yeast Draft Policy*: For this policy, the Committee recommended against reliance on any mycobactericidal or tuberculocidal claims to support emerging Fungal/Yeast claims without additional research into the comparative stringency of the M. bovis testing currently supporting claims and various filamentous fungal spores. However, the group did recommend that EPA could on a case-by-case basis reconsider utilization of mycobactericidal or tuberculocidal claims supported by carrier-based test methods (e.g., AOAC 965.12 Tuberculocidal Activity of Disinfectants, AOAC 961.02 Germicidal Spray Test) for hard, non-porous surface application as a prerequisite for emerging filamentous fungi claims where supply chain issues arise during in a public health crisis.

- *Emerging Fungal/Yeast Draft Policy*: For this policy, the Committee recommended against reliance on "fungicidal" claims that are based upon suspension test methods (e.g., AOAC 955.17 Fungicidal Activity of Disinfectants) as compared to the methods which utilize a test carrier with dried test organism (e.g., AOAC Use-Dilution Method modified for fungi, AOAC 961.02 Germicidal Spray Test) to support emerging fungal/yeast claims in order to better simulate product use and due to the higher stringency found with carrier-based methods.

- *Emerging Fungal/Yeast Draft Policy*: For this policy, the Committee recommended against reliance on any "fungicidal" or "virucidal" claims to support emerging fungal/yeast claims without further research on the differences in inactivation between the required test strains and the variety of species in these groups.

- *Emerging Fungal/Yeast Draft Policy*: For this policy, the Committee recommended against reliance on *C. auris* claims to support emerging filamentous fungal claims without additional research into the comparative stringency of *C. auris* testing currently supporting claims and various filamentous fungal spores. However, the Committee recommended use of *C. auris* claims to support emerging yeast strains. However, the group recommended against use of any other yeast strains (e.g., *C. albicans*) being used to support filamentous fungi or yeast emerging pathogen strains due to the relative ease with which many of these strains are killed.

- *Mildewstat and Fungicidal Testing*: The Committee called for cautious review of the test methodology used to support existing fungal claims. Registrants and regulatory reviewers should carefully review the fungicidal studies to assure that emerging pathogen claims are granted based upon carrier-based testing in fungicidal test methods. Registrants and regulatory reviewers should assure that emerging pathogen claims are not granted under the Policy on testing using suspension methods (e.g., AOAC 955.17 Fungicidal Activity of Disinfectants) or on hard surface or fabric mildew stat testing (e.g., EPA Product Performance Guidelines – Subdivision G, Section 93-15 and 93-30).

- *Mildewcidal Test Strain*: The Committee recommends additional testing/research on the comparative stringency of the required *Aspergillus* strains used to support mildewcidal claims with various filamentous fungi strains to confirm this requirement (e.g., EPA Product Performance Guidelines – Subdivision G, Section 93-15 and 93-30).

- *Fungicidal Test Methods*: The Committee recommends that EPA update the current test methods and guidance to require additional quality control observations on spore crops including spore size, percentage of live spores, and degree of clumping as these may impact the outcome and variability of fungicidal testing.

- <u>Bacteria</u>

  - *Emerging Bacteria Draft Policy*: For this policy, the Committee recommended against reliance on "sporicidal" claims that are based upon suspension test methods (e.g., D-value testing, ASTM E1891) as compared to the methods which utilize a test carrier with dried test organism (e.g., AOAC 966.04 Sporicidal Activity of Disinfectants, ASTM E2197, ASTM E3218) to support emerging bacterial claims in order to better simulate product use and due to the higher stringency found with carrier-based methods. However, the group did recommend that EPA could on a case-by-case basis reconsider utilization of this claim for hard, non-porous surface application as a prerequisite for emerging pathogen claims where supply chain issues arise during in a public health crisis.

  - *Emerging Bacteria Draft Policy*: For this policy, the Committee recommended against reliance on "mycobactericidal or tuberculocidal" claims that are based upon suspension test methods (e.g., EPA BEAD SOP M16 Quantitative Suspension Test (Ascenzi Method)) as compared to the methods which utilize a test carrier with dried test organism (e.g., AOAC 965.12 Tuberculocidal Activity of Disinfectants, AOAC 961.02 Germicidal Spray Test) to support emerging Bacterial claims in order to better simulate product use and due to the higher stringency found with carrier-based methods. However, the group did recommend that EPA could on a case-by-case basis reconsider utilization of this claim for hard, non-porous surface application as a prerequisite for emerging mycobacterial claims where supply chain issues arise during in a public health crisis.

- *Emerging Bacteria Draft Policy*: For this policy, the Committee recommended against reliance on "fungicidal" claims that are based upon suspension test methods (e.g., AOAC 955.17 Fungicidal Activity of Disinfectants) as compared to the methods which utilize a test carrier with dried test organism (e.g., AOAC Use-Dilution Method modified for fungi, AOAC 961.02 Germicidal Spray Test) to support emerging bacterial claims in order to better simulate product use and due to the higher stringency found with carrier-based methods.

- *Emerging Bacteria Draft Policy*: For this policy, the Committee recommended using *C. auris* claims to support emerging bacterial claims. However, the Committee recommended against use of any other yeast strains (e.g., *C. albicans*) being used to support bacterial emerging pathogen strains due to the relative ease with which many of these strains are killed.

- *Emerging Bacteria Draft Policy*: For this policy, the Committee recommended against reliance on "virucidal" claims to support emerging bacterial claims without further research on the relative inactivation rates between viral types and the range of potential emerging bacterial species. However, the Committee did recommend that EPA could on a case-by-case basis reconsider utilization of viral claims on non-enveloped viruses for hard, non-porous surface application as a prerequisite for emerging bacterial claims where supply chain issues arise during in a public health crisis.

FIGURE 1: Emerging Viral (Enveloped & Non-Enveloped) Pathogens: Summary of Policy Recommendations for Registration of Emerging Pathogen claims, and Identification of Potential Case-by-Case Prerequisites for EPA Internal Use Where Supply Chain Issues Arise

Registration Categories	Supports Emerging Enveloped and Non-Enveloped Viral Pathogen Claims
	Hard, Non-Porous Surfaces when tested on hard, non-porous carrier (stainless steel)
Sterilant	YES
Sporicidal	YES
Clostridioides **(formerly** ***Clostridium)*** ***difficile*** **Disinfectant**	YES
Tuberculocide	Not Considered
Fungicidal/*C. auris* Disinfectant	Not Considered
Small Non-Enveloped Virucidal Disinfectant	YES [a]
Large Non-Enveloped Virucidal Disinfectant	YES for Enveloped Virus only
Enveloped Virucidal Disinfectant	Not Recommended at this Time
Bacterial Disinfectant	Not Recommended at this Time

[a] See the EPA policy for required criteria to support small non-enveloped viruses (e.g., at least two small, non-enveloped viruses with each from a different viral family).

FIGURE 2: Emerging Bacterial Sporeforming Pathogens: Summary of Policy Recommendations for Registration of Emerging Pathogen claims, and Identification of Potential Case-by-Case Prerequisites for EPA Internal Use Where Supply Chain Issues Arise

Registration Categories	Supports Emerging Bacterial Sporeforming Pathogens (Bacillus and Clostridia/Clostridioides spp.) Claims		
	Hard, Non-Porous Surfaces when tested on hard, non-porous carrier (stainless steel)	**Hard, Porous Surfaces** when tested on hard, porous carrier (porcelain penicylinder)	**Soft Surfaces** when tested on soft carrier (suture loop)
Prions	YES for Clostridia/Clostridioides spp.	No registrations available	No registrations available
Sterilant	YES for Clostridia/Clostridioides spp.(EPA may consider reliance on suspension test methods on a case-by-case basis)	YES for Clostridia/Clostridioides spp.	YES for Clostridia/Clostridioides spp.
Sporicidal	YES for Clostridia/Clostridioides spp. (EPA may consider reliance on suspension test methods on a case-by-case basis)	YES for Clostridia/Clostridioides spp.	YES for Clostridia/Clostridioides spp.
***Clostridioides* (formerly *Clostridium*) *difficile* Disinfectant**	Not Recommended at this Time (EPA may consider on a case-by-case basis)	Not Recommended at this Time (EPA may consider on a case-by-case basis)	Not Recommended at this Time (EPA may consider on a case-by-case basis)
***B. anthracis* Decontaminant**	YES	YES	YES
B. thuringiensis Al Hakam, B. thuringiensis kurstaki HD-1 cry-, B. anthracis Sterne, or B. anthracis ΔSterne	YES	YES	YES

Other Microbes	Not Recommended at this Time	Not Recommended at this Time	Not Recommended at this Time

FIGURE 3: Emerging Mycobacterial Pathogens: Summary of Policy Recommendations for Registration of Emerging Pathogen claims, and Identification of Potential Case-by-Case Prerequisites for EPA Internal Use Where Supply Chain Issues Arise

Registration Categories	**Supports Emerging Mycobacterial Pathogen Claims[a]**		
	Hard, Non-Porous Surfaces when tested on hard, non-porous carrier (stainless steel, glass slide)	**Hard, Porous Surfaces** when tested on hard, porous carrier (porcelain penicylinder)	**Soft Surfaces** when tested on soft carrier (suture loop)
Sterilant	*YES* (EPA may consider reliance on suspension test methods on a case-by-case basis)	*YES*	*YES*
Sporicidal[b]	*YES* (EPA may consider reliance on suspension test methods on a case-by-case basis)	*YES*	*YES*
***Clostridioides* (formerly *Clostridium*) *difficile* Disinfectant**	*YES*	Not Recommended at this Time	Not Recommended at this Time
***Bacillus anthracis* Decontaminant**	*YES*	*YES*	*YES*
Tuberculocide[c]	*YES* (EPA may consider reliance on suspension test methods on a case-by-case basis)	*YES*	Not Recommended at this Time
***Candida auris* Disinfectant[d]**	*YES*	Not Recommended at this Time	Not Recommended at this Time
Fungicidal Disinfectant	Not Recommended at this Time	Not Recommended at this Time	Not Recommended at this Time
Small Non-Enveloped Virucidal Disinfectant (Two viruses from List Below)[e]	*YES*	Not Recommended at this Time	Not Recommended at this Time
Bacterial Disinfectant	Not Recommended at this Time	Not Recommended at this Time	Not Recommended at this Time

[a] In many cases, data is not available that directly evaluates whether indicated research categories are predictive for *Mycobacterium sp*. As such, recommendations provided are based on the collective expert opinion of the PPDC

Emerging Pathogen Implementation Committee whose input is based on published literature, and the research and testing experience of the assembled experts.

[b] The working group has also recommended that products with claims for the following bacterial sporeformers also be used to support emerging pathogenic mycobacteria: *B. thuringiensis Al Hakam, B. thuringiensis kurstaki* HD-1 cry-*, B. anthracis* Sterne*, or B. anthracis Δ*Sterne[8]. The type of test carrier used will determine the appropriate surface for the claim. EPA does not currently have products with these spore claims. EPA may require a new PRIA protocol review to add such claims. Please contact EPA prior to initiation of testing.

[c] Tuberculocidal claims supported by suspension testing described in 810.2200, Section I(1) will not be eligible to use this testing to support an emerging pathogen claim due to the Expert working group's concern of potentially reduced stringency associated with suspension methods and their lack of simulation of product use. These products may use other testing relying on dried test carriers as noted in the table to support an emerging pathogen claim. In a public health crisis, EPA may reconsider this stance on a case-by-case basis to address supply chain shortages.

[d] This recommendation is not proposed based organism structural hierarchy but based on CDC and EPA testing experience with registered tuberculocides demonstrating the stringency of the *M. bovis* test strain.[20-22]

[e] The registration must include at least two of the following viral stains, each from a different family, to make emerging mycobacterial pathogen claims: Parvovirus (canine, porcine, etc.), Hepatitis A virus, Feline Calicivirus, Murine Norovirus, Rhinovirus, and Poliovirus. The option to utilize Polioviruses to support emerging mycobacterial claims is not intended to encourage new testing but rather to utilize existing claims based on previously submitted and accepted data. We are aware and support efforts to contain polioviruses in the U.S. (U.S. National Authority for Containment of Poliovirus CDC (https://www.cdc.gov/orr/polioviruscontainment/index.htm).

FIGURE 4: Emerging Filamentous Fungi/Yeast Pathogens: Summary of Policy Recommendations for Registration of Emerging Pathogen claims, and Identification of Potential Case-by-Case Prerequisites for EPA Internal Use Where Supply Chain Issues Arise

Registration Categories	Supports Emerging Fungal/Yeast Pathogen Claims[a]		
	Hard, Non-Porous Surfaces when tested on hard, non-porous carrier (stainless steel, glass slide)	**Hard, Porous Surfaces** when tested on hard, porous carrier (porcelain penicylinder)	**Soft Surfaces** when tested on soft carrier (suture loop)
Sterilant	*YES* (EPA may consider reliance on suspension test methods on a case-by-case basis)	*YES*	*YES*
Sporicidal[b]	*YES* (EPA may consider reliance on suspension test methods on a case-by-case basis)	*YES*	*YES*
***Clostridioides difficile* Disinfectant**	*YES*	Not Recommended at this Time	Not Recommended at this Time
***Bacillus anthracis* Decontaminant**	*YES*	*YES*	*YES*
B. thuringiensis, etc.[b]	*YES*	*YES*	*YES*
Mycobacterial Disinfectant	Not Recommended at this Time (EPA may consider reliance on hard surface or suspension test methods on a case-by-case basis)	Not Recommended at this Time	Not Recommended at this Time
Fungicidal Disinfectant (T. interdigitale)[c]	*Yes for Trichophyton spp.* (Testing conducted by AOAC 955.17 suspension method is not eligible.)[c]	Not Recommended at this Time	Not Recommended at this Time
Mildewcidal Disinfectant (A. niger or A. brasiliensis[7]	*Yes for Trichophyton and Aspergillus spp.* (Testing conducted by AOAC 955.17 suspension method is not eligible.)[c]	Not Recommended at this Time	Not Recommended at this Time
***Candida auris* Disinfectant**	*Yes for Yeast* (Filamentous Fungi: EPA may consider reliance on hard surface test methods on a case-by-case basis)	Not Recommended at this Time	Not Recommended at this Time
Small Non-Enveloped Virucidal Disinfectant (Two viruses from List Below)[d]	*Yes for Filamentous Fungi*	Not Recommended at this Time	Not Recommended at this Time
Bacterial Disinfection	Not Recommended at this Time	Not Recommended at this Time	Not Recommended at this Time

[a] In many cases, data is not available that directly evaluates whether indicated research categories are predictive of activity against fungi. As such, recommendations provided are based on the collective expert opinion of the PPDC

Emerging Pathogen Implementation Committee whose input is based on published literature, and the research and testing experience of the assembled experts.

[b] The working group recommended that products with claims for the following bacterial sporeformers also be used to support emerging pathogenic fungi: *B. thuringiensis Al Hakam, B. thuringiensis kurstaki* HD-1 cry-*, B. anthracis* Sterne*, or B. anthracis Δ*Sterne[25]. The type of test carrier used will determine the appropriate surface for the claim. EPA does not currently have products with these spore claims. EPA may require a new PRIA protocol review to add such claims. Please contact EPA prior to initiation of testing.

[c] Fungal claims supported by AOAC 955.17 suspension testing described in 810.2200, Section H(1)[24] will not be eligible to support an emerging pathogen claim due to the Expert working group's concern of potentially reduced stringency associated with suspension methods and their lack of simulation of product use. These products may use other testing relying on dried test carriers as noted in the table to support an emerging pathogen claim. In a public health crisis, EPA may reconsider this stance on a case-by-case basis to address supply chain issues.

[d] The registration must include at least two of the following viral strains, each from a different family, to make emerging fungal pathogen claims: Parvovirus (canine, porcine, etc.), Hepatitis A virus, Feline Calicivirus, Murine Norovirus, Rhinovirus, and Poliovirus. The option to utilize Polioviruses to support emerging fungal claims is not intended to encourage new testing but rather to utilize existing claims based on previously submitted and accepted data. We are aware and support efforts to contain polioviruses in the U.S. (U.S. National Authority for Containment of Poliovirus CDC (https://www.cdc.gov/orr/polioviruscontainment/index.htm).

FIGURE 5: Emerging Bacterial Pathogens: Summary of Policy Recommendations for Registration of Emerging Pathogen claims, and Identification of Potential Case-by-Case Prerequisites for EPA Internal Use Where Supply Chain Issues Arise

Registration Categories[23,24]	**Supports Emerging Bacterial Pathogen Claims**[a]		
	Hard, Non-Porous Surfaces when tested on hard, non-porous carrier (stainless steel, glass slide)	**Hard, Porous Surfaces** when tested on hard, porous carrier (porcelain penicylinder)	**Soft Surfaces** when tested on soft carrier (suture loop)
Sterilant	*YES* (EPA may consider reliance on suspension test methods on a case-by-case basis)	*YES*	*YES*
Sporicidal[b]	*YES* (EPA may consider reliance on suspension test methods on a case-by-case basis)	*YES*	*YES*
***Clostridioides* (formerly *Clostridium) difficile)* Disinfectant**	*YES*	Not Recommended at this Time	Not Recommended at this Time
***Bacillus anthracis* Decontaminant**	*YES*	*YES*	*YES*
Mycobactericide[c]	*YES* (EPA may consider reliance on suspension test methods on a case-by-case basis)	Not Recommended at this Time	Not Recommended at this Time
A. niger / A. brasiliensis disinfectant[c]	*YES* (Testing conducted by AOAC 955.17 suspension method is not eligible.)[c]	Not Recommended at this Time	Not Recommended at this Time
T. interdigitales disinfectant[c]	*YES* (Testing conducted by AOAC 955.17 suspension method is not eligible.)[c]	Not Recommended at this Time	Not Recommended at this Time
***Candida auris* Disinfectant**	*YES*	Not Recommended at this Time	Not Recommended at this Time
Virucidal Disinfectant	Not Recommended at this Time (EPA may consider on a case-by-case basis)	Not Recommended at this Time	Not Recommended at this Time
Bacterial Disinfectant	Not Recommended at this Time	Not Recommended at this Time	Not Recommended at this Time

[a] In many cases, data is not available that directly evaluates whether indicated research categories are predictive for a *bacterial sp*. As such, recommendations provided are based on the collective expert opinion of the PPDC

Emerging Pathogen Implementation Committee whose input is based on published literature, and the research and testing experience of the assembled experts.

[b] The working group has also recommended that products with claims for the following bacterial sporeformers also be used to support emerging pathogenic bacteria: *B. thuringiensis Al Hakam, B. thuringiensis kurstaki* HD-1 cry-*, B. anthracis* Sterne*, or B. anthracis Δ*Sterne. The type of test carrier used will determine the appropriate surface for the claim. EPA does not currently have products with these spore claims. EPA may require a new PRIA protocol review to add such claims. Please contact EPA prior to initiation of testing.

[c] Claims supported by suspension testing described in 810.2200, will not be eligible to use this testing to support an emerging pathogen claim due to the Expert working group's concern of potentially reduced stringency associated with suspension methods and their lack of simulation of product use. These products may use other testing relying on dried test carriers as noted in the table to support an emerging pathogen claim. In a public health crisis, EPA may reconsider this stance on a case-by-case basis to address supply chain shortages.