Pesticide Program Dialogue Committee (PPDC)

Emerging Pathogen Workgroup (EPWG)

DRAFT Report

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Objectives of the EPWG

- Assess EPA's COVID-19 response and stakeholder experiences with the Emerging Viral Pathogens (EVP) Guidance for Antimicrobial Pesticides
- Assess some end-user's experiences with antimicrobial disinfection products registered by the EPA for infection control
- Provide recommendations to EPA for policy improvements and identify educational gaps

Based on the EPWG's objectives, the following charge questions were addressed by the group and several recommendations are provided to the U.S. Environmental Protection Agency (EPA) under this report. The EPWG recognizes that implementation of these recommendations will require time and significant resources. There are recommendations, however, that can be implemented immediately, and the EPWG urges the EPA to do so. The organizations and companies represented by members of the EPWG stand ready to assist the Agency, and we urge the EPA to next form a work group that is focused on assisting the Agency with implementation.

Charge Questions

(1) What are the strengths and weaknesses of the first use of the Emerging Viral Pathogens (EVP) Policy during the COVID-Pandemic?
(2) What flexibilities are needed (not provided) by guidance, regulations, etc., to address issues faced in a pandemic or other emergency?
(3) What education is needed during a pandemic or other emergency for the public, end users, and other regulating authorities?
(4) How can EPA's enforcement program be strengthened to expeditiously respond to fraudulent/misbranded products in the marketplace during a pandemic or other emergency? What flexibilities are needed (not provided) by guidance, regulations, etc., to address issues faced in a pandemic?

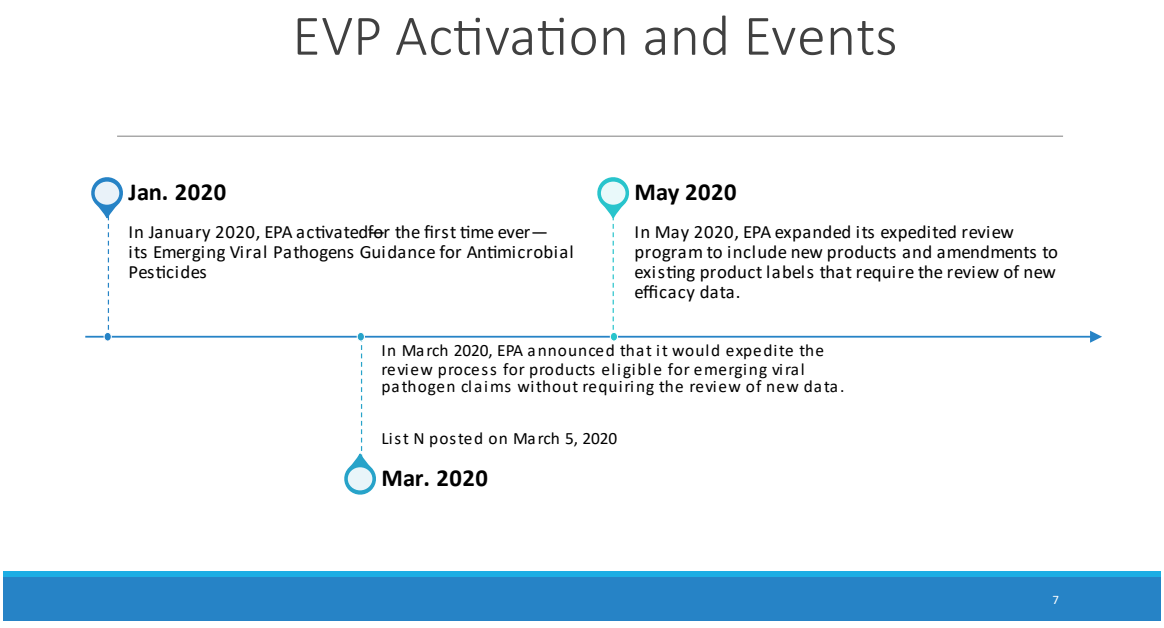
Definition of an Emergency

The Working Group believes that the EPA should be better prepared for future pandemics as well as the occurrence of other "emergencies". The recommendations provided in this report cite to "emergency" situations. The EPA, however, does not define what constitutes an "emergency" outside of providing guidance for emerging viral pathogens (EVP). However, workgroup members have had experience with "emergency" situations in the past that requires EPA to provide temporary accommodations. Drawing on these experiences, the Working Group has considered several definitions that would define an "emergency" by quantitative and/or qualitative terms and ultimately recommends that EPA adopt a definition that is broad and allows for the Agency's discretion when appropriate. The definition should encompass situations like the following, which is a list of examples but is not intended to be exhaustive:

1. Chemical shortage of 1,2-Benzisothiazol-3(2H)-one (BIT) s in 2018 because of plant closures in China.
2. Supply chain interruptions of ethylene oxide and propylene oxide as a result of weather events in the U.S. Gulf Coast in February 2021.
3. Ransomware attacks/data breaches that impact the supply chain.
4. A determination or notice by the U.S. Department of Agriculture of a virus or other condition that is having a significant effect upon animal health in the U.S.
5. A determination by the Centers of Disease Control that there is a virus or other condition that is a threat to human health in the U.S.
6. An event such as the blockage of the Suez Canal, which impacted the global supply chain.

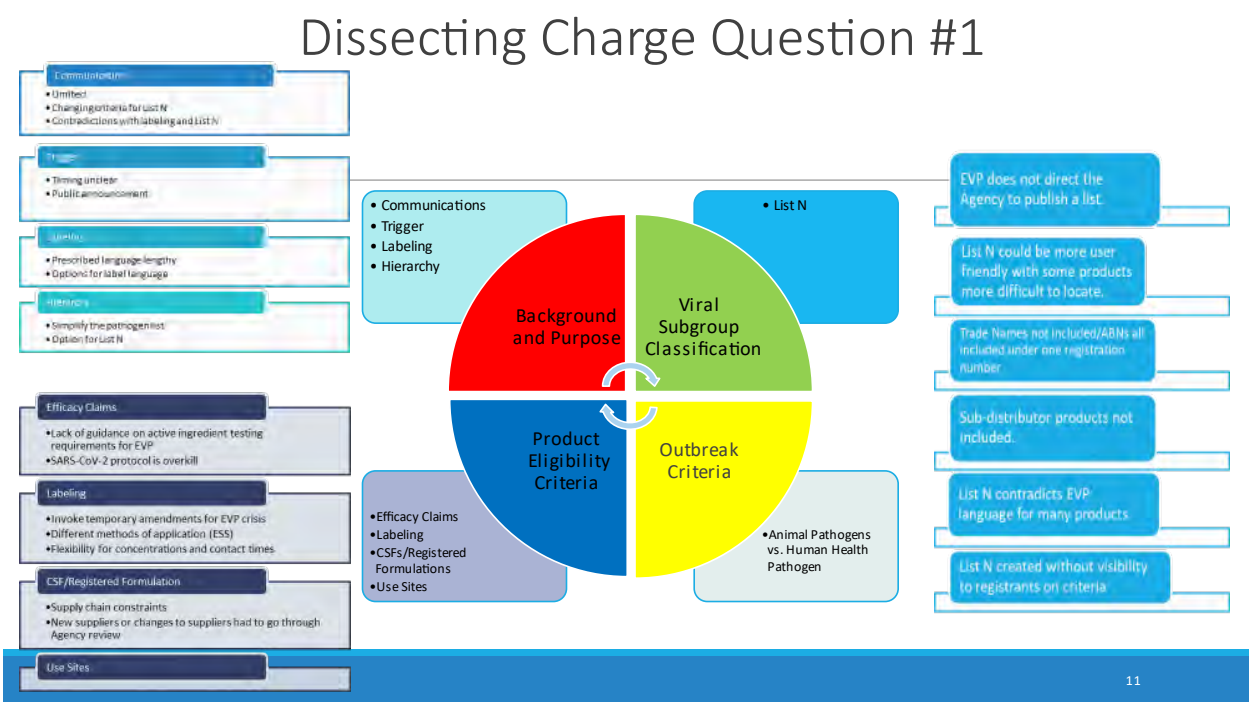
Background

- **In 2016 EPA finalized guidance for making claims against emerging viral pathogens that are not on EPA registered disinfectant labels:**
  - **https://www.epa.gov/pesticide-registration/guidance-registrants-process-making-claims-against-emerging-viral-pathogens**
  - **Followed a 30-day public comment period and included a response to comments**



- **On March 5, 2020,EPA posted List N: Disinfectants for Use Against SARS-CoV-2**
- **Significant improvements to the list have been made including:**
  - **the ability to search and sort a dynamic list**
  - **additional information helpful to end users (e.g., active ingredient, formulation type, use sites)**
- **Analytics**
  - **Number of Products on List N:**
  - **Products with EVP claims:**

Charge Question 1:
What are the strengths and weaknesses of the first use of the Emerging Viral Pathogens (EVP) Policy during the COVID-Pandemic?



Issue 1: The EVP is too ambiguous

- Greater clarity is needed for when the EVP has been triggered and how long it remains in force.
- There is No clear mechanism for registrants to identify products that could be used in response.
- Unclear whether EPA verification is needed prior to a registrant communicating under the EVP.
- Too much ambiguity in terms of the interpretation and execution of the three requirements in the EVP (See Section V of the EVP, *Outbreak Criteria Associated with Emerging Pathogens Process*).

Recommendations:

- Revise the EVP to reduce ambiguity to reduce interpretations of the 3 requirements, including explicit instruction for moving forward with marketing campaign.

- Revise the EVP to instruct the EPA to issue an explicit statement to the registrant community that there is a pandemic/emergency, and they can initiate EVP communications. Also, to instruct when the EVP communications must be halted or may be extended.
- Establish and maintain a webpage on EPA's website that addresses pandemics (updated as the pandemic progresses and needs to be transparent; keep a level playing field by communicating early and often).
    - Provide clear guidance on testing microorganisms of concern when said microorganism becomes available
    - Status table of each pandemic/emergency including what may be non-U.S. soil
    - Trigger dates
    - What lists to use
    - Cross reference FAQs and other authorities
    - Memo/situation reports to discuss economic or geo/political "emergencies" that impact supply chain
- Alternatively, allow EVP claims to exist on commercial labels and initiate proactive education to end users on its utility to avoid misunderstanding and misuse.

Issue 2: Communication pursuant to the EVP Policy was limited/ineffective

- EVP Communication Policy is too inflexible and creates challenges for registrants in conveying how to use a product via product labels.
- EPA had no standard procedure for communicating what antimicrobial pesticides would be responsive to the pandemic.
- EVP is written in such a way that an animal pathogen must be on US soil before it can be triggered. This is contrary to the needs of the livestock, meat, and poultry industries where prevention is key as well as healthcare preparedness.
- List N has limitations --
    - The changing criterion for effectiveness made maintaining a list (i.e., List N) extremely difficult.
    - List N has great limitation because brand names were not used and thus the average consumer had difficulty relying on it.
    - There were multiple steps needed for an end user to cross check if a product was suitable for use.
    - The primary audience for EPA's List N was unclear: many end users did not know there was a List N, and even if they did, they would not know how to use the information it contained.
    - Information was not exhaustive for products on the List N, although the EPA attempted to share useful information, some products have multiple forms, dilutions, and application types. These aspects could not possibly have been captured or communicated by EPA with intimate knowledge of the products and their distribution and use. This may have led to misuse scenarios.
    - Existing, non-List N lists need an overhaul and unfortunately are not reliable sources of information for end users.

- End user communities desire simplified and point of use communication on products suitable for use. This was not available until SARS-CoV-2 claims were approved.

Recommendations:

- Refine procedures for establishing, expanding, and pruning lists.
- Integrate this process into registration so that the lists are maintained in real time.
- Revise lists so that there are not Lists A-N but rather a consolidation of lists that are meaningful for end users e.g., Healthcare Community, Public Spaces (e.g., Education, Offices, Transport), Food Service, Food Processing. Consider consolidating EVP virus lists into an enveloped virus list, large non-enveloped list, and an enveloped list. Alternatively, push farther and agree all enveloped viruses are just as easy or easier to inactivate as the required bacteria; therefore, in an emergency any "disinfectant" could be used to respond to an outbreak of an enveloped viral pathogen, then old non-enveloped viruses need special considerations.
    - Determine the primary audience of any given list, balancing the need for accessibility and usability with the reality
- Revise the EVP to streamline definition or what meets the criterion.
- Revise the EVP to allow flexibility in the language framework on how registrants can describe product use and recommendations in labeling.
- Allow proactive education of EVP utility to customer/end user groups. This allows hospitals, long term care, education departments and other businesses to proactively choose products bearing EVP claims. This can be an important part of emergency planning for these entities.
- Recommend optional on-label/point of sale indicator of product performance or suitability during an outbreak of an emerging pathogen. For many this will negate the need for a list and simplify critical decisions during the outbreak.
- In order to make commercial label communication possible prior to an outbreak, registrants could choose a representative organism from one viral class and its directions for use to simplify use instructions for the end user. E.g., if the registrant has Norovirus claim, its use instructions may cover multiple viral classes. The EVP use directions can simply mirror Norovirus e.g., 3 min contact time.
- Allow an option for hang tag/sticker/logo communication during an outbreak if registrant chooses to wait for an outbreak to communicate EVP details.
- While commercial label text will drastically improve communication during an outbreak, our workgroup has concluded that a clearly identifiable logo/icon would have the most value and utility during an outbreak.
- Establish an icon that can be placed on products at the time of registration that identifies what tier of viral pathogen it will respond to; icon can also include other information such as dwell time.
- The icon can be a part of a broad interagency campaign supported by the media to communicate that end users should feel comfortable purchasing products with the icon/hangtag/sticker. This concept was seen by the EPWG as game changing for simplifying communication and preventing confusion for end users. Agencies, stakeholder groups, trade associations and registrants were

inundated with queries on product selection. Streamlining this process could save a lot of resources across the industry.

- Recommend formation of additional WG consisting of a subset of individuals from the EPWG (and maybe others) to further develop the icons through to finalization.

Charge Question 2:
What flexibilities are needed (not provided) by guidance, regulations, etc., to address issues faced in a pandemic or other emergency?

Documents Cited for Increased Flexibility:

- Emerging Viral Pathogens Guidance for Antimicrobial Pesticides
- PRN: 98-10 and Revised Temporary Amendment PRN: 98-10
- EPA Data Requirements for Registration of Antimicrobial Pesticides: Part 158w
- Pesticide Emergency Exemption (Section 18)
- Label Review Manual
- Pesticide Registration Manual
- Series 810 Product Performance Test Guideline
- Electrostatic Spray Application Directions for Use to Antimicrobial Product Registrations

Issue 1: The EVP requires additional flexibilities to address issues faced in a pandemic or other emergency.

Recommendations:

- The labeling requirements for wording and placement require greater flexibility; thus, the EVP should be amended to provide "guard rails" but should allow the registrants greater flexibility in language and placement.
- Currently, the EVP focuses on approved means of application of the pesticides, but during a pandemic the focus may be on how to allow for expanded use and new methods of delivery for already registered product, e.g., electrostatic sprayers. The scope of the EVP should be expanded to address this gap. Implementation should be based on an improved and more nimble approval process, which could include standing 98-10 guidance (subject to a trigger) that allows for self-certification or while under EPA review, "submit and go". The revised 98-10 guidance should identify data that will need be produced and which is producible by the registrant. There also should be strong enforcement consequences for foul play. For example: Tiger teams, PRIA codes and timelines.
- Currently, the EVP does not address ancillary consequences (e.g., economics, supply chain) and how these issues can hamper public health solutions. The EVP should be amended to add a statement or a note to the first paragraph or a footnote that acknowledges the complexity beyond only health related consequences (e.g., supply chain interruptions).
- The EVP should be updated to address how variants will be handled.
- To capture the experiences of the COVID-19 pandemic, EPA should develop and publish a supplement to the EVP that memorializes the issues faced and their resolution.
- EPA should provide more flexibility for claims that do not fit into current claims/product tiers (e.g., virus kill claims on a of range sanitizing products held to the same viral testing methods and efficacy standards as disinfectants). This will allow the replacement of aggressive disinfectant formulations with efficacious sanitizer products. These products would be eligible for EVP claims and use during a pandemic.
- EPA should continue to consider the development of a set of hierarchies for non-viral pathogens including bacteria, yeast, and mold to be used in emergencies. EPA could consider bacterial efficacy

as a surrogate for enveloped viral efficacy, and bacterial spore formers as a surrogate for all viral types (e.g., *C. difficile*).

- During a pandemic, products are being used more frequently and used in novel ways resulting in unintended consequences. EPA should develop a simple process for the public/end user reporting of adverse product reactions/incidents and misuses in specific applications related to List N products or novel products/applications.
- Recommend that if EPA establishes a webpage to address pandemics, links to the applicable sections of the Label Review Manual and/or Registration Manual should be included. In addition, cross references to these Manual sections should be incorporated into any FAQs that are published related to pandemics.
- Challenges in product selection experienced during the pandemic included those associated with the lack of diversity of products for certain use sites and segments. The reliance on disinfectants (products often formulated to achieve kill of much hardier organisms, even spores) meant that unnecessary human exposure, material compatibility, financial pressures, PPE requirements and raw materials demands (during severe shortages) were experienced by many sectors. The added layers of complexity on safety and compatibility restrictions for industries like airlines and ground transportation meant that the choice of products became extremely limited. Of the hundreds of products available on List N, once material compatibility and application needs were considered, only a handful were deemed suitable for these particular applications. We are aware of many incidents of premature degradation of assets (e.g., critical electronic components, seats, etc. on buses and planes) and safety systems (seat belts). Examples of end user difficulty are described below.
    - In one example from the education sector, decisions had to be made about how to balance repeated disinfection of buses with the safety of the occupants (mainly young children) and the need to control transmission. Could a less potent antimicrobial have made this task easier?
    - The food manufacturing and service industries, educated and experienced in use of sanitizers, had to establish new protocols and safety measures for bringing disinfectants into their facilities. Considerations for removal of disinfectant residue from surfaces to prevent adulteration of food were not always understood by the workforce in these industries.
- In order to address material compatibility EPA should lean on experts, registrants, and segment specific stakeholders on gathering fundamental information on material compatibility of categories of products. This could be a useful tool as end users make product selections. It is critical to use the minimum amount of chemical that provides adequate efficacy to the necessary use site.

Issue 2: Modifications to some guidance documents during the COVID-19 pandemic were only temporary, while other requisite documents remained unchanged or were adapted for use during the pandemic situation.

Temporarily Modified Document Recommendations

PRN 98-10, Non-Notifications and Minor Formulation Amendments

- Based on the experience of the COVID pandemic, several amendments should become permanent and further amendment is recommended to address issues faced in a pandemic or other

emergency. Alternatively, in the event the EVP is triggered or there is another "emergency", certain pre-determined provisions should be automatically enacted. (EVP and 98-10 should be cross-referenced).

- Recommend that the 98-10 is revised to discuss what happens if these are emergencies (general)/disasters vs a pandemic.
- Recommend that a revised 98-10 define "emergency" including possible differences between a microbial disease related emergency vs a general emergency.
- Recommend that a revised 98-10 incorporate self-certification as part of the program during an emergency to address possible supply chain strains.
- All or any inerts and active ingredients should be in scope.
- Provide a mechanism for expedited handling of routine CSF amendments that are needed to address acute ingredient shortages. This could greatly reduce "crisis situations."
- Complete the update and issuance of a revised PRN 98-10, following additional opportunity for public comment, including stakeholder briefings/webinars, specifically addressing issues raised by ingredient shortages.
- Expand the scope of CSF changes that can be made by notification and non-notification, on a temporary basis, specifically to address acute ingredient shortages. The revised change mechanism might be triggered by defined "emergency" declarations or acknowledgements.
- Expand the scope of CSF changes that can be made by notification and non-notification, on a permanent basis, specifically to address acute ingredient shortages.
- To make certain that such mechanisms are properly used, periodic random audits of such notifications and non-notifications could be conducted, subject to the range of FIFRA enforcement mechanisms.

Suggested Document Modifications Recommendations

Section 18, Pesticide Emergency Exemptions

- Section 18s should be reserved for situations where the EVP and similar mechanisms do not apply. The traditional model of Section 18 can be useful for a localized threat, not for a pandemic (e.g., Anthrax letter bioterrorism or localized infection that can be geographically contained). Allowance of Section 18s in one or two states for a situation that has the potential to spread throughout the country is not appropriate. The following are some recommendations:
    - In a pandemic, Section 18s should only be given on a federal level sponsored by any relevant Agency (e.g., HHS/CDC, FDA, or USDA) for use nationwide.
    - Other Federal agencies charged with oversight of human or animal health should be educated on the process and utility of Section 18s. A designated individual in each agency should be identified for this purpose.
    - Labeling and marketing requirements should be simplified by allowing or encouraging federal Section 18s. If a federal-level Section 18 is granted, a communications campaign should be launched so that all state and user groups are aware the Section 18 deployment.

- Efficacy Guidance: The EPWG recommends that EPA provide more guidance on the efficacy requirements and transparency around the efficacy required to support a Section 18 (e.g., study design, replication, wear, soiling, criteria, controls). Once a Section 18 has been granted for a specific use type (e.g., air sanitization, residual treatment), we recommend that EPA publish or update the outline of the needed data set to allow the regulated community to understand the study design and performance requirements and to reduce the burden on OPP staff of communicating this information and being approached with incomplete submissions, or ineffective products.

Office of Pesticide Programs (OPP), Label Review Manual, *which should be discussed and confirmed with state partners*

- Chapter 3: General Labeling Requirements
  - Chapter 3.II. Types of Labels and Labeling
    - E. Supplemental Labeling
      - EVP language could be added to a product via Supplemental Labeling. The supplemental EVP language may or may not be incorporated into the master label, depending on the nature of the outbreak.
    - F. Distributor Label
      - It is important for the end-user community that EVP language approved on a primary registration is passed along to all applicable distributor labels. Reference to EVP should be added to this section to ensure that this happens in a timely manner. Adoption of an "outbreak-ready" icon/logo/statement would greatly simplify this process.
    - I. Web-distributed labeling
      - As an alternative to on-container labeling, EVP language could potentially be addressed via web-distributed labeling. This option could benefit end users by allowing them to access streamlined labeling tailored for use during a particular outbreak.
    - J. Websites
      - Current language in this section states that "claims made on the website may not substantially differ from approved claims related to that product." If EVP language is allowed via Web, this would need to be clarified.
  - Chapter 3.IV.B. Other label contents
    - Another category addressing EVP language could be added to this section to cover products eligible for this claim.
- Chapter 12. Labeling claims
  - Language clarifying EVP claims could be added to Section VII. Efficacy-related claims. Should it be allowed to talk about EVP approval without having EVP be activated (i.e., can you suggest to customers the product is "Outbreak-Ready" so they can buy, for example, a "tier 1 EVP approved" product (vs. something without any approvals) in order to be prepared)?

- Chapter 16.II. Acceptable graphics and symbols
    - If the recommended EVP "Outbreak-Ready" logo is created, language regarding its use should be added to this chapter in Section II. Acceptable graphics and symbols.
- Chapter 18. Unique product labeling
    - A section detailing requirements for EVP labeling language could be added to this chapter.
- New separate chapter
    - In place of, or in addition to, adding language to the sections as outlined above, a new separate chapter covering EVP labeling issues could be added to the manual. This chapter could include:
        - Requirements for prescribed information – logo/icon, approved language, placement on labels
        - Use of logos/language on subset labels
        - How EVP logos/language are to be added to existing labels (e.g., via amendment, notification, other process)

Registration Manual

- Chapter 4 – Additional Considerations for Antimicrobial Products
    - Information regarding EVP requirements should be added here so registrants can proactively plan rather than react to an emergency situation. One suggestion is that the Efficacy Branch (EB) inform applicants in a cover letter from the agency that they qualify for EVP and push them to automatically add the language to avoid future work.

Series 810: Product Performance Test Guidelines

- 810.2000:
    - GLP Compliance: Similar to the temporary allowance for Non-GLP testing for characterization and efficacy during the pandemic for testing SARS-CoV-2, ESS, and Residual testing, this should be allowed by EPA in future pandemics.
- 810.2200:
    - SARS-CoV-2 Product Testing Guidance: EPA quickly introduced a novel SARS-CoV-2 Disinfectant testing "plan" (e.g., 3 lots, E1053, LCL lots, non-GLP allowance) for the pandemic strain. The information was distributed via email to labs and registrants. For future pandemics, we recommend this information be publicly posted on the EPA website for wide access to the regulated community and to reduce the communication burden on OPP staff in a format like the Interim Guidance. This "plan" should include a standard "off ramp" for transparency (e.g., EPA will provide a 90-day public written notice for the cancelation of the policy. EPA will review all studies under the existing plan where the protocol was signed prior to the 90-day deadline).
    - EPA expanded the test lot replication to 3 lots of LCL batches from the 810.2200 Guideline requirements, but the registrant community does not believe this added replication and LCL level was necessary for an enveloped virus. Standard disinfectant products are tested on viruses with greater mortality and transmission rates than SARS-CoV-2 currently without the added replication or LCL requirement. It is recommended that the current policy be

changed to return to the 810.2200 standard virucidal testing requirements, and future emerging pathogens be tested in accordance with the existing 810 Guidelines.

- 810 for Novel Products
    - Important to set some common standard or level of efficacy that should be achieved for novel technologies against the microbe of concern or a suitable surrogate. This will increase the level of trust and transparency of the products that will likely have a lot less testing and history associated with them than fully registered products. As to further validate the claims of applicant under 810 exemption, review of international data/G8 country approvals supplied by manufacturers to EPA as to performance of said product from all aspects including efficacy, safety, long term exposure, trials etc. shall be submitted for review.

Electrostatic Sprayer (ESS) Interim Guidance

- The Interim Guidance for Electrostatic Sprayer (ESS) testing was highly valued. The testing aligned with the current 810 guidelines but allowed for confirmatory testing level of replication. It is recommended that this guidance become a permanent part of the 810 Guidelines and that testing requirements be extended to other uses (e.g., food contact sanitizers, non-food contact sanitizers) and other strains (e.g., fungi, spores).

Residual Interim Guidance

- It is recommended that the Interim Residual Guidance become a permanent part of the 810 Guidelines and the testing be extended to other uses (e.g., food contact sanitizers, non-food contact sanitizers) and other strains (e.g., fungi, spores).

Areas to Extend Guidance Beyond Current Scope (these suggestions are not exclusive to a pandemic):

- Residual/ESS Guidance extend to other organisms (fungi, TB, spores) and uses (e.g., FCS, NFCSAN) as noted above.
- Virucidal performance is necessary in many use patterns that EPA does not currently allow (e.g., Food sanitization, home, and school sanitization). All areas of the 810 Guidelines should be reconsidered for expanding to add viral claims. In some cases, EPA has granted viral claims to various uses, but the 810 Guidelines do not yet reflect those changes (e.g., Virucidal Laundry Pre-Soak, Virucidal Laundry Disinfection, Virucidal Soft Surface Disinfection). The Guidelines should be brought up to date. For other areas, it is recommended that EPA allow the use of viral claims for food contact sanitization and non-food contact sanitization of hard surfaces. It is further recommended that the current testing requirements, replication, ASTM method, study design, and performance criteria be relied upon to add hard surface claims to these categories.
- For emerging “enveloped” viral pathogens, we recommend the Agency recognize the role of viral structure in the hierarchy of inactivation which has been published widely and is used by CDC and WHO to respond to crises. Enveloped viruses are among the easiest to kill pathogens and viruses. They are routinely significantly easier to kill than the bacterial strains required for disinfection claims. The EPA’s current experience with the addition of SARS-CoV-2 claims to 180 products at the same use directions as the disinfection claim supports this relationship. While the hierarchy is known to have exceptions, they are extremely rare with enveloped viruses. It is recommended that EPA explore with CDC a policy of communicating with users that emerging “enveloped” viruses can be disinfected using any EPA registered broad spectrum or hospital

disinfectant. This could lead to a more rapid, simplified communication to users as well as a ready supply of available products.

- For pandemic and other emergency situations which cause extensive backlog in testing laboratories, it is recommended that EPA expand allowance for submission and acceptance of Non-GLP efficacy and other studies. To gain additional confidence in non-GLP studies, EPA might require the submission of the raw data as evidence of study quality and substantiation.

Issue 3: EPA did not have other guidance prepared prior to the pandemic to address certain predictable issues.

Recommendations:

- EPA should prepare a suite of guidance prepared that can be triggered at the same time as the EVP on a temporary basis during a pandemic or emergency (e.g., guidance on expedited reviews).

Issue 4: EPA's Antimicrobial Division faced great resource strains during the pandemic

Recommendations:

- EPA Crisis Management Office (dovetail with preparedness) or the office best suited to respond to the pandemic or emergency must have authority to create tiger teams and demand coordination across the Agency.

Charge Question 3:
What education is needed during a pandemic or other emergency for the public, end users, and other regulating authorities?

Issue 1: 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.

Information Gathering Recommendations:

- Conduct surveys at each phase of the pandemic or emergency to determine how to communicate and what could have been done better
    - Collaborate with trade associations or other user groups to determine if surveys have been conducted by them
    - Reach out to other critical groups or stakeholders
    - A standardized survey could be created for all use sites and for each phase (pre, during, and post)
    - Consider permanent survey sites (e.g., survey monkey) to collect ongoing responses
- Communicate survey results to appropriate stakeholders

Communications Recommendations:

General messaging across all sectors

- Provide all documents in English and Spanish, at a minimum
- Identify the audience and develop documents that best speak to that specific audience
- Establish a clear dissemination process for documents (mainstream media channels, press, consumer unions for education/reports)
- Continue to educate through every phase
- Collaborate with other regulatory bodies and associations because of their sector expertise and inherent expertise to develop materials, respectively
- 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.
- Leverage trade organizations and other groups to better understand the challenges and best practices in a collaborative space

Pre-Pandemic

- Provide information on effective products
- Provide information on when and how to use products based on sector

- Correct any misinformation

During the Pandemic

- Provide information on effective products for the pathogen at issue if known
- Provide information on when and how to use products based on sector for the pathogen at issue
- Identify examples of frequent/high touch areas of concern/how they evolve
- Adjust product recommendations based on transmission routes /better clarification of products for use
- Consider consumer products that can be used at homes/effectively disinfectant the spectrum of fomites, etc.
- Reassure that products are suitable for use when used as directed
- Correct any misinformation

Post Pandemic

- If enhanced or elevated disinfection practices are being used during pandemic, communicate to sectors when they can go back to normal
- Correct any misinformation

Specialized Messaging for Identified Sectors

- Aircrafts/facilities
    - EPA should leverage trade organizations and other groups to better understand the challenges and best practices in a collaborative space.
    - Pre-Pandemic
        - Test and qualify as many products as possible through the airline testing/qualification program
        - Leverage other testing/certification programs
        - Identify if there is an international entity list of approved disinfectants for international use
    - During Pandemic
        - Identify products that may be incompatible with aircraft surfaces
- Cruise industry
    - EPA should leverage trade organizations and other groups to better understand the challenges and best practices in a collaborative space.
    - Pre-Pandemic/During Pandemic
        - Identify if there is an international list of approved disinfectants for international use
    - Post Pandemic

        - 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
        - Research what this industry has done to improve air system ventilation/filtration
        - Identify the targeted high touch areas in this industry
        - Identify what lessons can be learned from this industry
- Federal/State/local government
    - Pre-Pandemic
        - Share insights on EPA policies and practices related to pandemic/emergency responses to prevent divergence
        - Assess regulations and identify where there are conflicting and synergistic messaging related to the use of disinfectants
        - 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
        - Ensure extra communication for parties driving the messaging for the emergency event
        - 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
        - Communicate directly with the public (e.g., webinars)
    - Post Pandemic
        - 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
    - 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-Pandemic/During Pandemic/Post Pandemic
        - 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
    - 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-Pandemic/During Pandemic/Post Pandemic
    - Establish emergency procedures and product types (disinfectants) compatible with Food Code to avoid confusion and misinformation, misuse of products, etc. with collaboration with FDA

- Hotels/Hospitality
    - 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-Pandemic/During Pandemic
        - 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'.
    - During Pandemic
        - Educate on what this sector should be wary of could be useful

- Package delivery services
    - Leverage trade organizations and other groups to better understand the challenges and best practices in a collaborative space
    - Pre-Pandemic/During Pandemic
        - Identify consumer products that can be used at home
        - Identify effective disinfectants for use on package deliveries

- Schools/Education Institutions
    - Leverage teacher unions and other groups to better understand the challenges and best practices in a collaborative space
    - Use Social Media Outlets to reach certain age groups

Other possible areas for EPA to consider include commercial spaces, medical facilities, public spaces, and industry workplaces.

Charge Question 4:
How can EPA's enforcement program be strengthened to expeditiously respond to fraudulent/misbranded products in the marketplace during a pandemic or other emergency? What flexibilities are needed (not provided) by guidance, regulations, etc., to address issues faced in a pandemic?

Issue: Mechanisms to correct fraudulent/misbranded products during the pandemic were both resource intensive and significantly delayed, thereby allowing violators to operate unmonitored in the marketplace**.**

Recommendations

- Develop a mechanism to enlist resources/people to feed timely information to EPA
    - Develop and identify a trigger during a pandemic/emergency that allows EPA to secure additional resources to monitor and investigate violators and carry out enforcement reporting
    - Develop internal EPA group to address complaints and assist the Agency during pandemics and emergencies
    - Identify key trusted advisors and possibly deputize surveillance monitors
    - Identify whether the Federal Trade Commission (FTC) can be engaged to assist with monitoring violative products in the marketplace
- Develop a detailed communication plan for reporting violators
- EPA whistleblower process needs to more thoroughly developed
- EPA should develop a penalty scheme with greater penalties during a pandemic or other emergency