

# PPDC Mid-Year Meeting: Emerging Pathogens Workgroup (EPWG)

CO-CHAIRS: TAJAH BLACKBURN AND KOMAL JAIN

MAY 13, 2021

Membership/Organizations/Affiliations

Objectives of Emerging Pathogen Workgroup (EPWG)

Charge Questions/Outcomes

Next Steps: Goals for 2<sup>nd</sup> Phase

Questions

# Agenda

Emerging Pathogens Workgroup (EPWG) Members	Organization (Affiliation)	
Matthew Arduino	Centers for Disease Control and Prevention	Federal
Ellen Baldassare	LANXESS Corporation	Registrant (Animal Health)
Steve Bennett	Household & Commercial Products Association	Trade Association
Elaine Black	Ecolab	Registrant and Disinfectant Formulator
Diane Boesenberg	Exponent	Technical Consultant
Milady Brutofsky	Lonza, LLC	Registrant
Emily Burke	American Chemistry Council, Center for Biocide Chemistries	Trade Association
Alexander Cook	First Group USA	User (Ground Transportation)
Patti Costello	American Hospital Association	User (Healthcare)
Lisa Dreilinger	Reckitt Benckiser	Registrant
Seth Goldberg	Steptoe & Johnson LLP	Regulatory and Legal Consultant
Joseph Grzywacz	Florida State University	Academia and User
Rhonda Jones	Scientific & Regulatory Consultants, Inc.	Regulatory and Technical Consultant
Pat Quinn	The Accord Group	Regulatory and Technical Consultant
Jamie Quon	The Clorox Company	Registrant and Disinfectant Formulator
Virginia Rauh	Children's Health Protection Advisory Committee	User (children's health)
Nathan Sell	American Cleaning Institute	Trade Association
Marylou Verder-Carlos	Exponent	Regulatory and Technical Consultant
Cheryl Woodward	Thor Specialties, Inc.	Registrant
Nancy Young	Airlines for America	User (Air Transportation)
Komal Jain (Co-Chair)	American Chemistry Council, Center for Biocide Chemistries	Trade Association
Tajah Blackburn (Co-Chair)	US Environmental Protection Agency	Federal Regulatory

# Objectives of the EPWG

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

# Charge Question #1

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**What are the strengths and weaknesses of EPA's first use of the Emerging Viral Pathogens (EVP) policy during the COVID-19 pandemic?**

# Dissecting Charge Question #1

**Communication**

- Limited
- Changing criteria for List N
- Contradictions with labeling and List N

**Trigger**

- Timing unclear
- Public announcement

**Labeling**

- Prescribed language lengthy
- Options for label language

**Hierarchy**

- Simplify the pathogen list
- Option for List N

**Efficacy Claims**

- Lack of guidance on active ingredient testing requirements for EVP
- SARS-CoV-2 protocol is overkill

**Labeling**

- Invoke temporary amendments for EVP crisis
- Different methods of application (ESS)
- Flexibility for concentrations and contact times

**CSF/Registered Formulation**

- Supply chain constraints
- New suppliers or changes to suppliers had to go through Agency review

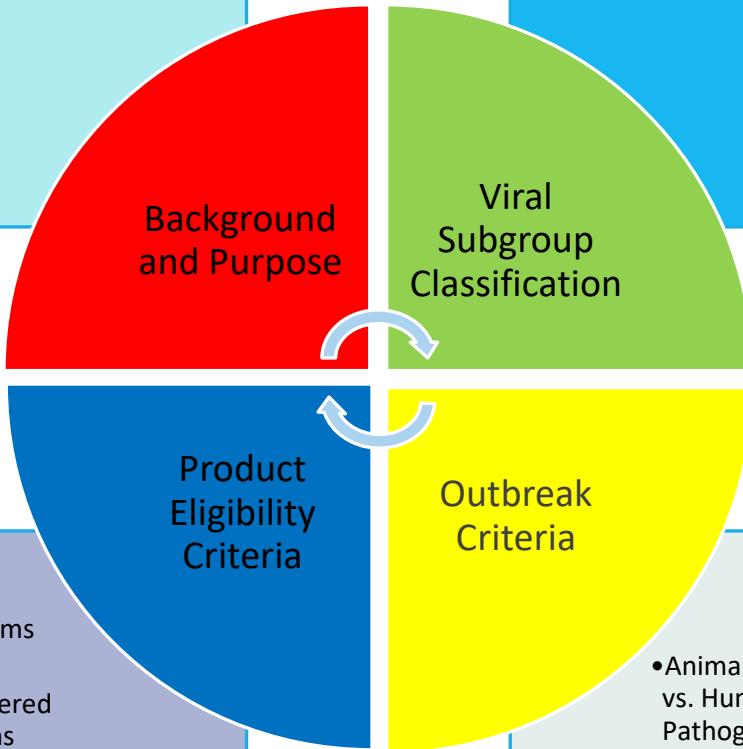
**Use Sites**

• Communications  
• Trigger  
• Labeling  
• Hierarchy

• Efficacy Claims  
• Labeling  
• CSFs/Registered Formulations  
• Use Sites

• List N

• Animal Pathogens vs. Human Health Pathogens



EVP does not direct the Agency to publish a list.

List N could be more user friendly with some products more difficult to locate.

Trade Names not included/ABNs all included under one registration number

Sub-distributor products not included.

List N contradicts EVP language for many products.

List N created without visibility to registrants on criteria

# Recap: Emerging Viral Pathogens (EVP) Guidance

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## **GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING VIRAL PATHOGENS NOT ON EPA-REGISTERED DISINFECTANT LABELS**

August 19, 2016

### **In this document:**

- I. Background and Purpose**
  - II. Viral Subgroup Classification**
  - III. Product Eligibility Criteria**
  - IV. Instructions for Using the Process**
  - V. Outbreak Criteria Associated with Emerging Pathogens Process**
  - VI. References**
  - Attachment 1 - Additional Terms of Registration**
  - Attachment 2 - Process Example**
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- 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

# EVP Activation and Events

**Jan. 2020**

In January 2020, EPA activated—for the first time ever—its Emerging Viral Pathogens Guidance for Antimicrobial Pesticides

**May 2020**

In May 2020, EPA expanded its expedited review program to include new products and amendments to existing product labels that require the review of new efficacy data.

In March 2020, EPA announced that it would expedite the review process for products eligible for emerging viral pathogen claims without requiring the review of new data.

List N posted on March 5, 2020

**Mar. 2020**



# EPA List N: Disinfectants for use against SARS-CoV-2

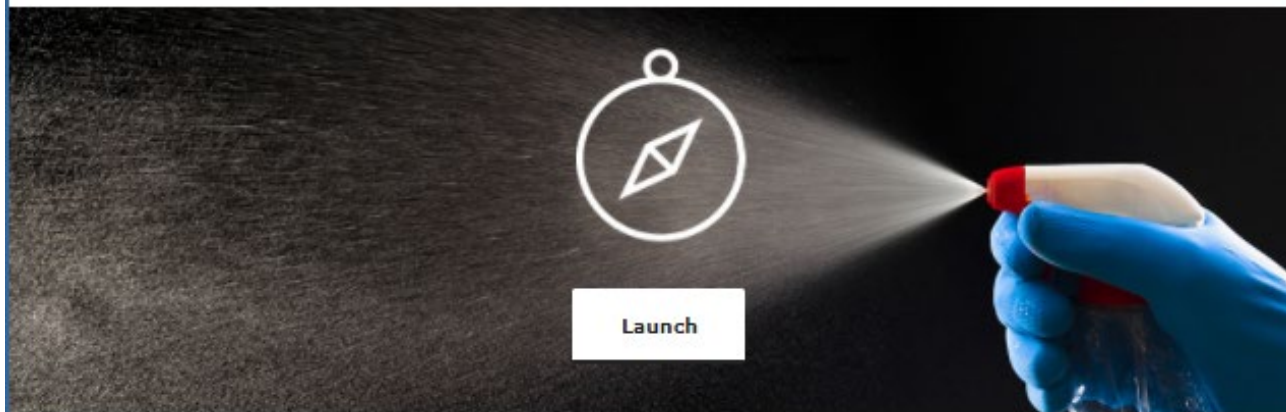
- On March 5, 2020, EPA posted List N: Disinfectants for Use Against SARS-CoV-2
  - Initial list contained ~90 products
- Significant improvements to the list have been made including:
  - the ability to search and sort a dynamic list
  - additional information helpful to end users (e.g., active ingredient, formulation type, use sites)

## Analytics

- Views: 23.5 million
- Number of Products on List N: 550
- Products with EVP claims: 377 (68%)

List N Tool: COVID-19 Disinfectants

Feedback



## List N: Disinfectants for Coronavirus (COVID-19)

**Find a Product to Kill Coronavirus (COVID-19)**

[Infographic: How to use disinfectants safely and effectively - IMPORTANT, PLEASE READ](#)

[Use our advanced search option to find a product](#)

# Charge Question #2 and Response

**What, if any, EPA documents/policies/guidances (e.g., PR-Notice 98-10 and EVP) should have increased flexibilities to respond to supply chain challenges during a pandemic or other emergency and what revisions should be made?**

- Immediately targeted documents:
  - Emerging Viral Pathogens (EVP) Guidance for Antimicrobial Pesticides
  - PR Notice 98-10 and its Temporary Amendments
  - Label Review Manual
  - Registration Review Manual,
  - Test guidelines, 158w (exceptions to GLP),
  - Provisions for importation/international supply chains



Antimicrobial Data Requirements  
40 CFR Part 158, Subpart W

Introduction and Overview

# Charge Question #2 Response (cont'd)

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- Define emergency (quantitative)/Regional impacts additional triggers
- Ability to change suppliers with just a notice
- Need for reciprocity with other countries (global-scale; “work-sharing”)
- Ability to change chemistry based on self-certification
- Consideration for other products beyond disinfectants/other surfaces/uses



# Charge Question #3 and Responses

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

## Pre-Pandemic/Emergency

- **GROUND TRANSPORTATION:** Materials incompatibility; DOT regulations
- **AIRLINES:** Assess FAA regulations on corrosivity/materials incompatibility; Work to get more products through the airline testing/qualifications/international flights and the list of disinfectants; is there a global use for these uses;
- **CRUISE:** Disinfectants for use in international waters;
- **GOVERNMENT:** “Ongoing” webinars with involvement of trade associations for centralizing messaging and resources

## During the Pandemic/Emergency

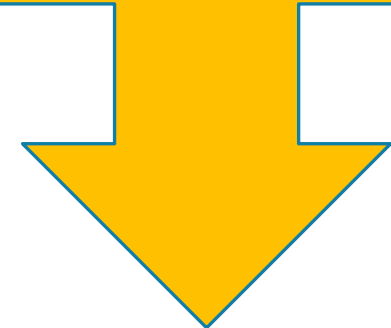
- **AIRLINES:** Incompatibility with many of List N products; high touch surfaces; targeting air treatment; “competing commitments or competing priorities”
- **GOVERNMENT:** Extra communication for parties driving the messaging the emergency event; enhance interagency communications

## Post-Pandemic/Emergency

- **CRUISE:** Practices the industry has implemented to taper cases; lessons learned ventilation, disinfecting high-touch surfaces, etc.
- **GOVERNMENT:** communicate with regulatory industries that oversee pandemic response to find common solutions for consistent messaging and leverage resources.

## ALL INDUSTRIES/Ongoing Efforts

- Assist with identification of effective products
- Proper Use as directed by the label
- Areas of concern; “High-touch” surfaces, air, etc.
- Surveys for impacted industries/identify gaps/lessons learned



# Goals for Next 6 months

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Prioritize responses to charge questions



Develop processes for short-term, high priority items



“Possibly” addressing additional charge questions



Questions?

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