PPDC END OF YEAR MEETING: EMERGING PATHOGENS WORKGROUP (EPWG)

PRESENTERS: RHONDA JONES and ALEX COOK

CO-CHAIRS: Komal K. Jain and Tajah Blackburn

OCTOBER 28, 2021

AGENDA

- Over-Arching Recommendations
- Background
- Membership/Organizations/Affiliations
- Objectives of Emerging Pathogen Workgroup (EPWG)
- Charge Questions/Recommendations
- Closing Remarks
- Questions

OVER-ARCHING RECOMMENDATIONS

Other "Emergency"

Implementation Workgroup

Building Better Communication Strategies

Utilizing Lessons Learned and Knowledge from Trade/User Groups

General and Specialized Educational Resources

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
Marylou Verder-Carlos	Exponent	Regulatory and Technical Consultant
Cheryl Woodward	Thor Specialties, Inc.	Registrant
Nancy Young	Airlines of America	User (Air Transportation)
Samantha Collins	US Environmental Protection Agency	Federal Regulatory
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

01

Assess EPA's COVID-19 response and stakeholder experiences with the Emerging Viral Pathogens (EVP) Guidance for Antimicrobial Pesticides

02

Assess the user experience with antimicrobial disinfection products registered by the EPA for infection control

03

Provide recommendations to EPA for policy improvements and identify educational gaps

RECAP: EMERGING VIRAL PATHOGENS (EVP) GUIDANCE

- 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

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

August 19, 2016

In this document:

EVP ACTIVATION AND EVENTS

Jan. 2020

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

Mar. 2020

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

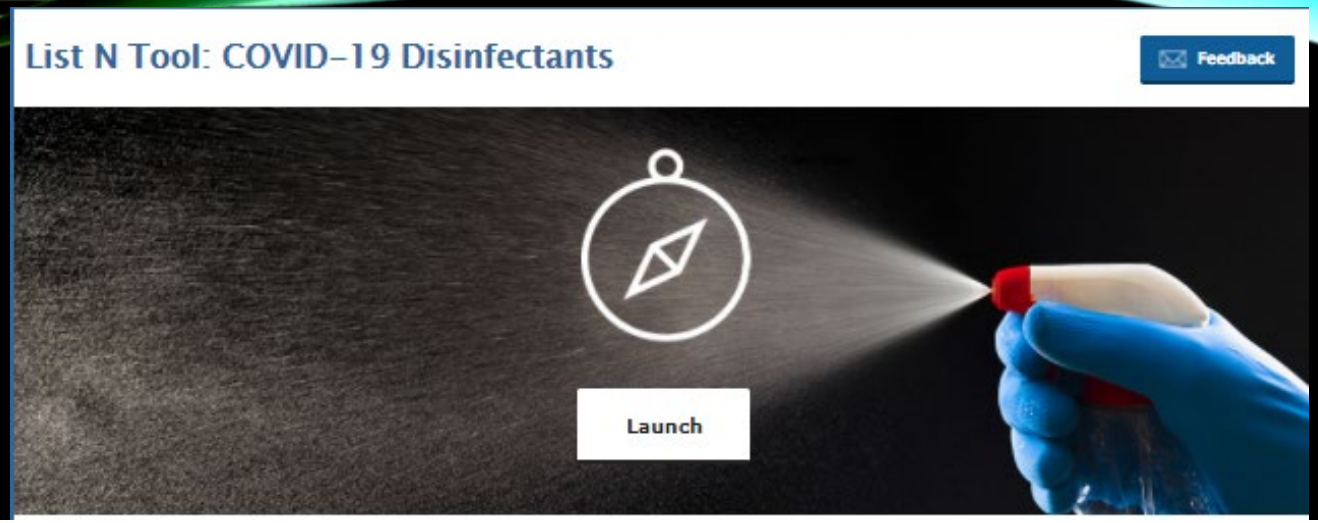
May 2020

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.

EPA LIST N: DISINFECTANTS FOR USE AGAINST SARS-COV-2

- On March 5, 2020, EPA posted : 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



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 #1

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

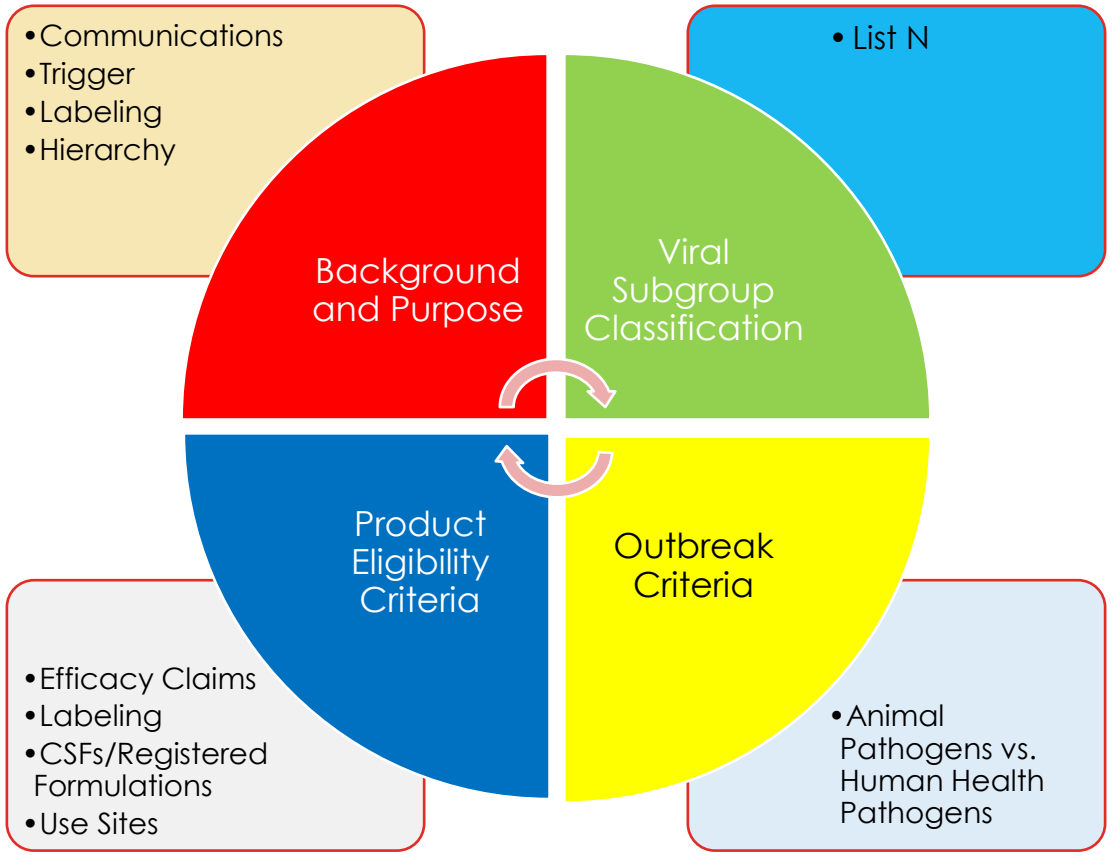
Hierarchy
- Simplify the pathogen list
- Option for List N

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



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

IDENTIFIED ISSUES

ISSUE #1: The EVP is too ambiguous.

- Clarity is needed for the EVP trigger
- Clarity for registrants in order to identify products that could be used in response
- Unclear whether EPA verification is needed prior to registrants' communications
- Too much ambiguity regarding the 3 terms for EVP execution

ISSUE #2: Communication pursuant to the EVP Policy was limited/ineffective.

- Too inflexible regarding label claims
- Lack clear standard procedure for communicating which products to use
- Not sensitive to animal pathogens not yet on US soil
- List N challenges (changing criteria, brand names not included, targeted audience unclear, information not exhaustive, etc.)

RECOMMENDATIONS

Revise	Revise EVP to instruct EPA to issue explicit statement to the registrant community to initiate, extend, and halt EVP communications.
Establish	Establish an EPA landing page that addresses pandemic related information in a clear and transparent manner (status table, when EVP is activated, what List to use, include references from other federal agencies, etc.)
Allow	Allow EVP claims on commercial labels
Revise and consolidate	Revise and consolidate Lists
Establish	Establish an icon that can be placed on products in advance that identifies the EVP viral tier

CHARGE QUESTION #2

What, if any, EPA documents/polices/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?

DEFINITION OF AN EMERGENCY

- **EPA should be better prepared for future pandemics as well as the occurrence of other "emergencies".**
- **Recommend 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. Ransom wear 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.

TARGETED DOCUMENTS

- Emerging Viral Pathogens (EVP) Guidance for Antimicrobial Pesticides
- PR Notice 98-10 and its Temporary Amendments
- Pesticide Emergency Exemption (Section 18)
- Label Review Manual
- Pesticide Registration Manual
- Section 810 Product Performance Test Guidelines
- EPA Data Requirements for Registration of Antimicrobial Pesticides (158w)
- ESS Application Directions for Use to Antimicrobial Product Registrations

IDENTIFIED ISSUES

1

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

2

Some guidance document modifications were only temporary, while other requisite documents remained unchanged or were adapted for use during the pandemic situation.

3

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

4

EPA's Antimicrobials Division faced great resource strains during the pandemic.

RECOMMENDATIONS

EVP focuses on approved means of pesticide applications but does not allow for expanded use or new methods (e.g., ESS).

EVP does not address ancillary consequences and how these issues can hamper public health situations.

EVP should be updated to address variants.

EPA should consider the development of a set of hierarchies for non-viral pathogens including bacteria, yeasts, and mold.

Lack of diversity in product selection offerings.

Some temporary amendments should become permanent.

Expand the scope of CSF changes that can be made by notifications and non-notifications.

During pandemic, Section 18 should only be given on a national level sponsored by relevant federal agency.

Non-GLP testing should be allowed for future pandemics.

EPA should prepare a suite of guidance documents that can be triggered at the same time as the EVP.

During a pandemic, EPA Crisis Management Office or best suited office should 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?

SPECIALIZED CHALLENGES INHERENT TO SOME INDUSTRIES

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;

During the Pandemic/Emergency

- AIRLINES: Incompatibility with many of List N products; high touch surfaces; targeting air treatment; "competing commitments or competing priorities"
- 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.

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.

IDENTIFIED ISSUE

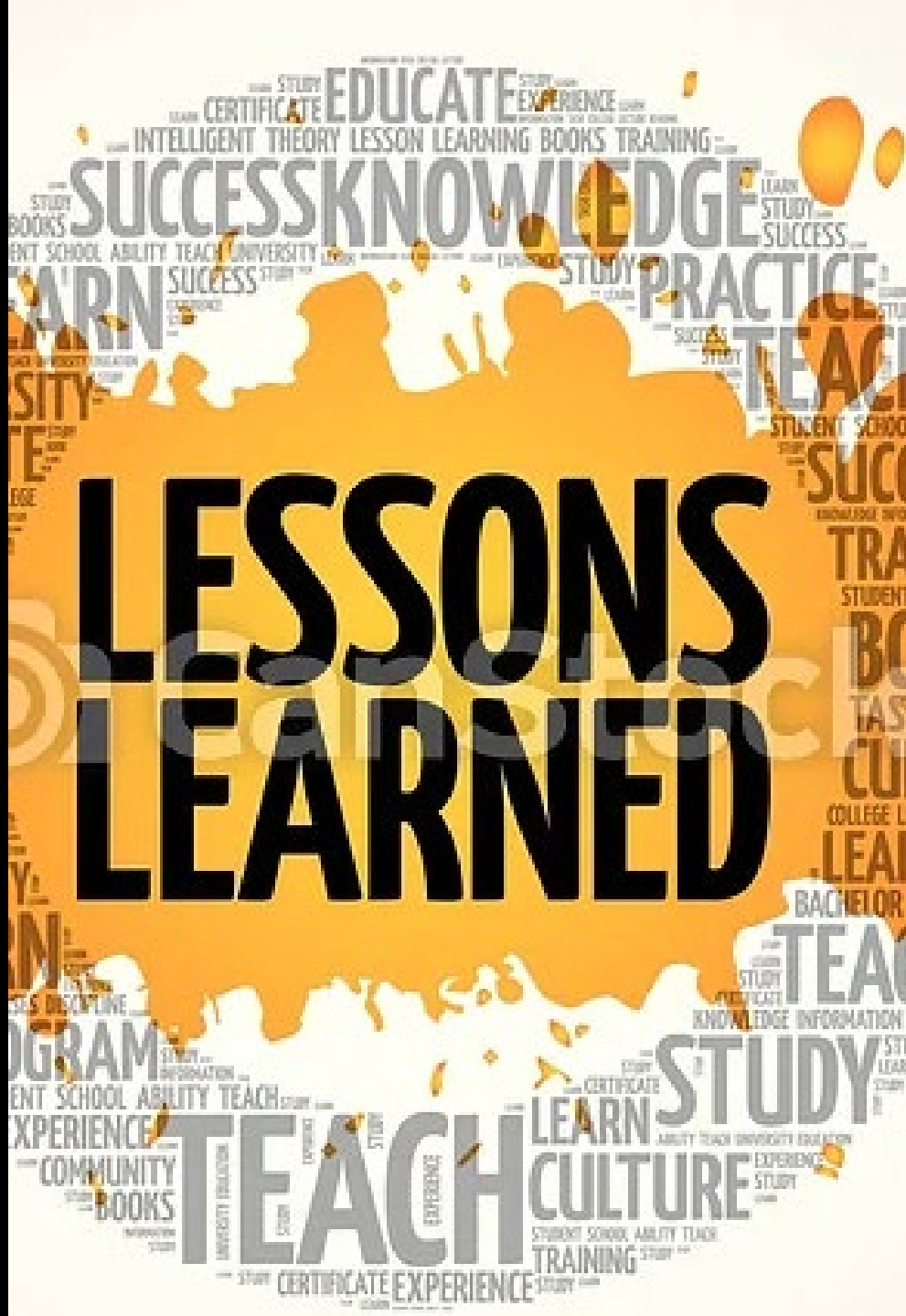
There was ineffective messaging across several sectors due to information and education gaps.

RECOMMENDATIONS

- Information Gathering
  - Conduct surveys at each phase (pre/during/post)
  - Collaborate with trade/user groups
- Communication Recommendations
  - Provide bilingual messaging
  - Provide specific messaging when required
  - Establish dissemination process
  - Continue to educate through every phase
- Specialized Messaging for Certain Sectors
  - Engaging trade/user groups (current list of product (international), certification programs, lessons learned

RESPONSE

Develop targeted resources and references for general and specialized messaging for key sectors at different stages of a pandemic/emergency gathered t hrough planned outreach tools (surveys, etc.) and lessons learned.



CHARGE QUESTION #4

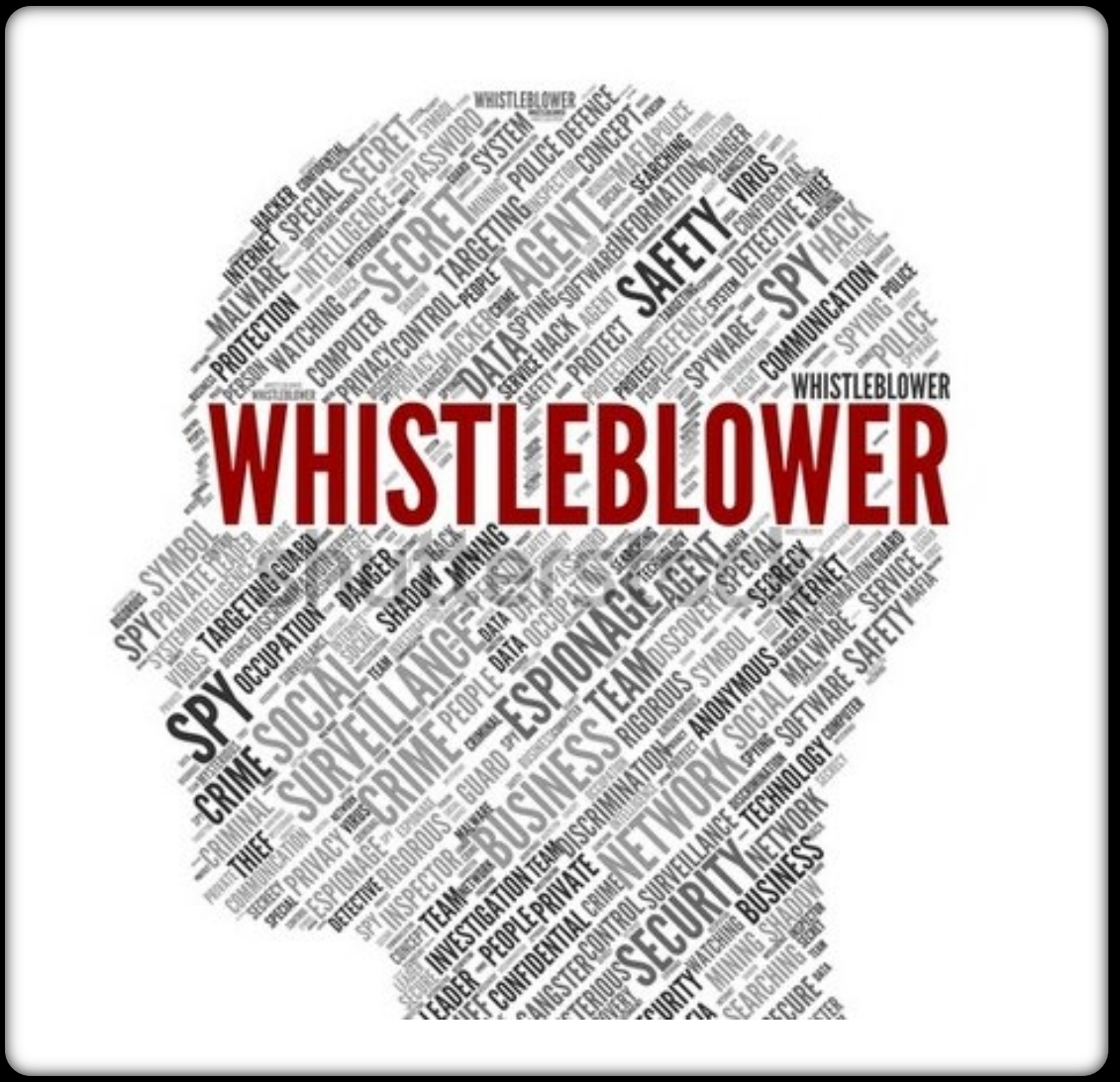
How can EPA's enforcement program be strengthened to expeditiously respond to fraudulent/misbranded products in the marketplace during a pandemic or other emergency? What flexibilities are needed (not provided) by guidance, regulations, etc., to address issues faced in a pandemic?

IDENTIFIED 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 mechanism to enlist resources/people to feed timely information to EPA.
  - Develop and identify trigger for EPA to secure additional monitoring resources.
  - Develop internal EPA group to address complaints.
  - Identify key trusted advisors and possibly deputize surveillance monitors.
  - FTC assist with monitoring products in marketplace.
- Develop detailed communication plan for reporting violators.
- EPA whistleblower process needs to be more thoroughly developed.
- EPA should develop a penalty scheme with greater penalties during a pandemic or other emergency.



CLOSING REMARKS

Pesticide Program Dialogue Committee (PPDC)

Emerging Pathogen Workgroup (EPWG)

OVER-ARCHING RECOMMENDATIONS

EPWG REPORT DETAILS

Questions?