

Emerging Pathogens Workgroup

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Topics for Discussion

- Emerging Viral Pathogen (EVP) Guidance Discussion
- Emerging Pathogen Workgroup Charge Questions

Overview

2016 Guidance for making claims against emerging viral pathogens



Process for adding emerging viral pathogens claims



Example of the process to add an emerging viral pathogens claim

Emerging Viral Pathogens Guidance

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

August 19, 2016

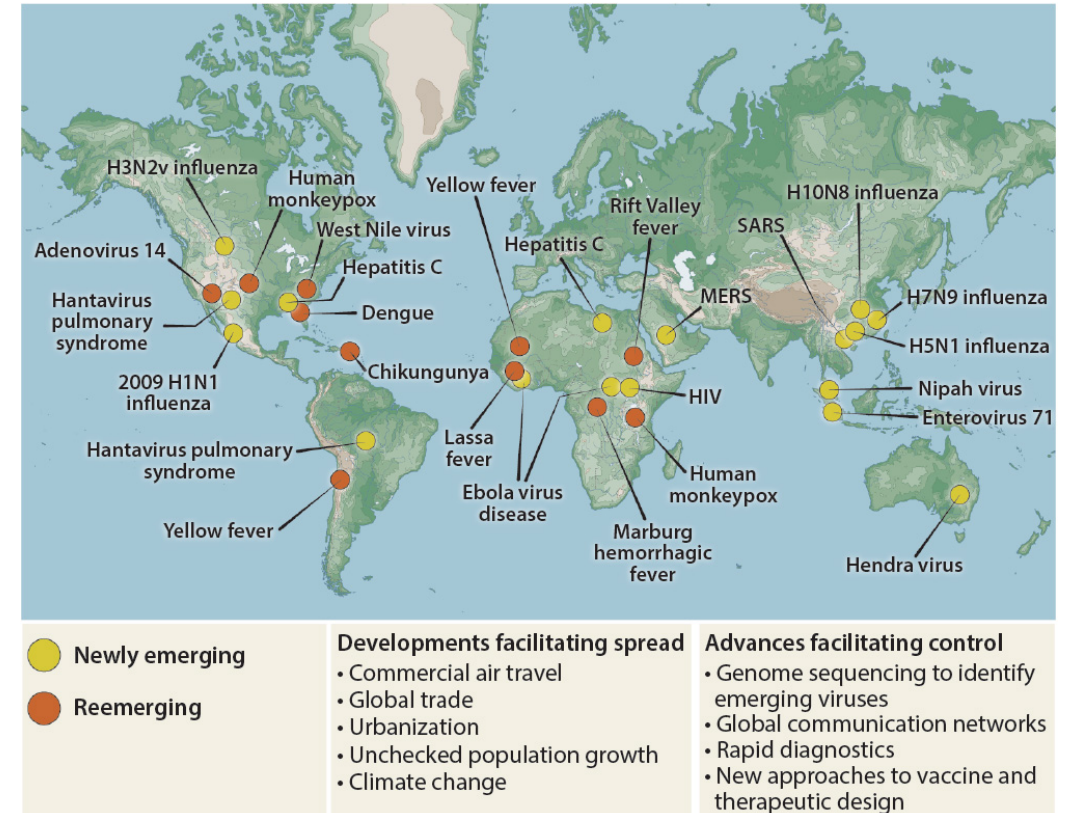
In this document:

- 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

Emerging viral pathogens guidance: Purpose

- Emerging viral pathogens are an increasing global public health concern
 - Viruses that cause 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
 - Example: 2014-2015 Ebola virus outbreak (discussed in the next part of this session)
- The ability of these viruses to persist on environmental surfaces may play a role in transmission of human disease
- Need for EPA-registered disinfectant products that are effective against these viruses. This presents a challenge due to:
 - Lack of commercially available sources for emerging viruses
 - Lack of standard methods for efficacy testing



Marston, HD et al. Science and Translational Medicine, 2014.

Emerging viral pathogens guidance: Purpose

- Difficult to add these viruses to existing product registrations, which requires the submission of efficacy data for agency review.
- Guidance provides a voluntary, two step process to enable the use of EPA-registered disinfectant products against emerging viral pathogens not identified on the product label
 - The contract company should use an Environmental Protection Agency (EPA)-registered hospital disinfectant (or professional product) with a label claim against a non-enveloped virus, such as norovirus, rotavirus, adenovirus, or poliovirus, according to manufacturer's instructions. **Currently, no EPA-registered disinfectant products will have a statement on the label that specifically says it can kill Ebola virus** However, any EPA-registered hospital disinfectant (or professional product) that is effective against a non-enveloped virus will also be effective against Ebola virus. One simple way to identify an appropriate product effective against Ebola virus is to use a product with a label claim against non-enveloped viruses, such as those included in EPA's List L: [Disinfectants for Use Against the Ebola Virus](#) . As certain disinfectants may be incompatible with aircraft components, any disinfectant used on board an aircraft should be cleared as acceptable for the aircraft.

<https://www.cdc.gov/vhf/ebola/prevention/cleaning-commercial-passenger-aircraft.html>

Emerging viral pathogens guidance: Process

Stage 1 Pre-outbreak

Registrants with eligible disinfectant products may request (via label amendment or during registration of a new product) to add an emerging viral pathogen designated statement to the master label and additional terms to the product registration



Stage 2 During outbreak

Registrants with previously approved emerging viral pathogen claims may make off-label communications that the disinfectant product (s) may be used against the specific emerging viral pathogen in the event of a disease outbreak.

Emerging viral pathogens guidance: Process

Product Eligibility Criteria

- 1) The product is an EPA-registered, hospital/healthcare or broad-spectrum disinfectant with directions for use on hard, porous or non-porous surfaces

NOTE: See the [810.2200 Efficacy test guidelines](#) for additional information on testing to support disinfectant claims

- 2) The currently accepted product label should have a disinfectant efficacy claim against at least one of the following viral pathogen groupings:

For an emerging viral pathogen that is an:

Product should be approved to inactivate:

Enveloped Virus

- 1+ large or small non-enveloped virus

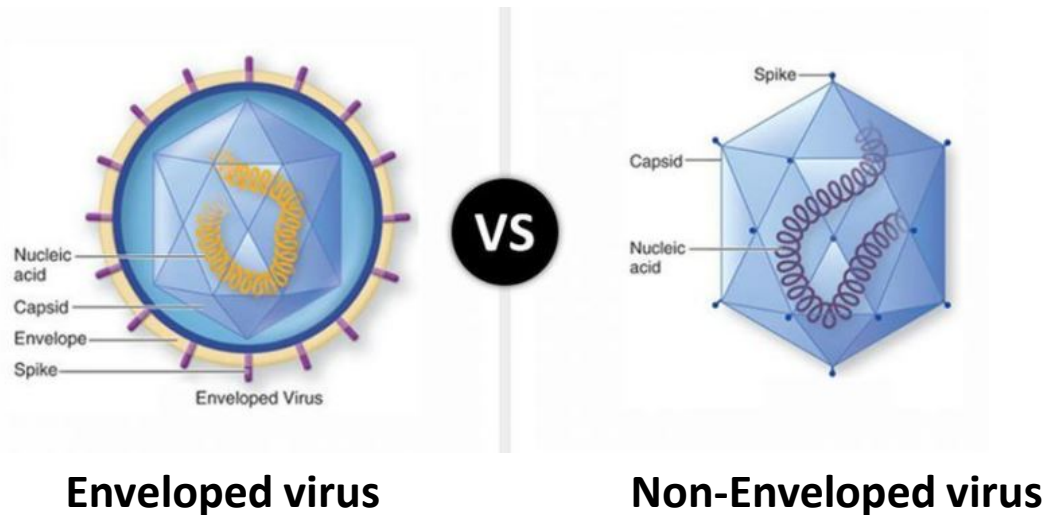
Large non-enveloped virus

- 1+ small non-enveloped virus

Small non-enveloped virus

- 2+ small non-enveloped viruses

Emerging viral pathogens guidance: Viral subgroups



- **Small, non-enveloped viruses (< 50nm)**

- Most difficult to inactivate
- Lack lipid envelope
- Include Picornaviridae, Parvoviridae, Caliciviridae, Astroviridae, and Polyomaviridae

- **Large, non-enveloped viruses (50-100nm)**

- Less resistant to inactivation than small, non-enveloped
- Include Adenoviridae, Reoviridae, and Papillomaviridae.

- **Enveloped viruses**

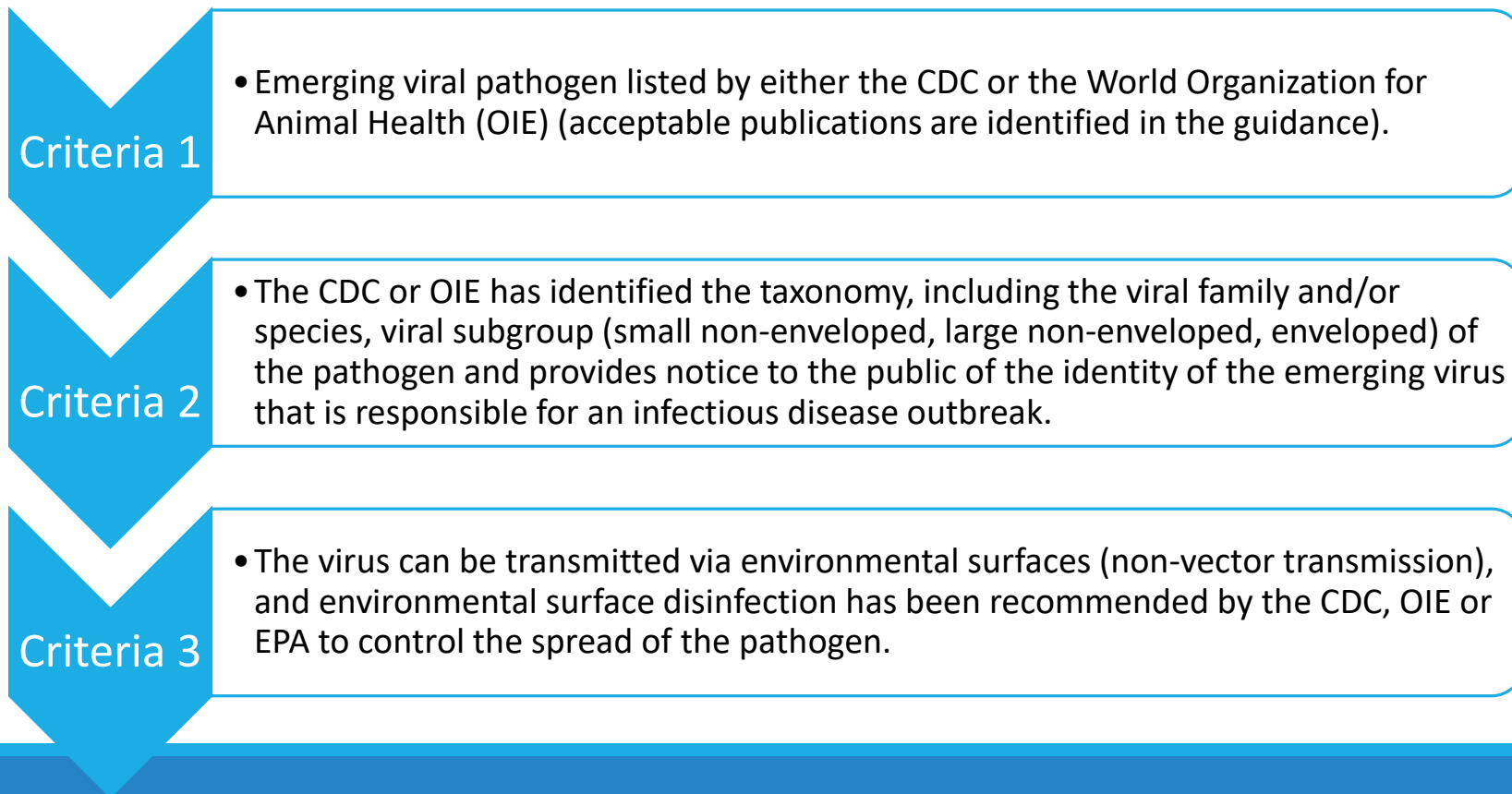
- Least resistant to inactivation
- Lipid envelope
- Not eligible to support emerging viral pathogens claims

Emerging viral pathogens guidance: Process

- To add a claim against emerging viral pathogens to an eligible registered product
 - Submit either an FQPA (fast-track, non-PRIA) or
 - PRIA label amendment request
 - Should include a request to add to the Terms of Registration for the product (attachment 1 of the guidance provides an example)
- Emerging viral pathogens claims are reviewed by the efficacy team. To ensure an efficient review process the efficacy team recommends including the following:
 - A cover letter specifying the emerging viral pathogens claims to be added (e.g. enveloped, large, non-enveloped and small, non-enveloped) and the viruses on the label intended to support the claims
 - An up to date data matrix that identifies the supporting efficacy studies
 - A proposed master product label with the addition of the emerging viral pathogens claims

Emerging viral pathogens guidance: Process

Stage 2: In the event of an outbreak, registrants whose registered master labels include the approved emerging viral pathogens statements, may publish the approved statements only upon a disease outbreak that meets all the following criteria:



Emerging viral pathogens guidance: Example

- Hypothetical EPA Registered Hospital Disinfectant Imitation Oxide has existing label claims for:
 - Influenza A (an enveloped virus),
 - Rotavirus (a large, non-enveloped virus) and
 - Rhinovirus (a small, non-enveloped virus)
- The registrant wants to add emerging viral pathogens claims. They submit an amendment with:
 - a terms of registration letter,
 - a cover letter indicating viral claims to add,
 - a data matrix and
 - proposed label to add the claims.

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	<u>One of the following:</u> Rhinovirus Rotavirus
Large, non-enveloped virus	<u>One of the following:</u> Rhinovirus

Emerging viral pathogens guidance: Example

- The efficacy team reviews the supporting studies and label claims and determines that the viruses indicated are eligible to support emerging viral pathogens claims. The following label language is approved on the proposed master label.

“This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain

emerging viral pathogens from the following viral category[ies]:

- Enveloped Viruses
- Large Non-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Rhinovirus Rotavirus
Large, non-enveloped virus	Rhinovirus

Acceptable claim language:

[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 virus(es)] on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] 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)] on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.

Emerging viral pathogens guidance: Example

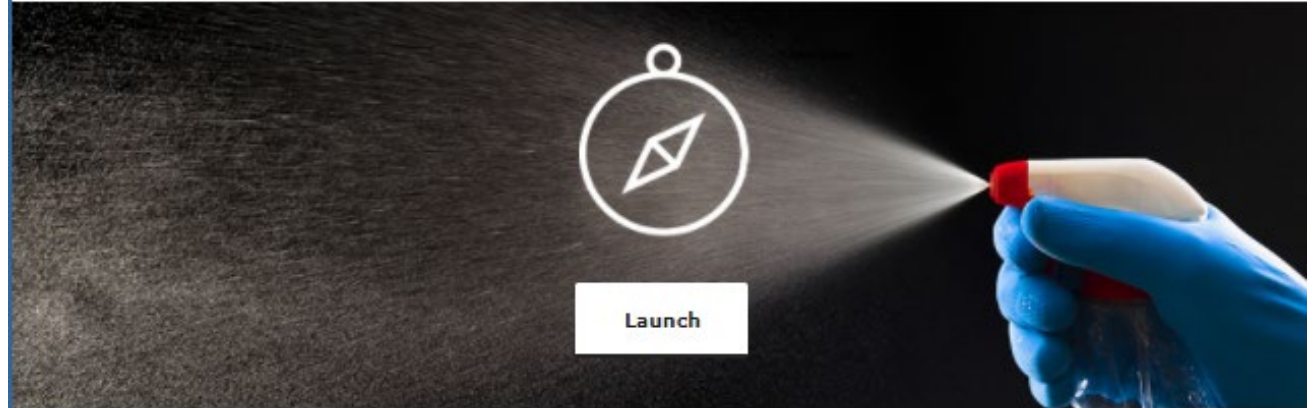
- The master label is approved and the terms of registration updated
- CDC identifies a public health outbreak via its website (www.cdc.gov/outbreaks), of an emerging enveloped viral pathogen called Superpox virus and surface disinfection is recommended.
- The registrant would be allowed to include the following statement in technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, non-label related websites, consumer information services, and social media sites:
- “Imitation Oxide has demonstrated effectiveness against viruses similar to Superpox virus on hard non-porous surfaces. Therefore, this product can be used against Superpox Virus when used in accordance with the directions for use against Rotavirus and Rhinovirus on hard, non-porous surfaces. Refer to the CDC website at www.cdc.gov/... for additional information.”

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
- The most recent list N update has over 500 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)
- EPA deployed a web app-based tool this summer for improved mobile device viewing

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](#)

Emerging Pathogens WG Charge Questions

- **What are the strengths and weaknesses of EPA's first use of the Emerging Viral Pathogens (EVP) policy during the COVID-19 pandemic?**
- **What lessons learned can be drawn from inaugural use for the COVID-19 pandemic? Should any modifications to the guidance be considered based on these lessons learned?**
 - Examples may be a single contact time for the most difficult to kill microorganism, standardized use directions (locations, clear, easy-to-follow) across all products, or expansion of the guidance for other microorganisms.
- **Are there educational outreach opportunities or stewardship programs that should be considered to help the public understand the EVP policy and get feedback on challenges faced by end users?**