

Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)

Purpose

In response to the emerging threat posed by the spread of Pandemic 2009 H1N1 influenza A Virus, the U.S. Environmental Protection Agency is clarifying testing requirements and providing labeling options for pandemic 2009 H1N1. EPA has previously posted information on its Web page regarding this virus.

This document provides guidance for antimicrobial pesticides sold as dilutable liquids and powders, ready-to-use or spray formulations, and towelettes, which are used to treat hard non-porous surfaces in healthcare facilities, commercial, industrial, institutional, and residential settings against Pandemic 2009 H1N1 influenza A Virus.

As guidance, this document is not binding on the EPA or any outside parties, and the EPA may depart from it where circumstances warrant and without prior notice. Registrants and applicants may propose alternatives to the recommendations described in this guidance, and the Agency will assess them for appropriateness on a case-by-case basis.

Background

EPA requires registrants to submit efficacy data to support all public health related label claims. If a registrant wants to list a specific public health microorganism on their product label (e.g., *Pseudomonas aeruginosa*, *Trichophyton mentagrophytes*, Herpes Simplex 1 Virus), they would need to generate and submit efficacy data against that specific microorganism.

However, there is a great deal of scientific information to support a disinfection hierarchy, which tiers a microorganism's resistance to disinfectants. Based on this disinfection hierarchy enveloped viruses are among the most susceptible microorganisms to disinfectants¹. In 2008, EPA adopted the disinfection hierarchy for use in identifying antimicrobial products that could be used against emerging enveloped and non-enveloped viruses without requiring a registrant to submit "virus-specific" efficacy data. EPA's adoption of the disinfection hierarchy allows the Agency to provide timely information to the infection control community and the general public regarding antimicrobial products that may be used during unique situations, such as an emerging pathogen outbreak.

Influenza A viruses are enveloped viruses that are capable of causing disease in a variety of hosts, including; humans, pigs, birds, dogs, and horses. Influenza A viruses are subtyped based on two surface proteins, hemagglutinin and neuraminidase. There are 16 recognized H types, and 9 N types, and these are known to occur in a number of different combinations.

A 2005 report from Sandia National Laboratories presented results from a study that concluded that influenza A viruses, both human and avian, are relatively easy to kill with disinfectants². The CDC uses the same guidance for environmental infection control of healthcare facilities for seasonal influenza virus, avian influenza A virus, and the 2009 H1N1 influenza A virus.

Based on the scientific community's understanding of the susceptibility of enveloped viruses to disinfectants, EPA is confident that the currently registered disinfectant products that bear label claims for effectiveness against influenza A viruses (human and animal) will be effective against all influenza A viruses, including Pandemic 2009 H1N1. In fact, the majority of the disinfectants for use against avian influenza are also labeled for use against human influenza A virus. As such, EPA believes the data that has been submitted by a registrant to support label claims against any influenza A virus is sufficient to support label claims against Pandemic 2009 H1N1 influenza A virus, and that additional data against 2009 H1N1 influenza A virus does not need to be generated or submitted to the Agency.

At this time, it is not the Agency's intent to adopt a broader use of the disinfection hierarchy beyond its current scope of emerging enveloped and non-enveloped viruses. All other public health related label claims will need to submit the applicable efficacy data to support the label claim prior to the claims being accepted on the label. In the event of a future emerging pathogen event, similar to Pandemic 2009 H1N1 influenza, where the Agency finds that it has sufficient product performance data on a microorganism that is related to the emerging pathogen, expanded use of this disinfection hierarchy may be considered. Such determinations will be made on a case-by-case basis.

Labeling Recommendations

Disinfectant products that bear label claims against human, avian, or swine influenza A virus, and have submitted and received approval of efficacy data to support those label claims, may also include the following statements:

- “Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product (Product Name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).”
- “This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.”
- “This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).”
- “Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).”
- “Kills Pandemic 2009 H1N1 influenza A virus.”

Current label claims for influenza A viruses are for products that are applied to hard, non-porous surfaces. Registrants who intend to make label claims for porous surfaces should contact the Antimicrobials Division for further guidance.

Guidance Implementation

Type of Application

Registrants desiring to amend their product labels to add a Pandemic 2009 H1N1 influenza A virus claim, and whose product(s) would qualify for such addition, may do so through Notification. The Agency will consider the request a Food Quality Protection Act (FQPA) action and the application will not be subject to Pesticide Registration Improvement Act (PRIA) fees. As noted above, the criterion for antimicrobial products subject to this guidance is that the Agency already has acceptable efficacy data for the product against at least one influenza A virus. Therefore, if that criterion is satisfied, additional efficacy data do not have to be submitted to support this amendment.

If a registrant does not have efficacy data supporting an influenza A label claim and would like to make a claim against Pandemic 2009 H1N1 influenza A virus, they must generate and submit efficacy data against any influenza A strain. The application will not be subject to the reduced review time period described below and will be subject to PRIA requirements.

Procedures for Notifications

For each product a notification should be submitted with a completed Application for Registration (EPA Form 8570-1). A photocopy of the EPA application form is acceptable; an original form is not needed. The application should bear the following statements:

"Notification of (insert type of change, such as Additional Influenza A virus) per PR Notice 98-10."

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Labeling

For each notification involving labeling changes, one (1) copy of the labeling must be submitted with the changes clearly marked so that they can be photocopied. Submitting applications to the Agency with label statements that vary from the examples presented in Section III may result in additional review time by the Agency.

Application Review Period

For applications containing a claim consistent with the example statements in Section III of this Guidance, the Agency generally expects to review the registrant's application and provide a written response to the registrant within 20 business days from the Agency's pin-punched date of receipt of the complete application. The absence of an Agency response within that time period does not constitute an approval of the application. If requested by the applicant, the Agency will provide its decision electronically to the applicant and subsequently send the applicant a letter

confirming the Agency's decision. The applicant's email address should be noted on the application, if an electronic response is desired.

For applications where efficacy data are submitted to support a new influenza A label claim, normal PRIA fees and timeframes will be followed.

Application Submission

Hard copies of the application request should be submitted to the Agency at the following mailing address:

Document Processing Desk (NOTIF)

Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Courier Address

Office of Pesticide Programs
Potomac Yard South Building
2777 South Crystal Drive
Arlington, VA 22202

Point of Contact

For additional information regarding this guidance, please contact the [Antimicrobials Division Ombudsman](#) (opp_AD_ombudsman@epa.gov).

¹Spaulding E.H. 1968. Chemical disinfection of medical and surgical materials. Disinfection, Sterilization, & Preservation, 3rd Edition, Block S (Ed), Lea & Febiger, Philadelphia, PA)

²Bieker, J.M., Souza, C. A., Oberst, R.D. 2005: Inactivation of Various Influenza Strains to Model Avian Influenza (Bird Flu) with Various Disinfectant Chemistries. Sandia Report: SAND2005-7633.