

# Agency Responses to Public Comments on Draft Emerging Pathogens Guidance

## **I. Background**

On April 4, 2016, EPA opened a 30-day public comment period for public participation for the Emerging Pathogens Guidance to receive comments on the Agency's Draft Guidance to Registrants: Process for Making Claims against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels. The comment period ended on May 6, 2016.

During the comment period the agency received 3 comment submissions. Below are summaries of the comments, organized by submitter, followed by the agency's response. The original comments are available through [www.regulations.gov](http://www.regulations.gov) (Docket ID: EPA-HQ-OPP-2016-0144).

## **II. Responses to Comments**

### **1. Submitter: Innovation Reform Group (IRG)**

#### **Comment 1:** Non-label Statements

Item A: IRG expresses concern with EPA's mandated non-label statements on product efficacy to consumers, stating that the agency's statements are "lengthy, unclear and potentially confusing for the average consumer." IRG proposed alternative language for the agency's consideration.

Item B: IRG stated that their proposed alternative language 'eliminates the potential confusion caused in the EPA statements which includes a reference to effectiveness against "similar viruses" but then requires the registrant to cite the specific virus being relied upon to predict efficacy ---which may be from a significantly more resistant viral class and provides no information of value to the consumer.'

#### **Response 1:**

Item A: Based on the IRG's request, the agency has removed certain language that could be considered redundant. The remaining differences between the IRG proposed language and the revised agency language are minimal with the exception of the statement "Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information." The agency chooses to retain this reference to the CDC and OIE websites as they may provide important user information on the decontamination practices for the subject outbreak.

Item B: The agency believes that the language including a reference to product "effectiveness against similar viruses" provides consumers with some information regarding the reason for using a product against an organism that is not specifically identified on the product label.

The agency thanks the IRG for suggesting this alternative non-label statement language.

**Comment 2:** Environmental Surface Eligibility

IRG notes that section V, #3 of the document requiring recommendation by CDC or OIE for environmental surface disinfection may result in “confusion and delay for consumers in receiving timely advice on disinfection tools” in the event of an outbreak. IRG suggests the addition of EPA to this statement.

**Response 2:** The agency thanks IRG for their suggestion and has included this recommendation in the revised Guidance document.

## **2. Submitter: Consumer Specialty Products Association (CSPA)**

**Comment 3:** Request for Clarification

CSPA expresses overall support for the agency’s guidance document and requests clarification on the following items:

- a) Different viral families: whether the two small non-enveloped viruses have to be from different virus families
- b) Coordination of disinfection recommendations between agencies: EPA, CDC, and OIE should have a process to ensure that guidance is consistent between agencies
- c) New Products: New product registrations should have the option to add recommended label text to the Master label during the application process.
- d) Approved claims –after an outbreak and during outbreak reoccurrence: (a) CSPA suggests that the agency allow for the language in the guidance to be added to the Master label at any time and that the claims are only to be used during an outbreak. (b) the agency should allow the use of hangtags or similar market label communications and consider other pathways for market communication. (c) EPA should clarify that language already appearing on the Master Label may remain after 24 months (after initial notification of outbreak) but communication to user community should follow guidance for removal or continuance based on agency guidance.
- e) Attachments 1 and 2 – Approved Statements: Statements should be simplified for ease of understanding (examples provided)
- f) References: Reference to Spaulding should be corrected.
- g) Website: CSPA suggests that the term hierarchy be removed from the site title, to read *Emerging Viral Pathogen Guidance for Antimicrobial Products*.

**Response 3:**

- a) The two small, non-enveloped viruses must be from different viral families in order to make emerging pathogen claims regarding small, non-enveloped viral pathogens.
- b) EPA is developing a coordinated process with CDC for the purpose of providing a more standardized and consistent approach to emerging viral pathogen outbreaks. Once this process is established, the agency expects to consult with USDA to develop a similar approach.
- c) The Guidance document allows for the addition of emerging pathogen claim language to the master label during the new product registration process if the product is eligible. Additional language has been added to multiple locations in the Guidance document to clarify that the process is appropriate for new product registrations.
- d) -The emerging pathogen claim language may be added to an eligible registered product master label at any time.

-The agency may consider allowing use of additional modes of claim communication under future versions of this Guidance document, however, hangtags and other promotional materials are not authorized at this time. Because the statements authorized under this Guidance are pesticidal claims that do not meet the FIFRA registration criteria, it is essential that these off-label claims are not made outside of an emerging pathogen outbreak as described in the Guidance. Accordingly, the Guidance limits these off-label claims primarily to communications outlets that are wholly within the registrant's control (800 numbers, social media and websites) from which the off-label claims can be immediately removed. Hangtags and other promotional materials directed towards general consumers are largely out of the registrant's control once the products enter the chain of commerce, and may persist long after the period during which the off-label claims are authorized.

It's worth noting that the Guidance does permit these off-label claims to be made in technical literature, provided that it's distributed exclusively to health care facilities, physicians, nurses and public health officials. In this situation, EPA expects that the targeted recipients will understand and appreciate the context of the off-label claims and the proper use of the pesticide products.

-Additional language has been added to the Guidance document clarifying the claim communication time limit as it relates to claims on the master label.

- e) Changes have been made to the Guidance document in order to clarify the claim statements.
- f) The reference to Spaulding has been corrected.
- g) The reference to the term "hierarchy" will be removed from the website title.

### **3. Submitter: D. Jones, Lonza Inc.**

**Comment 4:** Request for clarification

Lonza, Inc. requests that the hierarchy (emerging pathogens Guidance) remove references to animal pathogens and address human emerging pathogens only.

**Response 4:** The agency has determined that there is a need for identification of effective disinfectants against certain animal pathogens (viral pathogens of economic significance) during such outbreaks. As a result, the agency believes that this process provides a useful option for consumers.