



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 23, 2010

Re: Required Label Language for Indoor Total Release Fogger Products

Dear Registrant:

Background

You are receiving this letter because your company holds registrations for certain products used in or as indoor total release foggers. A 2008 report analyzing incidents with indoor total release foggers from the Centers for Disease Control¹ indicated that failure to vacate the premises, early reentry, and failure to air out the treated area account for about half of all exposure incidents. An additional 10% of incidents have been attributed to failure to tell others about the treatment. Additional total release fogger incident information from Washington State² highlighted some of the deficiencies in the current total release fogger labeling. The Agency also reviewed total release fogger incidents reported to the Agency under FIFRA 6(a)(2) as well as national American Association of Poison Control Centers incident data, and came to a similar conclusion.³

EPA also received information on fogger use from the New York City Department of Health and Mental Hygiene (DHMH).⁴ DHMH notes, based on its surveillance efforts, that “foggers are disproportionately used by low-income, minority residents, with low income Hispanics nearly four times as likely to use them than higher income Whites.” Data from the US Census Bureau indicate that Spanish is the second most spoken language in US households participating in the survey in 2008.⁵

¹ Illness and Injuries Related to Total Release Foggers ---Eight States, 2001-2006. October 17, 2008, 57(41); 1125-1129. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5741a3.htm>

² Letter from A. Wick and B. Morrissey, WSDA to J. Roelofs US EPA. July 21, 2008. <http://www.doh.wa.gov/EHP/PIRT/080721epaltr.pdf>

³ D373694. S. Winfield. Total Release Fogger Assessment in response to New York City Department of Health and Mental Hygiene Petition. February 16, 2010.

⁴ New York City Department of Health and Mental Hygiene Letter to Debra F. Edwards, Director of Office of Pesticide Programs. March 12, 2009.

⁵ US Census Bureau Selected Social Characteristics in the United States. 2008 American Community Survey 1-Year Estimates. (Link: http://factfinder.census.gov/servlet/ADPTable?_bm=y&-geo_id=01000US&-qr_name=ACS_2008_1YR_G00_DP2&-context=adp&-ds_name=ACS_2008_1YR_G00_-&-tree_id=306&-_lang=en&-redoLog=false&-format=)

EPA has developed improved label language and labeling instructions, provided in Attachment 1 of this letter, to address its concerns with these exposure incidents. The purpose of the revised labeling is to mitigate exposure incidents involving:

- Excessive product application,
- Failure to vacate the treated premises for the correct period of time,
- Failure to notify others that the premises have been treated, and
- Other failures to understand or observe application instructions.

Some or all of the elements of the revised labeling may already be on current labeling.

The Agency believes that in the absence of this revised labeling, indoor total release fogger products will not have sufficient directions for use and/or precautionary statements to adequately protect human health and the environment and could therefore be considered “misbranded” under section 2(q)(1)(F) of FIFRA.

What You Need to Do

For products containing pyrethrins, tetramethrin, piperonyl butoxide (PBO), resmethrin, permethrin, MGK-264, d-phenothrin (sumithrin®), and the allethrin stereoisomers, since these chemicals are currently undergoing product reregistration, registrants must:

- Submit amended labels for the products containing the affected chemicals with your response to the Product Data Call-In (PDCI) associated with the REDs; or
- Satisfactorily explain to EPA, before your response to the Product Data Call-In, why existing/alternative labeling is adequate to address the concerns described in this letter.

The eight month response deadlines for the PDCIs for these chemicals vary depending on when you received the package. Please refer to the chemical-specific PDCI package for specific due dates. If the eight month response deadline has past or you have already submitted your response, please submit the indoor total release fogger labels with these changes to the Pesticide Reevaluation Division by June 30, 2010. The labels should be submitted to the specific chemical review manager for your product. If your labeling is acceptable and all other product data⁶ are submitted, reviewed, and approved by EPA, your product(s) may be reregistered.

For products containing cypermethrin, since revised labels have already been submitted by the registrants, registrants must:

- Resubmit indoor total release fogger labels with these changes to the Pesticide Reevaluation Division (ATTN: Veronica Dutch) by June 30, 2010; or

⁶ This includes any product-specific data requirements for acute toxicity, efficacy, or product chemistry studies.

- Satisfactorily explain to EPA, before June 30, 2010, why existing/alternative labeling is adequate to address the concerns described in this letter.

Some products containing cypermethrin may also contain other active ingredients covered by other parts of this letter. Please respond separately for each chemical specific PDCI.

If your company holds registrations for indoor total release fogger products that do not contain the active ingredients listed above, you are required to:

- Submit revised labeling with these changes to the Product Manager in the Registration Division as an Agency-initiated amendment by October 29, 2010, or
- Satisfactorily explain to EPA, before October 29, 2010, why existing/alternative labeling is adequate to address the concerns described in this letter.

Recommended Design and Marketing Changes

In addition to specific label language, the Agency recommends the following design and marketing changes to reduce the likelihood of unintended exposures:

- avoid multipacks for consumer use
- adopt smaller unit sizes (2 oz. versus the standard 6 oz.)
- utilize a time-delayed release mechanism (3-5 seconds)
- switch to non-flammable propellants

All indoor total release fogger products, including distributor products, released for shipment after September 30, 2011, must be labeled in a manner that satisfactorily addresses the concerns described in this letter. If you have any questions regarding this letter, please contact Cathryn O'Connell in the Pesticide Re-evaluation Division at (703)308-0136; or Mark Suarez in the Registration Division at (703)305-0120.

Sincerely,



Richard P. Keigwin, Jr.
Director, Pesticide Re-evaluation Division



Lois A. Rossi
Director, Registration Division

Attachment 1: Improved Labeling for Indoor Total Release Fogger Products

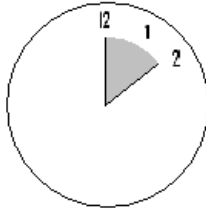
- Use simple terms to express the volume of space treated in terms of linear dimensions, with an assumed ceiling height, rather than in terms of cubic feet. Update the current statements to follow this model in the Directions for Use:
 - Example: “One canister of fogger will treat a room up to x feet by y feet with an 8 foot ceiling.”

All current restrictions and requirements regarding the size of the treated area remain unchanged.

- At a minimum include pictograms, where applicable, to illustrate the following list of restrictions and directions for use:
 - do not use multiple canisters in a room
 - do not use in small confined areas
 - turn off ignition sources
 - remove or cover exposed food
 - air out the room before entering
- Include the following directions that prohibit use in closed, confined spaces:
 - “Do not use in small, enclosed spaces such as closets, cabinets or under counters or tables. Use of a fogger in an enclosed space may cause the product to explode, resulting in injury to people or damage to property.”
- Include prominent headings using different font size or style (e.g., bold) in the directions, such as:
 - **To Use This Product Correctly** [before the standard language about small spaces and ignition sources]
 - **Before you fog** [cover food, remove pets, etc]
 - **To Start Fogging** [how to set up and activate]
 - **Airing Out** [how long]
- Include the following phrase in a prominent place in the directions and in boldface type:
 - **“Vacate the treated house, individual apartment unit, or other structure immediately”**
- In addition to the standard Precautionary Statements, add the following language to the Precautionary Statements section of the label:
 - “Breathing spray mist may be harmful.”
- Include the following statement in bold font in the Directions for Use:
 - **“Does not control bed bugs”**

- Include the phrase **“Do Not Re-enter for X Hours”** in a prominent place in the directions and in boldface type. Include a clock face pictogram shading the entry restriction immediately above or below this direction.

Example:



- Provide door knob hang tags at the point-of-sale with a space for customers to write-in when the entry restricted time has expired.
 - For example, the text on the hang tag could state: “Do not enter until [space for time] on [space for date].”
- Add the following statement to tell others of the treatment:
 - “Fill out and place hang-tag on the door to the treated area to alert family and others with access to the treated area not to enter for X hours.”
- Include label statements in both English and Spanish on all indoor total release fogger product labels. Verify that the Spanish language text is a true and accurate translation of the English text and submit verification statement to EPA. Include both language versions of the labeling on the product container.

Note: EPA is working to develop more general guidance for non-English pesticide labeling. If companies are interested in substituting a different language on product labels, in place of Spanish, please submit a rationale for such substitution along with the alternate label language.