July 6, 2011

Re: Update on Required Label Language for Indoor Total Release Fogger Products

Dear Registrant,

You are receiving this letter as a follow-up to the Agency’s March 23, 2010 letter regarding improved label language and labeling instructions to address concerns with adverse incident reports. At that time, the Agency specified that by September 30, 2011, all indoor total release fogger (TRF) products released for shipment would need to incorporate labeling adequate to address these concerns. Today, the Agency is extending the date by which these label changes must be made.

By September 30, 2011, all revised indoor total release fogger labels must be submitted to the appropriate Product Manager in the Registration Division and identified as Agency-initiated amendments. If the pre-approved pictograms are used, the Agency expects to complete its review by December 31, 2011. Indoor total release fogger products, including distributor products, distributed or sold¹ by the registrant (or supplemental distributor as described in 40 CFR 152.132) after September 30, 2012 must be labeled in a manner that satisfactorily addresses the concerns described in the Agency’s March 23, 2010 letter. In the event that a total release fogger registrant fails to take action necessary to meet the September 30, 2012, deadline, the Agency will take such action as necessary to assure that all TRF products comply with FIFRA. These deadlines supersede those previously described in the Agency’s March 23, 2010 letter.

What Registrants Need to Do

For indoor total release fogger products containing pyrethrins, tetramethrin, piperonyl butoxide (PBO), resmethrin, permethrin, MGK-264, d-phenothrin (sumethrin®), cypermethrin, and the allethrin stereoisomers, registrants must:

- Submit amended labels for the product containing the affected chemicals to the appropriate Product Manager in the Registration Division. Registrants should indicate in

¹ The term “distributed or sold,” as defined in 40 CFR 152.3, means the acts of distributing, selling, offering for sale, holding for sale shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any State.
their cover letter and on form 8570-1 that they are submitting the revised label in response to the Agency letter dated July 6, 2011.

- The only changes that should be made, relative to the last stamped approved label or accepted notification are those that mitigate the concerns identified in the Agency’s March 23, 2010 letter.

Products that were previously labeled for use against bed bugs do not need to add the bed bug disclaimer at this time. The acceptability of this claim will be determined on a case-by-case basis once the Agency has reviewed the data submitted to support claims against bed bugs. These procedural changes supersede the process outlined in the Agency’s March 23, 2010 letter.

For indoor total release fogger products that do not contain the active ingredients listed above, registrants must:

- Submit revised labeling with the changes specified in the Agency’s March 23, 2010 letter to the Product Manager in the Registration Division as an Agency-initiated amendment by September 30, 2011, or
- Satisfactorily explain to EPA, before September 30, 2011, why existing/alternative labeling is adequate to address the concerns described in the Agency’s March 23, 2010 letter.
- Products that were previously labeled for use against bed bugs do not need to add the bed bug disclaimer at this time. The acceptability of this claim will be determined on a case-by-case basis once the Agency has reviewed the data submitted to support claims against bed bugs.
- Registrants should indicate in their cover letter and on form 8570-1 that they are submitting the revised label in response to the Agency letter dated July 6, 2011.

Agency Pre-Approved Pictograms

The Agency has approved the pictograms that CSPA and RISE submitted for use on total release fogger labels (Attachment 1). The pictograms are available for use by all registrants. Image files of the approved pictograms are available at the Agency’s website: http://www.epa.gov/oppsrd1/reevaluation/foggers/fogger-pictograms.html. EPA is providing these files in order to facilitate the adoption of adequately clear pictograms in the labeling of fogger products. They do not represent an endorsement of any particular manufacturer or product.

If pre-approved images are to be used, the registrant need only include a reference to one pictogram from each of the necessary categories when submitting the amended label. The pictograms should be referenced using the following convention:

1) EPA PRE-APPROVED PICTOGRAM 1 representing "Do Not Use Multiple Canisters in a Room"
2) EPA PRE-APPROVED PICTOGRAM 2 representing "Do Not Use in Small Confined Spaces"
3) EPA PRE-APPROVED PICTOGRAM 3 representing "Unplug and Turn off Ignition Sources"
4) EPA PRE-APPROVED PICTOGRAM 4 representing "NO Flames or Pilot Lights"
5) EPA PRE-APPROVED PICTOGRAM 5 representing "Remove or Cover Exposed Food"
6) EPA PRE-APPROVED PICTOGRAM 6 representing "Air out the Room Before Entering"

To qualify as pre-approved, the approved pictogram selected must not be altered in any way, with the exception of increasing the image size.

If any pictogram other than the pre-approved pictograms is to be used, the registrant must include the full color pictogram image(s) with the proposed labeling and clearly indicate the dimension of each image to appear on the product.

If you have any questions regarding this letter, please contact Dana Friedman in the Pesticide Re-evaluation Division at (703) 347-8827 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: Agency Pre-Approved Pictograms for Total Release Fogger Labels

The Agency has created list of pre-approved pictograms available for use by registrants of total release fogger products. For use to qualify as pre-approved, the pictograms may not be altered in any way, with the exception of increasing the image size.

EPA PRE-APPROVED PICTOGRAM 1: "Do Not Use Multiple Canisters in a Room"

EPA PRE-APPROVED PICTOGRAM 2: "Do Not Use in Small Confined Spaces"

EPA PRE-APPROVED PICTOGRAM 3: "Unplug and Turn off Ignition Sources"

EPA PRE-APPROVED PICTOGRAM 4: "NO Flames or Pilot Lights"
EPA PRE-APPROVED PICTOGRAM 5: "Remove or Cover Exposed Food"

EPA PRE-APPROVED PICTOGRAM 6: "Air Out the Room Before Entering"

Pictograms 1-6 are used by permission of the copyright holders, who have also granted permission for any person to incorporate the pictograms into pesticide labeling. The EPA is providing these files to facilitate the adoption of clear pictograms in the labeling of fogger products. They do not represent an endorsement of any particular manufacturer or product.