UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Daniel Kass, M.S.P.H.
Assistant Commissioner
New York City Department of
Health and Mental Hygiene
22 Cortland Street, CN-34E
New York, NY 10007

Robert Hoffman, M. D.
Director
New York City Poison Control Center
455 First Avenue
New York, NY 10016

Dear Mr. Kass and Dr. Hoffman:

This is in response to your letter of March 12, 2009, which states that you are writing "…to petition the U.S. Environmental Protection Agency to move to restrict the use of structural insecticides formulated as total release foggers, and to consider additional labeling changes to ensure public health and safety." The Agency has evaluated the report on fogger-related incidents in New York City which accompanied your letter, as well as other sources of information about fogger incidents, including the article in the "Morbidity and Mortality Weekly Report" (MMWR) published in October 2008 to which you contributed.

Our general conclusion is that the recommendations for label improvements in the MMWR article, and similar recommendations sent to us independently by the Washington State Department of Health, have merit and represent an opportunity to reduce incidents of inadvertent exposure which may be occurring due to failure by users to see or comprehend certain key precautionary statements. The Agency has recently called for labeling changes for the pesticides used in most total release foggers (TRFs) to implement the label improvements listed in Attachment A to this letter. The Agency also plans to meet with TRF manufacturers to encourage packaging and marketing practices that will further address some of the factors identified as contributing to incidents. For example, the Agency is encouraging manufacturers to adopt smaller unit sizes (2 oz. versus the standard 6oz.), to avoid multiple units per package, to develop time-delayed release mechanisms, and to continue efforts to find non-flammable propellants.

On the issue of classifying foggers for restricted use, our assessment of the risks and the benefits of TRFs is that the available information does not meet the criteria set out by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and in regulations, for taking that action. The rest of this letter responds to the issues raised in your petition, and describes the Agency's risk/benefit analysis in detail.

I. Background

Total release foggers or TRFs have been marketed to consumers for residential pest control since the 1970s. There are about 150 federally registered products. The aggregate number of units sold in the U.S is approximately 50 million.

EPA took regulatory action regarding TRFs in 1998 by issuing a rule and an interpretive Pesticide Registration Notice concerning flammability warnings on TRF labels. The rule required TRFs using flammable propellants to have specific warning language, directions to extinguish all ignition sources before using the product, and an icon or pictogram of a flame. These requirements can be found at 40 CFR 156.78(d).

A number of TRFs have pyrethrins as the active ingredient, often in combination with a synergist such as piperonyl butoxide (PBO) or MGK 264. Some foggers employ synthetic pyrethroids, alone or in combination with pyrethrins. These include permethrin, cypermethrin, resmethrin, tetramethrin d-phenothrin, and allethrin stereoisomers. Between 2006 and 2008 all of these compounds completed the Agency's reregistration process, which is a detailed reassessment of each registered use of that chemical, and results in a reregistration eligibility decision (known as a RED). REDs address all the registered uses of the chemical. All of these chemicals were found eligible for reregistration, including use in TRFs.

As part of the RED process, the Agency issued data call-in (DCI) notices for these chemicals to ensure that there are appropriate supporting data (i.e., data that meet EPA test guidelines) for each use and that any gaps in supporting data will be filled by the registrants. Registrants have until October 2010 to respond to these DCIs. TRFs are marketed primarily for control of roaches and fleas which are considered by EPA as public health pests. Submission of efficacy data is one of the registration requirements for products marketed to control such public health pests. The Agency believes that most TRF products will be able to cite the efficacy data previously submitted in order to be reregistered. However, there may be some products for which the necessary efficacy data do not exist or do not meet EPA test guidelines, and any such data gaps will need to be filled by the registrants.

II. Recent TRF Concerns

A variety of concerns and recommendations about TRFs have been brought to EPA's attention from several sources. In July 2008 the Agency received a letter and report concerning 19 incidents of human exposure involving TRFs investigated by the Washington State Department of Health over a 2 year period. None of the incidents were described as serious, but the author made recommendations for several specific labeling and packaging improvements which she felt would reduce the likelihood of exposure incidents. In October of 2008, an article reporting on TRF adverse incidents appeared in the "Morbidity and Mortality Weekly Report" published by the Centers for Disease Control and Prevention (CDC). The article reported 466 TRF incidents from eight states

over the period 2001 to 2006. The article also made recommendations for improvements to precautionary language on TRF labels. At the time the MMWR article was published, the New York State Department of Environmental Conservation (NYDEC) issued a press release indicating the intention to classify TRFs for restricted use in the state.

In response to these events, the Office of Pesticide Programs (OPP) began an assessment of available incident data on TRFs, and to assess the scope of the issues raised and possible responses. In December of 2008 we asked state pesticide regulators to do an informal survey on the question of whether TRFs were posing significant incident problems in their states. The general response was that they were aware of occasional misuse incidents but did not view them as serious or warranting regulatory action.

After EPA received the petition in March 2009, we met with you to ensure that we understood your positions and the evidence you cited in support. We have also met with a group of TRF manufacturers to hear their views on the concerns you raised, and on two occasions we have met with individual TRF registrants who requested meetings to discuss safety- and efficacy-related issues for their products. Memoranda describing these meetings will be posted to the Agency's pesticide program website.

III. Summary of the Petition

This section gives a summary of what we understand to be the main points of the petition, and offers some comments on the evidence and arguments put forward. By "main points" we mean those that seem most directly relevant to the risk-benefit balancing determination required under FIFRA and its implementing regulations. We also comment on additional points made in the petition which seem to provide tangential support to the request. The Agency's analysis of the risk and benefit issues follows in the next section.

A. Main Points

- Petition states that TRF exposure incidents are frequent and medically consequential.

Comments: Without knowing the level of TRF use in New York City it is difficult to judge whether the New York City Poison Control Center (NYC PCC) data should be viewed as evidence of frequent incidents or relatively rare incidents, involving the misuse of a widely used class of consumer products. The petition states that between 45 and 71 people are treated in emergency rooms annually due to exposure to "an insecticide/fumigant in their homes." This figure seems to combine TRFs with aerosol sprays and perhaps other insecticides, so the contribution of TRFs can not be evaluated. EPA believes TRFs are likely heavily used in New York City. For this reason, EPA does not believe that the data reported in Table One of the petition, showing 69 moderate cases and 6 serious cases in a seven year period, establish that the reported incidents occur frequently. Since actual usage data localized for New York City is not available, the Agency further analyzed this issue on a national basis (see Section IV, below).

The term "medically consequential" is not used by EPA or by poison control centers (PCCs) to characterize the severity of incidents. It is not clear whether the petitioners intend this term to encompass all incidents in which reported exposure has been designated as related to the reported outcome, or only a subset of such incidents. EPA notes that the petition reports a higher proportion of moderate and serious cases than other sources, including the MMWR article. One reason may be that only cases considered to have a known medical outcome (i.e., the PCC definitively designated whether or not the reported exposure is related to the reported outcome) were included in assigning severity ratings. Poison control centers also count cases which the interviewers categorize as possible or probable exposures, but for which the relationship between reported exposure and outcome is uncertain or not known. If such possible and probable cases were counted but placed in an unknown effect category, it would raise the number of cases but diminish the relative proportion of cases rated moderate or severe.

- Petition suggests that misuse is a main cause of incidents, specifically, not reading or not following label directions and precautions.

Comments: Although the cover letter refers to consideration of additional labeling changes, the petition makes no specific labeling recommendations. The petitioner has suggested that the cause of TRF exposure incidents is often the user's failure to "understand or observe" product labeling, and that label improvement would therefore have little or no beneficial effect. The petition does not supply sufficient evidence to warrant this conclusion, however. Similarly, the petition's statements that consumers continue to use foggers, and that fogger exposures continue to occur, do not constitute a sufficient basis to conclude that prior education and outreach efforts have been "ineffective at mitigating the risks from foggers" (petition, page 6).

EPA believes that improved product labeling on TRF products is likely to improve users' understanding and observation of the use instructions. EPA's view is consistent with the views expressed in the MMWR and Washington State reports. These reports both recommended specific labeling improvements, such as clarifying the directions on the size of the area to be treated, better instructions to vacate, and instructions to inform others of the treatment.

- Petition states that risks are not justified given the "likely poor efficacy" of TRFs.

Comments: The petition mistakenly asserts that TRFs are not required to be supported by efficacy data because they are not used for public health purposes. As noted earlier, efficacy data is required for any product that claims to control pests of public health significance, which include fleas and roaches, even in a residential setting where health protection per se is not the purpose.

The petition notes that integrated pest management approaches "...consisting of cleaning, sealing and judicious use of bait-based insecticides are far superior to traditional pest control..." such as TRFs or aerosol space sprays. The Agency agrees that IPM

approaches are preferable to reliance on frequent use of conventional insecticides. EPA strongly supports IPM in many venues. For example, the Agency works with the Department of Housing and Urban Development, the Centers for Disease Control and Prevention and other agencies on a Healthy Housing Initiative which promotes awareness and adoption of IPM techniques, especially in public and low-income housing. Through our Pesticide Environmental Stewardship Program (PESP) EPA works with over 200 public and private sector organizations to promote IPM in schools, public housing, agriculture and a wide variety of other pest control venues.

However, encouraging the use of IPM is not a justification for restricting access to alternative products that meet the statutory criteria for registration. The petition asks EPA to consider the benefits of TRFs in the context of a specific regulatory action: classifying TRFs for restricted use. As described in the following section, the petition does not show, and EPA does not agree, that the decrease in risks resulting from restricting use of TRFs would exceed the decrease in benefits that currently accrue from general use classification.

- Petition states that TRF use regularly causes catastrophic fires and explosions.

Comment: Property damage is a reportable adverse effect under section 6(a)(2) of FIFRA, which requires pesticide registrants to submit reports of unreasonable adverse effects of their pesticide products to EPA. We have received about 70 reports of TRF fires or explosions since 1998. Some of these report significant property damage, but few report serious injuries and none report deaths.

Since fires and explosions are not systematically reported to any entity comparable to a poison control center, we understand that these data are incomplete. However, we can compare the proportion of fire/explosion incidents to exposure incidents in some of the TRF incident data available. The MMWR article reports that 19 cases or 4 percent of their incidents were fires or explosions. EPA's data show that property damage incidents filed since the 1998 rule to improve flammability warnings make up a little over 4% of total human-related incidents. Granted that these are rough estimates, nevertheless, the data indicate that fire/explosion incidents are about 20 times less frequent than reported exposure incidents. The frequency of both fire and exposure incidents is discussed more fully in section IV of this response.

The petition expresses some concern (page 7) about potential ignition sources that are less obvious than open flames. The flammability warnings on TRF labels are not limited to open flames, however. EPA's 1998 rule to improve the flammability precautions on fogger labels recognized the issue of appliances as potential ignition sources and required warnings about "…running electrical appliances that cycle off and on (i.e., refrigerators, thermostats, etc.)", as well as a prominent pictogram of a flame. In addition, the Agency has discussed the issue of non-flammable propellants with registrants, and we have pointed out that smaller sized fogger units could help to reduce risks of both exposure and fires.

B. Additional Points

- Petition states that TRFs are contraindicated for many urban apartments.

Comment: The petition makes the point several times that use of TRFs in multi-unit dwellings is problematic because, "...a single release may expose many other residents." However, no cases of such incidents are cited in the petition. The MMWR report cited one case of exposure in a house converted to apartments where a pesticide did infiltrate a common ventilation system. The exposure was reported as minor. We do not know of other cases of pesticide infiltrating neighboring residences or common spaces. The petition itself notes that over 90% of all exposures to TRFs occur in the home of the person exposed. EPA review of national poison control center data show similar figures: 92% in the exposed person's home; about 6% in the home of a relative or acquaintance; and about 2% in a workplace. Absent evidence that other residents of multi-unit dwellings are being exposed in TRF incidents, it is not clear that there is a basis for the concern stated.

- Petition states that TRFs are disproportionally used by low-income minority residents.

Comment: The Agency does not dispute the data cited in the petition regarding disproportionate use by low-income minority residents. However, it is not apparent to EPA, nor does the petition clearly explain, how this observation should inform the question of whether TRFs should be classified for restricted use. The data (petition, page 5, Figure 2) generally suggest that there is a substantial market for low-cost residential pest control, including foggers and aerosol sprays, among lower income groups. The same point is reinforced by the petitioners' observation (petition, page 6) that despite public outreach and education efforts promoting IPM and discouraging reliance on conventional insecticides, the use of foggers persists.

- Petition states that TRFs contribute to the human body burden of pyrethroid metabolites.

Comment: The petition states that "widespread use of foggers surely contributes to ... disproportionate exposure [for New York City residents]." The data cited on body burden of pyrethroid metabolites indicate that New York City residents are exposed to more pyrethroids than the national average. The health significance of the data cited is not clear, since there is no straightforward way for us to compare these urinary biomarker levels with the health effect endpoint reference levels EPA uses in risk assessment.

It should be noted that virtually all residential insecticides are now based on this class of active ingredients, so the data indicate a high level of residential treatments with pyrethroids, but not what products are in use. Thus, it is not clear is that removing TRFs from the consumer market would reduce exposure to pyrethroids. For example, space sprays labeled for roaches and other household pests, which might be substituted for TRFs if TRFs were classified for restricted use, are sold in larger units (17.5 ounces is

standard), and dispensed in more concentrated form than TRFs. For this reason, classifying TRFs for restricted use might actually *increase* exposure to pyrethroids.

- Petition states that exposure to TRFs is more likely to cause adverse effects than exposure to other pesticide products.

Comment: The Agency does not believe the comparisons offered between poison control center calls involving foggers and calls involving rodenticides and other types of pesticide products (pages 3 and 4) provide a meaningful basis to compare the relative risks of the different classes of product. It should be noted that in regard to rodenticides, the Agency did not classify these products for restricted use as the petition implies (page 3), but rather imposed packaging requirements to reduce risks to children. The Agency had a specific concern about children being exposed to rodenticides since several thousand cases of potential exposures were being reported each year, although very few experienced actual symptoms. EPA imposed a requirement for tamper resistant bait stations to reduce risks of children handling or consuming rodenticide baits. Our analysis of TRF incidents does not show that children are disproportionately or frequently exposed. Over 90% of TRF exposures are to adults, and when children are exposed, the severity ratings are generally lower than for adults.

In regard to comparing incident reports for different classes of products, we believe the public may be more inclined to report exposure to certain product types than others. For example, we believe that people are likely to report a possible exposure to a pesticide perceived to be dangerous, such as a rodenticide, especially if a child may have been exposed, even though only a small percentage of persons exposed turn out to have outcomes classified as related to the exposure. In contrast, the Agency believes that people are much less likely to call a poison control center about TRFs about possible exposure, unless they are actually experiencing discomforting symptoms. When TRF case narratives are available in the EPA incident data and those supplied by the Washington State report, virtually all report some symptoms. For this reason, a higher proportion of calls reporting TRF incidents may get a moderate to major rating, irrespective of the actual relative risk posed by TRF products.

- Petition states that TRFs are unsuitable for treating small-sized urban apartments.

Comment: This section of the petition (page 6) erroneously states that labels typically have the instruction "Use no more than one ounce per 1,000 cubic feet of space." In fact, we do not know of any label with that statement. The statement did appear as advice to consumers in an EPA website fact sheet on TRFs, but was removed when it was recognized as inappropriate and inconsistent with other label statements. TRF labels do have required language instructing that they not be used in a room smaller than 5 feet by 5 feet, and not to use more than one fogger per room.

Currently, the standard size of a TRF is 6 ounces, and the label will typically state that it is capable of treating up to 6,000 cubic feet of unobstructed space. The petition states that a room or apartment of less than 6,000 cubic feet can not "tolerate" a typical six ounce TRF. The petition is apparently confused about the meaning of the statement of capacity. The 6,000 cubic foot figure is meant to describe the upper limit of effective application and is not a safety threshold. Our risk assessments show that there are substantial margins of safety from acute toxicity levels of concern if a six ounce TRF unit is discharged, for example, in a small apartment as described in the petition (800 square feet with a 7 foot ceiling, or 5600 cubic feet), or even in a much smaller space such as a room measuring 10 by 10 feet with an 8 foot ceiling. The Agency does agree with the petition that describing the treatment capacity in cubic feet or expecting users to calculate in those terms is not realistic and may cause confusion that could contribute to misuse incidents.

- Petition states that TRF incidents are underreported.

Comment: The petition suggests that available data should be multiplied by a factor of twenty (i.e., "fewer than 5% of medically consequential poisonings are reported," petition page 3). The Agency has not evaluated the articles cited to support this statement in the petition, but can generally agree that all incident reporting systems are to some degree inefficient and undercount incidents. However, we believe EPA assessments need to be based on actual data in order to be credible, and that it would be inappropriate to inflate the known data.

IV. EPA Response to Petition

A. The FIFRA Framework for Restricted Use Classification

FIFRA § 3(d)(1)(C) provides for a pesticide to be classified for restricted use "if [EPA] determines that the pesticide, when applied in accordance with its directions for use…or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment."

EPA regulations at 40 CFR 152.170 give more detailed criteria for making a FIFRA § 3(d)(1)(C) determination for an end-use product. A restricted use determination is appropriate when:

- The product exceeds certain defined toxicity thresholds or other pertinent evidence (e.g., use history or accident data) substantiates that the product poses a serious hazard that can reasonably be mitigated by restricting use. 40 CFR 152.170(a), (d);
- Neither current labeling nor potential alternative labeling is adequate to mitigate these hazards. 40 CFR 152.170(a)(2), (e);
- Restriction of the product would decrease the risk of adverse effects. 40 CFR 152.170(a)(3); and
- The decrease in risks of the pesticide as a result of restriction would exceed the decrease in benefits. 40 CFR 152.170(a)(4).

Thus, when deciding whether to classify a product for restricted use, the Agency considers the toxicity of the product (along with other pertinent evidence of hazard) and, if any serious hazards that could reasonably be mitigated by restricting use are identified, examines whether labeling could adequately address those hazards. The Agency then weighs the seriousness and magnitude of the relevant risks and considers whether restricting use is an appropriate means of reducing those risks, taking into account the loss of the benefits the products offer by being available to the general public.

B. Assessment of TRF Toxicity and Incident Data

1. **Comparison of TRF hazard with restricted use hazard criteria**

EPA regulations provide for consideration of restricted use classification if a pesticide meets certain hazard criteria listed at 40 CFR 152.170(b). Toxicity values are determined for individual products as formulated for use, and thus vary among the approximately 150 registered products. For products intended for residential and institutional use, the main threshold values are:

- Acute oral LD50 (average lethal dose) of 1.5 grams/kilogram bodyweight or less;
- Acute dermal LD50 of 2000 mg/kg or less; and
- Acute inhalation concentration (LC50) of 0.5 mg/liter or less.

The petition does not claim that any TRF product meets the toxicity criteria for restricted use consideration. EPA has registered about 150 individual TRF products without finding that restricted use classification was appropriate or needed to address risk concerns. The reregistration reviews of the TRF active ingredients did not identify any concerns for chronic, subchronic or delayed toxic effects associated with residential uses, including, but not limited to, TRFs.

2. Incident Data: Severity of incidents

The Agency reviewed the NYC PCC data provided in the petition, the MMWR article, data provided by the Washington State Department of Health, the Agency's own incident data files going back to 1992 (largely consisting of incident reports from registrants required by section 6(a)(2) of FIFRA), and national data from the American Association of Poison Control Centers (AAPCC) for a six year period. The Agency reached the following conclusions on the severity and scope of TRF incidents.

All of the databases examined show the overwhelming majority of incidents with known outcomes are rated as minor, with short-term, reversible acute symptoms such as respiratory distress, dizziness or nausea.

- The petition rated severity somewhat higher than other sources, with 26% in the moderate category and 2.3% (6 cases) listed as severe. As noted earlier, this may be due to rating only cases with known medical outcome.

- EPA evaluates the national AAPCC data as showing 7.8 % in the moderate or severe categories. EPA believes it is appropriate to consider both cases classified with certainty (i.e., known medical outcomes) and cases classified with less certainty by poison control centers, since all reported cases signal potential exposures and outcomes, and underreporting is an acknowledged issue with this type of data. Thus the number of cases counted is larger, but the proportion of those rated as moderate or serious is relatively smaller.

- There does not appear to be a confirmed human fatality case in any of the data bases. The MMWR report cited one fatality considered suspicious. The AAPCC data includes one reported fatality; we believe it is different from the MMWR case, but details are not available. EPA's incident files listed 6 fatalities associated with foggers, but upon examination of the case files, none had a plausible connection to fogger exposure.

- Data on fires or explosions are very limited, but there are no known deaths. Some incidents have apparently involved serious damage to homes, but incident reports rarely specify a level of damage.

3. **Frequency of Incidents**

The Agency believes that the data presented in the petition as well as the other sources examined do not show that the occurrence of adverse incidents can reasonably be characterized as frequent or widespread in view of the numbers of TRFs used annually.

TRF manufacturers have provided a rough estimate of around 50 million units produced annually in the U.S. Since foggers are sold in packages rather than individual units, the calculation below is based on estimated sales of 15 million packages, not individual units. EPA used national poison control center (AAPCC) data to compare with sales estimates.

- Total incidents reported represent about 0.04% of TRF sales. Total incidents resulting in known medical outcomes represent about 0.02% of TRF sales. Total incidents resulting in medical outcomes of moderate or major severity represent about 0.0014% of TRF sales.
- This means that for every ten thousand TRF sales about 2 result in an incident with a known medical outcome and about 1 in a hundred thousand in moderate or major symptoms. This does not appear to be a frequent rate of misuse or accidents associated with a consumer pesticide product.
- There are no national data on TRF incidents for fires and explosions. However, if the 4 percent contribution of fires to total incidents that we find in both EPA and the MMWR data is indicative, we can roughly estimate that fire/explosion incidents occur in a range representing between 0.0016% and 0.0008% of TRF sales or between one in a hundred thousand and one in a million.

C. Would improved labeling adequately mitigate TRF risks?

One of the criteria for determining if restricted use classification is appropriate is a determination that labeling changes are inadequate to address the risk concerns. The petition takes the general position that incidents are essentially the result of users not reading the label, and it does not discuss or offer recommendations for label improvements. The Agency recognizes that some adverse incidents associated with TRFs, as well as for all other types of pesticide incidents, are due to users not reading or not obeying label instructions and precautions. Label improvements obviously cannot be expected to mitigate the occurrence of such incidents. However, it is also likely that many other incidents are essentially inadvertent on the part of the user, and result from not understanding or not noticing specific precautions. Both the MMWR article and the Washington State Department of Health report felt this to be the case and made various recommendations for label improvements.

The MMWR makes the general recommendation: "TRF labels should be improved to make information easier to find and understand." It then recommends: (1) a plain English description of the treatment area that does not rely on user calculations of cubic feet of volume, (2) time-delayed activation of foggers to better allow users to vacate before discharge, and (3) posting notification that premises are being fogged. Similarly, the Washington State report also recommended clarification of the treatment area, as well as smaller TRF unit sizes, and stronger warnings to vacate the premises and not breathe TRF vapors.

The petition and the MMWR report both estimate a percentage of incidents associated with specific causes. Both reports indicated that about a third of all incidents resulted from a failure to vacate the premises immediately upon discharging a fogger, or failure to completely leave the premises at all. When incidents resulting from early reentry and failure to air out (labels typically direct user to leave premises for 2 to 4 hours and then to air out treated premises for a half hour) are accounted for, nearly half of the incidents reported were attributable to not properly vacating and airing out the premises as the labels direct.

The Agency examined numerous TRF labels in the light of the causes described in the petition and reports and concluded that the following improvements will mitigate the risks of product use:

- Labels should use simple terms to describe the area that a TRF unit can treat, and not require computation of cubic feet for the treated area. For example "One fogger is enough to treat a room up to x feet by y feet with an 8 foot ceiling."

- In general, EPA found that TRF labels are inconsistent in their quality of organization for ease of reading by the user. Some labels are well organized with large headings such as "before you fog", "to start fogging" and "after you fog" with short blocks of text and pictograms that illustrate the procedures. Others are almost entirely small print text, such that directions and precautions are hard to find and read. Improved organization will make users more likely to understand

and observe the product labeling. EPA's conclusion is consistent with the recommendations of the MMWR report.

- EPA found that most labels give the instruction to "vacate immediately" in a block of text, and in small type. Only a few employ a clock-face pictogram to show the period of time one should stay out of the treated premises. Prominent instructions to vacate and identifying the time period in a prominent manner including a clockface pictogram, would be a significant improvement to help address the leading causes of inadvertent exposures.

- The MMWR report also identified "failure to tell others" as a cause of about 10% of incidents. In these cases, it is usually family members or friends with access who enter a treated area, unaware fogging has taken place. No current label has an instruction to inform others. Adding a label precaution to inform others will help prevent such incidents, and also reinforce the importance of vacating. The Agency is calling for manufacturers to include a hanging door tag with their products that warns visitors the premises have been treated and not to enter.

These labeling improvements are an adequate alternative to restricted use classification for a variety of reasons. First, they will not require users to perform complex operations or procedures requiring specialized training or experience. To the contrary, the labeling improvements will ask the user to compare the room dimensions to the appropriate room dimensions specified on the label, to vacate the premises for a fixed period of time, and to warn others of the TRF use. Second, the labeling improvements will not call for the user to employ any specialized apparatus, protective equipment, or materials unavailable to the general public. The only materials that the labeling improvements will call for will be the pesticide product itself and a warning door knob hang tag. Third, TRF use consistent with the labeling improvements, or use that deviates in minor ways from the instructions in the labeling improvements, is expected to result in few or no significant adverse effects. Finally, neither the incident data submitted by the petitioner nor the other data available to EPA indicate the existence of a widespread and commonly recognized use practice such that unreasonable adverse effects on the environment might occur. The available incident data do not demonstrate that TRFs generally cause unreasonable adverse effects. To the contrary, the majority of reported incidents are minor, and are infrequent in relation to the level of TRF use.

D. Would restricted use classification mitigate risk?

Once a pesticide has been classified for restricted use, in general it may only be applied by or under the direct supervision of a certified applicator. Because TRF products are designed and marketed for use directly by consumers, EPA believes that restricted use classification would effectively eliminate the market for TRF products.

Effectively eliminating TRF products through a restricted use classification would indeed reduce or eliminate risks to consumers from TRF use. However, EPA is not confident that this action is likely to achieve a net reduction in risk to the affected consumers. As

the petition points out, there is currently a significant market for low-cost, residential insecticides. EPA believes that eliminating TRF products from this market could trigger substitution effects that present counter-balancing risks:

- EPA's Region 2 Office in New York has tried for years, just as the petitioner's agency has, to stem the use of illegal pesticides in the area. EPA believes that making TRFs unavailable to the general consumer could exacerbate the use of illegal pesticide products, especially in the urban consumer markets of particular concern to the petitioner. Some of these illegal products are formulated with highly toxic agricultural insecticides such as aldicarb and carbofuran.

- EPA believes that the elimination of TRFs from the general consumer market could trigger an increase in the use of the alternative low-cost residential insecticides that would remain legal for general consumer use. Aerosol sprays are formulated with the same family of active ingredients (pyrethrins and synthetic pyrethroids) as TRFs and have similar toxicity values, however, the sprays released are more concentrated (i.e., large droplets that wet sprayed surfaces) compared to the fine mist released by a TRF, and since the spray can be directed only to a localized area, more material is likely to be applied to achieve pest control in a room or apartment. Thus, a shift from TRFs to alternative legal products would not necessarily result in a net reduction in risk, since aerosol space sprays are just as subject to overuse as TRFs, and are sold in larger volume units.

E. Benefits of TRFs

TRFs are an economical means of pest control and the registrations are supported by efficacy testing data.

- As the petition notes, TRFs are an alternative to professional pest control.
  - A TRF unit can treat an apartment for as little as $3.00.
  - A professional crack and crevice treatment will generally cost over $100.
- TRFs are supported by efficacy data which show good control for fleas and moderate control for roaches. The EPA guideline for testing residential aerosols, including TRFs, calls for 90% kill in the treatment time stated on the label. If residual claims are made, treated surfaces must continue to show 90% control over the period claimed on the label (e.g., 8 or 12 weeks).
  - The petition refers to "likely poor efficacy", but offers no evidence to support the statement.
  - EPA recognizes that efficacy under conditions of urban multi-unit housing, especially for non-residual pyrethrins, may be of limited duration before reinfestation takes place. However, for residents who can achieve relief, rapidly and at low cost, TRFs may be considered to offer a significant benefit.

F. Risk-Benefit Analysis

The question before the Agency is whether the weight of evidence available to us meets the criteria for restricted use classification, namely:

- Product use poses a serious hazard that can be reasonably mitigated by restricted use classification;
- Labeling is not adequate to mitigate these hazards;
- Restriction would decrease the risk of adverse effects; and
- The decrease in risks of the pesticide as a result of restriction would exceed the decrease in benefits.

The Agency is not persuaded that the evidence meet any of these criteria.

- The toxicity and incident data do not support a finding that TRFs pose a serious hazard. By a large margin, the majority of TRF incidents are minor, and are infrequent in relation to the level of product use.

- Labeling improvements are adequate to mitigate TRF hazards. While some misuse and inadvertent exposure will continue to occur despite labeling improvements, EPA does not believe that such risks warrant restricted use classification, given that the risks posed by current use, without the labeling improvements, are already below the level that would warrant restricted use classification.

- It is not clear that restriction of TRFs would reduce overall risks for consumers, since it is possible such an action would drive the consumers to use products that present equivalent or greater risk concerns.

- Restricted use would eliminate the benefits of TRFs as a low-cost means of home pest control for people, including low-income minorities, who can least afford alternatives. For the reasons described above, EPA does not believe that TRF use presents a sufficient risk to warrant the loss of these benefits.

Conclusion

In the course of analyzing TRF issues for this response, the Agency has taken several actions to address some of the concerns raised in the petition and in the other reports on TRF incidents.

- EPA is calling for labeling changes for TRF products that use the active ingredients that have recently been through the reregistration process (accounting for nearly all TRFs). These amended terms will call for the label improvements

generally discussed in this response letter: namely, improved organization and presentation of use instructions, use of certain pictograms to illustrate use procedures and precautions, simple terms describing the treatment area, prominent instructions to vacate and stay out for the proper time with a pictogram to illustrate the time period, and a new instruction to inform others of the treatment via a door knob hang-tag instructing people to stay out until a specified time. Attachment A is the document sent to TRF registrants concerning these improvements.

- Use of TRFs for bedbug control was not raised as an issue in the petition or the other reports, however, it is a concern to EPA because the widespread resurgence of bedbug infestations may lead consumers to use or overuse ineffective and inappropriate pesticides, potentially including TRFs. Most experts agree that TRFs, as typically deployed by consumers, would not offer effective control of a bedbug infestation. In addition, bedbugs are developing resistance to the pyrethroid insecticides, and this effect could be exacerbated by the use of foggers. To address this concern, EPA is calling for registrants to include a label statement to the effect that TRFs do not offer effective control of bedbug infestations. A registrant wishing to make bedbug claims on the label will need to provide appropriate data that supports the specific claim language.

- The Agency will continue to work with the TRF manufacturers to encourage a shift to smaller units, and to develop technical improvements like time-release mechanisms and non-flammable propellants. (One of the largest manufacturers has indicated that they will change their entire product line in 2010 to two-ounce units treating a more realistic 2,000 cubic foot residential space.)

Finally, the Agency recognizes that misuse of pesticide products is a perennial problem, and to the degree that misuse is due to outright refusal to read or obey the label, label improvements cannot prevent incidents from taking place. However, the data available to EPA do not indicate that the level of risk currently posed by TRFs, irrespective of root cause, is sufficient to warrant a restricted use classification. The label improvements and other ongoing EPA actions will further reduce the risks from TRF use.

For the reasons described above, the petition to EPA to classify total release foggers for restricted use is DENIED because the weight of evidence does not show that the products, when applied in accordance with their directions for use (or in accordance with widespread and commonly recognized practice) may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment.

By

Steven P. Bradbury, PhD., Acting Director
Office of Pesticide Programs

Attachment A

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 Control[1] 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 State[2] 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 data[6] 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]

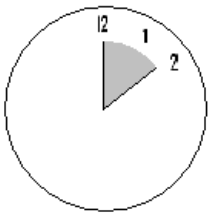
- Include the following phrase in a prominent place in the directions and in boldface type:
    - **"Vacate the treated house, individual apartment unit, or other structure immediately**"

- 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.