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



OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: February 16, 2010

SUBJECT: Total Release Fogger Assessment in response to New York City Department of Health and Mental Hygiene Petition

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I. CONCLUSIONS

The current review of Total Release Fogger (TRF) incident data indicates most TRF incidents appear to result from misuse, but are classified as low severity involving acute and reversible health effects. No fatalities have been definitively linked to these products, and severe incidents appear to predominantly result from gross misuse. Additionally, the data do not indicate these products pose a unique risk to children and/or pets.

II. ACTION REQUESTED

Review Total Release Fogger incident data to provide information regarding whether these products are appropriate for general public use (or should be restricted to use by certified applicators, as petitioned by the New York City Department of Health and Mental Hygiene). Additionally, consider whether the information indicates these products pose a unique risk to children and/or pets.

III. BACKGROUND

A class of consumer pesticide products known as Total Release Foggers (TRFs or “bug bombs”) has attracted concern and attention. In particular, the Centers for Disease Control and Prevention (CDC) published in the October 17, 2008 Morbidity and Mortality Weekly Report (MMWR) an analysis of illness and injuries related to TRF pesticide products. The report concludes that “TRFs pose a risk for acute, usually temporary health effects among users and bystanders. To reduce the risk for TRF-related health effects, integrated pest management control strategies that prevent pests' access to food, water, and shelter need to be promoted and adopted. In addition, awareness of the hazards and proper use of TRFs need to be better communicated on TRF labels and in public media campaigns.”

In response to the MMWR, the New York State Department of Environmental Conservation (NYS DEC) issued a statement indicating how NY State would be taking action to address risk from use of these products. Subsequently, on March 12, 2009 the New York City Department of Health and Mental Hygiene (NYC Health) petitioned the Environmental Protection Agency (EPA or Agency) to classify insecticidal foggers as restricted use pesticides (*i.e.*, restricted to use by certified applicators). Also, in July 2008 and May 2009 the Agency received letters from the Washington State Department of Agriculture and Department of Health, expressing similar findings and recommendations as outlined in the October 17, 2008 MMWR.

TRF products are assessed for their safety before being registered by the EPA. However, the Agency has taken risk mitigation actions in the past to improve the safety of these products. In 1998 EPA published a final rule “Flammability Labeling Requirements for Total Release Fogger Pesticides” as well as a pesticide registration notice on how to implement improved flammability warnings. Additionally, the Agency is planning to address some of the concerns raised about TRF labels via label changes with some of the popular active ingredients used in these products (*i.e.*, pyrethrins, tetramethrin, piperonyl butoxide, resmethrin, permethrin, MGK-264, d-phenothrin, and allethrin).

IV. RESULTS/DISCUSSION

The following are the main concerns, followed by the Agency’s consideration.

Concern 1 – Severity of TRF incidents

A primary concern of NYC Health was that an exposure to a TRF was likely to result in a medically consequential incident. NYC Health used New York City Poison Control Center

(NYC PCC) data from 2000 to 2006 to support their assertion. According to NYC Health, the percent of reported TRF incidents with known medical outcome is about 77%, and of these TRF incidents 28.5% are classified as resulting in moderate to severe medical outcomes. The Agency considered national poison control center data from the American Association of Poison Control Centers' National Poison Data System (AAPCC NPDS).^a The Agency, using AAPCC data, found the percent of reported TRF incidents with known medical outcome was about 45% for the years 2000 to 2005 (the Agency is in the process of obtaining the 2006 and 2007 AAPCC NPDS data). Of these TRF incidents, about 18% are moderate to severe medical outcome. However, when all TRF incidents are considered (including those where there is less confidence around the medical outcome, but judged a potential exposure), about 8% of TRF incidents result in a moderate to severe medical outcome. Although the NYC PCC and national AAPCC data are different in regards to severity, the symptoms most frequently reported as related to TRF incidents are similar (*i.e.*, coughing or choking, throat irritation, vomiting, nausea, vertigo or headache and difficulty breathing). See Appendix A for further details.

The Agency also considered incident information from the Office of Pesticide Programs Incident Data System (OPP IDS). Whereas AAPCC data are collected by trained professionals, IDS contains reports of alleged human health incidents from various sources, including mandatory reports from registrants, other federal and state health and environmental agencies and individual consumers. Unlike AAPCC, IDS incidents are often accompanied by a narrative. OPP does not draw firm conclusions regarding whether the pesticide exposure is causally associated with the reported health effects. Over the past 16 years, six fatal incidents and 51 serious incidents involving TRFs were submitted to OPP. Review of the narratives of the six fatalities indicates there is little to no evidence supporting an association between TRF exposure and death (for each incident and across incidents). Review of the serious incidents indicates misuse of foggers may cause health effects. See Appendix A for further details. These findings are similar to those articulated in the October 17, 2008 MMWR, which found TRF exposure may pose a risk for "acute, usually temporary health effects among users and bystanders," often resulting from misuse of the TRF product(s).

Concern 2 – Misuse, inappropriate use, and off-label uses of total release foggers are widespread

NYC Health reviewed case narratives of all reported NYC PCC incidents and identified 137 (37%) involved TRF misuse. The most common issues were failure to vacate, product used as an aerosol, early reentry, handled by a child and overuse of the product. The Agency does not have access to case narratives from AAPCC data, and therefore AAPCC data do not provide a high level of detail regarding how TRFs are misused. However, they do provide categories designating the reason for the exposure. The reasons for most TRF exposures in AAPCC are considered unintentional general or unintentional environmental exposures (78%). Unintentional misuse accounts for 16% of TRF exposures and intentional misuse accounts for 2%, but again, further details are not provided. See Appendix B for further information.

^a Although the Agency has access to AAPCC NPDS data, incidents do not contain information regarding which of the 61 poison control centers handled the incident.

NYC Health's observations are similar to the types of misuse identified in IDS and in the October 17, 2008 MMWR which reported TRF incidents "often resulted from inability or failure to vacate before the TRF discharged, reentry into the treated space too soon after the TRF was discharged, excessive use of TRFs for the space being treated, and failure to notify others nearby." NYC Health's observation that a common reason for misuse was handling by a child is addressed later in this document. When this misuse is considered in light of proprietary sales data, the issue does not appear widespread.

Concern 3 – TRFs are contraindicated in multi-unit dwellings

The Agency does not have information regarding the national (or NYC) TRF user population. However, to provide a very crude context, TRF incidents were compared to the populations of NYC and the US (assuming NYC represents a higher concentration of multi-unit dwellings as compared to the US). These are not only crude because the denominator is the entire population of NYC or the US, but also because incidents are known to be underreported (as pointed out by NYC Health in their petition), therefore, these proportions should only be considered relative to each other. After roughly correcting for population size, NYC does not appear to be disproportionately affected by fogger incidents compared to the US (0.0006% of NYC population and 0.002% of US population experience an incident with a fogger in a given year). See Appendix C for further information.

Concern 4 – Do TRFs pose particular risks to children or pets?

The various stakeholders concerned with TRFs did not focus on children and/or pets (although NYC Health pointed out that about 10% of the 37% of TRF incidents with label misuse involved children handling TRFs), however the Agency considered whether there are any trends/patterns regarding children and/or pets.

Considering AAPCC data (1993-2005), the majority of the incidents (94%) involved adults, 8% of which were designated as more severe, whereas about 1% of the incidents involving children were designated as severe. The designated reasons for exposure are not substantially different between adult incidents and children incidents, and do not indicate incidents involving children are a result of unintentional misuse (a category that could reflect children tampering with the products unintentionally).

The IDS incidents involving children did not appear to be associated with accidental triggering of the device. Many of these cases involved excessive use of the product in a small confined area and lack of appropriate ventilation. Again, these findings are similar to those identified in the October 17, 2008 MMWR.

In addition to considering children, the Agency considered pets. Pet incident data is available via IDS and the National Pesticide Information Center (NPIC). For both IDS and NPIC, the majority of TRF pet incidents involved owners leaving their pets in their home while the foggers were being activated, which is a misuse.

Conclusions

Based on the current review of TRF incident data, the data indicate the proportion of severe TRF incidents may be higher in NYC than nationally, although there appear to be fewer incidents per person in NYC than nationally. The data do not indicate these products pose a unique risk to children and/or pets. The data do indicate failure to follow the label (especially regarding amount used and re-entry instructions) can result in incidents with reported health effects; subsequently, the data do support efforts to clarify and convey the importance of following usage directions on labels. Although it is recognized that there have been serious/severe incidents with TRFs, as well as product misuse, the proportion of these exposures compared to those with minor and no effects indicate a majority of users are using the product safely.

References:

Wheeler et. al., 2008, Illnesses and Injuries Related to Total Release Foggers – Eight States, 2001-2006, Morbidity and Mortality Weekly Report, Vol. 57, No. 41, 10/17/2008.

Appendices:

Appendix A: Concern 1 – Severity of TRF incidents

NYC PCC and AAPCC Medical Outcome

NYC Health calculated the proportion of NYC PCC TRF incidents resulting in ‘any health effect’ (*i.e.*, incidents with known medical outcome) at 77% compared to all pesticides at 36%. The Agency calculated the proportion of AAPCC TRF incidents resulting in ‘any health effect’ at 45% compared to all pesticides, which was also 45%. NYC PCC TRF incidents appear to be coded more frequently with a known medical outcome, than other pesticide exposures, whereas nationally that does not appear to be the case.

NYC Health reported the proportion of NYC PCC TRF incidents resulting in moderate or major effects at 29%, compared to less than 12% for all pesticide incidents (*i.e.*, NYC PCC TRF incidents are about 3x as likely to result in a moderate or major effect). The Agency calculated the proportion of AAPCC TRF incidents resulting in moderate or major effects at 8% compared to 3% for all pesticide incidents (*i.e.*, AAPCC TRF incidents are about 3x as likely to result in a moderate or major effect). Both NYC PCC and AAPCC TRF incidents appear to be about 3x as likely to result in a moderate or major effect. Regardless, less than 10% of AAPCC incidents result in moderate or major effects (it is unclear why NYC PCC proportions are higher), and the narrative information we have (although not from AAPCC) indicates the more serious incidents are a result of frank misuse.

<i>NYC PCC as reported by NYC Health</i>	<i>NYC PCC TRF pesticide incidents</i>	<i>NYC PCC all pesticide incidents</i>
Unintentional TRF incidents (denominator)	100%	100%
Moderate or Major Effect	21.8%	< 12%
Minor, Moderate or Major Effect	59%	Not reported
Any Health Effect	77%	36%

<i>AAPCC Query details</i>	<i>AAPCC TRF pesticide incidents</i>	<i>AAPCC all pesticide incidents</i>
Unintentional TRF incidents (denominator)*	100% (33127)	100% (1361264)
Moderate or Major Effect**	7.8% (2574)	2.5% (33444)
Minor, Moderate or Major Effect***	35% (11752)	19% (260539)
Any Health Effect (Known Medical Outcome) ****	45% (15035)	45% (614124)

* TRF incidents identified as those containing *fogger* or *bomb* in product name and involving one substance; Reason for Exposure, codes: 1, 2, 3, 5 or 8

** Medical outcome codes: 2, 3 or 4

*** Medical outcome 1, 2, 3 or 4

**** Medical outcome 0, 1, 2, 3 or 4

AAPCC Medical outcome of incidents with *fogger* or *bomb* in product name, 2000-2005, involving one substance

Medical outcome	Count of associated incidents	%
Major effect (code 3)	52	0%
Moderate effect (code 2)	2696	8%
Minor effect (code 1)	9697	28%
No effect (code 0)	3422	10%
Other (not followed/judged nontoxic; not followed/minimal effects possible; unable to follow, judged potentially toxic; unrelated effect)	18897	54%

AAPCC Level of Healthcare provided to incidents with *fogger* or *bomb* in product name, 2000-2005, involving one substance, and resulting in a health effect (ie, medical outcomes minor, moderate, major or death)

Level of healthcare provided	Count of associated incidents	%
Admitted to psychiatric facility	13	0%
Admitted to critical care unit	92	1%
Admitted to noncritical care unit	98	1%
Patient lost to follow up/left AMA	294	2%
Patient refused referral/did not arrive at HCF	395	3%
Treated/evaluated and released	4036	32%
NULL	7517	60%

NYC PCC and AAPCC Symptoms

The most frequently reported symptoms (related to TRF exposures) are consistent in NYC and nationally.

Symptoms reported as related	NYC PCC (%)*	AAPCC (%)**
Coughing or choking	28.5	25
Throat irritation	15.1	10
Vomiting	16	8
Nausea	11.3	6
Vertigo or headache	7.3	7
Difficulty breathing	6.3	8
Eye irritation or pain	Not reported	6

* NYC Poison Control Center data, TRF incidents 2000-2006, as reported by NYC Health in petition to EPA

** AAPCC data, TRF incidents 2000-2005

IDS Severity Assessment

The IDS query for incidents involving “foggers” or “bombs” pulled up 9 fatalities and 51 “serious” injuries over the past 16 years. The 9 fatalities reported in the IDS aggregate summary were reviewed individually. They represent 6 fatalities (there were duplicate records). None of the 6 fatalities indicate that fogger use is causing people to die. However, a review for the 51 “serious” injuries indicates misuse of foggers may cause effects.

Details of 6 fatalities associated with ‘fogger’ or ‘bomb’ incidents:

- 3 year old child locked in a tent set outside of a house where fogger was applied; cause of death most likely heat stroke/hyperthermia (2003, Raid Concentrated Deep Reach Fogger EPA Reg. No. 4822-452, Raid Yard Guard Outdoor Fogger Formula VII, EPA Reg. No. 4822-394, Raid Fumigator Fumigating Fogger EPA Reg. No. 4822-278)
- A female of unknown age died 3 days after foggers were used in long-term care facility dining room; others got sick as well – symptoms suggest infection rather than pesticide poisoning, as does the delayed onset from exposure (2003, Raid Concentrated Deep Reach Fogger EPA Reg. No. 4822-452)
- A 49 year old man entered neighbor’s house that had been treated with a fogger (exposed for maybe 10-15 minutes); came home with no known symptoms, 11 hours later he died; History of drug abuse and alcohol and tobacco use. Cause of death unknown – but disconnect between exposure and death indicate the fogger exposure is an unlikely cause (2001, Patrol One Insect Fogger)
- A 46 year old male died after re-entering home treated with fogger (4 hours after); he developed a cough and then collapsed 3 hours later. He was obese, and previous night he had experienced chest pain; medical examiner thinks death was due to cardiac complication and obesity. Other conditions indicate the fogger is an unlikely cause (2000, Raid Concentrated Deep Reach Fogger EPA Reg. No. 4822-452)
- A 33 year old man committed suicide with a gun 6 months after exposure to a fogger (1994, Yardguard Outdoor Fogger EPA Reg. No. 4822-56)
- A woman of unknown age died after using 2 foggers in her basement. She had been sick with bronchitis 13 days prior, complained of flu symptoms the morning before setting off foggers, and has a history of health problems (chest pains; family history of coronary artery disease); husband found her unconscious on couch when he came from work; ER revived her, but she died the next day. Cause of death unknown – but pre-existing conditions indicate the fogger exposure is an unlikely cause (1992, Flea Fogger)

Appendix B: Concern 2 – Misuse, inappropriate use, and off-label uses of total release foggers are widespread

NYC PCC and AAPCC Misuse

NYC PCC

Of the 37% (137) with known label issues, the most common were:

- Failure to vacate (36.4%)
- The product was used as an aerosol rather than a TRF (16.4%)
- Early reentry (16.3%)
- Handled by a child (10.7%)
- Overuse of product (8.5%)

AAPCC Reason for exposure designations for incidents with *fogger* or *bomb* in product name, 2000-2005, involving one substance

Reason for exposure	Count of associated incidents	%
Unintentional-General	20376	59%
Unintentional-Environmental	6670	19%

Reason for exposure	Count of associated incidents	%
Unintentional-Misuse	5514	16%
Adverse rxn-Other	633	2%
Intentional-Misuse	545	2%
Unintentional-Occupational	494	1%
Other-Contamination/tampering	104	0%
Intentional-Suspected Suicide	90	0%
Other-Malicious	79	0%
Unintentional-Unknown	73	0%
Unknown reason	64	0%
Intentional-Unknown	47	0%
Intentional-Abuse	22	0%
Unintentional-Food poisoning	18	0%
Adverse rxn-Drug	10	0%
Unintentional-Bite/sting	10	0%
Unintentional-Therapeutic error	9	0%
Adverse rxn-Food	6	0%

Note: Although the “Reason for exposure” is predominantly “Unintentional-General” and “Unintentional-Environmental,” the Agency believes most of these involve improper use, such as failure to vacate and early re-entry. Incident data that include narrative information suggest this, and it is not expected that AAPCC Specialists in Poison Information are familiar with label directions for TRFs.

AAPCC Exposure site of incidents with *fogger* or *bomb* in product name, 2000-2005, involving one substance

Exposure site	Count of associated incidents	%
Own residence	32075	92%
Other residence	1461	4%
Workplace	780	2%
Other	188	1%
Public Area	149	0%
School	44	0%
Unknown	40	0%
Restaurant/food service	19	0%
Health care facility	8	0%

Appendix C: Concern 3 – TRFs are contraindicated in multi-unit dwellings

NYC versus US proportion of TRF incidents

In their petition, NYC Health reports 443 calls to the New York City Poison Control Center (NYC PCC) regarding foggers from 2000-2006, 344 of which involved exposures (incidents). Using recent census data, these incidents indicate on average about 0.0006% of NYC’s population experienced an incident with a fogger in a given year. Assuming these incidents only represent 5% of all incidents, the estimate would be 0.01%. Using the American Association of Poison Control Centers’ National Poison Data System (AAPCC NPDS) the Agency identified 36,637 incidents from 2000-2005 with *foggers* or *bombs* in product name (these incidents are not limited by the number of substances associated with the incident; however, about 95% of

these incidents involved one substance). Using recent census data, these incidents indicate on average 0.002% (0.04% if AAPCC NPDS incidents capture only 5% of all US incidents) of the US population experience an incident with a pesticide fogger or bomb product. Comparing these proportions indicates that NYC (which has a concentration of multi-unit dwellings) is not disproportionately burdened with TRF incidents.

0.0006% of NYC population – 50 incidents per year/8,000,000 people
 0.002% of US population – 6100 incidents per year/304,000,000 people

US Population

2008: 304,059,724
 2000: 281,421,906
 1990: 248,709,873

NYC Population

2007: 8,274,527
 2000: 8,008,278
 1990: 7,322,564

Source:

http://factfinder.census.gov/servlet/SAFFPopulation?_submenuId=population_0&_sse=on

Appendix D: Concern 4 – TRFs are particularly harmful to children and/or pets

Children and pets

Incident Databases Reviewed:

- PCC: identified incidents by querying for the word “fogger” and/or “bomb” in the product name; children defined as 12 years and younger; all incidents are considered (as the database lends itself to summary analysis)
- IDS: identified incidents by querying for the word “fogger” and/or “bomb” in the product name; deaths and major incidents are considered, as high severity incidents are generally of greater concern
- NPIC: identified cases involving foggers; cases identified as “major/probable/possible” are considered, as this subset should provide a good indication on whether there is an existing trend or pattern (minor and unlikely are not considered)

The tables below provide the results for the different populations by databases. Overall, the data do not indicate a heightened concern for children or pets compared to adult cases. The review generally supports the findings in the October 17, 2008 MMWR.

TRF incidents involving children and adults

Database	Cases	Adult%	Children%	Severity Of Effect
AAPCC 1993-2005	73,925	94%	6%	Low severity overall, children incidents less severe (proportionately), unintentional misuse accounted for ~13%, unintentional general/environmental for ~80%
IDS 1992-2008	51*	81%	15%	Reversible effects: vomiting, hives, fever, rash, respiratory effects
NPIC 2003-2008	99*	95%	~5%	Reversible effects: vomiting, choking, wheezing, gagging, hives, diarrhea
MMWR reported 2001-2006	466	Median age of affected persons was 35 years (range 0-90years); 67% (adults) were exposed at work. Three cases involved pregnant women. 80% of all these cases were classified low severity. One death noted in 10 month old infant put to bed in apartment previously treated with three		

		TRFs, classified suspicious.
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*reflects IDS major cases (as there were no IDS death incidents for foggers and children, after case review); NPIC cases considered probable/ possible were included.

PCC reported 73,925 fogger or bomb related incidents. The majority of these incidents (94%) involved adults. There was one adult death reported (female, unknown reason for exposure, exposure site unknown). 8% of the adult incidents designated as “major” or “moderate” medical outcome, and about 1% of the children incidents were designated as “major” or “moderate” medical outcomes (the rest of the medical outcomes are minor, no effect or possibly minor/no effect). The “Reason for Exposure” designations are not substantially different between adult incidents and children incidents, and do not indicate incidents involving children are a result of ‘unintentional misuse’ (a PCC category that would reflect children tampering with the products unintentionally).

The IDS and NPIC incidents involving children did not appear to be associated with accidental triggering of the device. Many of these cases involved excessive use of the product in a small confined area and lack of appropriate ventilation.

TRF incidents involving domestic animals

Database	Total Cases	Fatality %	Major/Moderate%
Incident Data System (IDS) 1992-2008	1394*	12%	4%
NPIC 2003-2008	18	Unknown	Not available -Many of these cases ranged from no symptoms to lethargy, and breathing difficulties

* Total for unique cases in IDS

For both IDS and NPIC, the majority of TRF pet incidents involved owners leaving their pets in their home while the foggers were being activated, which is a misuse.