

December 22, 2009

Anthony Britten Section 18 Team Leader U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, DC 20460–0001

Dear Mr. Britten,

It has come to our attention that the Ohio Department of Agriculture has requested the agency to allow an unregistered use of the neurotoxic and cancer causing insecticide propoxur under Section 18 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for use in residential settings to fight bed bugs, in what state officials are describing as an 'emergency' situation.

Bed bugs (*Cimex lectularius and C. hemipterus*) have become a serious pest control problem in many states across the United States. Bed bugs have rebounded in significant numbers, infesting apartment buildings, college dormitories, hospitals, homeless shelters and even top-rated hotels. Bed bug outbreaks have been reported in at least 27 states, including Honolulu, San Francisco, Cincinnati, Chicago, Houston and Miami. Persistent outbreaks are normally concentrated in low-income neighborhoods, where people cannot afford to replace or professionally clean bedding and soft furnishings. This growing pest control problem prompted the agency to convene the first ever National Bed Bug Summit (April 14-15, 2009) to solicit recommendations from scientists, state and local officials, pest control operators and the general public on how to tackle the resurgence of the blood sucking insects. From this meeting, stakeholders submitted recommendations<sup>1</sup> to the agency for combating the bedbug resurgence. Some of these include:

- Formulate integrated pest management (IPM) strategies
- Create a tracking system/clearinghouse for data
- Regulations for addressing recycled/refurbished mattresses; dealing with infested items
- Provide funding: research, education, training

<sup>&</sup>lt;sup>1</sup> USEPA. 2009. EPA's National Bed Bug Summit-Participant Recommendations. Available at <u>http://www.epa.gov/oppfead1/cb/ppdc/bedbug-summit/index.html</u>

- Recognize bed bugs as public health pest (classify as epidemic level)
- Consumer education and the use of public service announcements: TV, web, radio, billboard, hotlines
- Standardize PCO training
- Mandate IPM certification for bed bug control

It should also be noted that among these recommendations is the need for more efficacious chemicals. Stakeholders commented that less effective chemicals are applied more frequently, and EPA should consider more efficacious chemicals that can be applied less frequently. Given that chemical treatment has become less and less efficacious at controlling bedbugs, it is sensible that other alternatives, besides chemicals, be found. IPM practices offer the best long-term strategy for bed bug population control. As can be seen from recommendations of EPA's National Bed Bug Summit, stakeholders are of the opinion that IPM is the best solution.

#### **Growing Resistance**

Various broad spectrum insecticides have been used over the years to control bed bugs. Insecticides which kill common household insects -- such as cockroaches and ants -exposed bed bugs to a range of chemicals and allowed them to gradually build up resistance to these chemicals. As such, chemicals that were once effective at controlling bed bugs are no longer efficacious. Examples include esfenvalerate and other widely used synthetic pyrethroids.

#### Propoxur

The Ohio Department of Agriculture has requested the use of propoxur for the control of bed bugs in what the state has deemed an "emergency" situation. Propoxur (o-isopropoxyphenyl methylcarbamate), known by the trade name Baygon, is a carbamate insecticide first registered for indoor applications and very limited outdoor applications. It is also used on pets as a spray and in flea and tick collars.<sup>2</sup> According to EPA, propoxur is moderately toxic (Toxicity Category II) for oral exposure and slightly toxic (Toxicity Category III) via the dermal and inhalation routes of exposure.<sup>3</sup> Propoxur is classified as a probable human carcinogen (Group B2) by EPA,<sup>4</sup> and the state of California<sup>5</sup> lists it as a known human carcinogen. In 1988, prompted by concern over the carcinogenic risks for occupational exposures, EPA considered initiating a Special Review for propoxur. In 1995, the agency decided not to conduct the review, citing that the uses that posed the greatest concern (flea dips and shampoos for pets, and total-release fogger products) had been eliminated through voluntary cancellation or label amendment. Again in February 2007, the agency granted a request from the registrant for voluntary cancellation of "all propoxur indoor spray uses [including use in crack and crevices] that may result in non-occupational

<sup>&</sup>lt;sup>2</sup> USEPA. 1997. Reregistration Eligibility Decision (RED) Document. Office of Prevention, Pesticides and Toxic Substances. Washington DC.

<sup>&</sup>lt;sup>3</sup>Ref #2

<sup>&</sup>lt;sup>4</sup> Ref#2

<sup>&</sup>lt;sup>5</sup> OEHHA. Proposition 65 List of Chemicals. CA Environmental Protection Agency. Available at <u>http://www.oehha.ca.gov/prop65/prop65\_list/Newlist.html</u>

exposure for children."6

Also in 2007, the agency completed its cumulative risk assessment for N-methyl carbamates chemical class, of which propoxur is a member.<sup>7</sup> This was done after the agency concluded in 2004 that the N-methyl carbamate pesticides share a common mechanism of toxicity - cholinesterase inhibition. The N-methyl carbamates have been among EPA's highest priority pesticides for review.

Propoxur, like others in its chemical class, is classified as highly toxic.<sup>8</sup> Symptoms of propoxur poisoning include nausea, vomiting, abdominal cramps, sweating, diarrhea, excessive salivation, weakness, imbalance, blurring of vision, breathing difficulty, increased blood pressure or 'hypertension' and incontinence. Death may result from respiratory system failure associated with propoxur exposure. In rats, propoxur poisoning resulted in brain pattern and learning ability changes at lower concentrations than those which caused cholinesterase-inhibition and/or organ weight changes.<sup>9</sup> Chronic (long-term) inhalation exposure has resulted in depressed cholinesterase levels, headaches, vomiting, and nausea in humans. Chronic ingestion studies in animals have reported depressed cholinesterase levels, depressed body weight, effects to the liver and bladder, and a slight increase in neuropathy.<sup>10</sup> Studies have shown that propoxur is also a mutagen, a reproductive effector and it has been found to affect the immune and endocrine systems.<sup>11</sup>

## Dangers of Indoor Propoxur Use

The main route of exposure to propoxur is through the dermal and inhalation route. Propoxur is detected and persists in indoor air<sup>12</sup> and dust.<sup>13</sup> On surfaces, pesticide residues can persist for 60 hours or longer.<sup>14</sup> One study found that airborne concentrations were still detectable 33.5 hours after spraying propoxur indoors.<sup>15</sup> Another determined that the volatilization of propoxur from treated surfaces increased with humidity, resulting in higher air concentrations of propoxur.<sup>16</sup> In a study investigating indoor-air insecticide levels in inner-city residences, propoxur was found in over 90% of indoor air samples of homes with

<sup>9</sup> EXTOXNET. 1993, 1996, Pesticide Information Profile

<sup>&</sup>lt;sup>6</sup> USEPA. 2007. Notice of Receipt of Requests for Amendments to Delete Uses in Certain Pesticide Registrations,[EPA-HQ-OPP-2007-0244; FRL-8125-6].

<sup>&</sup>lt;sup>7</sup> USEPA. 2007. Revised *N*-Methyl Carbamate Cumulative Risk Assessment. Office of Pesticide Programs. Washington DC. <sup>8</sup> EXTOXNET. 1993, 1996. Pesticide Information Profile- Propoxur; Kegley, S.E., Hill, B.R., Orme S., Choi A.H., *PAN Pesticide Database*, Pesticide Action Network, North America (San Francisco, CA, 2009), http://www.pesticideinfo.org.

<sup>&</sup>lt;sup>10</sup> USEPA. 2000. Propoxur(Baygon) Hazard Summary Factsheet. TTN Air Toxics Website. Available at http://www.epa.gov/ttn/atw/hlthef/propoxur.html#ref4

<sup>&</sup>lt;sup>11</sup> NIOSH. 2009. Carbamic acid, methyl - o -isopropoxyphenyl ester. RTECS #: FC3150000. Available at http://www.cdc.gov/niosh/rtecs/fc3010b0.html

http://www.cdc.gov/niosh/rtecs/fc3010b0.html <sup>12</sup> Esteve-Turrillas FA, et al. 2009. Use of semipermeable membrane devices for monitoring pesticides in indoor air. *J AOAC Int*. 92(5):1557-65; Leva P et al. 2009. Evaluation of the fate of the active ingredients of insecticide sprays used indoors. *J Environ Sci Health B*. 44(1):51-7.

<sup>&</sup>lt;sup>13</sup> Colt JS et al. 2004. Comparison of pesticide levels in carpet dust and self-reported pest treatment practices in four US sites. *J Expo Anal Environ Epidemiol*. 14(1):74-83.

<sup>&</sup>lt;sup>14</sup> Class, TJ and Kintrup, J. 1991. Pyrethroids as household insecticides: analysis, indoor exposure and persistence. *Fresenius' Journal of Analytical Chemistry*. 340:446-453.

<sup>&</sup>lt;sup>15</sup> Kuo HW and Lee HM. 1999. Volatility of propoxur from different surface materials commonly found in homes. *Chemosphere*. 38(11):2695-705.

<sup>&</sup>lt;sup>16</sup> Miller, C. W. and Shafik, T. M. 1974. Concentrations of propoxur in air following repeated indoor applications. *Bull World Health Organ*. 51(1): 41–44.

pregnant women.<sup>17</sup> Inhalation studies have found that the effects of propoxur exposure were depressions of plasma by 20 to 30%, and of erythrocyte and brain cholinesterase activities.<sup>18</sup> Dermal absorption studies,<sup>19</sup> which have shown that propoxur is absorbed through the skin, also find that skin moisture (affected by high temperatures and humidity) influences the dermal uptake of propoxur.<sup>20</sup> A dermal LD<sub>50</sub> study with laboratory rats found that on the day of application of propoxur on skin, muscular fasciculations suggestive of cholinesterase inhibition were observed along with decreased motor activity.<sup>21</sup>

Various monitoring studies have confirmed that indoor residential pesticide applications increase the exposure and health risks of residents, especially infants. Indoor residues of pesticides have been detected in carpets, hard surfaces, walls and dust. In a study with inner city underserved mothers and newborns, propoxur levels were significantly higher in the personal air of women reporting use of an exterminator, can sprays, and/or pest bombs during pregnancy compared with women reporting no pesticide use or use of lower toxicity methods.<sup>22</sup> Humans exposed to indoor concentrations of propoxur resulting from indoor application are therefore at risk for short and long term effects mentioned above, including increased risk of developing cancer. Children are particularly at risk from this pesticide because their neurological and metabolic systems are still developing. These risks increase due to hand-to-mouth activities,<sup>23</sup> along with increased dermal and inhalation exposures since they take in more pesticides relative to their body weight than adults.<sup>24</sup> Studies of carbamates have found greater sensitivity of the young to these insecticides.<sup>25</sup> Researchers warn that exposure to cholinesterase inhibiting compounds, like propoxur, following broadcast applications, could result in doses at or above the threshold of toxicological response in infants, and should be minimized.<sup>26</sup>

<sup>&</sup>lt;sup>17</sup>Whyatt, RM et al. 2007. Within- and between-home variability in indoor-air insecticide levels during pregnancy among an inner-city cohort from New York City. *Environ Health Perspect*. 115(3):383-9.

<sup>&</sup>lt;sup>14</sup>Kimmerle G and Iyatomi, A. 1976. Toxicity of propoxur to rats by subacute inhalation. *Sangyo Igaku*. 18(4):375-82; Pauluhn J, Machemer L and Kimmerle G. 1987. Effects of inhaled cholinesterase inhibitors on bronchial tonus and on plasma and erythrocyte acetylcholine esterase activity in rats. *Toxicology*.46(2):177-90.

<sup>&</sup>lt;sup>19</sup> van de Sandt, J. et al. 2000. Comparative in Vitro–in Vivo Percutaneous Absorption of the Pesticide Propoxur. *Toxicological Sciences*. 58:15-22; Brouwer, R. et al. 1993. Skin contamination, airborne concentrations, and urinary metabolite excretion of propoxur during harvesting of flowers in greenhouses. *Amer. J. of Industrial Medicine*. 24(5):593-603.

<sup>&</sup>lt;sup>20</sup> Meuling, W.J.A, et al. 1997. The influence of skin moisture on the dermal absorption of propoxur in human volunteers: a consideration for biological monitoring practices. *Science of The Total Environment* 

<sup>199 (1-2):165-172</sup> 

<sup>&</sup>lt;sup>21</sup> Ref #2

<sup>&</sup>lt;sup>22</sup> Whyatt, RM, et al. 2003. Contemporary-use pesticides in personal air samples during pregnancy and blood samples at delivery among urban minority mothers and newborns. *Environ Health Perspect*. 111(5): 749–756.

 <sup>&</sup>lt;sup>23</sup> Berteau, PE et al. 1989. Insecticide Absorption from Indoor Surfaces. Hazard Assessment and Regulatory Requirements.
In Biological Monitoring for Pesticide Exposure, Chapter 24, pp 315–326 ACS Symposium Series, Vol. 382

<sup>&</sup>lt;sup>24</sup> USEPA. 1996. Environmental Health Threats to Children. Office of the Administrator, EPA 175-F-96-001. See also: Pesticides and Food: Why Children May be Especially Sensitive to Pesticides. Available at <u>http://www.epa.gov/pesticides/food/pest.htm</u>.

<sup>&</sup>lt;sup>25</sup> Moser V, et al. 2009. Time-Course, Dose-Response, and Age Comparative Sensitivity of N-Methyl Carbamates in Rats. *Toxicol Sci.* doi:10.1093/toxsci/kfp286

<sup>&</sup>lt;sup>26</sup> Fenske, F.A. et al. 1990. Potential exposure and health risks of infants following indoor residential pesticide applications. *Amer. J. of Public Health*. 80(6): 689-693

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#### **Broadcast Propoxur Applications Unsuitable for Multi-Dwelling Areas**

The agency must carefully consider these data and risks posed by widespread broadcast application of propoxur to residential and transient dwellings for the control of bedbugs. Multi-dwelling units, such as apartment buildings, condominiums, college dormitories, hotels and homeless shelters are most at risk for bed bug infestations. One study found that apartments (63%), homeless shelters (15%), and rooming houses (11%) documented the most complaints about bed bugs.<sup>27</sup> However, widespread application of propoxur is not suitable in these spaces if one wants to limit human exposures. These spaces are normally closed systems (lack of circulating fresh air) and have shared ventilation systems and limited ventilation during colder months. Occupants of these spaces are therefore at higher risk to propoxur exposure and poisonings via the routes mentioned above. Inhalation of contaminated air, residue migration onto food from treated or contaminated surfaces, longterm dermal contact with residues from mattresses, walls, floors, carpets and other hard and soft surfaces will occur if propoxur is allowed to be used in residential settings. Pregnant women, children and those with asthma are especially at risk. These exposure scenarios are expressly those which prompted the cancellation of all propoxur indoor spray uses (including use in crack and crevices) that result in non-occupational exposure for children in 2007. The agency must adhere to this decision.

## Propoxur Residential Sprays Were Cancelled With Good Reason

Before the proposed Special Review of propoxur initiated in 1988, the registrant submitted a request for the voluntary cancellation of, and amendment of labels deleting use of RTU liquids with trigger pump sprayers, which according to the agency, "eliminated those uses posing the greatest concern."<sup>28</sup> This development contributed to the agency's decision to not initiate a Special Review in 1995. In 2007, the registrant cancelled all propoxur indoor spray uses (including use in crack and crevices) that may result in non-occupational exposure for children.<sup>29</sup> It is evident based on independent data that propoxur use, in the form of liquid/sprays, poses significant exposure risks. The agency, given the data that exists for propoxur, would be hard pressed to justify a reversal of these decisions. The agency must not allow the use of propoxur, regardless of the emergency circumstances, since risks far outweigh any short-term potential benefit, especially in light of the availability of alternative methods and products.

# Section 18 Exemption

Section 18 of FIFRA authorizes the agency to allow a new use of a registered pesticide or the use of a pesticide whose registration is pending (and making progress toward registration) for a limited time if the agency determines that an emergency condition exists. EPA must perform a multi-disciplinary evaluation of the request including (1) assessment of the validity of the emergency claim and economic loss; (2) human dietary risk assessment; (3) occupational risk assessment (4) ecological and environmental risk assessment. The agency must deny an exemption request if the pesticide does not meet safety standards, or if

 <sup>&</sup>lt;sup>27</sup> Hwang, S.W. et al. 2005. Bed Bug Infestations in an Urban Environment. *Emerging Infectious Diseases* 11(4); 533-38
<sup>28</sup> USEPA. 1995. Propoxur (Baygon, Sendran); Proposed Decision Not to Initiate a Special Review. [OPP-30000/59; FRL-4918-8]

<sup>&</sup>lt;sup>29</sup> Ref #5

emergency criteria are not met. Without strict adherence to Section 18 criteria, allowance of unregistered pesticide uses and unregistered pesticides risks a public health problem. Most certainly, the program does not encourage nor allow the use of pesticides that have been cancelled or voluntarily withdrawn. A major concern with Section 18 exemptions is the effect that it will have on aggregate pesticide exposures. These exemptions must not ignore aggregate risks, thereby increasing pesticide exposures to levels that would exceed risk calculations and be deemed unsafe.

It is reported that other states across the U.S. have also expressed interest in this exemption. There is concern that once one state receives a Section 18 approval for the use of propoxur, other states will soon follow with their own approvals and this pesticide will be in wide use, contaminating millions of homes and other dwellings. Unlike other Section 18 requests that are used for seasonal agricultural pests, bed bugs are a year round issue and a one-time use of this toxic pesticide will just delay states' urgent need to address this long-term problem with IPM.

Propoxur should not be considered for a Section 18 exemption since the pesticide does not meet safety standards for indoor use and has already been cancelled for such uses based on exposure concerns. According to regulations, an emergency condition is defined as "an urgent, non-routine situation..."<sup>30</sup> However, bed bug infestations in the U.S. have become pervasive in multiple states, and their control is now routine. In fact, the increase in bed bug populations is predictable, necessitating preventive management processes that reduce infestations by utilizing mechanical and chemical products that are less hazardous. The agency, in light of this, should not grant an emergency exemption for propoxur and bed bugs.

# Alternatives for Combating the Resurgence of Bed Bugs

The bed bug problem, characterized by rebounding numbers in recent years, is partly due to the development of resistance to pesticide applications. The solution is not the usage of even *more* toxic pesticides to which these resilient insects would inevitably become resistant. The agency must encourage state and local municipalities to approach the problem strategically using collaborative methods and instituting IPM methods that are preventive and not reliant on hazardous chemicals.

The recommendations put forward by stakeholders at the national bed bug summit must not be sidelined. These experts recommended IPM strategies which include a communitybased component, as well as a public education campaign advising the public on the precautions it can take to avoid bed bugs. These effective measures, which emerged from the summit, can only be successful for the long-term if the agency provides assistance to state and local municipalities in the form of funding and/or training for educational programs, inspections, utilization of non-toxic treatments (e.g. steam or heat treatments), proper disposal of infected materials, and the use of least-toxic chemical applications such as borate/boric acid and diatomaceous earth which provide long-term protection against

<sup>&</sup>lt;sup>30</sup> <u>Title 40 of the Code of Federal Regulations, part 166</u>

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bed bugs and other common pests.<sup>31</sup> There are also several products on the market that are considered minimum risk products, such as  $\text{Eco}^{z}$  products, commercially used to treat bed bugs.

The agency should not violate the intent of the Section 18 process by allowing states to endanger the health of their citizens by promoting high toxicity chemicals like propoxur for short-term knockdowns. States must demonstrate that they have a system in place that will reduce or prevent pest infestations from becoming out of control. A long-term strategy, which includes IPM, is the only solution for effective bed bug management.

## **Environmental Justice**

Granting a Section 18 exemption for propoxur use would have disproportionately impact low-income and underserved communities. These communities, already at a higher risk for pesticide exposures and chemical body burden, would be the group most impacted because they often cannot afford or access more effective and less toxic long-term treatment methods. They also tend to live in multi-family buildings which are more susceptible to bed bug infestations. Residents of low-income, underserved communities in urban areas represent high risk groups for asthma, impaired development, and some types of cancer.<sup>32</sup> These impacts have been growing disproportionately for the past 20 years due to increased air pollution, chemical contamination and sub-standard sanitation. Exposure to asthmatriggers through pesticide spraying in and around homes has similarly increased. Spraying hazardous chemicals can not only lead to long-term health damage, like asthma and cancer, but elevated rates of acute poisonings. Inner-city underserved populations are also high-risk groups for adverse birth outcomes associated with exposures to environmental contaminants.<sup>33</sup> Application of propoxur, already detected in over 90% of indoor air samples of inner-city homes with pregnant women,<sup>34</sup> would significantly exacerbate these problems.

# **Conclusion**

The agency must not grant a Section 18 exemption to the Ohio Department of Agriculture for the use of propoxur for bed bug control. Since bed bugs have rapidly increased in numbers and are more difficult to treat with conventional pesticides, they cannot be defined as a "non-routine" situation. The approval of a cancelled product subject to agency scrutiny for elevated risk factors violates not only the Section 18 process, but also other regulations to which the agency must adhere. Propoxur is not currently registered for indoor residential use on cracks and crevices, and with good reason. Propoxur is a probable carcinogen (a known human carcinogen in California), and is highly toxic. Other, less toxic control methods are available and effective for bed bug treatment. For these reasons, propoxur should not be granted a Section 18 exemption. Propoxur would pose an

<sup>&</sup>lt;sup>31</sup> Kass, D. et al. 2009. Effectiveness of an Integrated Pest Management Intervention in Controlling Cockroaches, Mice, and Allergens in New York City Public Housing. *Environ. Health Perspect.* 117(8): 1219–1225

<sup>&</sup>lt;sup>32</sup> Perera, F.P et al. 2002. The challenge of preventing environmentally related disease in young children: community-based research in New York City. *Environ Health Perspect*. 110(2): 197–204.

<sup>&</sup>lt;sup>33</sup> Perera, F.P. et al. 2005. A Summary of Recent Findings on Birth Outcomes and Developmental Effects of Prenatal ETS, PAH, and Pesticide Exposures. *NeuroToxicology*. 26,(4):573-587

<sup>&</sup>lt;sup>34</sup> Ref #17

unacceptable human health risk if it was allowed to be widely used for indoor applications where humans would be exposed via inhalation and dermal contact with residues. Residents of homeless shelters, multi-dwelling units, hotels, and college dormitories, along with low-income and underserved communities would be disproportionately affected.

The agency should instead encourage the state of Ohio and others to put in place an IPM plan for long-term control of bed bugs, while sourcing other least-toxic control methods that are commercially available. The agency should also act upon the recommendations made by stakeholders at the National Bed Bug Summit, and make available funding and training to combat and control the bed bug resurgence.

Sincerely,

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