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U.S. Environmental Protection Agency
Office of Pesticide Programs
1200 Pennsylvania Ave., NW
Washington, DC 20460

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Comments of the
NATURAL RESOURCES DEFENSE COUNCIL
on the
Ohio Department of Agriculture
Application for Emergency Exemption For the Use of Propoxur

Docket ID: EPA-HQ-OPP-2009-0856
75 Federal Register 858 (January 6, 2010)

SUMMARY

The Natural Resources Defense Council (NRDC) appreciates this opportunity to comment on the Ohio Department of Agriculture's (ODA's) application for an emergency exemption from the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for the use of propoxur to treat indoor residential dwellings, commercial industrial buildings, and modes of transportation to control bed bugs.

On January 6, 2010, the U.S. Environmental Protection Agency (EPA) published a notice of the application requesting comments.[1] EPA was required to publish this notice because the application requests an emergency exemption for uses of propoxur that had been voluntarily cancelled in 2007 and because these uses pose a risk similar to the risk which was voluntarily cancelled.

Pesticides are poisons intentionally introduced into the human environment. Because of the inherent dangers with these products, Congress created a pesticide registration process under FIFRA to protect humans and the environment from unreasonable adverse

[1] 75 Fed. Reg. 858 (Jan. 6, 2010).

effects. The statutorily mandated risk assessments account for potential adverse effects such as carcinogenicity, developmental neurotoxicity, reproductive toxicity, and chronic toxicity. Propoxur has been linked to cancer and neurological toxicity.

Before this dangerous indoor use is allowed on such a widespread population in Ohio, the potential adverse health risks must be assessed. The application submitted by the ODA does not provide the necessary information to make either a determination that a real "emergency condition" exists or a determination that this use will not pose unreasonable risks to human health. The ODA application should not be approved as submitted.

Statutory Background

EPA regulates pesticides under the Federal Fungicide, Insecticide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.* FIFRA requires that pesticides must be registered to be sold in the United States.[2] EPA may not register a pesticide unless the chemical will perform its intended function without causing any "unreasonable adverse effects on the environment."[3] The Act allows either the Administrator to cancel the registrations of pesticides that do not comply with FIFRA or for registrants to voluntarily request cancellations.[4]

Section 18 of FIFRA allows the Administrator to exempt a pesticide from FIFRA provisions if she finds that "emergency conditions exist…."[5] An "emergency condition" is "an urgent, non-routine situation that requires the use of a pesticide(s)…."[6]

EPA regulations also enumerate specific information that must be included in all applications for exemptions.[7] Specifically, applications for specific, quarantine, or public health exemptions[8] must contain the following information: (1) identity of contact persons, (2) description of the pesticide, (3) description of the proposed use, (4) alternative methods of control, (5) effectiveness of the proposed use; (6) discussion of residues for food uses; (7) discussion of risk information; (8) coordination with other affected state of federal agencies; (9) acknowledgment by the registrant; and (10) description of proposed enforcement program.[9]

Factual Background

On October 21, 2009, Matt Beal, the Agriculture Inspection Administrator in the Pesticide Fertilizer Program at the ODA requested from EPA a Section 18 exemption for the use of propoxur to control bed bugs in, among others, residential dwellings, apartments, hotels, and motels. Based on the documents located in EPA's docket EPA-

[2] 7 U.S.C. § 136a.
[3] 7 U.S.C. § 136a(c)(5)(C).
[4] 7 U.S.C. § 136d(b) and (f).
[5] 7 U.S.C. § 136p
[6] 40 C.F.R. §166.3(d)
[7] 40 C.F.R. § 166.20
[8] A fourth type of exemption for crises exists, but ODA did not apply for this type of exemption.
[9] *Id.*

HQ-OPP-2009-0856, the application packet included a letter from Susan Jones, Associate Professor of Entomology at the Ohio State University, and letters from three registrants: Prentiss Inc., FMC Corp., and BASF Corp. The application claims that a letter from Dr. Michael Potter from the University of Kentucky is "forthcoming" but it does not appear in the docket.

In its application, the ODA identifies the contact persons, describes the pesticide, identifies the proposed use, states the period of use, and states that the ODA will handle the enforcement. Attached to the application is a letter from Susan Jones explaining the situation with bed bugs and the growth of bed bugs' resistance to pyrethroids.

SPECIFIC COMMENTS

Propoxur is a chemical in the N-methyl carbamate class of insecticides. In addition to its neurological toxicity, propoxur is a known human carcinogen. Propoxur interferes with an essential enzyme (acetylcholinesterase) that normally controls messaging between nerve cells. The result is spasmodic over-excitation of the nervous system. In extreme poisoning cases, this chemical can harm or kill humans. More commonly, at lower levels of exposure, propoxur causes a variety of poisoning symptoms, many of which can mimic common illnesses; these include nausea, vomiting, diarrhea, wheezing, sweating and tearing eyes. More severe poisoning can cause muscle twitching, drooling, seizures, respiratory paralysis and death. Some recent research indicates that exposure to this type of pesticide can impair children's neurological development, resulting in pervasive disorders that may include delays in motor development and attention deficit/hyperactivity disorder.[10] In August 2006, California added it to a list of chemicals known to the state to cause cancer.[11] Furthermore, as explained in more detail in the comments submitted by Beyond Pesticides to this docket, propoxur is a highly toxic pesticide that is a "mutagen, a reproductive effector and it has been found to affect the immune and endocrine systems."

Propoxur is used by pest control professionals to control insects around residences such as ants, roaches, and hornets, and it is used on pets.[12] In 1997, it was estimated that between 170,000 to 400,000 pounds of propoxur were used annually, with the majority of the use from consumer markets, rather than professional markets.[13]

NRDC finds that the application submitted by the ODA for an emergency exemption for propoxur lacks significant pieces of information which are critical to EPA's decision about whether to approve the application. To bypass the registration requirements of FIFRA – and therefore to bypass a full risk assessment to determine whether human

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[10] Rauh, V.A., Garfinkel, R., Perera, F.P., *et al.* "Impact of Prenatal Chlorpyrifos Exposure on Neurodevelopment in the First 3 Years of Life Among Inner-City Children." *Pediatrics*, December 2006 (Vol 118, No 6), pp 1845-59. Robin M. Whyatt, et al. "Prenatal Insecticide Exposures and Birth Weight and Length among an Urban Minority Cohort." *Environmental Health Perspectives.* July 2004. (Vol 112, No 10) pp 1125-32.
[11] California Health and Safety Code, section 25249.5, *et seq.,* commonly known as Proposition 65.
[12] U.S. EPA, "Reregistration Eligibility Determination: Propoxur", 1997, pgs. 2-3.
[13] *Id.* p.3.

health or the environment would be unreasonably affected by this proposed use – EPA should be armed with basic information from the applicant, including hazard and exposure information, a discussion of alternatives, and the efficacy of the proposed use. However, none of these issues are addressed by the applicant and other parts of the application are also lacking or insufficient. As a result, the ODA's application for an emergency exemption for indoor uses of propoxur should be denied in light of the deficiencies in these critical areas.

The bed bug situation in Ohio does not qualify as an "emergency condition"

To qualify for an emergency exemption, the situation for which the application is made must be "an urgent, non-routine situation" and exists only when each of three criteria are satisfied.

The first criteria is that "[n]o effective pesticides are available under the Act that have labeled uses registered for control of the pest under the conditions of the emergency." The second criteria requires that "no economically or environmentally feasible alternative practices which provide adequate control are available." Third, an emergency condition exists if the situation "will present significant risks to human health" or "will cause significant economic loss."[14] For non-crop related emergencies, a "significant economic loss" means that without the proposed pesticide use, the situation would be reasonably expected to cause a "substantial loss or impairment of capital assets, or a loss that would affect the long-term financial viability expected from the productive activity."[15]

For the first two criteria, the application fails to mention that there are alternatives to propoxur and pyrethroids available. First, there are currently registered pesticides – including diatomaceous earth and s-hydroprene – which are registered for use on bed bugs and are not toxic to humans. Second, there are non-chemical methods which are effective in treating bedbugs. Both of these are discussed further below.

In fact, the only discussion of these three criteria appears in the letter from Susan Jones attached to the application. She states that the bed bug crisis "poses grave economic concerns, quality of life issues, and potential health risks to the residents" of Ohio. However, without further explanation, these cursory statements cannot be enough to qualify for an emergency condition. That the bed bug situation poses "potential health risks to residents" does not rise to the level of posing "significant risks to human health." Similarly, without identifying any anticipated impairment of capital assets or loss affecting long term financial viability or other metric for the economic loss arising from the bed bug situation, Dr. Jones' simple claim of "grave economic concerns" should not be sufficient to allow the ODA to obtain an emergency exemption for this situation.

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[14] There are two other qualities which are recognized by the regulations, but they are inapposite to this situation. One is if the situation involves the introduction or dissemination of an invasive species and one is if the situation will present risks to threatened or endangered species, beneficial organisms, or the environment. Neither of these situations describes the problem that Ohio is having with bed bugs.
[15] 40 C.F.R. § 166.3(h)(2).

The bed bug situation in Ohio is not an emergency condition and does not warrant an emergency exemption for propoxur.

The Ohio Department of Agriculture's application is inadequate

EPA's rules regulating emergency exemptions enumerate ten areas where applicants must offer information about the proposed use of the pesticide. In its application to use propoxur in various residential and commercial buildings and transit, the ODA only offers information in three of these areas: contact information, description of the pesticide, and acknowledgement by the registrants. The rest of the application either provides a cursory and inadequate statement or completely ignores the specified requirement. Because propoxur is a toxic chemical that has been largely eliminated from indoor use where humans are most likely to be exposed, ODA's paltry application missing such important pieces of information cannot be granted by the EPA.

The application fails to discuss any risk information

The most glaring omission in the application is the failure to discuss "the potential risks to human health…and the environment expected to result from the proposed use, together with references to data and other supporting information."[16]

Propoxur was first registered for use in 1963 and was re-registered in 1997.[17] In 2005, EPA conducted a preliminary cumulative assessment of the N-methyl carbamates, including propoxur. In 2006, the registrant voluntarily cancelled the indoor residential uses of propoxur. In February 2007, EPA finalized the N-methyl carbamates cumulative risk assessment. Because of the voluntary cancellation of "all propoxur indoor spray uses that may result in non-occupational exposure for children," EPA ignored the risks associated with the residential indoor uses of propoxur in the final cumulative risk assessment.[18] As such, the Agency excluded "crack and crevice-type residential uses so as to reflect the Agency's final termination order."[19] Therefore, in finding that the risks associated with the N-methyl carbamates did not exceed the Agency's level of concern, EPA only incorporated the pet collar uses, and none of the indoor uses.

Although EPA did not assess the risk associated with the indoor uses of propoxur in its final cumulative assessment, in its 2005 "Estimation of Cumulative Risk from N-methyl Carbamate Pesticides: Preliminary Assessment," the Agency did include crack and crevice treatments as well as food uses and pet collar uses of propoxur. Given these uses, EPA preliminarily found that "[r]isk estimates for non-dietary oral exposure result in the lowest MOEs [margins of exposure], and are therefore of greatest concern to the Agency."[20] Furthermore, "for the three routes considered in the residential assessment exposure from hand-to-mouth activity by children and through the dermal route appears to be the most

[16] 40 C.F.R. § 166.20(a)(7)
[17] U.S. EPA, "Reregistration Eligibility Determination: Propoxur", 1997, p. 4.
[18] U.S. EPA, "Revised *N*-Methyl Carbamate Cumulative Risk Assessment" 2007, p. 25.
[19] U.S. EPA, "Revised *N*-Methyl Carbamate Cumulative Risk Assessment" 2007, p. 25.
[20] U.S. EPA, "Estimation of Cumulative Risk from N-methyl Carbamate Pesticides: Preliminary Assessment" 2005, p. 168.

significant contributors to the risk."[21] Therefore, the indoor residential uses were among those of greatest concern to the Agency.

Without any risk calculation by the Agency, and with no discussion by the applicant of the potential risks to human health and the environment, EPA cannot approve the use of this toxic chemical that has already raised enough concern for EPA to negotiate a voluntary cancellation from the registrant.

The application does not provide a detailed or complete explanation of alternative methods of control.

The ODA has failed to provide a "detailed explanation of why alternative practices, if available, either would not provide adequate control or would not be economically or environmentally feasible."[22] The Susan Jones letter attached to the application explains that the exemption is warranted because other existing labeled insecticides fail at controlling bed bugs, due in part to the bed bugs' built-up resistance to pyrethroid insecticides. It further notes the desirability of rotating insecticides from different classes to deal with the bed bugs.

There are two major problems with this explanation. First, carbamates are a significantly more toxic class of pesticides than are pyrethroids. The statement that it would be desirable to swap pyrethroids for carbamates is both unsupported and potentially irresponsible because carbamates are so dangerous. Carbamates are considered among the most highly toxic classes of pesticides. Members of the carbamates class are rated as highly hazardous (1b) by the World Health Organization, and listed by California under Proposition 65 as developmental toxins and as toxic to the male reproductive system. California has also recognized, pursuant to Proposition 65, that there is some evidence that they are associated with cancer. The carbamates are far more acutely toxic than the pyrethroids and therefore pose more of a health threat to people and the environment.

Second, the ODA offers no discussion of integrated pest management (IPM) procedures that can provide non-chemical alternatives for dealing with bedbugs. Some effective and affordable non-toxic treatment options that can be considered alone or in combination with each other include the following:

- Improving sanitation, minimizing clutter, and using mattress covers to enclose mattresses and box springs;
- Vacuuming, particularly with a high efficiency particulate air filtered vacuum;
- Physical treatments, including heat, cold, steam, and controlled atmospheres. For example, laundering infested linens or cloth items in hot water with detergent, followed by at least 20 minutes in a clothes dryer on low heat, will kill all life stages of bed bugs.

[21] U.S. EPA, "Estimation of Cumulative Risk from N-methyl Carbamate Pesticides: Preliminary Assessment" 2005, p. 7.
[22] 40 C.F.R. § 166.20(a)(4)(ii).

- Cryonite, a relatively recent commercial technology, uses CO_2 from cylinders deposited as a "snow" to kill bed bugs and a variety of pests by rapid freezing. The German Federal Environmental Agency reported that all life stages of common bed bugs were reportedly killed by constant exposure to very high concentrations of carbon dioxide (CO_2), at ambient atmospheric pressure, within 24 hours or less.[23] This technology is commercially available in many states already.[24]
- Applying diatomaceous earth powder to cracks and crevices behind baseboard coving and in floor cracks, and other hiding areas that are out of sight. Diatomaceous earth works by slicing open the exoskeleton (outer, hard covering) of insects, causing them to dehydrate and die.[25]
- Properly applying insect growth regulators to prevent egg hatching has virtually no effect on humans. Many are commercially available and include active ingredients such as (S)-Hydroprene.[26] [27]

Without complete information about all the viable alternatives available to deal with Ohio's bed bug problem, EPA cannot make an informed decision about whether propoxur should be reintroduced for indoor uses.

The application provides uncited information about efficacy

The ODA application fails to provide data, a discussion of field trials or other evidence that show that propoxur will be effective in dealing with the bed bug situation. The only information provided in the application available in the docket is a statement without citation by Susan Jones that Dr. Michael Potter has conducted bioassays finding that propoxur caused rapid mortality. This statement, without any references or attached data, does not provide a sufficient basis for the conclusion Ohio's bed bug emergency would be effectively dealt with using propoxur. Ohio must provide appropriate efficacy data, discuss the field trials or whatever evidence is available to make this showing.

The application does not provide a full description of the proposed use

An application for an emergency exemption is required to identify *all* of the following about the proposed use:

(i) Sites to be treated, including their locations within the State;
(ii) The method of application;
(iii) The rate of application in terms of active ingredient and product;
(iv) The maximum number of applications;

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[23] US Department of Defense Armed Forces Pest Management Board Technical Guide #44. Bed bugs – importance, biology, and control strategies. August, 2006. Available at http://www.afpmb.org/pubs/tims/TG44/TG44.htm
[24] Cryonite ® technology information available at http://www.cryonite.net/ and at http://www.bedbugcentral.com/bedbugfree/profile.cfm?id=92
[25] From the Colorado Dept of Public Health and the Environment. Available at http://www.cdphe.state.co.us/dc/zoonosis/bedbug.pdf
[26] Pesticide label available at http://www.domyownpestcontrol.com/msds/gentrol_IGR_label.pdf
[27] MSDS available at http://www.domyownpestcontrol.com/msds/gentrol_IGR_msds.pdf

(v) The total acreage or other appropriate unit proposed to be treated;
(vi) The total amount of pesticide proposed to be used in terms of both active ingredient and product;
(vii) All application restrictions and requirements concerning the proposed use which may not appear on labeling;
(viii) The duration of the proposed use; and
(ix) Earliest possible harvest dates.[28]

Of these nine requirements, only the last one would not be applicable to this application. Of the remaining eight requirements, only four are provided in Ohio's application, and even those provide scant information.

The ODA's application explains the types of buildings where propoxur will be used in Ohio, but does not give any indication of their locations within the state. There is no information about whether propoxur will be used only in urban areas, or in rural areas, or in selected cities. The application states that propoxur will be used "Year round" and that there is a retreatment restriction of 14 days. Otherwise, there is no other information about the method of application, the rate of application, the maximum number of applications, the total acreage (or even number of buildings, cities, percentage of the state) to be treated, and what total amount of propoxur will be used. The application does not provide enough information to determine or understand how much propoxur will be released into people's homes, office buildings, and other areas if the ODA's request is granted.

This information is important for identifying the risk that residents of Ohio would be exposed to if this exemption were approved. Without it, EPA cannot grant ODA's emergency exemption application.

The application does not consider the possibility that other State or Federal agencies may be affected

An emergency exemption application must identify contact and coordination with any other federal or state agencies that are likely to be concerned about the proposed use.[29] However, there is no indication in the ODA application that any state or federal agencies were contacted prior to submission of the application. At a minimum, the Ohio Department of Health (ODH) – whose website has some information about IPM and bed bugs – might be concerned about allowing widespread indoor use of a highly toxic pesticide in residential dwellings, hotels, motels, office buildings, modes of transportation, and commercial industrial buildings throughout Ohio. The ODA should have at least contacted the ODH and included any comments from the ODH in its application.

[28] 4 CFR §166.20(a)(3).
[29] 40 C.F.R. §166.20(a)(8).

The application does not discuss the possibility of residues for food uses

The ODA's application does not discuss whether this proposed use of propoxur would be expected to result in propoxur residues in or on food as is required by the regulations.[30] Specifically of concern to us, the ODA application does not clarify what facilities are included in the "commercial industrial buildings" that will be treated with propoxur. If any of these buildings were to store or manufacture food, then it is highly likely that residues of propoxur could end up in or on that food. Furthermore, the proposed labels attached to the application from the three registrants do not indicate that propoxur should not be used around food. The ODA application must include a discussion of the possibility of residues for food uses, an estimate of the maximum amount of residue likely to result from the proposed use, and the basis for that estimate. Without that discussion, the EPA cannot approve the request.

Conclusion

In light of the many glaring omissions in the ODA application for an emergency exemption to use propoxur on bed bugs, EPA should not grant the request. The toxicity of propoxur is clear; the State of California has identified it as likely to cause cancer. In assessing both the need to deal with the bed bug situation in Ohio with the potentially dangerous human health effects associated with indoor uses of propoxur, the EPA must be presented with a full application addressing all of the pertinent concerns. Without that information, EPA should not allow the State of Ohio to circumvent the safety precautions built into FIFRA and therefore should not grant the Ohio Department of Agriculture's request for an emergency exemption.

Respectfully submitted,

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[30] 40 C.F.S. §166.20(a)(6).