April 23, 2009

Marcia Mulkey
Director
Office of Pesticide Programs
1200 Pennsylvania Ave, NW
Washington, DC 20460
Re: Pesticide Registration Notice (PR) 2001-3
Docket Number: EPA-HQ-OPP-2007-0823

Dear Office of Pesticide Programs Director,

Thank you for the opportunity to comment on the Pesticide Registration Notice (PRN) 2001-3 "The Labeling Restrictions for Use on Infants and Children and Restrictions on Food Fragrances and Colors in Insect Repellents." I am a Master of Public Health (MPH) student at The George Washington University (GWU) School of Public Health and Health Services in the Environmental and Occupational Health track. GWU MPH students are committed to protecting human health, especially children's health, through prevention of unwanted exposures to environmental contaminants. The students are also committed to protecting the natural environment and advocating for its preservation.

I agree with and applaud the Agency for the ideas proposed in the PRN 2001-3. The PRN outlines that the labeling of pesticides, especially insect repellants, should be clear and concise. The PRN also recommends that labels should not mislead consumers with safety claims, use pictures of children, or use fragrances of food children typically enjoy. However, I feel that the PRN and the Agency could be more protective of children's health and highlight the social vulnerabilities inherent to children. For example, children are an extremely vulnerable sector of society and protective guidance language and recommendations to pesticide manufacturers would help reduce this vulnerability. I argue that since the PRN was released in 2001, inadvertent pesticide exposures from insect repellents have occurred that could have been prevented with increased education and stricter labeling regulations through the PRN.

Background:

The PRN attempts to prohibit images of children on insect repellent labels and restrict the use of food scents and colors in the repellents. Using food fragrances and colors theoretically makes the product more desirable for children, and encourages parents to assume the repellant is either safer for children than another product and/or that the product is specifically formulated for children.

Physiologically, children are most at risk for pesticide poisoning and death from pesticide exposure because of their developing body systems. Children's metabolism, skin permeability, absorption, higher respiratory and ventilation rates, CNS development, and the permeable blood brain barrier makes them more vulnerable than adults to health

effects from environmental exposures to toxicants, including pesticides used around the home, and as insect repellants. Faustman (2000) states that children have a higher (almost double) ratio of skin surface area to body weight providing more intensive contact with their environment. This higher ration provides increased susceptibility to dermal absorption of contaminants (Faustman 2000).

Behaviorally, children are also at greater risk for exposure to environmental contaminants. They are unable to read and comprehend the safety labels and they have more interaction with the ground and practice more hand to mouth behavior. This forces the children to be reliant on their parents to be knowledgeable about the specifics and safety of the insecticide itself, and proper use with children to reduce harmful exposures.

Pesticide labels:

The first pesticide control act in 1910, was implemented to "protect consumers from ineffective products and deceptive labeling." (EPA, FIFRA, 2007). EPA is charged with "regulating the use and sale of pesticides to protect human health and preserve the environment" (EPA FIFRA 2007). EPA is authorized to oversee the "sale and use of pesticides" meaning that EPA should oversee the ways in which pesticide manufacturers are using advertising to target consumers.

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires pesticide manufacturers to submit a label to EPA as part of the registration process (FIFRA Section 3). Each use of a pesticide must be registered and labeled separately. In order for the product to be registered the Administrator must find the following to be true:

1. The product's composition is such as to warrant the proposed claims for it;
2. The product's labeling and other material submitted complies with the requirements of the Act;
3. The product will perform its intended function without unreasonable adverse effects on the environment, when used in accordance with widespread and commonly recognized practice; and
4. The product will generally not cause unreasonable adverse effects on the environment. (EPA FIFRA 2007)

Therefore, the product must be proven to be effective, and not have an unreasonable adverse effect on the environment when used in a commonly recognized way. What if consumers lack education on the proper use for insect repellants? The label is not equipped to provide full education on a variety of situations, leaving the consumer, and potentially children, vulnerable to inadvertent exposures. In agricultural settings, this user may be a trained pesticide applicator. However, in residential settings, this user is a public consumer, and in some cases, a child. Providing guidance on the label contents is an important Agency function and should be protective of public health. The label should also reflect the most recent and accurate information available.

Stakeholders

I understand and appreciate that many stakeholders are involved in the pesticide registration and label approval process. Pesticide manufacturers must sell products, and

appropriate communication and advertising is an important part of their business objectives. Children and parents are also important stakeholders in this process, and EPA should be mindful of these underrepresented stakeholders when providing guidance to pesticide manufacturers submitting labels for review.

Children and Insect Repellants:

In 2004, the United Nations (UN) reported pesticide poisoning is a serious health problem, disproportionately affecting infants and children (UN 2004) and that one to five million cases of pesticide poisonings occur each year "resulting in several thousand fatalities, including children" (UN 2004). This is obviously an important issue worldwide, and entirely preventable through proper education and guidance from regulatory agencies.

Many studies have shown that children are indeed at risk for excess pesticide exposure and poisoning. Much of the relevant research has focused on the treatment of lice with lindane, in many instances resulting in an overexposure of the insecticide.

The Centers for Disease Control (CDC) reported that from 1998 to 2003, a total of 870 cases of unintentional lindane ingestions were reported, mostly due to people mistaking the insecticide for liquid oral medication (cough syrup) (CDC 2005). The Food and Drug Administration (FDA) recommended dispensing lindane in manufacturer-produced one or two ounce single use containers to reduce the likelihood of overexposure (CDC 2005). Once all products were sold in smaller containers and lindane was only used as a second line of defense, there was a 67% decrease in lindane prescriptions from 1998 to 2003 (CDC 2005) representing a decreased likelihood of unintentional children's exposures to this pesticide.

Forrester et al. (2004) examined lindane exposure as a treatment for pediculosis (lice). Exposure was associated with adverse reactions, and as a result, lindane use requirements have become stricter. Forrester et al. (2004) examined the patterns of lindane exposures reported to poison control centers in Texas during 1998-2002. A total of 528 exposures occurred, and misuse or abuse of lindane were reported in at least 87% of the cases. Of these overexposures, 45% were under the age of six, and 23% were 6-19 years of age (Forrester *et al.* 2004) demonstrating the need for increased education directed towards children and strict labeling requirements against targeting children on pesticide labels. While the EPA does not regulate pharmaceutical use of lindane, it could still benefit from this data.

Karr and colleagues (2007) reviewed the health effects of common home and garden pesticides. The study discussed both the chronic and acute symptoms that may occur from over exposure to pesticides, including: nausea, headaches, skin rashes, eye irritation, seizures, coma, death, birth defects, cancer, and neurodevelopmental and neurobehavioral effects (Karr *et al.* 2007). The researchers discussed a case study of one, full-term, previously healthy four month old female child. On the day her house was sprayed the child became "irritable and congested in her upper airway with a thick, whitish nasal discharge" (Karr *et al.* 2007). The symptoms worsened over the following days, and her parents transported her to a nearby emergency room. The child received treatment for

hypernatremia and dehydration but was discharged with a diagnosis of upper respiratory infection (Karr *et al.* 2007). A year later her home was evaluated when an epidemic of illegal applications of agricultural pesticide in residences was recognized. The child's urinary level for p-nitrophenol, a pesticide metabolite, was found to be 89 ppb (Karr *et al.* 2007). The CDC population reference level of the metabolite in the U.S. population is 63 ppb (Karr *et al.* 2007). This case study demonstrates the adverse health effects of overexposure to pesticides, due to lack of knowledge.

Also according to Karr and colleagues (2007), DEET (*N,N*-Diethyl-*meta*-toluamide) is recommended by the CDC as a strategy for prevention of mosquito-borne disease. DEET is available in OFF, Cutter, Outdoorsman, Sawyer, Ultrathon products. However, the CDC also recommends using precaution when applying this product to children and suggests use of lower concentrations DEET products (less than 10% DEET, and no more than 30% DEET), avoiding formulations containing ethanol or permethrin and using the product only on intact, uncovered skin to reduce the dermal-absorption dose (Karr et al. 2007). Similarly, use is not recommended for infants younger than two months because infants have increased dermal absorption rates (Karr *et al*. 2007). Surprisingly, because of its availability and target user base of children, products containing mixtures of DEET and sunscreen should be avoided, because sunscreen requires reapplication many times throughout the day, and DEET should only be applied once daily (Karr *et al.* 2007).

Insect repellants provide a valuable service to society, including protecting against malaria, West Nile virus, dengue and lime disease (Katz *et al.* 2008). Katz and colleagues (2008) argue that the safety record for DEET is excellent, 43 cases reported DEET toxicity in the past five decades. However, two children had adverse central nervous system symptoms after overuse of DEET (Katz *et al.* 2008).

A new insect repellant, Picadrin is formulated as an alternative to DEET because of insect resistance. The pyrethroid acts as a repellant and is effective against ticks, mosquitoes and other arthropods. The mechanism of action (MOA) of DEET requires direct contact with the insect, making the compound poorly suited for skin application. The repellant is currently sold commercially as Cutter Advanced. Picadrin is not intended for use in children under two years of age and is sold at a 7% formulation. However, on the manufacturer's website, advertisements for "Cutter Advanced", which contains Picadrin, children are used in the advertisements.

Recommendations:

Three recommendations should be made to improve the guidance on pesticide labels to reduce marketing towards children. In addition to providing guidance that insect repellants should not include children on the label, or smell or taste like food, I suggest the following recommendations.

1. Increased Education of End-users

Perhaps the EPA could provide guidance that the pesticide manufacturer, as part of best practice and stewardship corporate responsibilities, should provide additional education materials targeted toward the end user (consumers, parents, and children) on the safe use

of insect repellants. Cross sectional studies have indicated that insect repellant exposures would be reduced with educational outreach to improve parent's use of repellants (Katz et al. 2008). Education "plays a key role, as parents often do not read labels and many left repellants on their children's skin overnight, theoretically increasing potential chemical exposure" (Katz et al. 2008).

2. Recommend/require products be in single use containers

EPA could recommend that insect repellants be manufactured in single use containers, with specific use guidelines on each container, to reduce overexposure. As stated above, FDA recommended dispensing lindane in manufacturer-produced one or two ounce single use containers to reduce the likelihood of overexposure when treating lice infestations. Once all lindane products were sold in smaller containers, 67% decrease in lindane prescriptions from 1998 to 2003 (CDC 2005) representing a decreased likelihood of exposure. This example provides a tested framework to reduce unintentional overexposure, and still allows manufacturers to produce beneficial products.

3. Overall incorporation of children in the risk assessment process

EPA should include the social vulnerability of children as part of the risk assessment process, in addition to the 10x safety factor required by the Food Quality Protection Act (FQPA). This 10x safety factor may not provide adequate protection of children's health. Children should be highlighted in existing risk assessment methodology for pesticides, and perhaps new risk assessment procedures should be developed apart from existing regimes. Faustman reports that three to ten percent of congenital abnormalities are attributed to exogenous and environmental agents (2000). A focus on prevention pathways would reduce social and economic costs in the future (Faustman 2000). To handle these vulnerabilities child-specific risk assessment methods (Faustman 2000) should be developed.

In conclusion, I support the EPA PRN to reduce unnecessary targeting of children for insect repellants. I encourage EPA to review the above recommendations, and continue to provide requirements for clear, concise pesticide labels. I believe increased education, and restrictions on size of repellants would provide a benefit to children's health and the environment.

Thank you for the opportunity to comment on this PRN.

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