



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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MEMORANDUM

Subject: EPA Response to Issues Raised in Public Comments, but Unrelated to Issues in NRDC 2,4-D Petition

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And

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To: Public Docket EPA-HQ-OPP-2008-0877

The Natural Resources Defense Council (NRDC) submitted a petition to the U.S. Environmental Protection Agency (EPA or Agency) on November 6, 2008 requesting that the Agency revoke all tolerances and cancel all registrations for 2,4-D.¹ EPA's response to NRDC's requests to revoke all tolerances and cancel all 2,4-D registrations are addressed separately in an Order and letter, respectively.² This document constitutes EPA's response to two issues raised in public comments, but not mentioned in the Petition.

In its public comments on the 2,4-D petition, Beyond Pesticides expressed concern regarding the possible association of the use of lawn chemicals such as 2,4-D and cancer in residential pets.³ In addition, in separate comments, Beyond Pesticides⁴ and New York State⁵ requested an alternatives assessment for 2,4-D. The first section below addresses 2,4-D and

¹ Petition of Natural Resources Defense Council to Revoke All Tolerances and Cancel All Registrations for the Pesticide 2,4-D (November 6, 2008).

² 2,4-D; Order Denying NRDC's Petition to Revoke Tolerances, EPA-HQ-OPP-2008-0877; FRL-9344-1; EPA Denial of November 6, 2008 NRDC Petition to Cancel All 2,4-D Registrations, EPA-HQ-OPP-2008-0877.

³ Public Comment by Beyond Pesticides (February 23, 2009) at 4.

⁴ Id. at 7.

⁵ Public Comment by New York State Departments of Environmental Conservation and Health (February 23, 2009) at 2.

residential pet exposure and the second section addresses the request for an alternatives assessment.

I. 2,4-D and Residential Pets

During the public comment period on NRDC's petition, Beyond Pesticides raised an issue unrelated to those raised in the NRDC petition. Specifically, Beyond Pesticides is concerned about the use of 2,4-D for lawn care and the possible association of cancer in pets due to this exposure. In support of its claim that there is a relationship between 2,4-D treated lawns and canine cancer, Beyond Pesticides cited several studies (Glickman et al. 2004, Hayes et al. 1991, Hayes et al. 1995, Reynolds et al. 1994).

EPA evaluated the studies cited by Beyond Pesticides and the studies do not change the Agency's current conclusions. The two studies conducted by Hayes et al. in 1991 and 1995 focused on an epidemiological evaluation (i.e., case control study) of the relationship between 2,4-D use on lawns and the incidence of malignant lymphoma in companion dogs. This evaluation used a hospital-based recall questionnaire approach. There were several criticisms of this paper which were addressed in 1995 by Hayes et al., including issues associated with the exposure assessment process and the uncertainties associated with low odds ratios.⁶ The authors acknowledged major weaknesses with the studies were a lack of environmental or personal sampling and possible recall bias. Further, significant uncertainty exists due to the lack of exposure data. In addition, the 2005 RED required that, in order for a product to be eligible for reregistration, label language needed to be added restricting pet access to treatment areas during and immediately after application. All labels now have this language, which changes the use patterns that existed during the time of the Hayes studies in the early 1990s because now pets should not be in the treatment area during or immediately after application. Further, the authors concurred with several commenters that the studies do not prove that 2,4-D exposure in a home environment is a cause of malignant lymphoma in companion dogs. Therefore, Hayes *et al* does not impact the Agency's previous assessment.

Reynolds et al. 1994 attempted to supplement Hayes et al. by attempting to refine the ability to predict exposures from lawn herbicides like 2,4-D by collecting exposure characteristics using an interview/questionnaire approach and by monitoring of 2,4-D in pet urine. They concluded that gathering data via owner questionnaires could be a good surrogate predictor of exposure. Among 44 dogs potentially exposed to 2,4-D-treated lawns an average of 10.9 days after application, 2,4-D concentrations greater than or equal to 10.0 µg/l were found in 33 dogs (75%) and concentrations of ≥50 µg/l were found in 17 (39%). Among 15 dogs with no known exposure to a 2,4-D-treated lawn in the previous 42 days, 4 (27%) had evidence of 2,4-D in urine, one at a concentration of ≥50 µg/l. The odds ratio for the association between exposure to a 2,4-D-treated lawn and the detection of ≥50 µg/l 2,4-D in urine was 8.8 (95% confidence interval, 1.4-56.2). Dogs exposed to lawns treated within 7 days before urine collection were more than 50 times as likely to have 2,4-D at concentrations ≥50 µg/l than dogs with exposure to a lawn treated more than one week previously (odds ratio = 56.0; 95% confidence interval, 10.0-312.2). The highest mean concentration of 2,4-D in urine (21.3 mg/l) was found in dogs sampled

⁶ U.S. EPA, *2,4-D: Evaluation of Data Identified In NRDC Petition and Associated Documents* (March 27, 2012) at 65-66 (hereinafter HED).

within two days after application of the herbicide. The authors indicated that these findings demonstrate that dogs living in and around residences with recent 2,4-D lawn treatment, absorb measurable amounts of the herbicide for several days after application and, thus, may constitute a useful animal model for evaluating the effects of herbicides on the induction of lymphoid cancer. EPA believes the use of interviews/questionnaires may have some utility as a surrogate means of predicting exposures in epidemiological research. However, with regard to the specific issue of establishing a model specific to 2,4-D exposure and cancer induction the results are incomplete and have considerable uncertainty, which is consistent with the findings of the investigators who concluded that additional research on this matter is needed.⁷

In summary, the studies cited by Beyond Pesticides, in its comments to support its assertion that 2,4-D has been shown to induce lymphoma in pets, did not address key uncertainties (lack of sampling, timing of the studies, and recall bias) in the study results. In particular, Beyond Pesticides failed to note the relatively weak association between exposure and lymphoma onset described by Hayes et al. Further, because these studies were conducted prior to the risk mitigation measure identified in the RED, and now reflected on all 2,4-D product labels (i.e., limiting pet access during and immediately following application), the resulting new use patterns should result in reduced exposure. As such, while the Agency concurs that perhaps additional research is warranted, it does not believe that there is evidence of critical animal health issues which warrant changes to its current conclusions.

C. Alternatives Assessment for 2,4-D

Beyond Pesticides and New York State's Department of Environmental Conservation and Department of Health submitted comments stating that a comprehensive evaluation of alternatives to 2,4-D is needed. They assert that the evaluation should include a comparison of environmental fate characteristics, application rates and methods, efficacy, and risks (incorporating both toxicological properties and estimated exposures) to public health and non-target organisms. These commenters felt that there are viable organic lawn management practices that eliminate the need for 2,4-D, as well as non-chemical alternatives to be considered.

Generally, the Agency does not assess alternatives where it has not identified any risks of concern. Where a pesticide has no risks of concern, it is unnecessary to consider the risk profiles of alternative pesticides in determining whether the pesticide being assessed will cause unreasonable adverse effects on the environment. Further, EPA may not deny registration to a pesticide because it is non-essential. See 7 U.S.C. § 136a(c)(5).

EPA evaluated the studies cited in the Petition and public comments and concluded that the studies do not alter the Agency's current conclusion that 2,4-D does not present a risk of concern. Many of the studies and their deficiencies are specifically addressed in this response or in EPA's separate Order addressing tolerances. EPA's complete analysis of all the studies cited in the Petition and public comments can be found in the EPA's *2,4-D: Evaluation of Data Identified In NRDC Petition and Associated Documents* located in docket number EPA-HQ-OPP-200-0877. Because the studies cited by the Petition and in public comments do not alter the

⁷ Id.

Agency's conclusions that 2,4-D does not present a risk of concern, the Agency does not believe it is appropriate or necessary to conduct an alternatives assessment at this time.