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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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Natural Resources Defense Council
1152 15th Street NW, Suite 300
Washington, D.C. 20005

Re: EPA Denial of November 6, 2008 NRDC Petition to Cancel All 2,4-D Registrations

Dear Dr. Solomon and Ms. Wu:

This letter constitutes a partial response to the petition dated November 6, 2008 (Petition) submitted by the Natural Resources Defense Council (NRDC) requesting that the U.S. Environmental Protection Agency (EPA or Agency) revoke all tolerances and cancel all registrations for 2,4-D.

To the extent that the Petition seeks to have EPA revoke all tolerances for 2,4-D, the issues raised in the Petition relevant to the findings that must be made under section 408(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (including issues related to residential and dietary risks) are being addressed separately in an Order[1] that will be published in the Federal Register pursuant to section 408(d)(4) of the FFDCA. This letter constitutes EPA's response to the Petition insofar as it seeks the cancellation of all 2,4-D registrations based on ecological and worker risk issues. For the reasons identified below, the Agency denies petitioners request to cancel all 2,4-D registrations.

In addition, several commenters raised issues not mentioned in the Petition. Those comments by Beyond Pesticides regarding 2,4-D and residential pets and separate comments by New York State and Beyond Pesticides' requesting an alternatives assessment for 2,4-D are addressed by EPA in a response to public comment document located in docket number EPA-HQ-OPP-200-0877.[2]

The first section of this response lays out the legal framework, discussing applicable statutes and reregistration eligibility decisions. The second section provides the regulatory

[1] 2,4-D; Order Denying NRDC's Petition to Revoke Tolerances, EPA-HQ-OPP-2008-0877; FRL-9344-1.
[2] See Memorandum: EPA Response to Issues Raised in Public Comments, but Unrelated to Issues in NRDC 2,4-D Petition.

background for 2,4-D. The fourth section contains EPA's response to those FIFRA claims made in the Petition. The final section is the conclusion.

I. Legal Framework

EPA regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). FIFRA sets forth a federal licensing scheme for the sale, distribution and use of pesticides; FFDCA establishes the mechanism and standards by which EPA sets tolerances establishing allowable levels for pesticide residues in food. As a general matter, under FIFRA Section 3, before a pesticide can be distributed or sold in the United States, it must be registered by EPA.

FIFRA Section 6 authorizes EPA to cancel pesticide registrations that do not comply with FIFRA and, in certain circumstances, to suspend those registrations pending the completion of cancellation proceedings. Registration decisions, insofar as non-dietary risks are concerned, are governed by a "risk-benefit" standard. In order for EPA to register a pesticide, it must not pose "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." FIFRA §§ 2(bb) and 3(c)(5). This response only addresses NRDC's assertions of unreasonable adverse effects on the environment and occupational exposures (dietary risk issues are addressed in EPA's response to the Petition to revoke 2,4-D tolerances).

Because FIFRA imposes a risk-benefit standard for dealing with risks which occur because of exposures other than through the diet, whether to grant or retain a registration is not simply a matter of whether there are risks of concern, but rather whether those risks are reasonable in light of the benefits associated with use of the pesticide. In making both initial registration decisions and decisions as to whether products should remain registered, EPA first typically looks to determine whether a particular use of a pesticide poses a meaningful risk (often referred to as a "risk of concern").

If a use does not pose a risk of concern, EPA generally finds the use to be an acceptable one without regard to the benefits associated with the use. If EPA determines that the use does pose a risk of concern (either based on an initial examination or upon further refinement of the risk), EPA then looks to determine whether changes to the terms and conditions of use of the pesticide can feasibly and effectively mitigate the risk to levels that do not exceed levels of concern. These changes can include changes to the directions for use on the product's label (such as changes in application rates and methods, extending restricted entry levels, requiring protective clothing or equipment, etc.), or they can include changes to the pesticide's formulation or packaging. If these changes are adopted voluntarily by a registrant, the use is then generally found to be acceptable.

If a registrant does not agree to changes to the terms and conditions of a registration, or if effective changes cannot reasonably be implemented, the Agency then must determine whether the risks associated with the use are justified by the benefits associated with that use. If the Agency determines the risks associated with the use are not justified by the benefits associated with that use without changes to the terms and conditions of the registration, the Agency will, in

the case of a not-yet-registered pesticide, deny registration under FIFRA section 3(c)(6) or, in the case of a registered pesticide, initiate appropriate regulatory action under FIFRA section 6 unless the necessary changes (if any are possible) are made by the registrant. If, on the other hand, the Agency determines that the risks associated with a use are justified by the benefits, the use would continue to meet the FIFRA standard for registration.

II. Background

On June 30, 2005, EPA issued a Reregistration Eligibility Decision (RED) for 2,4-D. In the RED for 2,4-D, EPA evaluated the human health and ecological risks associated with all registered uses of 2,4-D. EPA determined that there is a reasonable certainty that no harm will result to human health from exposure to the food uses of the pesticide. In considering all potential occupational and ecological exposures, the Agency concluded that with the adoption of the risk mitigation measures identified in the 2,4-D RED, all of the registered uses for 2,4-D meet the "no unreasonable adverse effects" standard applicable to registration decisions under FIFRA Section 3(c)(5).

Specifically in the RED, to address concerns regarding ecological risks to fish, aquatic invertebrates, birds, mammals, and non-target terrestrial and aquatic plants, EPA required mitigation measures which included reducing the maximum application rate and measures to control spray drift in order to reduce 2,4-D risks to wildlife and non-target plants. In order to address concerns regarding risks to workers associated with the handling of 2,4-D products, the Agency prescribed new personal protective equipment (PPE) requirements in the RED, which replaced the PPE requirements prescribed in the 1992 exposure reduction plan. These requirements are reflected on product labels.

III. Petition Response

For the reasons set forth below, EPA denies the NRDC Petition insofar as NRDC seeks to have EPA make a finding under FIFRA section 2(bb)(1) that 2,4-D causes unreasonable adverse effects on the environment and, therefore, must cancel all 2,4-D registrations. As mentioned earlier, that portion of NRDC's Petition that seeks either cancellation of registrations or revocation of tolerances based on issues related to dietary or residential risks are being addressed separately in an Order to be published in the Federal Register pursuant to section 408(d)(4) of the FFDCA.

EPA considers this portion of the response to NRDC's petition to be final action, and believes the petitioner may challenge now this portion of the Agency's petition denial in federal court pursuant to section 16 of FIFRA. Because, as explained below, EPA is today denying petitioners' request to cancel on the basis of endocrine effects on ecological species and the adequacy of personal protective equipment for workers, this letter will constitute a final Agency action as it relates to those specific issues. As noted, the remaining issues are subject to review as provided in section 408 of the FFDCA.

In terms of the issues addressed in this portion of EPA's response to NRDC's Petition, NRDC raises a number of generic concerns as to why EPA cannot make the FIFRA determination that 2,4-D does not cause unreasonable adverse effects on the environment. In

general, NRDC asserts that EPA cannot make its FIFRA determination based upon inadequately supported assumptions, ignored data, and reliance on inadequate studies.

These claims by NRDC do not allege sufficient grounds for cancellation of the 2,4-D registrations. The statutory standard for cancellation of a pesticide is that the pesticide "when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." 7 U.S.C. 136d(b). As explained in Unit I above, EPA this standard is a "risk-benefit" standard that requires consideration of benefits before a use can be found not to meet the standard. Thus, whether a pesticide should be cancelled is not simply a question of a pesticide's potential to cause harm but an issue involving a combination of factors including the pesticide's potential harms, the pesticide's potency (i.e. at what exposure levels will it cause harm), the level of human exposure to the pesticide, and the benefits the pesticide's use provides.

The flaw in NRDC's petition with regard to its request to cancel all 2,4-D registrations is that it addresses only 2,4-D's potential harm without addressing whether that harm is likely to occur or whether it would be unreasonable when weighed against 2,4-D's benefits. For example, NRDC claims that 2,4-D has the "potential to cause endocrine disrupting effects . . . [and] EPA should have quantitatively incorporated [this information on 2,4-D's harmful effects] in its risk assessment of 2,4-D." While the reference to endocrine effects clearly addresses the first element of the risk assessment process – identification of a harm or toxic effect, NRDC's assertion that EPA should quantitatively incorporate the endocrine studies cited by NRDC in its risk assessment falls far short of addressing the other elements of the risk assessment process or a risk-benefit balancing. Similarly, NRDC alleges that factors EPA did not consider would enhance the exposure of 2,4-D to workers. Again, NRDC's assertion falls short of addressing other elements necessary for a complete risk assessment process or risk-benefit balancing.

NRDC does not allege that quantitative incorporation of the studies it cites would alter EPA's prior conclusion regarding whether risks of concern exist or how they would compare to benefits for 2,4-D. At best, NRDC is asking EPA to take a revised look at the toxicity of 2,4-D for ecological effects and the exposure to 2,4-D for occupational risk. Yet, the ground for cancelation is a finding that risks outweigh benefits. Accordingly, NRDC's claims that the 2,4-D registrations should be cancelled due to 2,4-D's ecological effects or worker risk is denied due to a failure to make a proper claim for cancellation by, at the very least, alleging facts that, if proven, would meet the statutory standard for cancellation.

Despite the inadequacy of petitioner's claims regarding 2,4-D's endocrine effects on ecological species and occupational exposure, the following is EPA's response to the specific issues raised in the Petition relevant to NRDC's contention that all 2,4-D registrations should be cancelled for reasons unrelated to whether the 2,4-D tolerances meet the safety standard of FFDCA section 408.

A. Endocrine effects on ecological species

NRDC accuses the Agency of failing to consider endocrine disrupting effects during reregistration of 2,4-D.[3] NRDC further contends that EPA ignored adverse effects to aquatic species from 2,4-D, yet approved 2,4-D for use in or near water. To support its claims against the Agency, NRDC cited to various studies.[4]

Specifically, NRDC cited a study by Xie et al. (2005)[5] to support its claim that 2,4-D has an estrogenic effect in fish.[6] In the study, juvenile rainbow trout were exposed to 2,4-D for 7 days and produced a 93-fold increase in an egg hormone (vitellogenin) compared to untreated fish. While NRDC cites these findings as highlighting the ecological risk to fish when 2,4-D is applied to water bodies for controlling weeds, EPA evaluated the study and found important deficiencies with the study such that the results could not be considered reliable.[7]

In particular, EPA determined that the Xie et al. study lacked details regarding the sex of the sample set of rainbow trout.[8] Knowing the sex of the trout is important because male fish maintain null or very low levels of vitellogenin in their natural state and when in the presence of endocrine disruptors, male fish have significant levels of vitellogenin in their blood. In contrast, female fish have naturally increasing levels of vitellogenin as they approach maturity and maintain those levels upon maturation. Without knowing the fish sex it is not possible to make the appropriate inferences regarding vitellogenin levels. Additionally, the sample size was very small, with only six fish used per test concentration. This small sample size, combined with the lack of details regarding the fish sex, minimizes the reliability of the study. Due to these deficiencies, EPA believes it would be inappropriate to rely on the study to alter the Agency's risk assessment conclusions.

NRDC also cited a study by Rawlings et al. (1998)[9] to support its claim of the endocrine disruptive effect of 2,4-D on ecological species.[10] NRDC referenced this study to demonstrate that thyroid hormone levels are significantly suppressed in ewes dosed with 2,4-D, thus, supporting its claim that 2,4-D interferes with neurological function in fish because NRDC claims that slight thyroid suppression affects neurological development.[11] EPA, in analyzing the Rawlings et al. study, determined that the study could not be directly incorporated into the

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[3] Petition of Natural Resources Defense Council to Revoke All Tolerances and Cancel All Registrations for the Pesticide 2,4-D (November 6, 2008) at 2, 4 (hereinafter Petition).
[4] For EPA's analysis of all studies cited in the Petition and public comments see *2,4-D: Evaluation of Data Identified In NRDC Petition and Associated Documents* (March 27, 2012) (hereinafter HED).
[5] Xie, L., K. Thrippleton, M.A. Irwin, G.S. Siemering, A. Mekebri, D. Crane, K. Berry, and D. Schlenk. 2005. Evaluation of Estrogenic Activities of Aquatic Herbicides and Surfactants Using a Rainbow Trout Vitellogenin Assay. Toxicological Sciences. 87: 391-398.
[6] Petition at 4.
[7] U.S. EPA *Review of Selected Studies in Support of NRDC Petition for Tolerance Revocation and Cancellation of 2,4-D* at 3 (February 24, 2011) (hereinafter EFED).
[8] EFED at 3.
[9] Rawlings, N.C., S.J. Cook, and D. Waldbillig, 1998. Effects of the pesticides carbofuran, chlorpyrifos, dimethoate, lindane, triallate, trifluralin, 2,4-D, and pentachlorophenol on the metabolic endocrine and reproductive endocrine system in ewes. Journal of toxicology and Environmental Health, Part A, 54:1, 21-36.
[10] Petition at 4.
[11] Id. at 4, 5.

Agency risk assessment process because the study endpoints could not be related in a mathematical fashion to a corresponding level of effect for an apical endpoint in the whole organism.[12]

Nevertheless, comparing the effects endpoint (10 mg/kg-bw) reported by Rawlings with the chronic mammalian effects threshold used by the Agency for mammalian wildlife risk assessment (2-generation rat reproduction NOEL of 5 mg/kg-bw) suggests that the Agency risk assessment for mammalian wildlife is adequately protective even if the Rawlings' study had been considered in the assessment.[13] Therefore, the Rawlings study has no impact on the Agency's current risk assessment conclusions.

NRDC claims that the two studies addressed above, which deal specifically with fish, and several other studies it cited (Haddow et al., 1999; Charles et al., 1996; Liu et, 1996; Kim et al., 2005; Kim et al., 2002, Dufford et al., 1995; Lerda et al., 1991; and Garry et al., 1996),[14] which deal with rodents and humans, show that EPA should not allow applications of 2,4-D to waterways where fish may be exposed because of endocrine disrupting effects. While NRDC's claims that studies showing possible endocrine effects in humans and rodents indicate the same effects for fish, the Agency believes that any confident extrapolation across broad taxonomic groups must be mindful of other lines of evidence, notably the comparative metabolism of the chemical in question. The NRDC petition does not make a case that the distribution and fate of 2,4-D in other animals such as mammals follows the same patterns as in fish. Therefore, based upon the Agency's analysis, the studies cited by NRDC do not impact the Agency's quantitative ecological risk assessments or alter its conclusions.

Additionally, during the public comment period, several other studies were cited in support of NRDC's claims (see Filkowski et al., 2003, cited by Beyond Pesticides and the State of New York) as well as to counter its claims (see Hurst and Sheahan, 2003; Petit et al., 1997; Schubert et al., 2008; Spiteri et al., 1999; and Vonier et al., 1996 cited by the Industry Task Force II on 2,4-D Research Data). As with the studies cited by NRDC in its petition, EPA analyzed each study to determine whether the studies met the basic scientific quality criteria outlined in the Agency's data evaluation guidance, whether acceptable study results could be translatable to an exposure of 2,4-D in whole organisms, whether any resulting effects could be clearly and quantitatively related to apical adverse outcomes in those organisms, and ultimately whether the results would alter the Agency's ecological risk assessments for 2,4-D.

Based upon EPA's analysis, one study was found to be unacceptable for risk assessment use because of a lack of measured 2,4-D exposure that would allow for an establishment of 2,4-D as the source of any observable effects (Schubert et al.).[15] This study would therefore have no impact on the quantitative risk assessment performed by the Agency.

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[12] EFED at 3.
[13] Id.
[14] Collectively addressed separately in 2,4-D; Order Denying NRDC's Petition to Revoke Tolerances, EPA-HQ-OPP-2008-0877; FRL-9344-1
[15] EFED at 1.

Three other studies EPA evaluated examined the effects of 2,4-D in yeast cells, brown trout or alligator tissue isolates (Hurst and Sheahan, 2003; Petit et al., 1997; and Vonier et al., 1996). The Hurst and Sheahan and Petit et al. studies reported no estrogenic response for 2,4-D in yeast cells. Vonier et al. reported no statistically significant competitive binding of 2,4-D for estrogen receptors.[16] Moreover, these three studies cannot be related in a mathematical fashion to responses in whole higher organism and do not establish effects endpoints based on exposure routes and levels translatable to whole organism exposure routes. Therefore, these studies have no impact on the quantitative risk assessment performed by the Agency.

The Spiteri et al. study that EPA evaluated, involved direct application of 2,4-D to alligator eggs, involved whole organisms and had a relevant relationship between the exposure route and the measurements for risk assessment exposure calculations. However, this study showed no statistically significant effects associated with 2,4-D exposure relative to controls.[17] Therefore, the results of this study support the Agency's previous risk assessment conclusions.

EPA evaluated the Filkowski et al. study, which reported that 2,4-D produced mutagenic effects in *Arabidopsis thaliana*. However, in the absence of a quantitative peer-reviewed relationship linking mutation to adverse apical effects on plant fitness (survival, growth, or reproduction), the Agency cannot quantitatively assess the whole organism consequences of genotoxic measurement endpoints.[18] Therefore, this study would not influence the Agency's risk assessment because genotoxic endpoints in this case are not considered to be quantifiably relatable to an adverse outcome in the whole organism.

In summary, the Agency concluded that none of the cited studies would have a material impact on the conclusions of the current ecological risk assessment. Additionally, EPA utilizes conservative exposure scenarios when assessing ecological risk generally. While these conservatisms are not expressly employed in EPA's assessment to address the uncertainties in relying on surrogate species data, they ultimately serve the same purpose; they add a measure of protection to account for uncertainties in EPA's assessment. Therefore, EPA is confident that its assessment is protective of aquatic species.

For the discussion regarding the Agency's endocrine disruptor screening program, see the separate Order that will be published in the Federal Register pursuant to section 408(d)(4) of the FFDCA.

B. Personal Protective Equipment (PPE) for workers

NRDC, in its petition, questioned the adequacy of the Agency's evaluation of worker exposure and PPE.[19] In support of its assertions regarding worker exposure, NRDC cited three studies in its petition (Riviere et al., 2003; Moody et al., 1992; and McDuffie et al., 2005).[20] Additionally, NRDC claims the Agency did not address the potential enhancement of 2,4-D

[16] Id. at 1-2.
[17] Id. at 2.
[18] Id.
[19] Petition at 13.
[20] Id. at 13.

absorption due to alcohol consumption, DEET exposure, and sunscreen.[21] Because it is relevant to residential risk, NRDC's dermal absorption claim regarding 2,4-D, and the additional studies cited to support the claim, are addressed in a separate Order that will be published in the Federal Register pursuant to section 408(d)(4) of the FFDCA.

For its claim regarding 2,4-D and worker exposure issues, NRDC cited the Riviere et al. study to claim that occlusion can significantly enhance skin absorption of 2,4-D.[22] The stated goal of the Riviere study was to determine the impact of co-exposure factors that could modulate transdermal flux of topically applied DEET. Results suggest that co-exposure to a number of chemicals that potentially could be encountered in a military environment may modulate the percutaneous absorption of topically applied DEET beyond that seen for normal vehicles, at typically applied concentrations. Also observed was that covering DEET dose areas with an occlusive dressing, or even fabric, enhances absorption.

The Agency is aware that occlusive coverings increase skin hydration status by preventing water loss, and that hydrated skin is generally more permeable to pesticides than un-hydrated skin. Therefore, occlusive coverings would be expected to increase exposure via the dermal route, resulting in increased risk. However, in EPA's evaluation of this study, it found that the Agency's risk assessment already accounts for any uncertainty raised by NRDC relative to the findings of Riviere et al.[23]

In the 2005 risk assessment, it should be noted that EPA used a protective value for quantifying dermal absorption from a human volunteer study. EPA derived an initial dermal absorption factor of 5.8%, based upon the mean-percent absorbed value from four different human dermal absorption studies. However, EPA ultimately used a value of 10%, in order to be protective, based on the upper range of the variability observed in the results.

EPA believes that its use of a 10-percent dermal absorption value for 2,4-D is protective. EPA's conclusion is supported by an extensive set of high quality human research results. EPA principally relied on an *in vivo* human study which showed average human dermal absorption at 5.8 percent.[24] EPA also considered four other *in vivo* human studies.[25] These studies involved

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[21] Id. at 2.
[22] Id. at 13.
[23] HED at 36.
[24] Feldmann, R.J., Maibach, H.I., 1974. Percutaneous penetration of some pesticides and herbicides in man. Toxicol. Appl. Pharmacol. 28, 126–132.
[25] Harris, S.A., Solomon, K.R., 1992. Percutaneous penetration of 2,4-dichlorophenoxyacetic acid and 2,4-D dimethylamine salt in human volunteers. J. Toxicol. Environ. Health 36, 233–240, MRID 48772104; Maibach, H.I., Feldmann, R.J., 1974. Systemic absorption of pesticides through the skin of man. In: Occupational Exposure to Pesticides: Report to the Federal Working Group on Pest Management from the Task Group on Occupational Exposure to Pesticides, Appendix B. US Government Printing Office, 0-551-026, Washington, DC, pp. 120–127, MIRD 46859102; Moody RP, Wester RC, Melendres JL, Maibach HI. Dermal absorption of the phenoxy herbicide 2,4-D dimethylamine in humans effect of DEET and anatomic site. J Toxicol Environ Health 36(3):241-50.,1992, 48772102; Wester, R.C., Melendres, J., Sedik, L., Maibach, H., Riviere, J.E., 1998. Percutaneous absorption of salicylic acid, theophylline, 2,4-dimethylamine, diethyl hexyl phthalic acid, and p-aminobenzoic acid in the isolated perfused porcine skin flap compared to man invivo. Toxicol. Appl. Pharmacol. 151, 159–165, MRID 48772101.

eight separate trials using a total of 34 participants and had an average dermal absorption value of 5.7 percent.[26] To account for potential variability EPA chose a value of 10 percent.

There are several factors that support reliance on these data and demonstrate the reasonableness of EPA's choice of a 10-percent dermal absorption factor.[27] First, the data relied upon by EPA are from *in vivo* human studies. NRDC, with one exception, has cited only to *in vitro* data. EPA generally does not rely on *in vitro* dermal absorption data without corroboration from *in vivo* testing. The critical limitations with *in vitro* dermal absorption testing, such as the lack of an intact vasculature, make it an uncertain guide for risk assessment. Finally, the value chosen by EPA for dermal absorption was nearly twice the average value seen in human testing.

Additionally, NRDC cited a Moody et al. study to support its claim regarding the permeability of worker gloves in conjunction with exposure to DEET and sunlight simultaneously.[28] However, EPA does not concur with these conclusions because the conditions of this research do not represent likely exposure conditions that would be expected in current agricultural practices.[29] This is because the study only describes the permeability changes in a single glove material after exposure to UVA, and also DEET coupled with 2,4-D and the glove's composition was unclear. Current production methods for gloves have improved since the Moody et al. research was completed in 1992. Now, gloves most likely include UVA and UVB stabilizers in the manufacturing process, thus making the glove UVA/UVB impervious. It should also be noted that 2,4-D exposures used to calculate risks have been measured under real world conditions with actual glove use by pesticide handlers. Consequently, any possible effects on glove efficacy due to field conditions would already be taken into account in the risk assessment.

The third study cited by NRDC claiming that PPE for workers is insufficient was McDuffie et al.[30] NRDC claims that this study creates an inference that 2,4-D may be penetrating the skin even when workers are wearing gloves.[31] The Agency noted a number of uncertainties with this study. Specifically, the study investigators failed to address factors such as glove type and timing of DEET use.[32] Additionally, the study authors did not indicate if glove permeability contributed to higher exposures.[33] It should again be noted that the exposure values for users wearing gloves in the 2,4-D risk assessment are based on exposures to actual workers using gloves under real world exposure conditions and therefore takes into account actual field conditions.

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[26] Ross RH, Driver JH, Harris SA, Maibach HI. (2005). Dermal absorption of 2, 4-D: a review of species differences. Regulatory Toxicology and Pharmacology 41: 82-91; 84, Table 2.
[27] See 2,4-D; Order Denying NRDC's Petition to Revoke Tolerances, EPA-HQ-OPP-2008-0877; FRL-9344-1 for additional discussion regarding the factors supporting the Agency's choice of a 10 percent dermal absorption factor.
[28] Petition at 13.
[29] HED at 59, 66.
[30] Id. at 62.
[31] Petition at 13.
[32] HED at 62.
[33] Id.

Further, in the 2005 RED, EPA required changes to labels which required that additional personal protective equipment be used by 2,4-D pesticide handlers.[34] For example, the PPE requirements for liquids, wettable powder, formulations in water-soluble packages, and water-dispersible granules as: "All mixers, loaders, applicators, flaggers, and other handlers must wear:

- long-sleeved shirt and long pants,
- shoes plus socks,
- chemical resistant gloves, when applying postharvest dips or sprays to citrus, applying with any handheld nozzle or equipment, mixing or loading, cleaning up spills or equipment, or otherwise exposed to the concentrate, and
- chemical resistant apron when applying postharvest dips or sprays to citrus, mixing or loading, cleaning up spills or equipment, or otherwise exposed to the concentrate.[35]

Because of the PPE changes identified in the 2005 RED, and which are now reflected on product labels, EPA believes worker dermal exposure issues have been adequately mitigated. However, the Agency continues to refine many of its exposure assessment inputs and to establish better methods for considering epidemiological research into the regulatory process (i.e., 2010 SAP review). The Agency is also re-evaluating pesticide risks on a cyclical basis under its registration review process. As such, unless changes to the science dictate an earlier review, the Agency will reevaluate research related to 2,4-D during registration review.

In summary, with regard to the worker exposure claims presented by NRDC and in the related public comments, the conclusions of the studies cited are similar, and overall, the results do not impact the risk conclusions which the Agency developed for 2,4-D. Therefore, the studies do not provide EPA with a basis to modify or question its current risk assessment conclusions for 2,4-D.

IV. Conclusion.

For the reasons discussed above and in the RED issued for 2,4-D, I hereby deny the Petition insofar as it seeks the cancellation of all 2,4-D registrations because of alleged ecological and worker risks.

Steven P. Bradbury, Ph.D.
Director, Office of Pesticide Programs

[34] U.S. EPA, *Reregistration Eligibility Decision for 2,4-D:* (July 2005) at 114 (hereinafter RED).
[35] RED at 114.