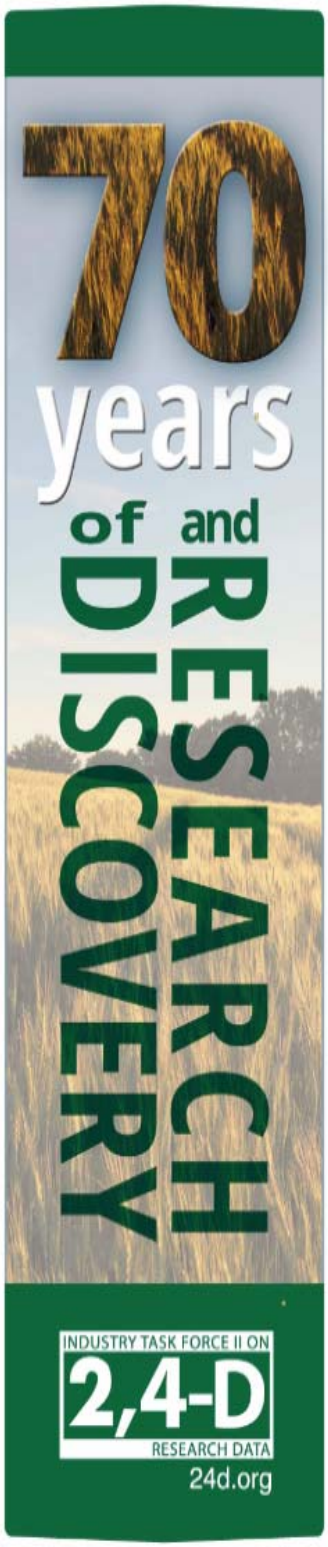


EPA Response to NRDC Petition to Revoke Tolerances and Cancel Registrations of 2,4-D Herbicide

In November 2008, the Natural Resources Defense Council (NRDC) submitted a petition to the Environmental Protection Agency (EPA) which requested that the EPA revoke all tolerances and cancel all registrations for the pesticide 2,4-D. The NRDC petition made six major complaints of the EPA's Risk Assessment?:

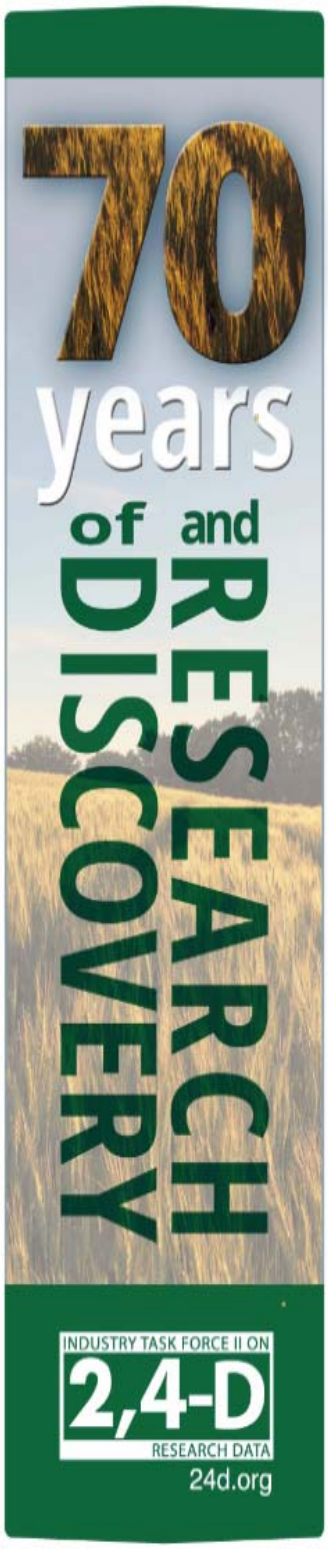
- Failure to incorporate information on the endocrine disrupting effects of 2,4-D into its human health risk assessments;
- Disregard for data that indicated that 2,4-D is a potential neurotoxin;
- Disregard for data demonstrating that 2,4-D is a potential mutagen;
- Failure to consider potential exposure of 2,4-D via breast milk to infants;
- Disregard for data regarding the possible association of 2,4-D and cancer in residential pets; and,
- Failure to conduct adequate aggregate risk assessment and not consider increased exposure from contaminated soil, residential track-in, or absorption enhanced by sunscreen and DEET.

Separately, a number of groups along with the NRDC requested an alternatives assessment for 2,4-D.

In April 2012, the EPA denied the NRDC's petition, on the basis that the claims were either without scientific merit, misinterpreted, or failed to state sufficient grounds for revocation.

1. EPA's Risk Assessment Process

When considering registration of pesticides and other substances, the EPA uses a risk-benefit standard for all forms of exposure other than dietary. The EPA first identifies any meaningful risks, or risks of concern, associated with a product or a specific use of that product. If no risks of concern are identified, the product is registered.



If a risk of concern is identified, label changes are made and the benefits of the product are weighed against that risk. The grounds for registration cancellation or revocation is finding that unreasonable risks outweigh benefits – the NRDC petition failed that test.

The EPA assesses risk by comparing two values, the real-world exposure levels of a chemical and the No Observable Adverse Effects Level (NOAEL), which is the highest exposure level measured in laboratory tests where no adverse effects were noted.

The ratio between these two values is known as the Margin of Exposure (MOE); for 2,4-D to meet the EPA safety standards, the MOE would have to be at least 100x.

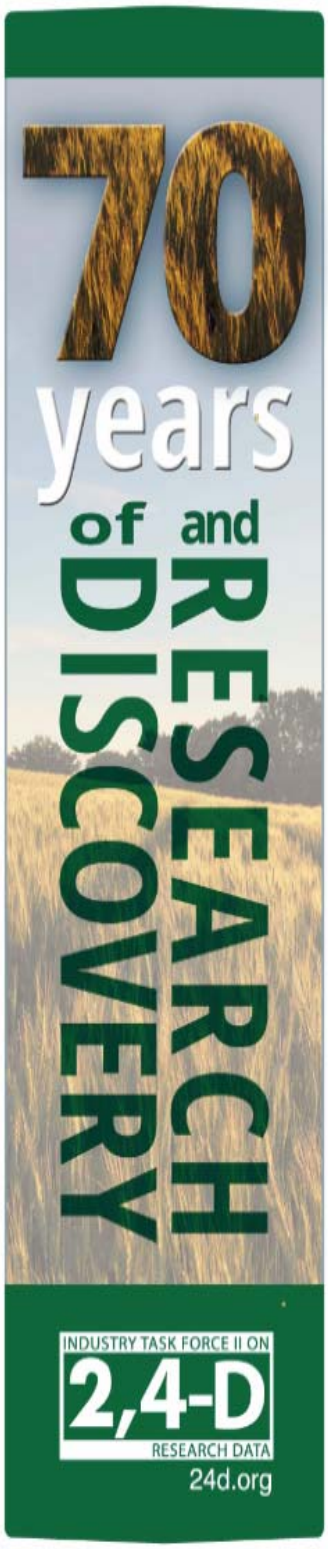
The EPA risk assessment process involves three steps:

- Identifying the harms or toxic effects caused by the pesticide;
- Ascertaining the safe level of exposure to those harms; and,
- Determining whether aggregate exposure to the pesticide exceeds safe levels.

The EPA completed all of these steps in their assessment of 2,4-D and determined that it can be used safely when label directions are followed , which is to say “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” (FR Notice Vol. 77 No. 75, VII.a.1.c., page 23145)

2. Endocrine Disruption

The NRDC claims regarding 2,4-D’s status as an endocrine disruptor only addresses the chemical’s potential hazard and not the risk it actually poses. The petitioner cited studies where 2,4-D showed endocrine disrupting activity; though this is not consistent with the weight-of-evidence on 2,4-D. Further, this only fulfills the first step of the EPA risk assessment process; identifying harms or toxic effects caused by the pesticide.



In order for the EPA to consider revocation, the petitioner would have to at least claim that real world exposure to the chemical could adversely affect the endocrine system, which they do not. The EPA concluded from its own scientific data – which includes a number of recent state-of-the-science studies – that 2,4-D has "no adverse effects" on the endocrine system. (FR Notice Vol. 77 No. 75, p. 23145)

3. Neurotoxicity

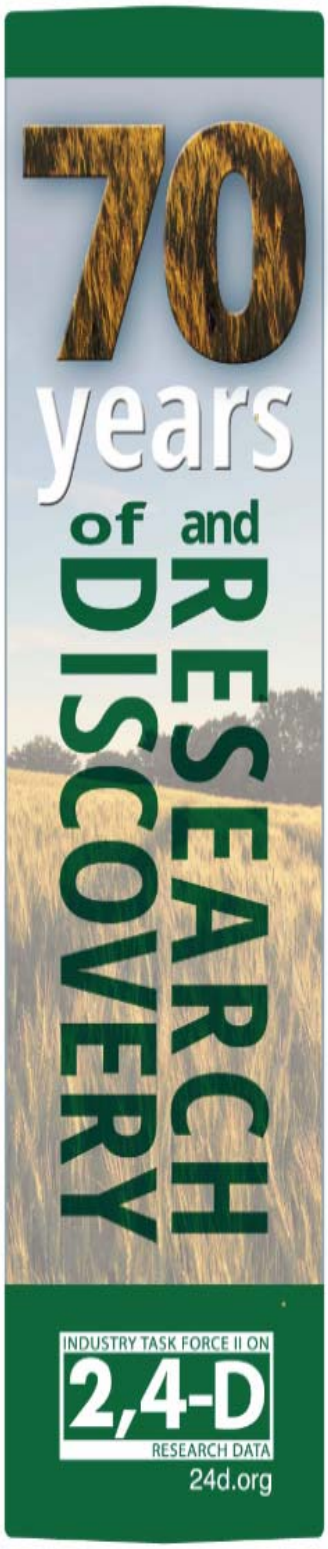
The petitioner took the position that the mere fact that 2,4-D could have neurotoxic effects shows that it is unsafe. These conclusions are drawn from a small pool of studies of questionable validity. As with the endocrine arguments, these claims fail to address all the steps in the risk assessment process necessary to determine safety. While some data shows that 2,4-D can have neurotoxic effects at extreme exposure levels, the EPA has determined that aggregate exposure to 2,4-D is well below safety levels.

4. Mutagenicity

As with both of the previous arguments, the petitioner's claims about 2,4-D's potential mutagenic properties: a) contradict the majority of evidence; b) are based on questionable science; and, c) fail to address the requirements of the EPA's safety standards. The EPA determined that the pattern of responses observed in both *in vivo* and *in vitro* tests indicated that 2,4-D was not mutagenic. (FR Notice Vol. 77 No. 75, p. 23150)

5. Breast Milk

Despite the inadequacy of petitioner's claim regarding 2,4-D exposure in human breast milk, EPA examined the evidence cited by the petitioner for the purpose of evaluating whether the evidence raises sufficient grounds for concern regarding 2,4-D. NRDC is incorrect in stating the EPA assumed that humans are not exposed to 2,4-D through maternal milk. To the contrary, EPA assumed, in its RED risk assessment, that all milk – whether animal or human – contained 2,4-D at levels that may be present in cow's milk. This is an extremely conservative assumption as it pertains to human breast milk and the Agency has no concerns.



6. 2,4-D and Residential Pets

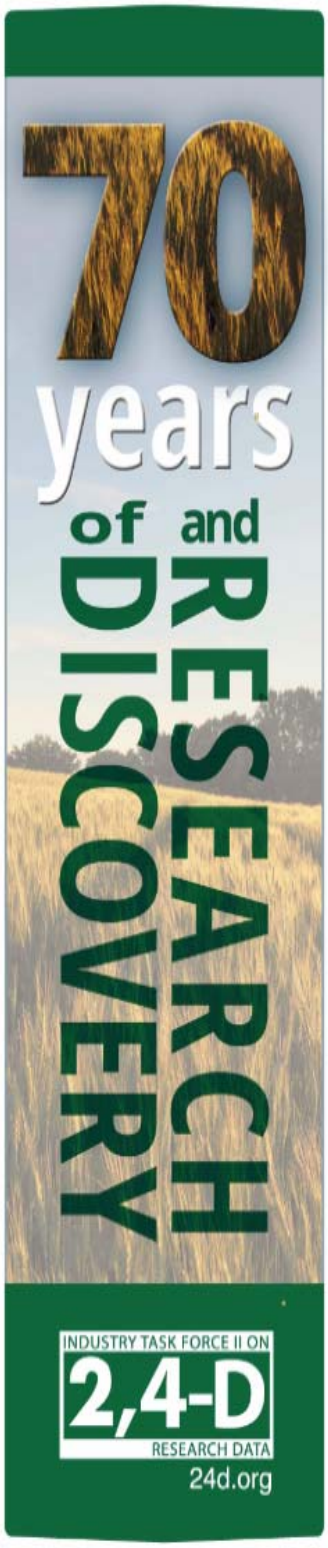
Work by a former researcher at the National Cancer Institute (Hayes *et al.* 1991 and 1995) suggested a link between dogs with Canine Malignant Lymphoma (CML) and dog-owners that applied 2,4-D to their lawn. An independent panel concluded in 1992 that the study design was severely flawed and, in fact, did not show an association between CML and 2,4-D use. In 1999, scientists at the School of Veterinary Medicine at Michigan State University re-examined the NCI data and also concluded that there was no relationship between 2,4-D use and CML. Most recently, the EPA determined that the studies cited do not affect the Agency's previous assessment: 2,4-D is not an animal carcinogen.

7. Exposure

The NRDC raised concerns about the contamination of indoor track-in dust by 2,4-D, and made claims that this contamination could increase aggregate exposure beyond safe levels. The NRDC was especially concerned about exposure to young children, whose unique behavior patterns could potentially increase exposure. When considering the risk of dust contamination, the EPA assumed that toddlers consume on average 100 mg/day of dust. The EPA also assumed the highest concentration levels found in the studies the NRDC cited, of 67ug/g of dust. It should be noted that this value was the absolute highest in the study; the median value was only 10 ug/g. The EPA had considered young children in its original risk assessment, and found that, even combined with other exposures, soil exposure levels did not present a risk of concern.

The petitioner claimed that wearing sunscreen containing the insect repellent DEET increased the skin's absorption of 2,4-D, increasing overall exposure potentially beyond safe levels. This claim was based on the results of a study that the NRDC misinterpreted. Several studies show no significant increase in absorption of 2,4-D in humans wearing sunscreen or DEET. Additionally, the EPA assessed the safety of 2,4-D under the assumption that absorption was more than twice as high as real world levels, and still concluded that exposure level was acceptable.

Based on even this artificially high exposure level, margins of exposure ranged from 32,000 to 150,000, depending on the duration of exposure. Even when assuming that the contaminated dust persisted in impacted residences, which it does not, margins of exposure were still over 11,000. Based on these estimates, the EPA found that 2,4-D was still well within safety standards.



8. Alternatives Assessment for 2,4-D

Several groups called on the EPA to consider a comprehensive evaluation of alternatives to 2,4-D. In responding to the petitioner and other pressure groups, the EPA stated:

> "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."

To summarize its most recent decision, the EPA unambiguously stated:

> "After considering public comment received on the petition and all the available studies, including a state-of-the-science one-generation reproduction study, EPA is denying the request to revoke all tolerances and the request to cancel all registrations."

About the Task Force

The Industry Task Force II on 2,4-D Research Data is organized to provide funding for the on-going Good Laboratory Practice (GLP) research studies required to respond to the US EPA registration review and PMRA pesticide re-evaluation programs. The 2,4-D Task Force is comprised of those companies holding technical 2,4-D registrations: Dow AgroSciences (U.S.), Nufarm, Ltd. (Australia) and Agro-Gor Corp., a U.S. corporation jointly owned by Albaugh, LLC. (U.S.) and PBI-Gordon Corp. (U.S.).

March 17, 2016