



Canadian Environmental Law
Association

L'Association canadienne du droit de
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TORONTO ENVIRONMENTAL
ALLIANCE



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Alternative Strategies and Regulatory Affairs Division
Publications Coordinator
Pest Management Regulatory Agency
2720 Riverside Drive
A.L. 6605C
Ottawa, ON, K1A 0K9

VIA FAX (613) 736-3758

**Re: Response to Proposed Acceptability for Continuing Registration (PACR) 2005-01:
Re-evaluation of the Lawn and Turf Uses of (2,4-Dichlorophenoxy) acetic Acid [2,4-D]**

About CELA

The Canadian Environmental Law Association (CELA) is a non-profit, public interest organization and environmental law clinic – within Legal Aid Ontario - dedicated to providing legal services to low income people and disadvantaged communities, and advancing the cause of strong environmental protection through advocacy, education and law reform. CELA's law reform and public educational mandates include advocacy on ensuring access to environmental justice and protecting public environmental rights. CELA has worked on pesticide issues, on behalf of clients and for the sake of improved pesticide legislation, for over twenty years. For more information, please visit www.cela.ca.

About TEA

The Toronto Environmental Alliance (TEA) is a non-profit, non-governmental grassroots organization providing public education and advocacy on local and national issues such as smog, pesticides, waste, and water quality. Over the last 10 years, TEA has been involved in many important initiatives to reduce pesticide use on urban landscape through educating the public on natural lawn care alternatives and encouraging government regulation to end the non-essential use of pesticide that pose potential human health and environmental impacts. For more information, please visit www.torontoenvironment.org.

About WWF

WWF's mission is to stop the degradation of the planet's natural environment and to build a future in which humans live in harmony with nature by conserving the world's biological diversity; ensuring that the use of renewable natural resources is sustainable; and promoting the reduction of pollution and wasteful consumption. World Wildlife Fund was established in 1961 and operates in more than 100 countries, investing nearly \$500 million per year in worldwide conservation efforts. WWF-Canada focuses its conservation efforts by identifying solutions to the challenges associated with endangered species, toxic pollution, climate change, oceans and coasts, freshwater and forests, concentrating on long-term partnerships with governments, businesses and other NGOs, local communities and Aboriginal peoples to overcome obstacles, instigate field-level conservation, magnify existing effort, and influence through targeted legislation, market forces and voluntary commitments. For more information, please visit www.wwf.ca.

In responding to the Proposed Acceptability for Continuing Registration (PACR2005-01) document for 2,4-D, we have organized our comments in the following areas:

1. PMRA Communication Materials regarding PACR 2005-01
2. Human Health Assessment
3. Exposure Assessment
4. Value Assessment
5. Environmental Assessment
6. The Precautionary Principle and application of the revised *Pest Control Products Act*

1. PMRA Communications Materials regarding PACR 2005-01

In reviewing the PACR document and associated communications materials, we are concerned about inconsistent and misleading statements regarding the safety of 2,4-D, and definitive language which implies that the PMRA's decision is final and not "proposed" as stated. Additional concerns arise due to the fact that the proposed decision on re-evaluation is being made when additional data requirements are outstanding and necessary to fill important gaps in the available information about 2,4-D toxicity.

The PACR contains appropriately qualified statements that are contradicted by definitive statements about safety or targets being "inherently protective." Even more definitive statements about the "safety" of 2,4-D and supporting scientific information, are contained in the associated background materials – the news release, background *Information Note* and the document entitled "Questions and Answers about 2,4-D."

For example:

- **The PMRA's use of the words "safe" and "safely"**

In the PACR document, the statement is made in several instances that 2,4-D "does not entail an unacceptable risk of harm to human health and the environment." This statement is also accompanied by qualifying language noting that it is made on the basis of currently available

information. This language is appropriate within the context of the risk assessment methodology being employed and, more important, is appropriate language to be used in a document for which the re-evaluation decision remains *proposed*, not finalized.

In contrast, the PMRA news release, *Information Note* and Q and A document (all on-line at the PMRA website) consistently describe the use of 2,4-D as “safe” or that it “can be used safely.” While the latter statement is sometimes accompanied by “when label instructions are followed,” this is not always the case, most notably in the title of the *Information Note*. Such definitive language about safety would be inappropriate even if the document were finalized, which it is not. The PMRA’s communications choices leave us wondering why to bother responding to a consultation document for which the agency appears to have made a final decision.

This matter was raised recently on April 11 when the PMRA’s new Executive Director, Karen Dodds, appeared before the Parliamentary Standing Committee on Health. In response to concerns raised about the inappropriateness of such language in PMRA public materials, Ms. Dodds stated, “we are working to clarify our communications.” No change is yet apparent on the PMRA website materials with respect to the documents associated with the 2,4-D PACR. In the past four years of CELA’s and WWF’s participation in the Pest Management Advisory Council (PMAC), similar concerns about PMRA communications have been raised numerous times. At the most recent meeting a working group was established to address this matter. When concerns have been raised at the PMAC meetings, PMRA officials have provided the exact same response recently heard from Ms. Dodds – “we are working to clarify our communications.” The “work to clarify communications” in the PMRA is not yet apparent when, once again, on a matter of considerable concern to the Canadian public, the PMRA has used inappropriate and potentially misleading language to describe a proposed regulatory decision.

- **Statements in the PACR about the scientific information base.**

There are several statements throughout the PACR review of toxicology data (for 2,4-D acid, BEE, EHE and DMA) that highlight the nature of uncertainty and/or ignorance about toxicological effects.

Specifically, on page 9, with respect to developmental neurotoxicity:

Although these [developmental neurotoxicity] effects were observed at much higher dose levels relative to the doses causing the primary target effects in the short- and long-term studies, these findings may be an indication of offspring sensitivity after exposure to 2,4-D during prenatal and postnatal development.

And again on page 9-10, with respect to developmental toxicity studies:

An increased incidence of maternal death in pregnant rabbits indicated that rabbits were more sensitive than rats to the toxic effects of 2,4-D. The developmental toxicity studies, which used gavage dosing, often indicated a steep dose-response between serious effects (i.e., mortality, abortions) and the no-effect level. Although a similar response was not evident in the dietary studies, suggesting that the steep dose-response was attributed to bolus dosing, this observation remains a concern.

On page 11, with respect to the human evidence concerning reproductive effects:

In the absence of any direct measurements of exposure to 2,4-D, the current scientific evidence to support adverse reproductive and developmental effects in humans, in association with exposure to 2,4-D, remains unclear.

Although these are just a few examples of the stated level of uncertainty, they are of the greatest concern to those interested in understanding the potential hazards on 2,4-D to the fetus and young children. Yet, despite the considerable uncertainty that remains in the scientific information base summarized in the PACR, and the fact that the data requirements relating to chemistry and toxicology (noted in section 9 - Additional data requirements) remain outstanding, the following statement is repeated three times in the document:

This target MOE [margin of exposure] is *inherently protective of any* uncertainty regarding potential sensitivity to the young. (emphasis added).

The above statement is made on pages 14 and 22, concerning the conclusions reached about exposure assessment, and again on page 23, with the additional clause,
...including to the unborn child of a pregnant worker.

The PACR does not provide the scientific justification for making such definitive statements. Rather, the opposite impression is left: that the level of uncertainty and gaps in information remaining to be filled, would lead to the conclusion that making such a definitive statement would be impossible.

- **Statements in PACR misrepresented in the PMRA communication materials**

On page 11, the PACR notes, that:

PMRA concurs [with other regulatory agencies] that 2,4-D cannot be classified as to its human carcinogenicity.

In contrast, in the document entitled Questions and Answers about 2,4-D, the following inaccurate and misleading statement is made:

THE PMRA found that 2,4-D does not cause cancer.

Again, the PACR does not provide the scientific justification for making such a definitive statement.

- **Statements in the supporting communications materials unsupported by data review in the PACR**

The document entitled Questions and Answers about 2,4-D contains the question: “Should I be concerned about exposure to 2,4-D from track-in of residues into my home?” The answer is “No” followed by a description of a risk assessment that is not described or analyzed in any detail whatsoever in the PACR. We consider the PMRA’s omission of tracked-in exposures to be a significant deficiency in the PACR exposure assessment, as discussed further below.

2. Human Health Assessment

While above we note concerns about PMRA *communications* about possible human health impacts, the PACR human health assessment raises substantive and troubling concerns. First are concerns related to developmental neurotoxicity, developmental toxicity, and reproductive toxicity outlined above.

Secondly, we are concerned that inadequate safety factors have been applied, without rationale. In spite of a very long regulatory history of 2,4-D re-evaluation, as described in the PACR (begun in 1980, renewed in 1994 and then made a “priority” in September 2000 in terms of the lawn and turf uses), the PACR describes ongoing scientific uncertainty about human health effects. Notably, considerable uncertainty and a significant paucity of data remains concerning effects on foetal and child health. We therefore find it surprising that the option of applying a 10-fold safety factor for children has been reduced to a 3-fold safety factor in the risk assessment calculations.

Third, Section 9 of the PACR describes data requirements for chemistry data with respect to possible dioxin contamination and levels of NDMA in products containing DMA. Section 9 also sets out data requirements for addressing uncertainties with respect to developmental neurotoxicity and reproductive effects via a multi-generation reproduction study. We submit that the data requirements described in Section 9 of the PACR should be received by the PMRA before a decision on acceptability is made. Moreover, given the potential seriousness and controversy concerning the possibility of dioxin contamination, the chemistry data requirements must be subject to independent testing.

Fourthly, the PACR review of data concerning cancer risk is unacceptably limited and only presented in summary format. It appears that the review was confined to the various contradictory findings with respect to associations between 2,4-D and soft-tissue sarcoma and non-Hodgkin’s lymphoma. We are not as inclined to dismiss these contradictory findings from epidemiological studies. A precautionary response is warranted when considering the results of these studies and the weight of evidence from these studies is suggestive of an association with non-Hodgkin’s lymphoma.

In addition, it is unclear whether evidence was reviewed concerning a suspected link between chlorophenoxy herbicides and cancer of the thyroid gland. This suspected link is noted in the *Overview of the Special Vulnerability and Health Problems of Children*, one of the Paper Series on Children’s Health and the Environment, published in 2003 by the USEPA. The suspected link between chlorophenoxy herbicides and thyroid gland cancer cites a 1991 *Lancet* study concerning cancer mortality on workers exposed to chlorophenoxy herbicides and chlorophenols. Since thyroid cancer is rising among young adults in Canada faster than any other form of cancer, we would like to know whether the PMRA investigated this line of evidence in the review of cancer risk with respect to 2,4-D.

Finally, our organizations regularly receive calls from individuals who experience chemical sensitivity. They report experiencing significant acute reactions when common lawncare

pesticides are used in their neighbourhoods. We are regularly told of respiratory distress, headaches, fatigue and other symptoms that are sometimes brought on by simply walking past a neighbour's recently sprayed lawn. Even more worrying is that more and more people seem to be experiencing these kinds of chemical sensitivities. The PACR does not address this growing issue and the PMRA has a responsibility to access this human health concern, which may entail additional data requirements before re-registration is approved.

3. Exposure Assessment

The PACR and associated communications materials repeatedly state that the PMRA risk assessment of 2,4-D considers the risk resulting from:

...combined exposures from *all sources and routes*, including food, drinking water and *residential exposures*" (emphasis added).

PMRA Executive Director Karen Dodds repeated this claim in her statements to the Parliamentary Standing Committee on Health.

We disagree with this statement and consider the omission of "tracked-in" exposures to be a shortcoming in the risk assessment that serves to undermine the integrity of the final risk calculations. Tracked-in exposures are not addressed in any detail in the PACR, despite the unsubstantiated statements made in the Q and A document, as noted above, and in spite of the list of references provided in the PACR noting some, though not all, of the salient references from the literature on this topic although they are not cited anywhere in the text of the PACR itself.

Also not reviewed or evaluated in the PACR is the evidence concerning the rate and degree to which substances like 2,4 -D break down once they are tracked indoors and no longer subject to the weathering effects of sun, wind and rain. The PACR contains information about the break down of 2,4-D in only the outdoor environment.

These omissions and therefore lack of any review and evaluation of this information in the PACR exposure assessment needs to be corrected for the statement quoted above to be accurate.

We also wish to draw attention to proposals arising from the Federal-Provincial-Territorial Committee on Pest Management and Pesticides concerning a harmonized products classification scheme. Those proposals include recommendations that so-called "weed n feed" products (combining lawn care herbicides and fertilizer) be placed in a higher risk category to address exposure concerns. This recommendation recognizes that greater risk of exposure occurs with such products since people are in direct contact with the product and are less likely to take precautions to avoid exposure when it is not obvious or even understood that such products contain pesticide. Indirect exposure is also addressed with a higher risk designation in recognition of the opportunity for gardening equipment, such as water hoses, to rub across a lawn and pick up the pesticide providing an opportunity for unnoticed exposure when this equipment is handled. There is no indication in the PACR that these kinds of exposures, that can quite reasonably be expected to occur, were considered in the exposure calculations.

We strongly support the re-classification of pesticide-fertilizer combination products as "higher risk" domestic products. Studies have found that "the original hypothesis that the use of a weed and feed formulation of 2,4-D results in lower exposure to the applicator than a liquid formulation cannot be substantiated" (see: Harris SA, Solomon KR and Stephenson GR. (1992) Exposure of homeowners and bystanders to 2,4-dichlorophenoxyacetic acid (2,4-D). *J. Environ. Sci. Health.* B27:23-38.).

A designation as higher risk can serve to increase consumer awareness of the need for special precautions and clear information that they are indeed using pesticides when applying a "weed and feed" product. More important, the continued registration of any combination products, particularly those with competing use regimens, is ill-advised. The decision to eliminate the registration of combined insect repellent and sunscreen products is a comparable precautionary measure and should be similarly applied to weed and feed combination products.

4. Value Assessment

The PACR value assessment of 2,4-D contains several statements that are surprising coming from a regulatory agency. The efficacy of the chemical in terms of its ability to kill target pest species is provided, as is required under the statute. However, the value assessment contains statements about the use of 2,4-D on turf that sound like a product advertisement. For example, on page 30:

Over the past 40 years, 2,4-D has played an important role in the maintenance of turf. Without it, the number of broadleaf weed control products presently available to homeowners would be severely limited.

This statement is completely subjective and denies the reality that over 70 municipalities in Canada have banned the use of 2,4-D for general turf maintenance.. In addition, there are hundreds, perhaps thousands, of public parks and school boards that have not used herbicides for broadleaf weed control for many years, in some cases since the early 1990s. Most importantly, it is not necessary for Canada's pesticide regulatory agency to discuss efficacy of a product beyond whether it works as designed. Moving into the realm of "cheerleading" for a product that many people and public institutions consider irrelevant for turf management undermines the credibility of the entire PACR.

5. Environmental Assessment

The PACR environmental assessment is unclear and somewhat contradictory. On page 27, it states:

Based on reproductive toxicity, the potential risk to mammals from application of liquid formulations was determined to be moderate, except at the highest application rates (exceeding 1.75 kg 2,4-D/ha), where the potential risk of reproductive effects (decreased pup survival) was determined to be high.

Considering the serious consequences of negative interference with reproduction at the individual and population level, one would expect that data showing that 2,4-D has moderate to

high risk for reproductive effects in mammals would be considered in detail and, at the very least, be addressed in the environmental risk assessment conclusion. It is striking and unacceptable omission for neither the risk conclusion nor mitigation sections on page 28 to address this evidence of potential risk of reproductive toxicity in mammals.

The environmental assessment consistently generalizes and minimizes 2,4-D's effects and fate. For example, we aware that toxicity to fish varies widely depending on the species and the form of 2,4-D. Also, its half life in soil depends on other environmental conditions (i.e. temperature) and type of soil; 2,4-D is biodegraded to various hydroxylic aromatic products with typical half-lives in soil of one day to several weeks, depending on the type of soil, temperature, soil water and organic content. In coarse-grained sandy soil where both biodegradation and adsorption is low, leaching to ground water may occur. A three-year study, conducted at Lethbridge, Alberta, showed traces of 2,4-D (0.05-5.2 ppb) contamination in samples collected from 6-meter monitoring wells; a large variation occurred in herbicide levels depending on the time of last application, and timing and amounts of subsequent moisture events (rain fall/irrigation) after application. Similarly, in Ontario 2,4-D residue have been found in drinking water. Of 237 wells sampled, 73 wells had concentrations ranging from 0.01-14,600 ppb. Typical half-life of 2,4-D in water is 10 to over 50 days, depending on type of water, organic particulate matter, sunlight, temperature, and oxygen content. Given such variability, the appropriate response would be to use so-called worst-case scenarios and err on the side of caution.

Further, the subtler effects of 2,4-D on environmental/ecosystem health has not been adequately taken into account in the assessment. Although not acutely toxic to wildlife in the same way that many insecticides are, 2,4-D indirectly affects herbivorous species by eliminating and/or contaminating their food source. Given the extent of this herbicide's use, the total impact can be enormous. For example in British Columbia, plants classified as "high importance" for moose, elk, bighorn, sheep etc. have been severely damaged by 2,4D amines and esters.

6. The Precautionary Principle and application of the revised *Pest Control Products Act*

Although the revised *Pest Control Products Act* is not yet in force, the PMRA has repeatedly stated, including in the 2,4-D PACR document, that the provisions of the new Act are largely being applied. However, as outlined in this submission, important new provisions in the revised law have not and should be applied to the re-evaluation of 2,4-D, specifically:

- Apply the 10-fold safety factor to compensate for data gaps and uncertainty intended to increase protection of fetal and child health. Specific gaps and uncertainties related to human health and environmental health have been outlined above.
- Address aggregate/total exposure from all sources and assess chemicals in the context of multiple chemicals having a common mechanism of toxicity. Blatantly missing is any evaluation of combinations of products, in spite of the PACR value assessment stating that the majority of products contain combinations of either 2,4-D, mecoprop and dicamba, or 2,4-D and mecoprop. It also notes that these substances act synergistically, although this is in the context of their efficacy. However, since 2,4-D use is so commonly

associated with these combinations of similar chemicals, it begs the question as to what combined effects might exist in terms of toxicity. The PACR should indicate the extent to which research has determined whether or not there is a common mechanism of toxicity across these and other chlorophenoxy herbicides. If there is some evidence showing possible common mechanism of toxicity, and given the stated commitment to apply the provisions of the revised law, an evaluation of 2,4-D should be conducted with such other substances which are regularly applied with 2,4-D. As well, if the product's formulations (i.e, the 2,4-D product combinations) are in fact reviewed in the evaluation, the PACR does not indicate this, leaving this issue unresolved.

- Make the information used in the re-evaluation available for public review. Currently, much of the information used is considered proprietary data
- Apply a precautionary approach. In the revised law, the onus of determining acceptable risk will change, statutorily, from the PMRA, to the registrant and the Minister will have a positive obligation not to register a product, or accept its continued registration, unless the registrant has fully demonstrated that risks are acceptable. It is astounding that there is no mention of the precautionary approach in the PACR.

It is our submission that such acceptability of risk has not been demonstrated in the PACR. We base this on the need for additional toxicological data, the uncertainties and gaps in existing data, concerns regarding the adequacy and completeness of the human health data and its treatment, shortcomings in the treatment of environmental toxicity and fate data in the environmental assessment, the omission of a key source and route of exposure (tracking-in), and other shortcoming and concerns outlined above.

In light of all the foregoing comments and unanswered questions, we submit that the proposed acceptability for continuing registration of the lawn and turf uses of 2,4-D is premature and ill-advised.

Yours truly,

Kathleen Cooper, Senior Researcher
Canadian Environmental Law Association
130 Spadina Avenue, Suite 301, Toronto, ON M5V 2L4

Katrina Miller, Researcher
Toronto Environmental Alliance
30 Duncan Street, Suite 201, Toronto, ON M5V 2C3

Julia Langer, Director, International Conservation Program
Susan Sang, PhD, Senior Manager Arctic and Marine Conservation Programs
World Wildlife Fund Canada
245 Eglinton Avenue East, Suite 410 Toronto, Ontario M4P 3J1