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An Open Letter concerning the PMRA's re-evaluation of 2,4-D, as prepared by CCHE:



www.cche-info.com

Re: PACR2005-01, Re-evaluation of the Lawn and Turf Uses of (2,4-Dichlorophenoxy) acetic Acid [2,4-D]

The Canadian Coalition for Health and Environment (CCHE) is responding to the invitation to comment on the Proposed Acceptability for Continuing Registration of the herbicide, 2,4-dichlorophenoxy acetic acid (2,4-D). The CCHE is a national coalition of groups and individuals, including scientists and physicians. The CCHE encourages and supports the use of ecological strategies to protect human health and the environment.

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Earth Day April 22, 2005.

# **Summary - Conclusions and recommendations**

The CCHE objects to the use of 2,4-D for turf because:

- Clear risks are associated with the use of 2,4-D, so the Precautionary Principle<sup>1</sup> should prevail the health of us, our children and future generations and our environment are overwhelmingly more important than killing weeds in grass by using toxic chemicals.
- This chemical has no true "value" because ecologically-based, sustainable landscaping practices
  enable citizens to have better lawns and landscapes than they would have with the use of toxic
  chemicals to produce a monoculture. These landscaping practices also require less fossil fuel
  (slowing climate change), require less water, foster biodiversity and increase the health and

**†** 

ecological resilience of the landscape.

### The CCHE objects to the PACR2005-01 because:

- The document was published before crucial information had been provided by the registrants (neurotoxicity and reproductive studies, and dioxin analyses)
- The PMRA did not require analyses of all relevant dioxin contaminants
- The more-toxic diethanolamine salt of 2,4-D was excluded from assessment, but this active
  ingredient is probably in most pesticide products on the shelf.
- Child cancer was given short shrift. The independent Science Advisory Panel said it merited more study, but animal (rat) data was preferred, in spite of the fact that rats have detoxification enzymes that humans lack.
- Significant risk to human health from phenoxy herbicides is apparent in the epidemiological literature for reproductive, neurological and genotoxic / malignancy endpoints.
- Cumulative risk from various phenoxy herbicides in a mixture were not accounted for.

#### The CCHE asks that:

- The PMRA conduct future pesticide assessments according to established standards for systematic review in medical research, and in a transparent manner. Exclusion and inclusion criteria should be explicit, and should exclude unethical studies. Canada must be bound by the Nuremburg Code.
- Future pesticide assessments include analysis of all toxic contaminants and breakdown products, including all track 1 toxic substances identified under the Canadian Environmental Protection Act. It is urgent that complete dioxin analyses be conducted for phenoxy herbicide products, and in the environment of intensively maintained turf.
- The PMRA clearly solicit additional public comment on this and other issues, and refrain from publishing claims of "safety". Rather than soliciting comment, the PMRA published an unsubstantiated "safety" claim. The Pest Control Products Act restricts language of advertising. The PMRA should publicly withdraw the 2,4-D Information Note.
- The regulations to put the new (2002) PCPA in force be promulgated as soon as possible, and that the Precautionary Principle immediately be incorporated in all decision-making.
- Combination herbicide / fertilizer products be immediately phased out, because they are
  incompatible products one should be spread over the entire area, while herbicides, if they are to be
  used, should be targeted to undesired plants. This is analogous to sunscreen / insect repellent
  combination products that were discontinued.
- Indoor exposures to pesticides should be estimated in a protective manner, and be used rigorously
  in all assessments.
- Pesticide packaging and labels clearly indicate the period and status of registration..

#### Introduction

The CCHE believes that human and ecosystem health must be considered of paramount importance, and that the Precautionary Principle must prevail. If there is reason to believe that harm may occur, action should be taken even in the absence of absolute scientific certainty.

The PMRA is presently assessing many pesticides for turf and gardens, where children play. These reassessments have nothing to do with food production. Comments made in this submission pertain to the all assessments of pesticides for landscaping purposes.

The process of examination of evidence during assessments must aim for the truth. Much thought and many innovations have been incorporated in order to discern truth and transparency in medical research, that should be applied to pesticide assessment.

Assessments address many topics. We have concerns regarding:

- · Procedures and protocols for assessments
- Potential harms and mechanisms thereof for humans, other species and ecosystems

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- What comes along with the pesticide? contaminants, formulants, breakdown products
- "Value" of the pesticide.

#### **Process of Assessment**

The PMRA is in the impossible position of designer of research, recipient of funds from the proponent for review, peer reviewer of research they requested, and negotiator with powerful multi-national companies. Pharmaceutical trials and federal drug approvals have recently received considerable negative attention.<sup>2</sup> However, a much greater proportion of the drug data is in the public domain. In this context, the medical community has been improving accountability and transparency by instituting trial registration,<sup>3</sup> and standards for trial design, reporting<sup>4</sup> and systematic review.<sup>5</sup> None of these measures are in place for pesticides. Health Canada and the PMRA should take note.

Researchers who have been reforming medical science would be appalled with the conduct of pesticide assessment. The point of the disagreement is essentially: "on what do you base decisions?" Incredibly, Canada's pesticide regulator is openly criticizing the Ontario College of Family Physicians (OCFP) for its report urging caution and avoidance of toxic chemicals. Systematic review, the process employed by the OCFP, lays out criteria to judge original research reports, for inclusion in the synthesis of medical evidence. These criteria address ethics, blinding, study design and thoroughness of reporting, including confounding factors. The OCFP report is criticized for lack of inclusion of data (to some of which the PMRA had denied access), and the well-accepted process of systematic literature review. Problems with the PMRA's assessments include: industry-provided, secret studies; reliance upon reviews by interested parties rather than independent systematic reviews of primary literature; and even reliance upon unethical studies such as human ingestion of 2,4-D. Canada must be bound by the Nuremburg Code!

At the most basic level, the PACR is deficient and flawed. The most recent reference cited was several years old, although important studies have been published more recently. However, Garabrant's description of human ingestion of 2,4-D in a slurry of milk was included in the short list of references. If recent studies are not included, and unethical studies are included, what is or isn't in the secret studies the public cannot see?

The PACR was published before reproductive and developmental neurotoxicity studies, as well as dioxin analyses, required by the PMRA, were received from the Industry Task Force II for 2,4-D Research Data. The PMRA has since indicated that these were "confirmatory" studies. However, given that considerable evidence exists that these are outcomes associated with harm from 2,4-D, it is very dangerous and contrary to its mandate for the PMRA to be pre-judging the outcomes of studies.

It is completely inappropriate that the PMRA continually presume that a pesticide is harmless. The most glaring public example of this was seen with the proclamation of a conclusion rather than announcement of public consultation. The Information Note should be publicly withdrawn, and proper public notice be given for further consultation. In its actions, the PMRA is demonstrating that it is not dispassionate or objective. If that is not bad enough, as discussed below, decades of ignoring the principle dioxin contaminants of 2,4-D make the PMRA complicit in a possible (in our view probable) long-term toxic cover-up.

The diethanolamine salt (DEA) is particularly toxic, and was explicitly excluded from the PACR. However, searches by P. Hjertaas, of label information, PMRA information requests and fertilizer information provided by the Canadian Food Inspection Agency confirm that "mixed amines", generally containing DEA, are in many herbicide and "weed and feed" type products.

Finally, Canada still does not track pesticide sales or use, and has no adverse effects reporting system (although these are supposed to be "in the works"). Canadian pesticide use and harm data are needed, on which to base epidemiological assessments. It is unconscionable that we know so little after sixty years of spreading this toxic chemical in our environment..

### **Harms of Pesticides**

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### **Health Effects - Background**

Human health effects of pesticides are difficult to ascertain, because the "gold standard" randomized controlled trial cannot ethically be conducted.

**Epidemiology** may indicate possible adverse effects, but in today's chemically complex world, with dubious chemicals in our foods, pharmaceuticals, personal care and cleaning products, housing materials etc., pesticides effects may be obscured by myriad other factors. In this context, a null result in an epidemiological study cannot be considered vindication of a chemical. However, positive associations with maladies must be taken very seriously, and be considered the "tip of the iceberg". For example, weak associations were originally seen between smoking and lung cancer when control groups were non-smokers within the same household, but with better control groups the potency of the role of tobacco smoke in several maladies became apparent. There is no good control group for pesticides, so associations with maladies, obscured by confounding factors, must in fact be quite strong to have been observed at all.

Another important point is that people's reproducible experiences must be adequately addressed, even if we cannot fully understand them. Multiple chemical sensitivity is now firmly established in Canada, with consensus diagnostic criteria. Health Canada and the Ontario Commissioner of Human Rights have recognised that people with chemical sensitivities must be protected from pesticide exposures. The testimony of many regarding debilitating responses to pesticides, including phenoxy herbicides, collected by Health Canada over many years, should be given heavy weight when re-assessing lawn chemicals.

**Toxicology** and *in vitro* studies may contribute to understanding of toxic effects, in terms of mechanism and plausibility. However, these studies cannot trump positive epidemiological associations. The reliance primarily upon animal toxicology, with single chemicals and animals in otherwise "clean" environments, is a major failing of Canada's pesticide approvals process. This may be difficult to avoid when examining new products, but it is inexcusable for re-assessments, particularly of pesticides used over 60 years. Moreover, extrapolation from studies in rats may be inappropriate, because rats have genes that do not exist in people, for detoxification of chemicals.<sup>11</sup>.

# Specific Health Effects of 2,4-D

The CCHE is not commenting on the detailed calculations of risk, because fundamental flaws in the assessment render these calculations of little value.

#### Cancer

Non-Hodgkin's lymphoma, leukemia and sarcoma are frequently noted in association with phenoxy herbicides. The PMRA classified 2,4-D in group "D" - not classifiable as to carcinogenicity - despite human and canine studies linking the herbicide to cancers. Noteably, the recent findings of four fold increased incidence of canine bladder cancer with exposure to phenoxy herbicides were not included in the list of references. The PMRA's Science Advisory Panel wisely advised that childhood cancer merited more study. The EPA recently revised its guidelines for carcinogenic risk assessment for children and recognised that children are many times more susceptible to carcinogens than adults. Older health care professionals speak of the virtual absence of childhood malignancies before pesticides were common. The incidence of intractable childhood neurological malignancies is doubled when landscaping pesticides are used around the home.

### **Reproductive Difficulties**

2,4-D has been found in urine and semen<sup>16</sup> and chlorophenoxy herbicides have been linked to sperm abnormalities,<sup>17</sup> increased miscarriage rates,<sup>18</sup> difficulties conceiving and bearing children and to birth defects.<sup>19</sup> An animal study demonstrated failure of pregnancy using an "off-the-shelf" phenoxy herbicide mixture.<sup>20</sup> Clear risks have been observed, and no number of "confirmatory studies" can make this go away.

# **Neurological Impairment**

Lawn pesticides are implicated in neurological disorders such as Alzheimer's disease, Parkinson's disease, ALS, autism, and attention deficit hyperactivity disorder. The PMRA clearly recognised this risk because possible neurological impairment (dizziness, muscle weakness, loss of coordination, fatigue) is noted in the PACR for the pesticide label for professional applicators. Homeowners were not to be so warned. Such warnings should be given to everyone.

The PACR was published before a developmental neurotoxicity study had been received from industry, although myelin deficiencies were noted in exposed animals. Thus, the epidemiology and toxicology both indicate possible harm, and users are warned of the possible harm. There are clear risks, and the Precautionary Principle must prevail.

# 2,4-D in the environment

2,4-D runs off of turf into waterways, and has been detected in many locations, including Toronto<sup>21</sup> and Ottawa.<sup>22</sup> It is difficult to ascertain long-term environmental and health effects of such chronic, low-level exposures, but they should be of serious concern, and certainly not tolerated for the sake of killing unwanted plants in turf. Reports such as these have not examined toxic breakdown products such as chlorinated phenols nor dioxin contaminants.

Although 2,4-D breaks down relatively quickly with bacterial action in moist soil, once tracked indoors it lingers for months or years.<sup>23,24</sup> Children's exposure from playing with shoes, and on contaminated surfaces, is unpredictable and may be considerable - many times more than through their diet. Clearly the PACR under-estimates children's risk, particularly since the default 10x safety factor was reduced to 3x.

#### **Dioxins**

Polychlorodibenzodioxins (PCDDs) are persistent, bio-accumulative chemicals that may cause cancer, harm neurological development, impair reproduction, disrupt the endocrine system and alter immune function. PCDDs are formed during phenoxy herbicide manufacturing, with higher-chlorinated congeners, and furans, being produced at increased temperature. Normally, dioxins with 2 or 3 chlorine atoms will be formed in the manufacture of 2,4-D.<sup>25,26</sup>

PCDDs with more than 2 chlorine atoms are "Track 1 substances", targeted for virtual elimination under the Canadian Environmental Protection Act (CEPA).<sup>27</sup>

Not only was the PACR published before dioxin analyses had been supplied by the industry, the PMRA asked only for analyses of dioxins with 4 or more chlorine atoms. The PMRA's Toxic Substances Management Policy (appendix 2)<sup>28</sup> should reflect current Track 1 Substances, not a list that is six years old. Focusing only on 2,3,7,8-TCDD, a principal toxin in Agent Orange, the PMRA is ignoring the bulk of the problem (lower-chlorinated congeners) and flouting the CEPA. Prudence calls for independent measurement of contamination in "off-the-shelf" products, and in areas of highly-maintained turf such as golf courses.

Following the scandalous poisonings of many with Agent Orange, phenoxy herbicide manufacturing was evidently altered in the early 1980's. The PMRA would not provide details when asked. However, a footnote in the PACR indicates that tetra-chlorinated dioxins are no longer a problem since 2,4,5-trichlorophenol is no longer used in the synthesis of 2,4-D. In fact, 2,4,5-trichlorophenol is used to make the notorious 2,4,5-T, not 2,4-D. The heretofore mysterious change in manufacturing process initiated at the beginning of the 1980's was to no longer put in the wrong ingredient! While the precursor phenol stream may have been better refined, no information has been put forward and there is no reason to believe that the method of production of 2,4-D has changed in the past 25 years. Thus, the dioxin contaminates identified by the World Health Organization in the 1980's would still be present. It is amply clear that no one has looked for them, or if they have, they didn't report them. For all pesticide registrations, all track 1 substances, and the most likely contaminates must be analysed - not just a convenient subset, expected in lower concentrations.

After decades of ignoring / covering up this problem by regulators and the industry, it is urgent that Health

Canada and Environment Canada carry out independent analyses of the complete dioxin contaminants of phenoxy herbicides, and similarly that dioxins be analysed in the environment, in areas of highly maintained turf such as golf courses..

# Mixtures, Formulants, Breakdown Products

**Diethanolamine** salt of 2,4-D is particularly toxic, and and was explicitly excluded from the PACR. However, searches of label information,<sup>29</sup> PMRA information requests and fertilizer information provided by the Canadian Food Inspection Agency confirm that "mixed amines", generally containing DEA, are in many herbicide and "weed and feed" type products. The PMRA had indicated that the DEA issue is being dealt with as part of examination of formulants. This is clearly inappropriate, since the DEA salt is an active ingredient.

The fact that the PMRA considers the DEA salt to be a formulant issue highlights the weakness of the present process of assessing chemicals in isolation and not accounting for synergistic toxicities from additives or products used at the same time. Formulants historically used in 2,4-D cause a number of adverse health effects, <sup>30</sup> and these ingredients are still on the PMRA's recently published list of formulants. <sup>31</sup> Apparent softening of data requirements for formulants in the formulants policy regulatory directive <sup>32</sup> is cause for concern and should be reviewed. This is important for many reasons, most obviously because hydrophobic formulants or additives, or the concomitant use of a skin cream or insect repellent may dramatically increase absorption of pesticides, including 2,4-D through the skin.

**Weed and Feed** type combination fertiliser / pesticide products are very popular, and enormous bags are piled high in garden centres across Canada - except in Québec, where they are wisely banned. This type of product **should be prohibited** because:

- Granular "weed and feed" products are designed to persist longer in the environment (they are "slow release"). They out-gas over extended periods of time, and neighbours whose health is impaired don't even know when it is safe to return to their homes.
- Granular "weed and feed" products are over applied to the entire lawn, not merely to areas of
  weeds, so are counter to pesticide reduction strategies. The mixture of fertiliser and herbicide is
  incompatible because one ingredient should be applied to the entire lawn, and one is intended for
  problem spots. Indeed, unfinished packages of the product are commonly used even when there are
  no weeds, and the homeowner merely wants some fertiliser. Combination products are responsible
  for untold excessive use of pesticide.
- Granular "weed and feed" products stick on shoes and children's hands and are very mobile. Dust is
  carried by the wind and tracked indoors. As noted above, children's exposures from dust may
  greatly exceed expected exposure from food.
- Birds eat "weed and feed" granules as grit.

### **Breakdown Products**

Exposures and assessments of health impacts of breakdown products should be addressed. Chlorinated phenols are extremely toxic and irritating, and are responsible in large part for the stench of phenoxy herbicides. Incredibly, the chemicals that will inevitably be produced were not even mentioned in the PACR.

# "Acceptability of Risk" and "Value" of 2,4-D

"Value" and "acceptability" of risk cannot be assessed according to scientific criteria. These are determinations that must be made by the Canadian Public.

Canadians are speaking loudly that the risk is not acceptable, and now over 1/3 of Canadians are being protected by pesticide bylaws and the Pesticide Code.<sup>33</sup> The PMRA has not accurately determined the risks in this PACR.

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The PMRA's determination of "value" is more accurately a determination of efficacy. However, "value" must take into consideration alternatives, and this was not included in the PACR. The plethora of successful organic landscaping businesses across the nation point clearly to the success of alternative strategies. In this context 2,4-D has no "value", and its risks mean that it must not be re-approved.

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To read CHO's highlights of major problems associated with the PMRA's Feb. 21, 2005 Review on 2,4-D Herbicide, please <u>click here</u>.



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