

Submission

Bill C-53 & CHILDREN'S HEALTH

**Submitted to:
Standing Committee on Health**

Ottawa, Ontario

Submitted by:



POLLUTION PROBE
CLEAN AIR. CLEAN WATER.

**Sandra Schwartz
Manager, Child Health Programme
Pollution Probe
63 Sparks Street, Suite 101
Ottawa, ON K1P 5A6**

April 25, 2002

First, let me thank you for inviting Pollution Probe to address this important piece of legislation, and to present our analysis to the Standing Committee on Health. In our presentation today, we would like to discuss the specific susceptibility of children to the effects of pesticide exposure, and provide recommendations for improvements to Bill C-53, such as the need for entrenchment of the precautionary principle as both a guiding principle and operational force, the inclusion of a mandatory 10-fold safety factor, and the need for a mandatory public advisory council.

Bill C-53 is a substantial improvement over its predecessor of the same title, *Pest Control Products Act*, which was passed in 1969 and has not been amended since. Unlike the current 30-year-old legislation, the mandate of C-53 is essential to ensuring that the pesticide management system is operated with the health of people and the environment as the principle aim. It is anticipated that Bill C-53 will help to protect the health of Canadian children, provided that amendments to soften the legislation are not made.

I will begin with an explanation of THE SPECIAL VULNERABILITY OF CHILDREN. Children are exposed to many chemical pesticides from a wide range of sources. From conception to adolescence, children are more sensitive and more exposed to pesticides than the average adult.

On average, children receive greater exposures to pesticides because kilogram for kilogram, they eat more food, drink more water, and breathe more air than adults, and their diets are somewhat different from that of adults. Furthermore, depending on their age, children's ability to metabolize, detoxify and excrete many toxicants is different from that of adults.

Pesticides can cause a variety of long-term or acute effects, depending on the type of pesticide, the dose, the route of exposure and the sensitivity of the exposed individual.

Exposure to low levels of some pesticides over many months or years can cause cancer, nervous system impairment, immune suppression, infertility, and behavioural and developmental effects. Household use of pesticides has been identified as a risk factor in causing chronic health problems in children, mainly leukemia and brain tumours. Recent evidence indicates that some pesticides, at extremely low levels and potentially after a single exposure, can disrupt the body's endocrine system. The developing embryo is particularly sensitive to the effects of these chemicals as the brain, sexual organs and other structural elements of the body are dependent on finely tuned hormone signals for proper development.

Therefore, there is an urgent need to MAKE CHILDREN A PESTICIDE POLICY PRIORITY. Despite children's extensive and heightened vulnerability to environmental contaminants, there is currently no coherent risk assessment and management strategy which ensures children will grow up safe from exposure to pest control products.

In Canada, the pesticide regulation system *currently* does not take explicit account of children's special vulnerabilities, unlike that in the United States. The *Food Quality*

Protection Act (FQPA), the 1996 U.S. pesticide reform law, was motivated in part by the 1993 National Academy of Sciences study, *Pesticides in the Diets of Infants and Children*, which found that the regulatory process did not account for children's special vulnerabilities and which recommended that the process be changed to better safeguard the health of infants and children. The law was adopted unanimously based on the overwhelming evidence presented in the study.

Under the US Food Quality Protection Act (FQPA), the Environmental Protection Agency (EPA) is required to use an additional 10-fold safety factor when assessing and setting regulatory limits for pesticides so as to provide reasonable certainty that no harm would result to infants and children. Section 408(b)(2)(C) of the FQPA states:

“In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall—

- (i) ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and*
- (ii) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.*

In the case of threshold effects, for purposes of clause (ii) (I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.”

This safety factor is meant to cover any heightened risks during and after pregnancy, as well as account for the incompleteness of toxicity and exposure data for children. In order to protect Canadian children from pesticide exposure, we need similar *mandatory* child-centred protection strategies within our own government structures.

Therefore, we recommend the wording of Sections 7(7)(b)(ii), 11(2)(b), and 19(2)(b)(ii) to read as follows:

“In the case of a threshold effect, apply a margin of safety that is ten times greater than the margin of safety that would otherwise be applicable under subparagraph(i) in respect of that threshold effect, to take into account potential pre- and post-natal toxicity and completeness of the data with respect to the exposure of, and toxicity to, infants and children.”

We recommend the removal of the discretionary language *“unless, on the basis of reliable scientific data, the Minister has determined that a different margin of safety would be appropriate”*. Let me explain our rationale for the removal of this language. By conventional practice in Canada now, the safety or harm of a substance is assessed by comparing a substance's toxicity, as determined by animal studies, to the level of exposure thought to be occurring. Even when good scientific data exist for a substance, however, uncertainty generally remains regarding its safety. This is because humans may be more susceptible than lab animals, and some people may be more sensitive than

others. The uncertainty, and the need to be purposefully health-protective, increases when research is limited. Risk assessment accounts for this imprecision by dividing the greatest exposure level known to not cause harm to young or adult animals, by uncertainty factors.

The standard uncertainty factors currently in use include a 10-fold factor to account for the difference between animals and humans, and an additional 10-fold factor to account for vulnerable populations like children. These are accounted for in Bill C-53, under Sections 7(7)(b)(i) and 19(2)(b)(i). Although the uncertainty factors are widely used, there is currently no formal requirement that Canadian regulators do so when considering children's extensive and heightened vulnerability to environmental contaminants. Bill C-53 would change this. For the most part, these uncertainty factors are added to safe doses for adult animals because adequate studies on young animals rarely exist. Furthermore, information on exposures to potentially toxic substances is limited, and the scientific research we can ethically do is rarely able to determine accurately how harmful a substance might be to children and others.

Thus, we believe there is a need for a *mandatory* 10-fold safety factor specifically to protect children. While Bill C-53 does have provisions for this extra margin of safety, use of discretionary language implies the *full* 10-fold safety factor will only be applied in a case-by-case basis. This mandatory safety factor would need to be applied in addition to the two standard uncertainty factors currently used in the evaluation of new substances and the re-evaluation of old ones. Imposing this factor would mean reducing regulatory limits for any substance to one tenth of the initial value, to ensure that they are truly protective of children.

By removing the discretionary language, it would ensure the Minister has the authority to retain the full 10-fold safety factor in all cases, unlike under the current US FQPA. According to a letter dated March 30, 1999 written by Susan Wayland, Acting Assistant Administrator of the EPA Office of Prevention, Pesticides and Toxic Substances, between adoption of the FQPA in 1996 to 1999, of the 120 conventional active ingredients which the US EPA evaluated under the Act, the Agency retained the children's 10-fold safety factor for only 15, or 12.5%. Thus, if the primary objective of Bill C-53 is "to prevent unacceptable risks to people and the environment from the use of pest control products", then it is imperative that an amendment be made to Sections (7)(b)(ii), 11(2)(b), and 19(2)(b)(ii).

Child-protective safety factors would not be a necessary default in risk assessment if good data were available on children's exposure and sensitivity to each of the many chemicals that they encounter. That, however, is not the case. Quantitative data on the exposures of fetuses, infants, and children to most chemicals are limited, as are data on the toxicity of most chemicals. For example, a recent analysis by the US EPA indicated that even minimal toxicological data exist for only 43% of the 15,000 chemicals produced each year in quantities of over 10,000 pounds; data on developmental toxicity, the sort of data that would permit direct comparison of child versus adult sensitivities, are available for only about 20% of these high-production volume chemicals. In the absence

of toxicological testing data, there is simply no way to know which are the chemicals to which children are especially sensitive. An additional safety factor is added to avoid potential harm, even in the absence of scientific proof that the factor is needed for that substance.

While the addition of an extra margin of safety is part of a strong precautionary approach to regulating substances, there is only limited application of the PRECAUTIONARY PRINCIPLE in Bill C-53. The precautionary principle is only mentioned in the *Re-evaluation and Special Review* provision under Sections 20(1)(b) and 20(2), where:

“(1) The Minister may cancel or amend the registration of a pest control product if... (b) in the course of a re-evaluation or special review, the Minister has reasonable grounds to believe that the cancellation or amendment is necessary to deal with a situation that endangers human health or safety or the environment, taking into account the precautionary principle set out in subsection (2) where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent adverse health impact or environmental degradation.”

This limited application of the precautionary principle is of great concern. Bill C-53 fails to entrench the precautionary principle as a guiding principle or to effectively operationalize it. We believe that the precautionary principle needs to be included in the Preamble and registration sections of Bill C-53 in order to enable the Minister of Health and the Pest Management Regulatory Agency to act even in the absence of complete proof of harm, particularly when there is scientific uncertainty about causal links.

We understand that science cannot deliver unequivocal answers to environmental health problems. To deal with this gap between science and politics, therefore, legislation such as Bill C-53 must be based on the precautionary principle. According to the precautionary principle, when substantial evidence of any kind gives us good reason to believe that an activity, technology, or substance may be harmful, we should act to prevent harm. Often an environmental health problem is too large, its cause too diverse, and the effects too long term to be sorted out with scientific experiments that would prove cause and effect. It is hard to take such problems into the laboratory. Instead, we have to rely on observations, case studies, and extrapolated data from dose/response studies to hypothesize a potential health risk. If we always wait for scientific certainty, effects on the fetus and child with long term consequences for adult health may be the outcome, and damage to the natural world may be irreversible.

Applying the precautionary principle insists that action to protect human health and the environment cannot be delayed until a causal link is established beyond any reasonable doubt. Lack of scientific certainty on the effects of pesticides on human and ecological health, therefore, should not be used as an excuse for postponing measures that may prevent potentially irreversible outcomes. Thus, we recommend the precautionary principle be a fundamental concept underlying all aspects of the legislation. In the final analysis, precaution is about preventing harm, not assessing risk.

In addition to amendments regarding the precautionary principle, it is essential that Bill C-53 create a *mandatory* provision for the establishment of a PUBLIC ADVISORY COUNCIL. Currently, there are provisions for the establishment of an advisory council in Bill C-53 under Section 5(1):

“In carrying out duties under this Act, the Minister may establish an advisory council of persons whose interests and concerns are affected by this Act, and may specify the functions of the council and the means by which it is to perform those functions”.

We recommend that this section be amended to read:

“In carrying out duties under this Act, the Minister shall establish a public advisory council of citizens and public interest representatives, in addition to persons whose interests and concerns are affected by this Act, and may specify the functions of the council and the means by which it is to perform those functions”

This will ensure that this is a mandatory requirement under Bill C-53, and that the majority of the membership of this council be comprised of citizens and public interest representatives, in addition to industry stakeholders. Furthermore, provisions should be made to include a terms of reference for this council which would act in several ways to: ensure transparency and accountability; verify implementation of the legislation; ascertain the existing body of knowledge; ensure current knowledge is widely disseminated; determine the key information gaps; promote research and aid policy development; and, identify opportunities for coordination with other agencies. Social consensus and hence the legitimacy of standard setting decisions is unlikely to occur if the public is unable to have effective and timely input to key parts of the decision-making framework.

IN SUMMARY, any legislation whose mandate is to protect human health from effects of environmental hazards, such as Bill C-53, must be formulated not only in the absence of definitive data concerning key issues, but also with a likelihood that such data will not be available before final decisions must be made. It is possible that clear, demonstrable causal associations between health effects and exposure to specific pesticides may not be established beyond doubt for many possible associations. If such is the case despite vigorous research, there will always be a question of whether the effect did not occur or simply could not be measured.

Thus, scientific evidence of causal effect should not be the only determining factor in regulatory action, but decisions on pest control products must be taken on the basis of inadequate knowledge. When factual empirical information is not available, the estimation of health impact will require modelling, extrapolation, prediction, and estimation of worst-case scenarios. Uncertainty is endemic within environmental health research; therefore, action on developing targets through enforceable legislation is presently needed, in order to protect the health and well-being of our children.

While there are improvements that can be made to strengthen the mandate of the new *Pest Control Products Act*, Pollution Probe supports Bill C-53 as currently written. However, in order for Bill C-53 to have potency, the Act should read at the outset: “An

Act to protect human health and safety and the environment by regulating products used for the control of pests, which holds the precautionary principle at its core". This amendment, in addition to the inclusion of a mandatory 10-fold safety factor and the establishment of a mandatory public advisory council would further strengthen the primary objective "*to prevent unacceptable risks to people and the environment from the use of pest control products*", and would provide incentive for industry to produce and sell safer alternatives to pesticides. We strongly encourage the Standing Committee on Health to consider these amendments as they would strengthen the ability of Health Canada and the Pest Management Regulatory Agency to effectively and appropriately act to protect human health and safety and the environment.

Recommendations for Improvements to Bill C-53

1. Entrenchment of the precautionary principle as both a guiding principle and operational force underlying all aspects of the legislation.
 - a. Amend the wording of the Act to read as follows:

“An Act to protect human health and safety and the environment by regulating products used for the control of pests, which holds the precautionary principle at its core”
2. Inclusion of a **mandatory** 10-fold safety factor.
 - a. Amend the wording of Sections 7(7)(b)(ii), 11(2)(b), and 19(2)(b)(ii) to read as follows:

“In the case of a threshold effect, apply a margin of safety that is ten times greater than the margin of safety that would otherwise be applicable under subparagraph(i) in respect of that threshold effect, to take into account potential pre- and post-natal toxicity and completeness of the data with respect to the exposure of, and toxicity to, infants and children.”
 - b. Remove of the discretionary language in Sections 7(7)(b)(ii), 11(2)(b), and 19(2)(b)(ii) *“unless, on the basis of reliable scientific data, the Minister has determined that a different margin of safety would be appropriate”*.
3. Provision for the establishment of a public advisory council in Bill C-53.
 - a. Amend the wording of Section 5(1) to read as follows:

“In carrying out duties under this Act, the Minister shall establish a public advisory council of citizens and public interest representatives, in addition to persons whose interests and concerns are affected by this Act, and may specify the functions of the council and the means by which it is to perform those functions”.