Case Study #2: Regulating Pesticides to Protect Children's Health

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9.1 INTRODUCTION

This case study addresses the health effects of pesticides and the regulatory response by the Canadian Pest Management Regulatory Agency (PMRA). To provide input to a Parliamentary Standing Committee review of pesticide regulation, it was published earlier than the main study. Information in this Chapter is therefore current to December 1, 1999. More recent information relevant to this chapter, particularly regulatory matters, is reviewed in Chapter 4. Most important, the PMRA has recently stated that it will follow the lead of the United States Environmental Protection Agency with respect to pesticide re-evaluation. Hence, the recommendations contained herein regarding the conduct and transparency of the PMRA's risk assessment process for both new and currently registered pesticides need to be viewed in that context.

In contrast to the first case study which summarizes the comparatively vast amount of health effect information on one specific contaminant, lead, this review examines the relatively more limited information on a varied group of environmental contaminants collectively called, pesticides.

On the regulatory side, this case study focuses on a review of the Pest Management Regulatory Agency (PMRA) while the Lead Case Study is a broader canvassing of regulatory controls on all aspects of lead use and environmental emissions. The Lead Case Study provides the regulatory "cautionary tale" since it documents how regulatory action on lead has been consistently denied or delayed in the face of troubling but inconclusive evidence of harm. The current situation with pesticides both in terms of the knowledge about human health effects, the troubling results from animal studies, and the inadequate regulatory response is very similar to the early chapters of the "cautionary tale" of lead.

9.1.2 Children: Greater Exposure and Potential for Serious Health Effects

In Canada, most pesticides are commonly applied in agriculture and by the forestry industry.[1] However, they are also frequently used in the household setting, both indoors and outdoors. Common household pesticide applications target garden weeds, insect infestations (indoors and outdoors), fleas on pets, and lice, scabies, bugs and bacteria on people. Pesticides are also used in wood preservation. Many pesticide uses can therefore bring people into contact with these chemicals through their living environment and via occupational exposure. Spraying (i.e., for crops, lawns, gardens or indoor pests) means wide, airborne dispersal of pesticide which allows for an effective route of exposure to humans via inhalation, ingestion or skin absorption. Some pesticides, or their breakdown products have been measured in trace or higher levels in soil, air, water and food.[2] Although there are assuredly health and other benefits to the

[1] Niedert, Eli, R.B. Trotman and P.W. Saschenbrecker. Levels and incidences of pesticide residues in selected agricultural food commodities available in Canada. *Journal of AOAC International*. 77 (1994), pp. 18-33.

[2] *Ibid*; U.S. Environmental Protection Agency, Atmospheric Research and Exposure Assessment Laboratory. *Nonoccupational Pesticide Exposure Study (NOPES)*. EPA Report Number EPA/600/3-90/003. Research Triangle Park, NC, (1990); National Research Council. *Pesticides in the Diets of Infants and Children.* (Washington: National Academy Press, 1993); Niedert Eli and P.W. Saschenbrecker. Occurrences of pesticide residues in selected agricultural food commodities available in Canada. *Journal of AOAC International*. 79 (1996), pp. 549-566; and Health Canada. *Persistent Environmental Contaminants and the Great Lakes Basin Population: An Exposure Assessment*. Minister of Public Works and Government

use of pesticides in terms of food production and eradication of household pests, such as cockroaches that may pose health problems,[3] the exposure to pesticides through a variety of media and pathways spells a potential health risk to people, especially children.

The 1993 report of the U.S. National Research Council, *Pesticides in the Diet of Infants and Children*[4] was a pivotal work that focused attention on the greater susceptibility and exposure of children to environmental contaminants in general, but particularly from pesticide residues in foods. Research since the NRC report lends further support to the conviction that there is potential for children to encounter widespread, low-level exposure to pesticides for two reasons: 1) pesticides are present in environmental media such as food, air, water, soil and dust, and, 2) children's small size and unique behaviours translate into relatively greater intake than adults of pesticides encountered in their environment.[5] Aside from these sources of pesticides that children (like adults) may ingest, inhale or absorb through their skin, children may also be exposed *in utero* via the placenta, as well as postnatally through their mother's milk.

The range of known or potential health effects from pesticides includes: abnormalities in physical development, cancer, immune system suppression, neurotoxicity, reproductive effects, and alterations in endocrine function. However, the NRC report also highlighted that the gaps in our knowledge regarding the effects from pesticide exposures at a young age and over the course of childhood development are such that we cannot be certain of the long term effects on children's health. It is clear that there is a growing consensus among researchers and medical practitioners around the globe that we should be concerned about the hazards of pesticides to children's health. There are still many unknowns and gaps in our knowledge. However, this situation does not exonerate pesticides, nor should it be used as a reason to delay regulatory action; particularly cautionary and preventative action.

Section 9.2 below reviews the circumstances by which children are generally more highly exposed to pesticides than are adults. Section 9.3 reviews the scientific literature concerning the health effects of pesticides including the results from both animal studies and those addressing human health.

9.1.3 The Public Policy Response

Given the range and severity of both the demonstrated and potential effects of pesticide exposure, adequate pesticide regulation is critical to human and environmental health, and in particular, children's health. Globally, governments have begun to recognize the dangers associated with pesticides and are reassessing the safety of those that are currently in use. These governments are also applying new knowledge and assessment techniques in their evaluation of pest control products.

Government efforts to minimize the risks associated with pesticide use have also resulted in a number of international initiatives, of which Canada is a participant. For example, Canada is a signatory to the 1997

Services, Canada. Catalogue No. H46-2/98-218E. (1998a).

[3] Toronto Public Health. *Cockroach Control in the Housing Sector: Evaluation of an Integrated Pest Management (IPM Demonstration Project for an Apartment Complex*. Prepared for the Ontario Ministry of the Environment (OMOE) and the Canada Mortgage and Housing Corporation (CMHC) (1998).

[4] National Research Council. 1993, *op.cit.*

[5] Brenda Eskenazi, *et al.* Exposures of children to Organophosphate pesticides and their potential adverse health effects. *Environmental Health Perspectives* 107 (Suppl 3) (1999), pp. 409-419.

Declaration of the Environment Leaders of the Eight on Children's Environmental Health. In that declaration, Canada pledged to establish national policies regarding environmental hazards that, "take into account the specific exposure pathways and dose-response characteristics of children when conducting environmental risk assessments and setting protective standards."[6]

In Canada, a new federal government agency, the Pest Management Regulatory Agency (PMRA), was created in 1995 to regulate pesticide use across the country. Sections 9.4 through 9.12 below provide a detailed review of issues concerning pesticide regulation as undertaken by the federal Pest Management Regulatory Agency (PMRA). Section 9.13 addresses the political will and funding necessary to implement both existing unfulfilled commitments to improve federal pesticide regulation as well as additional recommendations arising from this review. Sections 9.14 and 9.15 provide, respectively, the case study conclusions and a consolidated list of recommendations.

9.1.4 Unfulfilled Commitments in Canada

Since 1994, the federal government has made a number of commitments to improve its regulation of pesticide use. However, this investigation reveals that the great majority of these commitments remain unfulfilled. The federal government's failure to improve its regulation of pesticide use seriously calls into question the capacity of the current pesticide regulatory system to protect children's health.

Despite its length, this case study is far from being a comprehensive investigation of the complex pesticide regulatory system. Instead, it focuses on a number of issues that are critical to pesticide regulation and the protection of children's health. Even this limited focus proved difficult, however, as no comprehensive documents have been produced by the PMRA regarding its risk assessment and management processes. Information concerning these processes is difficult to access and understand. At times, it appears contradictory. Lack of clarity on the application of risk assessment and risk management processes is of significant concern given the well-documented problems with the subjective nature of this evaluation and management tool. The additional and more fundamental shortcomings of risk assessment, including its inability to assess "real-world" combinations of chemicals in a child's environment or their cumulative or synergistic effects, have yet to be effectively addressed by any advocates or practitioners of risk assessment. The PMRA's failure to explicitly set out its risk assessment and risk management approach, in a format for public consumption, is a key criticism of the case study and a factor that limited its scope.

Nevertheless, detailed recommendations can be made with respect to improving the transparency and effectiveness of regulating pesticides to protect children's health. Indeed, many of the Case Study recommendations have to do with the detailed steps necessary to implement a wide range of unfulfilled government commitments with respect to pesticides management. These include the fact that the PMRA has so far failed to:

- adequately implement the Toxic Substances Management Policy;
- develop a regulatory policy on formulants;
- develop a national compliance policy;
- develop a re-evaluation policy and a comprehensive program of pesticide re-evaluation;

[6] *1997 Declaration of the Environment Leaders of the Eight on Children's Environmental Health*, as found in Pollution Probe and Canadian Institute of Child Health. *The Air Children Breathe: the Effects on Their Health*, Conference Proceedings, January 19 and 20, 1998.

- develop a pesticide risk reduction policy;
- produce Proposed Regulatory Decision Documents (PRDD) for proposed registration, re-evaluation and special review decisions;
- create a national database on pesticide use;
- require mandatory reporting of adverse effects by registrants; or
- support the integration of pest management with the broader goal of environmental sustainability including setting targets and establishing workplans for the reduction of pesticide use in all sectors.

9.1.4.1 The Environmental Commissioner's Report

This investigation confirms and expands upon the findings in the May, 1999 *Report of the Commissioner of the Environment and Sustainable Development to the House of Commons*.[7] That report included troubling criticisms of the federal government's ability to protect Canadians from the risks of toxic chemicals in general and the PMRA's regulatory management of pesticides in particular. The report was critical of the PMRA in many respects including identifying the existence of conflicts and lack of integration, cooperation or collaboration with other government departments, lack of public access to pesticides-related information and the long-identified problem of lack of effective or coordinated monitoring (of environmental fate, effects, etc.) to complement the federal research agenda for toxic substances, including pesticides.

The Commissioner also found that the PMRA procedures for applying risk assessment and risk management are inconsistent and sometimes in conflict with other government departments. Chapter 4 documents the shortcomings of risk assessment and the need to more effectively adopt a precautionary approach to the management of toxic substances, including pesticides. As the Commissioner's report notes, the Toxic Substances Management Policy is an over-arching tool which provides the federal government's most important basis for implementing a preventative and precautionary approach to harmful pesticides and industrial chemicals. Although limited progress has been made, neither the PMRA, nor any other federal government department, has adequately implemented this policy.

The lack of adequate resources in PMRA and other departments alongside increased demands and increased private sector influence over research agendas were also noted as problems for the federal government's management of toxic chemicals, including pesticides.

The Commissioner's review of the federal government's 13-year-old commitment to pesticide re-evaluation found the actions of the PMRA to be largely inadequate and concluded that no assurance exists that Canadians are not being exposed to unacceptable risks from pesticides needing to be re-evaluated. This case study reaches the same conclusion.

9.2 EXPOSURE

9.2.1 Contaminant Uses & Information

Pesticides are commonly used in several settings including agricultural, industrial, residential and

[7] *Report of the Commissioner of the Environment and Sustainable Development to the House of Commons*. (Minister of Public Works and Government Services, 1999) http://www.oag-bvg.ca

institutional, among others. In Canada, there are approximately 7500 pest control products registered for use and therein, approximately 600 pesticides are the active ingredients in the end-use products.[8]

Agriculture represents the vast proportion of annual pesticide use in the U.S. and Canada.[9] Nonagricultural uses of pesticides are varied and numerous. The most common nonagricultural use of pesticides is for structural pest control in commercial, institutional and residential buildings including school, day-cares, hospitals, stores, office buildings, sports facilities, homes, etc. Pesticide spraying is common on passenger aircraft that fly to or from specific international destinations and is also part of regular maintenance of airplanes by some airlines.[10] Weed management for home and commercial lawns, golf courses, parks, recreation areas, highways, railroad beds and power transmission lines represents another common nonagricultural use of pesticides. Industrial uses for pesticides are considerable. A substantial application of pesticides is as a preservative for wood that ends up in a variety of uses including railroad ties, utility poles, and lumber.[11]

Pesticides can also be found in products containing lanolin as a result of the practice of "dipping" sheep in pesticides. Since many pesticides tend to be lipophilic (they bind to oil/fat molecules), the oil-rich lanolin in the sheep wool can be contaminated with such pesticides. Metals, such as mercury, are used to inhibit the growth of fungus and moulds in paint. In response to evidence of hazardous levels of mercury vapours following paint application and the well known health hazards of mercury, new regulations to greatly reduce the allowable level of mercury in paint are being implemented in the United States and Canada is following suit.[12]

Pesticides are classified according to their chemical structure. Chemical structure is a key to the action of the pesticide and hence, its intended function. All pesticides are designed and intended to kill living organisms and this is achieved by different modes of action.

It is beyond the scope of the present document to adequately profile the full range of pesticides and their ingredients that may pose harm to human health. It is our intention to highlight those compounds that are most commonly used and hence, to which there is greatest possibility of human exposure. Table 9.1 in Appendix 2 to this Case Study summarizes the information on major classes of pesticides.

9.2.1.1 Insecticides

[8] Pest Management Regulatory Agency. Product Group Counts, not including discontinued products: effective to September 30, 1998 (98-09D). Data provided by PMRA (As cited in: City of Toronto, Public Health, Environmental Protection Office. *Pesticides: A Public Health Perspective*. Unpublished report released October 30, 1998); and facsimile to the Canadian Environmental Law Association from Julie Chagnon, PMRA, March 19, 1999.

[9] Moses, Marion. Pesticides. In: *Occupational and Environmental Reproductive Hazards: A Guide for Clinicians.* Maureen Paul (Ed.) (Baltimore: Williams & Wilkins, 1993), pp. 296-309; and Agriculture Canada, Agri-Food Safety Division. *Annual Report*. (Ottawa, Ontario Canada. 1989)

[10] Northwest Coalition for Alternatives to Pesticides. "Flyers Beware: Pesticide Use on International and Domestic Aircraft and Flights." (1998) http://www.pesticides.org/AirlineSpray.html

[11] Moses, Marion. 1993, *op.cit.*

[12] See Section 8.4.6.3 of Case Study #1 for a discussion of Canada's revised regulations for the lead and mercury content of paint.

Organophosphates & Carbamates

The above two categories of pesticides are commonly used to control household pests such as ants, fleas, cockroaches, earwigs, wasps and silverfish. Organophosphates (OPs), the most widely used insecticide type, are designed to be neurotoxic to living organisms. OPs and Carbamates interfere with the activity of cholinesterase, an enzyme which breaks down acetylcholine, a neurotransmitter. When cholinesterase activity is inhibited, the neurotransmitter acetylcholine is not broken down and as a result there is overstimulation of nerve endings causing acute symptoms such as, serious sensory and behavioural disturbances, impaired coordination, muscle twitching, weakness, reduced heart rate, depressed cognition and coma. Because OPs are neurotoxic, can cross the placenta and have shown dose-related reproductive toxicity in animal studies, there is concern for potential developmental effects in humans.

Organochlorines

While organochlorine insecticides are no longer applied in agriculture in Europe and North America because of their environmental effects, they are still produced in some countries and exported for use in developing countries (on crops and in malaria control programs). Organochlorine insecticides were important pesticides for the precise reasons that they have been banned here since the 1970s. That is, because of their chemical stability and resistance to degradation they were highly efficient chemicals, but these same features, plus their long-range transport and cycling in the ecosystem, mean that they continue to contribute to the environmental load and human body burden measured globally. Until recently, the organochlorine Lindane was the active ingredient found in some medical treatments used against lice and scabies, such as Kwellada.[13] As will be discussed below, several banned organochlorine pesticides such as chlordane and toxaphene (among others) have been detected in the current food supply of Inuit in northern Canada.[14]

Pyrethrins/Pyrethroids

Pyrethrins are insecticides derived from chrysanthemums and pyrethroids are the synthetic versions of this type of compound. These chemicals attack the nervous system. They are generally deemed to be of low toxicity (both acute and chronic) to humans, hence their frequent use as a replacement for more toxic insecticides such as OPs and carbamates. They have also replaced Lindane in treatments for lice and scabies. However, recently, some pyrethroids have been associated with neurologic and respiratory reactivity as well as potential hormonal effects.[15]

Insect Repellants

The pesticide N,N-diethyltoluamil is the substance found in DEET, the most commonly used compound to repel mosquitoes and other insects. It enters the body by absorption through skin or with ingestion. It is commonly applied directly to the skin of children and adults by spray or cream.

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[13] The manufacturer of Kwellada recently released a new formulation that contains permethrin as the active ingredient.

[14] Chan, HM, *et al.* Evaluation of the population distribution of dietary contaminant exposure in an Arctic population using Monte Carlo statistics. *Environmental Health Perspectives* 105 (1997), pp. 316-21.

[15] Vijverberg, HP, van den Bercken, J. Neurotoxicological effects and the mode of action of pyrethroid insecticides. *Crit. Rev. Toxicol*. 21 (1990), pp. 105-126; Cantalamassa, F. Acute toxicity of two pyrethroids, permethrin, and cypermethrin in neonatal and adult rats. *Arch. Toxicol*. 67 (1993), pp. 510-513; Garey, J. Wolff, MS. Estrogenic and anti-progestagenic activities of pyrethroid insecticides. *Biochem. Biophys. Res. Comm.* 251 (1998), pp. 855-859; Go, V, Garey, J., Wolff, MS, Pogo, BGT. Estrogenic potential of certain pyrethoid compounds in the human breast carcinoma cell line MCF7. *Environ. Health Perspectives* 107 (1999), pp. 173-177, as cited in Landrigan et. al, Pesticides and inner-city children: Exposures, risks, and prevention. *Environmental Health Perspectives*, 107 Suppl 3 (1999), pp. 431-437.

Neurobehavioural effects have been observed with heavy exposure to DEET, in laboratory animals, workers and children.[16]

9.2.1.2 Herbicides

Chlorphenoxy Group
These herbicides (e.g. 2, 4-D, MCPA) are the most widely used in the removal of weeds such as dandelions. Therefore they are commonly applied in both agriculture and on lawns. They have low acute toxicity to humans, however, high level ingestion or absorption can cause symptoms such as nausea, vomiting, spasms, seizure and coma and there are reports of peripheral neuropathy[17] being a delayed effect of heavy chronic exposure to 2,4-D.[18]

9.2.1.3 Fungicides

Fungicides are active against many kinds of fungi and are used on seeds, crops and in gardens. Because fungicides are not easily absorbed by the human body they are considered to be of low toxicity, especially with short term exposure, however, they can produce a range of health effects from acute exposure in high doses as listed in Table 9.1. The fungicide Benomyl has been the subject of alleged prenatal exposures that led to babies born with eye defects.[19]

9.2.1.4 Other types of pesticides

This report is not intended to provide an exhaustive listing of all types of pesticides, but rather, to focus on those to which there is greatest opportunity of human exposure, those that are used in greatest volume and those that are particularly toxic to humans. For a thorough treatment of pesticide toxicology, the reader is referred to Hayes & Laws[20] which classifies all pesticides into *eleve*n different categories, including several not covered here such as fumigants, rodenticides, biocides and metal-based pesticides.

9.2.1.5 Formulants

Formulants (also called "inert" substances in the United States) are added to pesticides and are distinct from the active ingredients in that they are not intended to affect the target pest. However, they are not necessarily inactive in their own right. Many formulants may independently cause health problems in humans, may increase exposure to the active ingredients in the product and, those that are volatile organic compounds, may increase concentrations of ground-level ozone.[21] These substances are

[16] Rossenstock, Cullen (Eds.) *Textbook of Clinical and Occupational Medicine*. (New York: Saunders, 1994)

[17] Peripheral neuropathy denotes "damage to the nerves that stimulate the limbs" (City of Toronto, 1998: 17, *op.cit.*).

[18] Costa, L. Basic toxicology of pesticides. *Occupational Medicine: State of the Art Reviews*. 12(2) (1997).

[19] Dyer, C. U.S. court case starts over eyeless babies. *British Medical Journal.* 312 (1996), p. 1247.

[20] Hayes, W.L. and E.R. Laws. *Handbook of Pesticide Toxicology*. (New York: Academic Press, 1991.)

[21] For example, the formulant 4-nonylphenol (4-NP) is 75% by weight of the insecticide Matacil 1.8D, whose active ingredient is aminocarb. 4-NP is known to be a potent hormone disruptor that likely played a role in the

generally inadequately studied for health effects.[22] See section 9.10 below for a discussion of the regulation of pesticide formulants.

9.2.2 Exposure Sources, Routes, Media & Pathways

There are different routes by which humans are exposed to pesticides according to the mode of application and the pathway through which the chemical travels. All routes must be taken into account to gain a full estimate of total exposure. While exposure to pesticides via any single medium may be minute, when one accounts for the variety of sources of pesticides, the possibility exists for a considerably higher *overall* level of exposure. Table 9.2 summarizes many of the potential sources of exposure to pesticides that are most relevant to children.[23]

Exposure to pesticides is often indirect. That is, exposure can occur via media through which pesticides travel in the environment after they have been sprayed or applied. These media include water, air, soil, dust and sediments. Food is another important medium of indirect exposure. Because of our seasonal climate, Canadian food stuffs must come from foreign as well as domestic markets. Therefore, we have to be concerned about exposure to the pesticides that are used in other countries despite their being banned from use in this country. Since some pesticides become distributed throughout the global food chain, they may be ingested from imported agricultural foods that are treated directly with pesticides, or they may be ingested in the meat, milk and eggs of other animals that ingest them from foods or grasses. This is particularly the case with the persistent, bioaccumulating pesticides that become stored in animal tissues and therefore, become increasingly concentrated in organisms higher up in the food chain.

Pesticides enter the body by being ingested, inhaled or absorbed through direct skin contact. Pesticides may also cross the placenta to reach the developing fetus[24] and they may be transferred through mother's milk to the breastfed infant. These represent the main routes of pesticide exposure in humans and children, specifically.

There is little information that quantifies the activity patterns of Canadian children that render them vulnerable to exposure to pesticides. There is also, in general, relatively limited biological evidence of

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drastic decline in the Atlantic Salmon population after Matacil 1.8D application in eastern Canadian forests in the mid-1970s. See: Fairchild, W.L. *et.al.* Does an association between pesticide use and subsequent declines in the catch of Atlantic salmon (*Salmo salar*) represent a case of endocrine disruption? *Environmental Health Perspectives* 107(5) (1999), pp. 349-357.

[22] CALPIRG - California Public Interest Research Group (CALPIRG) Charitable Trust and PSR - Physicians for Social Responsibility (Greater SF Bay & LA Chapters). *Generations at Risk: How Environmental Toxicants May Affect Reproductive Health in California*. (Report released November, 1998.); and Davies, Katherine. *Pesticides and Your Child. An Overview of Exposures and Risks*. Prepared for The Campaign for Pesticide Reduction (CPR!). Ottawa, Ontario. (1998), 38 pp.; and City of Toronto, 1998, *op.cit*.

[23] See discussion in Chapter 2 and Figure 2.1 for clarification of the specific uses here for the terms: route, pathway and medium.

[24] Canadian and U.S. researchers recently presented startling results of a study which detected levels of p,p'-DDE, a breakdown product of the organochlorine pesticide, DDT, in 30% of a small sample of second trimester human amniotic fluid. (Foster, Warren et al, In utero exposure of the human fetus to xenobiotic endocrine disrupting chemicals: Detection of organochlorine compounds in samples of second trimester human amniotic fluid. Paper presented at 81st annual meeting of the Endocrine Society, San Diego, June 14, 1999.)

pesticide exposure in children.[25] Chapter 2 discusses in greater detail the reasons that children are more *likely* to be exposed to contaminants including pesticides. This has do to primarily with behavioural differences as well as the phenomenon wherein, because of their small size, children take in greater volume of substances from their environment, relative to their body size. Children's exposure to pesticides will differ according to the behaviours they exhibit that are characteristic for each developmental stage. For instance, young infants are more likely exposed to pesticides through breast milk, whereas older infants (over 6 months) will also be exposed via the foods they eat. When babies become more mobile they explore their environment more extensively and come into greater contact with the items that might harbour pesticide residues. Their hand-to-mouth and oral exploratory behaviour render them much more likely to ingest or absorb the pesticides that linger in their environment.

Table 9.2 Sources of Exposure Relevant to Children (Adapted from Davies, 1998:10, *op.cit.*)

1. The Home (in the child's home & homes of playmates)	*Applications of pesticides* • Indoor commercial application of pesticides to control rodents, cockroaches, ants, termites, earwigs, etc. • Homeowner/resident use of insecticide sprays, strips, baits • Application of insect repellents directly on skin or scalp (e.g. personal bug sprays, shampoos for lice, scabies) • Collars or powders to treat household pets for fleas, ticks, etc. • Commercial application of lawn and garden insecticides, herbicides and fungicides • Insecticides, herbicides and fungicides used in the garden or on the lawn by the homeowner or resident *Storage and handling of pesticides* • Storage of household pesticides in areas accessible to children • Disposal of pesticides in household garbage *Pesticide life cycle and pathways* • Pesticide residues in house dust and in soil tracked in from outdoors • Pesticide residues on furniture, drapes, toys, pet fur, absorbent items
2. Public Places (schools, daycare, etc.)	Commercial applications of pesticides for rodents, cockroaches, termites, weeds, mould and decay, etc. • Storage of pesticides in areas accessible to children • Disposal of pesticides and pesticide containers in regular school garbage • Maintaining playgrounds, playing fields • Wood preservatives on play structures • Pesticide application in other public places, e.g. airplanes, restaurants, malls, offices, etc.
3. Via Air & Water	Pesticides in indoor air (from uses above for household and public places) Pesticides in outdoor air • Pesticide drift from spraying (agricultural, municipal, household) • Long range transport of persistent pesticides (e.g. DDT) and incorporation into the food chain • Pesticides in drinking water - treated tap water or well water • Pesticides in swimming water - lake and river sediments, algicides in swimming pools

[25] Eskenazi et al. 1999, *op.cit.*

4. Via Food	• Food crops that are routinely sprayed and form a significant part of juvenile diet. E.g. fruits, vegetable, grains • Foods prepared from agricultural products. E.g. baby foods • Bioaccumulation in other animals and their products. E.g. meat, fish, eggs, dairy products • Mother's intake and transfer across placenta • Mother's body burden transferred to breast milk.

9.2.2.1 Residential - Household & Garden

Children encounter considerable concentrations of pesticides in household dust as well as through air, soil and food, from residential application of pesticides.[26] Indoor application can lead to a much greater chance of exposure to pesticides. Whereas pesticides applied outdoors are subject to biodegradation from the effects of sunlight, wind and water, pesticides applied indoors may persist longer and linger on household surfaces such as furniture, floors and toys, as well as accumulate in house dust. Some particularly long-lasting pesticides have been measured in homes for *years* and even decades after a treatment.[27] Several studies suggest that children's exposure to pesticides may be higher than "other(s) living in the same contaminated environment, in part because young children spend more of their time indoors at home." [28]

Household uses also allow for greater risk of accidental exposures when pesticides are improperly applied or stored in the home or garden. Most pesticide poisonings result from home uses and children are at greatest risk of such accidental exposures.[29] According to data for Canada, accidental pesticide exposure accounts for about 4% of all reported childhood poisonings.[30]

Since young children are closer to the ground and frequently put objects and their hands in their mouths, they are much more likely to accidentally ingest the pesticide residues that persist and accumulate in the household setting. A recent experimental study showed that even two weeks after a spraying of

[26] Whitmore, R.W. et al. Non-occupational exposures to pesticides for residents of two U.S. cities. *Arch. Env. Contam. Toxicol*. 26 (1993), pp. 1-13.

[27] For example, chlorpyrifos was found to accumulate on surfaces that were not in the immediate area sprayed and to be detected in homes for several years after its use. Fenske, RA, et al. Potential exposure and health risks of infants following outdoor residential pesticide applications. *Am. J. Pub. Health* 80 (1990), pp. 689-693;, Wright, CG, et al. Chlorpyrifos in the air and soil of houses eight years after its application for termite control. *Bull. Environ. Contam. Toxicol*. 52 (1994), pp. 131-134. Homes where the organochlorine chlordane was used to kill termites have demonstrated detectable levels of the pesticide for over three decades after its use. See: Savage, EP. Termiticide use and indoor air quality in the United States. *Rev. Environ. Contam. Toxicol.* 110 (1989), pp. 117-130.

[28] Eskenazi et al. 1999: 410, *op.cit.*

[29] Roberts, J.R. et al. Epidemiologic evidence of the effects of pesticides on human health in Canada. Monograph II In: *Strengths and limitations of Benefit-Cost analyses Applied to the Assessment of Industrial Organic Chemicals Including Pesticides. Associate Committee on Scientific Criteria for Environmental Quality*. National Research Council of Canada. NRCC No. 22852. (1985)

[30] Canadian Hospitals Injury Reporting and Prevention Program (CHIRPP). Pesticide-related injuries and poisonings to children less than 20 years of age from the entire CHIRPP database as of December 1994. Laboratory Centre for Disease Control, Health Canada. (1995), 6 pp.

chlorpyrifos, a particularly long-acting organophosphate pesticide, there were sizeable levels of the pesticide measured on toys and other absorbent surfaces in the apartment.[31] The researchers had followed the manufacturer's directions as to what was deemed an appropriate period post-application.[32] They determined that even if parents' followed product instructions, children would still be exposed to significant amounts of chlorpyrifos after the "safe" period for re-entry. The findings of this and other studies suggest that indoor spraying exposes children to between 20 and 120 times the recommended reference dose of 3µg/kg/day of chlorpyrifos from all sources.[33]

Other indoor pesticide uses that allow for human, and especially, child exposures include: hanging no-pest strips, pet flea collars and shampoos, personal bug sprays, shampoo and lotion treatments for lice and scabies, antimicrobial soaps, etc. Use of herbicides, fungicides and insecticides in gardens and on lawns is another route of pesticide exposure. Children may be exposed while playing on grass in their home yard, schoolyards and daycares that have been treated with pesticides. These outdoor residues can also be brought indoors on clothing and shoes and by pets.

9.2.2.2 Agricultural & Industrial

There has been mounting concern over children's exposure to pesticides in food items from pesticide use on fruits, vegetables and grains during the growth season, and in some crops, to control pests during storage, transport and processing.

The main food crops that are eaten in highest proportions by children include apples, pears, peaches, grapes, oranges, green beans, peas, potatoes and tomatoes. Fruits, in particular, are very popular with children and infants, representing about 31% and 16% of the diets of nursing and non-nursing infants, respectively and over 11% of the diet of one to six year-old children.[34]

Consumers Union of the United States recently analyzed data on pesticide residues in over 27,000 samples of foods collected by the U.S. Department of Agriculture's Pesticide Data Program (PDP) between 1994 and 1997. Consumer's Union researchers calculated a Toxicity Index (TI)[35] for each food. The majority of foods had some degree of pesticide contamination, with TI values ranging from low to high (TI of 10 to 300[36]). Notably, there were unacceptably high[37] toxicity scores in seven of the fruits

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[31] Gurunathan, S. et al. Accumulation of Chlorpyrifos on residential surfaces and toys accessible to children. *Environmental Health Perspectives.* 106 (1998), pp. 9-16.

[32] It is of note that Dow has recently withdrawn some products with chlorpyrifos from the market. (U.S. EPA. Agreement reached between EPA and chlorpyrifos pesticide registrants. EPA Press release. Washington, DC: U.S. Environmental Protection Agency, 6 June, 1997). It is not clear, however, if the ban on the part of Dow is comprehensive and is being honoured by other potential manufacturers (Personal communication. Julia Langer, Director, World Wildlife Fund. Phone interview, October 8, 1999).

[33] Davis, D.L., and A.K. Ahmed. Exposures from indoor spraying of chlorpyrifos pose greater health risks to children than currently estimated. *Environmental Health Perspectives* 106(6) (1998), pp. 299-301.

[34] Consumers Union. *Worst First: High-Risk Insecticide Uses, Children's Foods and Safer Alternatives.* (Washington: Consumers Union of U.S., Inc. Sept. 1998: 13)

[35] The TI value takes into account the amount of pesticide present in the food, the relative toxicity of the individual pesticide chemicals detected, and the frequency of pesticide detection. Foods with high TI values have relatively higher pesticide residue concentration or more toxic pesticide residues or both.

[36] TI values for all foods tested ranged from 0.01 to 5,376.

and vegetables popular among children such as, apples, grapes, pears, spinach, peaches, green beans, and winter squash.[38] Consumer's Union states that, with few exceptions,[39] "all of the residues … are within U.S. legal limits for the pesticides on those foods."[40] There is concern, however, that the legal limits do not equate to a safe level for children when their particular dietary habits are taken into consideration. Sample calculations for several pesticides indicate that infants may be exposed to levels that exceed the ADIs by many times.[41]

Exposure levels in children are higher because of the low variety of food sources in their diets (for example, after milk or dairy products, apples constitute the next largest[42] component of the infant diet) and also because of their greater relative consumption of food. Children eat about three to four times the amount of food that adults do, when calculated on a per unit body weight basis.[43] For example, when a child eats one banana it is relatively the equivalent of an adult eating about five bananas.[44]

Organophosphate (OP) and carbamate insecticides are identified as high risk pesticides for three main reasons: 1) several individual chemicals of these two classes are relatively very toxic; 2) they often leave residues in food; and 3) their residues appear in foods that are consumed most by children.[45] Specific pesticides which contribute significantly to toxicity include methyl parathion (an OP) which, until recently (in the United States at least),[46] was heavily used on apples and green beans, and aldicarb (a carbamate) which has recently been detected in potatoes grown in the U.S.[47] Aldicarb was the subject of investigation in 1991 because of unusually high residues in bananas, as reported by the manufacturer. While the *average* aldicarb residue level was below the established TDI, the levels in some individual bananas, was enough that infants and toddlers would receive more than the allowable limit and potentially would become quite ill by eating only small portions of such "hot" bananas.[48]

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[37] High toxicity was defined as a TI value greater than 100. Foods with TI values less than 10 were considered "clean" and those with scores between 10 and 100 have low to moderate levels of pesticide residues (Consumer's Union, 1999: 1,*op.cit.*).

[38] Specifically, the seven foods with consistently high TI scores were: domestic and imported apples, grapes, pears, spinach; fresh peaches (both domestic and imported); U.S.-grown green beans; and U.S.-grown frozen and fresh winter squash (Consumer's Union, 1999, *op.cit.*).

[39] Violations (between 1 and 5% in different years sampled) were not typically due to excessive levels of legally registered pesticides, but low levels of pesticides not registered for use on a given food, including persistent types (Consumer's Union, 1999, *op.cit.*).

[40] Consumers Union. *Do You Know What You're Eating? An Analysis of U.S. Government Data on Pesticide Residues in Foods*. Consumers Union of United States, Inc. Public Service Projects Department, Technical Division, Groth, E., C. Benbrook, and K. Lutz. (February, 1999), p. 1.

[41] See for example, Schilter, B., A.G. Renwick and A.C. Huggett. Limits for pesticide residues in infant foods: A safety-based proposal. *Reg. Tox. Pharm*. 24 (1996), pp. 126-140.

[42] The proportion of the average infant dietary intake from apples, either fresh or from juice, is 15.5% for nursing, or 7.6% for non-nursing infants (NRC, 1993: 184, *op.cit.*).

[43] National Research Council. 1993, *op.cit*.

[44] Goldman, L.R. Case studies of environmental risks to children. *The Future of Children.* 5 (1995), pp. 27-33.

[45] Consumers Union. 1998, *op.cit.*

[46] Note that in August of 1999, in response to children's health concerns, the United States Environmental Protection Agency moved to eliminate many uses of methyl parathion. See Section 4.3.4 of Chapter 4.

[47] Consumers Union. 1999, *op.cit.*

[48] As a result, the manufacturer voluntarily agreed to stop selling aldicarb for use on bananas (Goldman, 1995,

Not all food items carry equivalent risk of exposure to pesticides. Grain products have little evidence of insecticides used during the growing season, however they may have detectable residues from pesticides applied during storage, transport or processing of the grain. Processed foods are also generally found to have lower pesticide residues.[49]

Considerable environmental exposure to pesticides comes from the persistent organochlorine type, many of which have been banned or in restricted use since the 1970s. Organochlorine pesticides can still be measured in organic substances because of their tendency to bioaccumulate and appear in higher concentrations as one moves up the food chain. In most cases, they appear in the environment due to leakage from hazardous waste disposal sites, run-off from contaminated soils and via long-range atmospheric transport and deposition. They reach humans mainly through consumption of animal foods, especially fatty species, that are contaminated directly or due to the biomagnification phenomenon. Animal foods like freshwater fish, meat and dairy products are particularly likely to carry persistent pesticides in their fat stores. Lactation is one route of excretion of a mammal's stored burden of fat soluble contaminants. Therefore eating the fatty flesh and consuming the milk and milk products of animals means exposure to these persistent pesticides. Persistent pesticides may also be detected on some food crops grown in polluted soil.[50]

Those who work in the pesticide industry, whether in the manufacture, application, handling or transport of pesticides, will be occupationally exposed to higher levels of pesticides than the general population. The children of these workers may also be exposed to relatively higher levels as well since pesticide residues may be brought into the home environment on clothing and shoes. Women who work in the pesticide industry will also additionally transfer their intake of some pesticides to their children via the placenta or breast milk. Lack of basic information about the health effects of these occupational exposures is of concern (see discussion in Section 9.12.5 below).

9.2.3 Exposure Data for Ontario and Canada

Exposure estimates can be made based on a) the presence of contaminants in various media, including air, water, soil and food and, b) the most likely estimates of intake from inhalation, absorption and ingestion. The levels of pesticides measured in various human tissues can also provide an approximation of body burden which may indicate the degree of past exposure to pesticides.

9.2.3.1 Environmental Levels

The main source of information available to us concerning the presence of pesticides in the Canadian environment comes from published analyses of food levels.

The Canadian Food Inspection Agency was created in 1997 under authority of the *Canadian Food Inspection Agency Act*.[51] The agency, which reports to the Minister of Agriculture and Agri-Food, is

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op.cit.).

[49] Consumers Union. 1998, *op.cit.*; and Consumers Union. 1999, *op.cit.*

[50] Niedert, Eli, R.B., et. al. 1994, *op.cit.*

[51] *Canadian Food Inspection Agency Act*, R.S.C. 1997, c. C-16.5.

responsible for all federally-mandated food inspection, including that required by the *Food and Drugs Act*. Monitoring for pesticide residue levels for the period 1994-1998 revealed that 1.2% of the 6,879 domestic fresh produce samples had residue levels that were in *excess* of their Maximum Residue Levels (MRL).[52] The corresponding value for imported produce was 2% of 34,591 samples.[53] The bulk of the pesticides detected were those most commonly used, however, there were also some samples with measurable levels of pesticides that have been banned or are no longer used, including many of the organochlorine types. The banned, persistent pesticides were found more often in imported foods and in samples of food crops that mature on or below the soil, indicating that polluted soil is the likely medium by which they are transferred to foods. Noteworthy is the fact that of the Canadian food samples with higher pesticide residues, between 50 to 70% of these represented pesticides that were *not approved* for use by Agriculture Canada on the particular food crop.[54]

Market basket surveys are conducted by the Food Directorate at Health Canada checking about 100 different food items for a variety of environmental contaminants. Food that would represent approximately 80% of the Canadian diet is purchased, prepared and tested for pesticides and other toxins. Toxin concentration values are then multiplied by estimates of food intake (see below) to determine estimates of total intake of different pesticides. These data are compared with standards for intake set by the World Health Organization. [55]

9.2.3.2 Estimates of Intake

The Bureau of Chemical Safety at Health Canada evaluates potential exposures to pesticides through food by estimating consumption patterns of Canadians. The types of food and quantities eaten are then verified more directly via post-market surveillance. Post-market surveys are important for detecting differences between actual versus estimated exposures.[56]

The food consumption data specific for Canadian infants and children is sorely out of date, relying on data provided by the 1972 Nutrition Canada Survey.[57] The PMRA reports that it now uses the 1996 USDA *Continuing Survey of Food Intakes by Individuals.*[58] The Food Research Division of Health

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[52] Maximum residue limits are the regulatory criteria that establish limits for pesticide residues in foods. It is assumed that if residues do not exceed MRLs there is low likelihood of adverse health effects. See section 9.8.3 for further discussion of how MRLs are established.

[53] Eli Neidert and Glenn Havelock, CFIA. *Report on Levels and Incidences of Pesticide Residues in Selected Agricultural Food Commodities Available in Canada During 1994-1998.* November 6, 1998.

[54] Niedert, Eli, R.B. *et.al.* 1994, *op.cit.*; and Niedert and Saschenbrecker, 1996, *op.cit*.

[55] Personal Communication, Robert Dabeka, Food Directorate, Food Research Division, Health Canada. October 1999.

[56] For instance, using the example of the food additive aspartame, pre-market values predicted that adolescents would have greatest exposure to this substance, whereas, according to post-market surveys, it was revealed that infants and children under five had higher consumption relative to body weight, hence this group actually received the highest doses of aspartame.See: Conacher, H.B.S. Do current systems for control of potentially hazardous chemicals in food adequately protect the health of infants and children? In*:* Canadian Institute for Child Health, *Proceedings from National Symposium on Environmental Contaminants and the Implications for Child Health*. (May 1997), pp. 67-68.

[57] *Ibid*.

[58] Personal Communication, Danielle Prevost, Information Officer, PMRA, September 30, 1999.

Canada's Food Directorate, reports that it recognizes the need for more recent Canadian nutritional intake information, however, they have not been able to access such data for a Canadian sample.[59]

Doubtless eating patterns in North America have changed substantially over the last two or three decades making it vital to use the most recent nutritional intake data available. Comparison of two comprehensive U.S. national food consumption surveys, one from 1977-78 and a more recent one conducted in 1996 by the USDA, indicated that relative to two decades ago, American children now consume:[60]

- more beverages, especially packaged juice drinks and soft drinks;
- more grain-based snacks and combination foods like pizza;
- less milk and fat; and
- more foods away from home.

9.2.3.3 Body Burdens

The National Human Milk Survey has been responsible for collecting and analysing breast milk samples every five years for the last two decades and thereby monitors current exposures of breastfed infants and past exposures of mothers to various chemicals, including pesticides.[61]

The Great Lakes Health Effects Program (Health Canada) recently published extensive results including human exposure to chemical contaminants in the Great Lakes region. They provided information on the levels of the priority persistent contaminants, therefore this only reflects exposure to older organochlorine pesticides such as; aldrin/dieldrin, hexachlorobenzene, mirex,[62] toxaphene and DDT and its metabolite, DDE. They report that the DDT and DDE levels in blood, adipose tissue and breast milk are on a declining trend. While the levels are generally well below those that would cause any clinical symptoms for the average individual, the long-term persistence of these pesticides is an issue for children's health. There is concern, in particular, that breast-fed infants and adults and children who eat considerable amounts of freshwater fish and wildlife may be exposed to higher than the tolerable daily intakes for some of these pesticides.[63]

9.2.3.4 Communities at Risk

Farming families are at considerable risk for exposure to pesticides and particularly, the children are

[59] Personal Communication, Robert Dabeka, Food Directorate, Food Research Division, Health Canada. October 1999.

[60] Consumers Union. 1998, *op.cit.*

[61] Conacher, H.B.S. 1997, *op.cit.*

[62] Mirex was used against fire ants in the southern United States and although incorporated as a fire retardant into plastic, rubber and paper products, was never registered as a pesticide in Canada.

[63] Riedel, D., N. Tremblay and E. Tompkins. *State of Knowledge Report on Environmental Contaminants and Human Health in the Great Lakes Basin*. Great Lakes Health Effects Program (Health Canada). (1997); and Health Canada. 1998a. *Persistent Environmental Contaminants and the Great Lakes Basin Population: An Exposure Assessment*. Minister of Public Works and Government Services, Canada. Catalogue No. H46-2/98-218E.

unique by virtue of living where their parents work and potentially being exposed to occupational agents.[64] The Ontario Farm Family Health Study conducted by Health Canada has shown increased rates of fetal loss and decreased ability to conceive.[65] A large retrospective cohort study of Norwegian farm families has demonstrated that use of pesticides is associated with cancer at an early age in the offspring of farmers.[66] Health Canada's Pesticide Exposure Assessment Study which began in the spring of 1996, is assessing direct and indirect exposure to pesticides among applicators and their families, by data collected from diaries of handling practices, body fluid samples, well-water and swabs of household surfaces.[67] Results are still forthcoming from much of this study. However, results from well-water testing showed that 21% of wells tested had detectable (although non-violative) levels of a pesticide, usually atrazine,[68] indicating the persistence of this chemical and the general point that pesticides applied on crops can find their way into ground water which can then become a source of exposure for people. A recent pilot study in rural California suggested that children living in households with a farm worker were exposed to higher levels of pesticide residues in house dust. This study also predicts that these children could be exposed to levels of the pesticide diazinon that would exceed the U.S. EPA's reference dose simply through ingestion of household dust.[69]

Because of the persistence of the older, banned organochlorine pesticides and their tendency to bioaccumulate, those individuals who consume fish caught in the polluted waters of the Great Lakes are also more often exposed to these pesticides. Among the communities where children are most likely to be at risk for this type of exposure are aboriginal groups, who, because of their traditional culture, maintain use of wild fish and game foods, as well as families of anglers, and immigrant groups who may be less likely to know about fish advisories and guides to eating and preparing sport fish.[70]

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[64] Kristensen, P., A. Andersen, L.M. Irgens, A.S. Bye and L. Sundheim. Cancer in offspring of parents engaged in agricultural activities in Norway: Incidence and risk factors in the farm environment. *Int. J. Cancer.* 65 (1996), pp. 39-50.

[65] Health Canada. Health Protection Branch. Laboratory Centre for Disease Control. Looking at pesticides and pregnancy. *Farm Family Health*. 6 (1) (Spring 1998b) http://www.hc-sc.gc.ca/main/lcdc/web/publicat/farmfam/vol6-1/ff6-1j_e.htm ; and Curtis, K.M., D.A. Savitz,C.R. Weinberg, T.E. Arbuckle. The effect of pesticide exposure on time to pregnancy. *Epidemiology*.10 (1999), pp. 112-117.

[66] Kristensen, P., A. *et.al.*, 1996, *op.cit*.

[67] Health Canada. Health Protection Branch. Laboratory Centre for Disease Control. Researchers analyze pesticide exposure data. *Farm Family Health.* 5 (2) (Fall 1997a) http://www.hc-sc.gc.ca/main/lcdc/web/publicat/farmfam/vol5-2

[68] Atrazine has recently been found in rain water and drinking water samples in areas of Europe and the midwestern U.S. (*Rachel's Environment & Health Weekly*, Headlines: Pesticides in the News, #660. July 22, 1999); see also: Health Canada. Health Protection Branch. Laboratory Centre for Disease Control. Well-water contaminants: results from PEAS. *Farm Family Health.* 5 (2) (Fall 1997b) http://www.hc-sc.gc.ca/main/lcdc/web/publicat/farmfam/vol5-2

[69] Bradman MA, Harnly ME, Draper W, Seidel S, Teran S, Wakeham D, Neutra R. 1997. Pesticide exposures to children from California's Central Valley: results of a pilot study. *Journal of Exposure Analysis & Environmental Epidemiology*. 7(2):217-34.

[70] Health Canada. *Persistent Environmental Contaminants and the Great Lakes Basin Population: An Exposure Assessment*. Minister of Public Works and Government Services, Canada. Catalogue No. H46-2/98-218E. (1998a); and Dawson, Jennifer and the Fish and Wildlife Nutrition Project. Working Paper E. *Have They Been Hooked?: A Look at How Fishers Use the Guide to Eating Ontario Sport Fish*. Great Lakes Health Effects Program. (1997)

Researchers from McGill University and Universite de Laval have drawn attention to the fact that compared to all other groups in Canada, the Inuit in northern regions have an unparalleled exposure to persistent contaminants, including pesticides, as these have been detected in their traditional food supply (particularly fish and marine mammals) and breast milk.[71]

Urban children of low income families are an additional group at risk of exposure to pesticides. Living in poor neighbourhoods and poorer quality, older homes that may have insect or rodent problems, raises concerns that children of low income families are more likely to be exposed to pesticides applied in their home and surroundings.[72] There is evidence that those of low income or minority status suffer relatively greater health effects from exposure to environmental contaminants.[73] In the case of lead, we know that poor nutrition is a risk factor for greater health effects because it enhances lead uptake (see section 8.2.3 in Case Study #1for further details). It is worthy of investigating whether the same may be said for exposure to other contaminants such as pesticides.

9.2.4 Summary of Information on Pesticide Exposure

- Children are *relatively* more often exposed to pesticides compared to other age groups.
- There are numerous routes of exposure by which children may come into contact with pesticides, from everyday applications in their homes and yards, through to dietary exposure to residues from agricultural application.
- The main exposure routes of concern (and critical exposure periods) are: a) prenatal exposure from current maternal exposure or from mother's stored body burden, b) exposure from breast milk and/or cow's milk during infancy, c) skin absorption, ingestion and inhalation from indoor and lawn applications and d) dietary exposure from pesticide use on fruits and vegetables that are important food items for young children.
- While those who work with pesticides and people living in agricultural communities are at greatest risk for exposure to pesticides, monitoring data for Canada and Ontario indicate that there are detectable levels of currently registered and banned pesticides found in the environment and in certain foodstuffs, indicating the potential for general population exposure to these chemicals.
- Measures of the organochlorine pesticides (measured in blood, fat and breast milk of Great Lakes populations) indicate that most people carry a body burden of these persistent chemicals. There is concern regarding the effects from these same exposures which, in pregnant women and their unborn children, breastfed infants and children who eat freshwater fish or wildlife, may mean exposure to higher than acceptable doses of certain pesticides.
- Aboriginal children and especially, Inuit children are potentially exposed to the highest levels of persistent organochlorine pesticides because of the presence of these in traditional food items and their mother's milk.
- Poverty and minority status are additional factors that influence a child's exposure to pesticides.

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[71] See for example, Chan *et al.* 1997 *op.cit.*; Dewailly E *et al.* Inuit exposure to organochlorines through the aquatic food chain in Arctic Quebec. *Environ Health Perspect* 101 (1993), pp. 618-20. Berti, P.R., *et al.* Food Use and Nutrient Adequacy in Baffin Inuit Children and Adolescents. *Canadian Journal of Dietetic Practice and Research* 60 (1999, pp. 63-70.

[72] Landrigan *et.al.*, Pesticides and inner-city children: Exposures, risks, and prevention. *Environmental Health Perspectives*, 107 Suppl 3 (1999), pp. 431-437.

[73] Haynes, R.C. Environmental justice in action. *Environmental Health Perspectives.* 105 (1997), pp. 374-377.

Poor children are more likely to live in areas and in homes that have pest infestations and therefore they may be more often exposed to pesticides applied in their household and surroundings.

9.3 HEALTH CONCERNS

Ultimately, by their very nature, pesticides may be hazardous for human health since they are designed and intended to kill living organisms. They are also used in "situations that intimately affect human activity"[74] and therefore there is ample opportunity for humans to be exposed. There is thus good reason to be vigilant in continuing research to characterize the exact nature of their effects on human health.

The nature of the health effects from pesticides depends on the type of pesticide, the dose, timing and duration of exposure, as well as the particular susceptibility of the exposed individual.

9.3.1 Evidence

Evidence for the health effects of pesticides in humans comes from a number of sources including experimental toxicological studies on animals or on tissue or cell cultures in test tubes, and epidemiological data summarizing the effects in people mainly from occupational or accidental exposures. Few of these studies on humans have been able to specifically examine children's exposures.

As is discussed in greater detail below, Health Canada's Pest Management Regulatory Agency has a battery of toxicological testing requirements for *new* pesticides and hence there are more data available for more recently registered pesticides. Of concern, however, is the fact that many of the most commonly used pesticides on the market today were registered prior to the current testing requirements. Hence, the toxicological information on many widely used, older pesticides is incomplete and rarely accounts for certain subtle and delayed developmental effects, such as developmental neurotoxicity, behavioural effects and endocrine disruption, that have recently gained attention as health problems stemming from low dose exposures in animals and children.[75]

9.3.2 Animal & Experimental Studies

9.3.2.1 Reproductive/Endocrine Disruption

Several types of pesticides have been implicated as endocrine mimics or inhibitors, evidence being supported largely by the effects noted in exposed wildlife populations.[76] Exposure to organochlorine pesticides in animals has produced effects on estrogen, androgen, prolactin and thyroid hormone functioning, as well as fetal loss, reduced sperm counts, alterations in reproductive behaviour and defects

[74] Jackson, R.J. The hazards of pesticides to children. In: *Environmental Medicine*. Brooks, Stuart M. et al (Eds). (St. Louis: Mosby, 1995), p. 377.

[75] City of Toronto, 1998, *op.cit.*; and CALPIRG and PSR, 1998, *op.cit.*

[76] There has been much research published on the effects of endocrine disruptors as seen from wildlife studies. (Some of these are described in greater detail in Chapter 2.) An important series of papers came out of the symposium entitled "Estrogens in the Environment, III: Global Health implications" in 1994 (see *Environmental Health Perspectives* volume 103 Supplement 7, October 1995).

in the penis and testicles. Organophosphates and carbamates are also associated with hormonal changes and with abnormal sperm, ovarian follicles and eggs. Some herbicides are toxic to sperm and increase fetal loss. Certain fungicides are also associated with risk of fetal death and damage to testicles and sperm.[77]

9.3.2.2 Congenital Defects

A number of pesticides of several different types have produced birth defects in the offspring of exposed pregnant animals. As mentioned above, organochlorines and certain fungicides are associated with defects in male reproductive anatomy. Certain organophosphates and carbamates have shown dose-dependent effects that give rise to congenital anomalies of various types in rats, dogs and monkeys. These were associated with exposure to chlorpyrifos and carbaryl, respectively.[78]

Several fungicides have been associated with structural defects. Dithiocarbamate fungicides are associated with defects in the brain and limbs. The Registry of Toxic Effects of Chemical Substances (RTECS)[79] record for the fungicide Benomyl[80] lists reproductive effects from over a dozen different tests performed at the lowest published toxic dose on pregnant rodents. Among the observed developmental abnormalities listed are effects on the eye, ear, other craniofacial structures including the nose and tongue, the central nervous system, musculoskeletal system, urogenital system and the body wall. The observation of craniofacial defects in animals is disturbing in view of the recent concern surrounding babies with gross eye defects born to mothers who were presumed to have had exposure to Benomyl early in their pregnancy.[81]

9.3.2.3 Growth

In utero exposure to various types of pesticides, including organophosphates, carbamates, herbicides, and fungicides has affected fetal growth as indicated by experimental observations of smaller pup weight, stunted fetus and reduced postnatal weight gain.[82]

9.3.2.4 Neurodevelopmental Toxicity

Many pesticides function as poisons to the nervous system and therefore act as neurotoxins in animals. The criteria for assessing developmental toxicity from animal studies include premature death of the organism, structural abnormalities, alterations in growth and long-term functional deficits.[83]

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[77] CALPIRG and PSR, 1998, *op.cit.*

[78] *Ibid.*

[79] RTECS is compiled by the US National Institute for Occupational Safety and Health (NIOSH) and provides detailed toxicological profiles, reviews and citations on over 140,000 chemical substances. (See http://ccinfoweb.ccohs.ca/databases.)

[80] Benomyl is among selected pesticides listed as teratogenic by the U.S. Environmental Protection Agency See: Moses, 1993, *op.cit.*

[81] Dyer, C. 1996, *op.cit.*

[82] CALPIRG and PSR, 1998, *op.cit.*

[83] Moore, *et.al*. An evaluative process for assessing human reproductive and developmental toxicity of agents.

Organophosphates and carbamates are particularly neurotoxic and animal studies have demonstrated immediate and long-term delayed neurodevelopmental and behavioural effects associated with pre- and peri-natal exposure. Brenda Eskenazi and colleagues summarize the evidence from over 35 experimental studies investigating the effects of different OP pesticides on the developing nervous system.[84] Exposure to the organophosphate DFP in neonatal[85] mice was found to cause altered spontaneous motor behaviour as well as decreased brain neurotransmitter receptor levels in the adult at age 4 months.[86] Newborn rats exposed to levels of chlorpyrifos which did not produce overt toxicity of any kind did exhibit inhibition of protein and DNA synthesis in the brain when assessed as adults.[87] Pregnant mice exposed daily to diazinon at relatively low doses (0.18 mg/kg/day) had young with no visible defects at birth, however, these mice showed impairments of neuromuscular endurance and coordination when tested as adults.[88]

9.3.2.5 Carcinogenicity

There are limits in the ability of toxicological tests to identify substances that may be carcinogenic by any of the recognized mechanisms. (See Chapter 2, section 2.6.9 for an explanation of mechanisms of carcinogenicity). With this in mind, it is apparent that data on the carcinogenicity of pesticides and other environmental chemicals cannot help but be incomplete. Evaluation of pesticides for carcinogenicity in animals has suggested nonetheless that there are carcinogens represented from all major classes of pesticides including organochlorine and organophosphate insecticides, herbicides, fungicides and fumigants.[89] From over 45 pesticides identified by the International Agency for Research on Cancer (IARC) as being potential or known carcinogens in animals, almost half (n=20) are still registered and in common use in the U.S., including: the herbicide atrazine; insecticides dichlorvos, dicofol and lindane; and the fungicides captan, pentachlorophenol and creosote.[90]

An Italian experimental study which exposed rats to a mixture of 15 pesticides showed DNA damage at low doses, but paradoxically, not at high doses of the chemical mixes.[91] These investigators also determined that the toxicity of the mixture was significantly reduced if the fungicide Benomyl was

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Reprod. Toxicol. 9 (1995), pp. 61-95.

[84] Eskenazi *et al.* 1999, *op.cit.*

[85] Neurodevelopmental differences between rodent and human are such that the first 10 days postnatal are equivalent to the processes occurring the last trimester of human fetal gestation. See: Dobbing, J. and J. Sands. Comparative aspects of the brain growth spurt. *Early Hum. Devel.* 3 (1979), pp. 79-83.

[86] Ahlbom, J., A. Frederiksson and P. Eriksson. Exposure to an organophosphate (DFP) during a defined period in neonatal life induces permanent changes in muscarine receptors and behaviour in adult mice. *Brain Res*. 677 (1995), pp. 13-19.

[87] Whitney, K.D., F.J. Seidler and T.A. Slotkin. Developmental neurotoxicity of chlorpyrifos: cellular mechanisms. *Toxicol. Appl. Pharmacol*. 134 (1995), pp. 53-62.

[88] Spyker, J.M. and D.L. Avery. Neurobehavioural effects of prenatal exposure to the organophosphate Diazinon in mice. *J. Toxicol. Environ Health*. 3(5-6) (1977), pp. 989-1002.

[89] City of Toronto, 1998, *op.cit.*

[90] Hoar Zahm, S., M. Ward and A. Blair. Pesticides and cancer. *Occupational Medicine: State of the Art Reviews*. 12 (2) (1997)

[91] Lodovic, M. et al. Effects of a mixture of 15 commonly used pesticides on DNA levels of 8-hydroxy-2-deoxyguanosine and xenobiotic metabolizing enzymes in rat liver. *J. Env. Path. Tox & Onc*. 13 (1994), pp. 163-68.

excluded. Results such as these indicate that the mechanisms of toxicity and carcinogenicity for chemical mixtures are complex and unpredictable.

Several studies also indicate that when human tissue cultures are exposed to pesticides such as cypermethrin or diazinon, researchers have observed changes such as an increased number of micronuclei and increased sister chromatid exchange. These outcomes are DNA alterations that signal the potential for disruption of normal cell division to a cancerous pattern.[92]

9.3.2.6 Immune System Suppression

There appears to be substantial experimental evidence of immunotoxic effects from exposure to pesticides. In their report for the World Resources Institute (WRI), Repetto & Baliga[93] present the key points from this research which suggests that many types of pesticides, but especially organochlorine, organophosphate, carbamate and metal-based pesticides, alter immune function in animals and cell cultures. These are hypothesized to cause immunosuppressive effects manifest as diminished host resistance to infections, as well as promotion of tumour growth, providing an alternative mechanism for carcinogenicity from these substances. The array of studies conducted using many different pesticides, on different animal species and on cell cultures, and examining several different aspects of immune function alteration is too numerous to outline here, but the reader is referred to Repetto & Baliga and their cited sources for further detail. A critique by Acquavella and colleagues[94] suggests that the WRI review focussed too exclusively on acute, high dose toxicological studies, the doses for which would not directly reflect the (lower) exposures more typical for humans. It is their contention that 1) "in current practice, immunotoxicity is usually evaluated at doses lower than those producing overt toxicity"[95] and that, 2) pesticides are not routinely considered to be immunotoxicants.[96] Quite rightly, they also criticize the WRI report for failing to distinguish between findings that were statistically significant versus non-significant and for inaccurate citation of results from some studies.

These criticisms aside, observations of *wildlife* populations appear to demonstrate that environmental exposure to contaminants, many of which are the older, bioaccumulating organochlorine type pesticides, is associated with immunotoxicity in fish, birds and marine mammals.[97] An interesting prospective

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[92] Surralles, J., N. Xamena, A. Creus, J. Catalan, H. Norppa and R. Marcos. Induction of micronuclei by five Pyrethroid Insecticides in whole-blood and isolated human lymphocyte cultures. *Mutation Research.* 341 (1995), pp. 169-184.; Bianchi-Santamaria, A., M. Gobbi, M. Cembran and A. Arnaboldi. Human lymphocyte micronucleus genotoxicity test with mixtures of phytochemicals in environmental concentrations. *Mutation Research* 388 (1997), pp. 27-32; and City of Toronto, 1998, *op.cit.*

[93] Repetto, R. and S.S. Baliga. *Pesticides and the Immune System: The Public Health Risks*. (Washington: World Resources Institute, 1996), 103 p.

[94] Of note is the fact that the eight authors of this critique cite affiliation with five different chemical companies including Monsanto, Dow, du Pont de Nemours and BASF of the U.S. and Zeneca Co. of England. See: Acquavella, J. et al. A critique of the World Resources Institute's report on Pesticides and the Immune System: The Public Health Risks. *Environmental Health Perspectives* 106 (1998a), pp.51-54. This scientific critique was organized by the American Crop Protection Association.

[95] *Ibid*, Acquavella, J. et al. 1998a, p. 52.

[96] *Ibid*, p. 53.

[97] Repetto, R. and S.S. Baliga, 1996, *op.cit.*

experiment[98] with harbour seal pups captured from relatively unpolluted waters and housed for several years in controlled conditions determined that those fed herring from the polluted Baltic Sea exhibited substantially weaker immune responses and had a greater prevalence of infections compared to controls.[99] Interestingly, the Baltic Sea fish for the experiment was purchased from markets where it was intended for human consumption.

Despite contradictory opinions toward the WRI report, both the WRI researchers and critics from the chemical industry agree that the potential for immune system dysfunction from pesticides is an important issue that warrants: a) measures to restrict exposure to pesticides; b) improved and routine screening of pesticides for immunological toxicity; and c) further careful epidemiological studies that investigate the precise immune system effects in humans.[100]

9.3.2.7 Summary

Experimental (i.e. animal) studies indicate that several different types of pesticides have a variety of effects on reproduction, development, growth, neurological development, behaviour, cancer risk and the functioning of immune and endocrine systems.[101] The degree to which these observed effects are translatable to health risks in humans is not absolutely clear since some of these health effects have mainly been demonstrated only after exposure levels that are higher than those likely to be experienced by humans. Animal studies have also suggested, however, that there is increased sensitivity to pesticides in young, developing animals (both pre- and post-natally), that neurological and behavioural effects in the young may occur at low levels of exposure, manifesting at later stages in life, and that there is also the potential for transgenerational effects to occur.

9.3.3 Human Studies

Although there is extensive literature concerning the toxic effects of pesticides in humans from high dose, accidental exposures, there are limited data on low-level pesticide toxicity in humans, both in the young and in adults.[102] Researchers speculate that, while it is likely that the toxic effects of pesticides are similar between children and adults and across different species, there may be differences due to the unique windows of vulnerability at different times during development. For example, a number of studies looking at cancer outcomes have shown that the organ systems affected by pesticides vary according to species of mammal. The effects of pesticides during human adolescence cannot be replicated in weeks of animal maturation[103] and neurological, behavioural and possibly immunological

[98] This work was conducted by researchers from the Netherlands National Institute of Public Health and Environmental Protection. See: De Swart , R.L., P.S. Ross, H.H. Timmerman, H.W. Vos, P.J.H. Reijnders, J.G. Vos and A.D.M.E. Osterhaus. Impaired cellular immune response in Harbour Seals (*Phoca vitulina*) feeding on environmentally contaminated herring. *Clin Exptl Immunol*. 101 (1995), pp. 480-86.

[99] *Ibid*, De Swart , R.L., *et.al.*, 1995.

[100] Robert Repetto & Sanjay Baliga. Response to the ACPA's critique. EHP 106(2) (1998), pp. A52-53; Acquavella *et.al.* , Response. Environmental Health Perspectives, 106(2) (1998b), p. A53.

[101] CALPIRG and PSR, 1998, *op.cit.*; and City of Toronto, 1998, *op.cit*.

[102] NRC. 1993, *op.cit.*; and Schilter, B, Renwick, G & Huggett AC. Limits for pesticide residues in infant foods: A safety-based proposal. *Reg. Toxicol. Pharm*. 24 (1996), pp. 126-140.

[103] This is a fundamental problem with animal studies in that the stages of development in animal species are not

outcomes cannot reliably be extrapolated from animal studies.[104] Therefore, although animal studies offer important experimental evidence, they are not always sufficient for estimating the risks to humans. The evidence from human accidental exposures does suggest that the young are more susceptible to ill effects from exposure to pesticides like OPs and carbamates.[105] This is because of the sensitivity of their developing systems, such as the brain and central nervous system and because they have insufficient activity of the necessary de-toxifying enzymes. [106]

Our knowledge of human health effects from pesticides comes largely from case reports of acutely exposed individuals (either accidental or occupational exposure) which indicates what the results of short-term, high exposure will be. We also gain information from examining the patterns of health problems at the population level, that is, from epidemiological studies. The latter is an important source of information for evaluating the health risks to humans from exposure to pesticides, because it indicates the health effects from real-world exposures, i.e. chronic or longterm exposures to lower levels of pesticides.

Epidemiological studies are observational, as opposed to being experimental, as we do not have the option of experimentally exposing groups of people to toxic chemicals.[107] Epidemiologists recognize that the strength of evidence from epidemiological studies depends upon the quality of information that identifies, among other factors, populations at risk[108], cases (i.e., individuals with a given health problem), exposure levels[109] and dose[110] received. (See Section 4.3 of Chapter 4 for a discussion of the fundamentals of epidemiological studies.) The challenges of epidemiology are such that it is very difficult to adequately determine all relevant variables so that cause-and-effect relationships are proven conclusively.[111] However, observational studies are the best possible evidence and the clear complement to animal studies for increasing information on human health effects from pesticides.

Epidemiological studies of the effects from pesticides have focused on two types of samples, 1) those exposed because of agricultural occupation and 2) those exposed by virtue of where they live (i.e. in areas where pesticides are routinely applied). Just about all human populations have had some exposure

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entirely comparable to human developmental periods.

[104] National Research Council, 1993 *op.cit.*; and Schilter *et al*.1996 *op.cit.*

[105] NRC, 1993, *op.cit.*; Schilter, *et al.* 1996, *op.cit.*; and Eskenazi et al. 1999, *op.cit.*

[106] *Ibid.*

[107] However, pesticide companies have crossed this line in the past and in recent years have increased the practice of testing pesticides on human "volunteers." See more detailed discussion in Section 4.4.3.2 in Chapter 4.

[108] Population at risk refers to the group of individuals among whom the particular health problems might be observed, or all people who are susceptible to or could have the disease or health problem (or a representative sample of them). (See: Fletcher RH. *et al*. *Clinical Epidemiology: The Essentials*. 1988. Baltimore: Williams & Wilkins.) In environmental health studies these would be people who by virtue of their occupation, residence, activities or physiology are exposed to a given environmental chemical.

[109] Exposure refers to "the extent of contact between the toxicant and the surfaces of the human body." See: Roberts, J.R. et al.,1985 *op.cit.*

[110] Dose refers to "the amount of toxicant in the critical organ or tissue." *Ibid*, Roberts et al, 1985: 1.

[111] This has been a criticism commonly invoked by spokespersons for the pesticide industry and it echoes the response of the tobacco industry to scientific studies that demonstrated an association between lung cancer and cigarette smoking. (Kelly Martin MD CCFP-EM, presentation to Standing Committee on Environment and Sustainable Development, December 1, 1999, Ottawa.)

to multiple pesticides.[112] Aside from case reports and anecdotal data of acute pediatric pesticide poisoning, there is also incomplete knowledge of the specific health effects in children since they have not been adequately studied.

9.3.3.1 Accidental Exposure

While those who work with pesticides undoubtedly receive the highest exposures, others, including children, may also receive high doses from the use of pesticides in buildings, by drift from aerial spraying or by accidental ingestion of improperly stored pesticides. Aside from the concern from low-level environmental exposure to pesticides, accidental poisoning is the most significant health hazard for children from pesticides.[113] Symptoms of acute exposure to pesticides are agent specific. That is, they reflect the intended action of each pesticide.[114] Symptoms may mimic those of more common conditions, such as diarrhea, influenza, or other uncommon conditions and therefore may not always be easily diagnosed, especially in children.

Large numbers of people were exposed to a metabolic product of the highly neurotoxic pesticide aldicarb in California in 1985.[115] Individuals reported symptoms of headache, nausea, vomiting, diarrhea, increased salivation, blurred vision and muscle twitching.[116] The common source of the poisonings was determined as contaminated watermelons. The accidental poisoning of seventy-nine people in Jamaica from flour contaminated with parathion demonstrated that proportionately more children than adults died from the exposure and that the reported fatal dose for children was twenty to thirty times *lower* than the estimated fatal dose for the adult.[117]

9.3.3.2 Occupational Exposure

Those with occupational exposure to pesticides, e.g., farm workers and pesticide mixers and applicators, have provided essential data on the range of potential effects in adults from acute exposure.

9.3.3.3 Reproduction, Fertility

Despite a dearth of published data on reproductive toxicity from pesticides currently in use, there is some evidence that acute exposures to pesticides may be associated with fertility problems in both men and women. Female farm workers in Ontario whose activities exposed them to pesticides had an increased time to pregnancy although the association was not significant.[118] There is evidence that a number of

[112] CALPIRG & PSR, 1998, *op.cit.*

[113] Jackson, R.J. The hazards of pesticides to children. In: *Environmental Medicine*. Brooks, Stuart M. et al (Eds). (St. Louis: Mosby, 1995), pp. 377-382.

[114] *Ibid*.

[115] *Ibid.*

[116] Muscle twitching is evidence of denervation effects from exposure.

[117] Diggory HJ *et al.* Fatal parathion poisoning caused by contamination of flour in international commerce. *Am.J.Epidemiol*. 106 (1977), pp. 145-53.

[118] Curtis, K.M., D.A. Savitz,C.R. Weinberg, T.E. Arbuckle. The effect of pesticide exposure on time to pregnancy. *Epidemiology*.10 (1999), pp. 112-117.

different pesticides can cross the placenta and therefore can affect fetal development and survival.[119] Studies have found that women who work in agriculture or had environmental exposure to pesticides during pregnancy have higher risk of spontaneous abortion or stillborn babies, although there is inconsistency in these studies.[120] Research suggests that male fecundity may be affected by both occupational and environmental exposures to pesticides as determined by neuroendocrine status, testicular function and pesticides detected in seminal plasma.[121] Declining sperm count and increased abnormal sperm were found to be associated with exposure to 2,4-D in farm sprayers.[122] The Ontario Farm Family Health Study has shown that there was increased risk of miscarriage where fathers had participated in specific handling of herbicides and where they reported using certain pesticides such as thiocarbamates or carbaryl in the three months prior to conception.[123] Data are suggestive that reproductive risks are generally higher for maternal as opposed to paternal exposures.[124]

9.3.3.4 Developmental Malformations

There are few epidemiological studies with solid evidence of the effects of *in utero* exposure to pesticides. A Minnesota (ecological)[125] study of agricultural workers and the general population revealed higher rates of birth defects in infants conceived in spring and in areas where chlorphenoxy herbicides were used.[126] In Iowa, exposure to herbicides through contaminated municipal water was associated with an increased risk of fetal growth retardation in the general population.[127]

Based on experimental data in pregnant animals and several studies of women occupationally or environmentally exposed to pesticides during early pregnancy, it appears that pesticides may be associated with an elevated risk of specific birth defects (including cleft lip and palate, spina bifida and

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[119] Arbuckle,T.E. and L.E. Sever. Pesticide exposures and fetal death: A review of the epidemiologic literature. *Critical Reviews in Toxicology*. 28(3) (1998), pp. 229-270.

[120] *Ibid*; and Nurimen, Tuula. Maternal pesticide exposure and pregnancy outcome. *J. Occ. Env. Med*. 37 (1995), pp. 935-940.

[121] Mattison, D.R. et al. Reproductive effects of pesticides. In: *The Effects of Pesticides on Human Health. Advances in Modern Environmental Toxicology*.Vol XVIII. Baker S.R. and C.F. Wilkinson, (Eds.) (Princeton: Princeton Scientific Publishers, 1990) pp. 297-389; and Whorton, D. et al. Infertility in male pesticide workers. *Lancet.* 2 (1977), p. 1259.

[122] Lerda, D. and R. Rizzi. Study of reproductive function in persons occupationally exposed to 2,4-dichlorophenoxyacetic acid (2,4-D). *Mutation Research.* 262 (1991), pp. 47-50.

[123] Health Canada. Health Protection Branch. Laboratory Centre for Disease Control. Looking at pesticides and pregnancy. *Farm Family Health*. 6 (1) (Spring 1998b) http://www.hc-sc.gc.ca/main/lcdc/web/publicat/farmfam/vol6-1

[124] Arbuckle,T.E. and L.E. Sever, 1998 *op.cit.*

[125] Ecological studies are epidemiological studies that examine and compare disease rates in different groups and look for associations between environment or other group factors that might explain variation in rates from one group to another. Ecological studies might also compare time trends and look for changes in exposure among various groups that may correlate with observed changes in disease rates.

[126] Garry, V.F. et al. Pesticide appliers, biocides, and birth defects in rural Minnesota. *Environmental Health Perspectives.* 104 (1996), pp. 394-399.

[127] Munger R. et al. Intrauterine growth retardation in Iowa communities with herbicide-contaminated drinking water supplies. *Environmental Health Perspectives.* 105 (1997), pp. 308-314.

limb reductions) depending on timing of the exposure.[128] The media has focused attention on reports of isolated cases in Canada, United States and Britain, where women with presumed first trimester exposure to the pesticide *Benomyl*, gave birth to babies with improper development of the eyes (i.e., either no eyes - anophthalmia, or small eyes - microphthalmia).[129]

A recent report by Weidner and colleagues[130] found an increased incidence of malformations of the penis (hypospadias) and of undescended testes (cryptorchidism) in the male children of a study sample of farmers and gardeners.

9.3.3.5 Neurotoxicity

Poisoning from organophosphate pesticides is associated with subsequent chronic or delayed-onset effects. There is evidence that peripheral neuropathy, a condition that affects nerves in the extremities, can manifest weeks after initial acute exposure and may persist or decrease over time.[131]

Cognitive and affective symptoms and long term neuropsychologic defects are also being recognized as chronic sequelae to an organophosphate pesticide poisoning. The largest study has shown that men who had experienced systemic poisoning (n=128), performed significantly worse on sustained visual attention[132] and mood scale[133] tests, out of 10 tests of neurobehavioural functioning performed.[134] Those who had suffered poisonings severe enough to be hospitalized performed relatively poorly on a third test, symbol digit,[135] suggesting a dose-response relationship between exposure and outcome in this case. This study also found some evidence of injury to the peripheral nerves demonstrated as reduced vibrotactile sensitivity[136] with more severe poisonings in general, and deficits in nerve conduction velocity specifically from chlorpyrifos poisoning.[137]

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[128] CALPIRG and PSR, 1998, *op.cit.*

[129] Dyer, 1996, *op.cit.*, p. 1247.

[130] Weidner, I.S., H. Moller, T.K. Jensen and N.E. Skakkebæk. Cryptorchidism and hypospadias in sons of gardeners and farmers. *Environmental Health Perspectives*. 106 (1998), pp. 793-6.

[131] Cherniak, M. Toxicological screening for organophosphate-induced delayed neurotoxicity. *Neurotoxicol.* 9 (1988), pp. 249-272; and Kaloyanova, F. and M. E. Batawi. *Human Toxicology of Pesticides.* (Boca Raton, Fla: CRC Press, 1991)

[132] See: Steenland, K., B. Jenkins, R.G. Ames, M. O'Malley, D. Chrislip and J. Russo. Chronic neurological sequelae to organophophate pesticide poisoning. *Am. J. Epid.* 84(1994), p. 732): A sustained visual attention, or continuous performance test "requires pressing a key quickly when a certain letter appears amid a temporal sequence of various letters."

[133] *Ibid*: Tests of mood scale or affect, "measure the subjects' self-reported transient states of tension, depression, anxiety, fatigue and confusion." Higher scores mean the subject has a more heightened experience of these states and represents a worse performance.

[134] *Ibid*, pp. 731-736.

[135] *Ibid*: p. 732: The symbol digit, or coding speed test, "requires matching digits to symbols as fast as possible following an exhibited matched pattern."

[136] *Ibid*: Vibrotactile sensitivity is one test from a protocol of standard tests for neurological function. It assesses sensitivity to vibration "as a measure of the possible axonal degeneration in the sensory nerves of the index finger and big toe."

[137] *Ibid*, pp. 731-736.

While the focus of this case study is not adult exposures to high doses of pesticides, the above epidemiological findings related to occupational exposure are worth noting. These particularly worrisome health effects may signal the potential for serious long-term health problems and deficits in children because of the greater susceptibility of the developing brain and nervous system.

9.3.4 Human Studies - Chronic Effects

The more controversial and inconsistent data concern effects, especially delayed effects, from chronic, low-level exposure to pesticides.[138] Because this type of exposure has the potential to affect large numbers of children and because the observed health effects are severe, these types of exposures are of significant public health concern.

9.3.4.1 Cancer

There is evidence that rising incidence of certain cancers in children or young adults may be related to pesticide exposures either directly or via parental exposure.

Exposure to organochlorine insecticides and to herbicides such as the phenoxy acids 2,4-D and 2,4,5-T, is deemed to be a risk factor for development of non-Hodgkin's lymphoma (NHL), which, while a relatively rare cancer, has witnessed a rapid, steady increase in incidence worldwide.[139] Swedish researchers have demonstrated the association between NHL and exposure to phenoxy herbicides in a case-control epidemiological study.[140]

A recent report by Daniels and colleagues[141] analyzed the results of thirty-one previous studies examining the association between pesticide exposure and incidence of various childhood cancers. Such meta-analyses allow for greater confidence in the inferences made about health effects from pesticide exposure. This report highlighted some of the considerable difficulties in epidemiological studies where exposure to environmental contaminants is involved. Despite significant problems with lack of standardization in the methods used in these studies, Daniels and co-workers conclude that there is reason to suspect that pre-conceptional, prenatal and early childhood exposures to pesticides are associated with moderate increases in childhood brain tumours and leukemias. Home use of pesticides appeared to account for the greatest risk of these cancers.[142] For example, brain cancer was found to be in association with childhood use of Lindane for lice treatment.[143]

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[138] Steenland, K. Chronic neurological effects of organophosphate pesticides. *British Medical Journal* 312 (1996), pp. 1312-1313.

[139] Hoffman, W. Organochlorine compounds: Risk of Non-Hodgkins Lymphoma and Breast Cancer?. *Arch. Env. Health.* 51 (1996), pp.189-192.

[140] Hardell, L. and M. Eriksson, A case-control study of non-Hodgkin's lymphoma and exposure to pesticides. *Cancer* 85(6)(1999): 1353-60.

[141] Daniels, J.L. et al. Pesticides and childhood cancers. *Environmental Health Perspectives.* 105 (1997), pp. 1068-1077.

[142] *Ibid*; and Leiss, J.K. and D.A. Savitz. Home pesticide use and childhood cancer: A case-control study. *Am. J. Pub. Health*. 85 (1995), pp. 249-252.

[143] Davis, J.R. et al. Family pesticide use and childhood brain cancer. *Arch. Environ Contam Toxicol.* 24 (1993),

A large retrospective cohort study of Norwegian farm families has determined that there was increased risk of developing certain brain tumours, non-Hodgkins lymphoma, Wilms tumour and other cancers of infancy in farm children, associated with various proxy measures of parental pesticide exposure and use.[144]

There is no single explanation for how pesticide exposure might increase the risk of childhood cancers, however a number of possible causal mechanisms exist. Preconceptional exposure of the parents might increase inherited chromosomal mutations (i.e. those occurring in parents' eggs or sperm). Prenatal exposure from pesticides that cross the placenta may cause chromosomal mutations in the developing fetus. Finally, postnatal incidental exposure might result in alterations in the immune system, hormone functioning or DNA repair mechanisms in the young individual. All of these mechanisms would explain the appearance of cancer at a later stage in life.[145] For a more thorough discussion of the mechanisms of cancer causation, see Section 2.6.9 of Chapter 2.

9.3.4.2 Neurotoxicity

Despite the fact that the tolerable limits for pesticide exposure[146] are frequently based on neurotoxic effects[147] in exposed animals, there has been limited research concerning neurotoxicity of pesticide from real-world *human* exposure. Animal studies suggest that latent neurobehavioural disorders such as impaired endurance and coordination and behavioural alterations observed in adults were caused by exposure to organophosphates and carbamates in the neonate. Case-control and cross-sectional studies in humans have indicated that those with prior pesticide exposure have problems with memory loss and deficits in cognitive function later in life.

The mechanisms of action of certain pesticides such as organochlorines and organophosphates indicate that they do produce neurological symptoms after acute exposure. Subclinical neurological damage may also occur from lower level, long-term exposure to OP pesticides, although these studies are few in number and have inconsistent results, suggesting the need for well-designed, longer follow-up research.[148] Notably, few of these studies have specifically examined the potential for neurotoxic effects in children.

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pp. 87-92.

[144] Kristensen, P., A. Andersen, L.M. Irgens, A.S. Bye and L. Sundheim. Cancer in offspring of parents engaged in agricultural activities in Norway: Incidence and risk factors in the farm environment. *Int. J. Cancer.* 65 (1996), pp. 39-50.

[145] CALPIRG and PSR, 1998, *op.cit.*

[146] The term used to denote the exposure level for humans that will be without adverse health effects is the NOAEL or No Observed Adverse Effect Level. This is typically based on animal tests which determine the different health effects that occur at different levels or timing of pesticide exposure. For chemicals believed to cause cancer, however, there is thought to be no threshold dose, since there is believed to be a risk of developing cancer from even very low levels of exposure. For a thorough discussion of the rationale for calculating "safe" and "tolerable" levels of exposure to environmental contaminants, see discussion of risk assessment in Chapter 4.

[147] Pesticides are most often neurotoxic poisons by design.

[148] Steenland, K. 1996, *op.cit.*

A remarkable, recent study[149] compared two small samples of preschool children in northwestern Mexico for neurobehavioural impacts from pesticide exposure. Children from the Yaqui Valley Indian community are routinely exposed to aerial pesticide spraying as well as daily household bug spraying and there have been high levels of organochlorine pesticides measured in newborn cord blood and breast milk in this community. This group was compared to children from the foothills region, who are less exposed but are similar for several other features that might influence growth and development.[150] Children were assessed for cognition, memory and motor ability.[151] Although there were no differences in growth patterns between the two groups, children from the exposed valley community exhibited impaired stamina, gross and fine motor coordination, memory and drawing ability, as well as other differences in play behaviour. Figure 9.1 shows representative drawings of people done by the children in Guillette and colleagues' study.

[149] Guillette et al. An anthropological approach to the evaluation of preschool children exposed to pesticides in Mexico. *Environmental Health Perspectives.* 106 (1998), pp. 347-353.

[150] Groups were similar for genetic origin, living conditions, social and cultural behaviours, as well as diet and water mineral content.

[151] Children were asked to perform simple repetitive tasks such as jumping up and down on the spot, putting raisins into bottle caps, and catching balls, and they performed memory drills and were asked to draw a picture of a person.

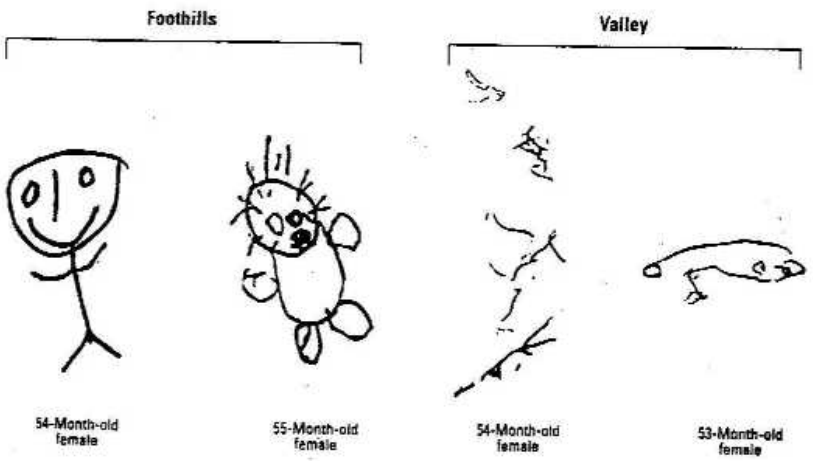

Figure 9.1(a). Representative drawings of a person by 4-year-old Yaqui children from the valley and foothills of Sonora, Mexico.

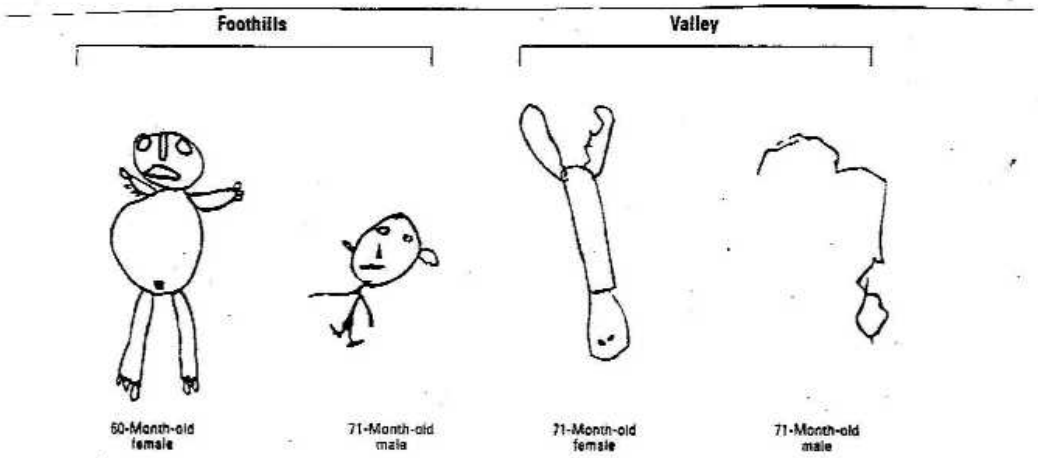

Figure 9.1(b). Representative drawings of a person by 5-year-old Yaqui children from the valley and foothills of Sonora, Mexico.
(Source: Guillette *et.al.*, 1998, *op.cit.)*

Recent reviews of the adverse health effects of exposure to OPs and carbamates have raised the question of their role in the etiology of respiratory problems. Eskenazi and colleagues present the hypothesis supported by some researchers, that there is a biologically plausible association between exposure to OP pesticides and respiratory disease in children. More of the experimental studies of OP exposure have focussed on their effects on the central nervous system. However, because OP pesticides inhibit acetylcholinesterase, they can cause disruption of both autonomic and parasympathetic control of airways and as such, may be important in the occurrence and severity of asthma in the young. This area is under-researched in terms of the risks to humans and there has been no research exploring the role of pesticide exposure in childhood asthma. A small number of epidemiological studies have shown however an association between increased occurrence of asthma among those exposed to select OP and carbamate pesticides.[152]

[152] See for example: Senthilselvan, A. et al. Association of asthma with use of pesticide. Results of a cross-sectional survey of farmers. *Am. Rev. Respir. Dis*. 146 (1992):884-887; Garry, V. et al. Survey of health and use

9.3.4.3 Immune System

There has been increasing attention paid to the possible immune suppressive effects from exposure to pesticides. The World Resources Institute report, *Pesticides and the Immune System*[153] presents evidence, mainly from epidemiological studies in the former Soviet Union, suggesting that pesticides may be linked to a weakening of the immune system which in turn increases susceptibility to infectious diseases and certain cancers. They also cite longitudinal evidence of increased rates of *otitis media* and altered T cell ratios from studies among Canadian Inuit children who are exposed to high levels of organochlorine chemicals (mainly PCBs but including DDT) via breastmilk and traditional food items. Despite the fact that human data to support immune system effects are incomplete, the majority of researchers conclude that this is an important area for further research and critical evaluation of scientific evidence nonetheless.[154]

9.3.4.4 Endocrine Disruption

Organochlorine pesticides have been linked to endocrine disruption involving estrogen, androgen, prolactin and thyroid hormone, as observed from animal studies. These pesticides interfere with hormone function by several mechanisms. Firstly, they may mimic or block at the receptor site for a given hormone. For example, the herbicide atrazine has been shown to have either estrogenic or anti-estrogenic effects depending on the experimental study design.[155] Endocrine disruptors may also act by altering the interaction between hormones and the carrier proteins that transport them through the circulation. For instance, some pyrethroid insecticides are known to displace testosterone from its carrier protein.[156] They are also implicated in causing reproductive developmental abnormalities in wildlife. There have been little data to confirm that these troubling effects occur in humans. Many of these organochlorine pesticides are no longer in use in the western world, however, they are still found in the environment because of their persistence, ability to bioaccumulate, use in many developing countries and long range transport. Levels of DDT and other organochlorine pesticides are detectable in human tissues including breast milk, therefore infants in the Great Lakes region are routinely exposed to these substances at a young age. Accordingly, these health effects are of concern for Ontario's children.

9.3.5 Summary of Human Health Effects from Pesticides

- The potential for the health of children to be affected by pesticides is undeniable.

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characterization of pesticide appliers in Minnesota. *Arch. Environ. Health*. 49 (1994):337-343; and Thrasher, JD, R. Madison & A. Broughton. Immunologic abnormalities in humans exposed to chlorpyrifos: preliminary observations. *Arch. Environ. Health*. 48 (1993): 89-93.)

[153] Repetto, R. and S.S. Baliga, 1996, *op.cit*.

[154] See for example, Repetto & Baliga, 1998, *op.cit.*; Acquavella *et.al.*, 1998a *op.cit.*, and 1998b, *op.cit.*; and Charles Marwick, Provocative report issued on use of pesticides. *JAMA* 275(12) (1996), pp. 899-900.

[155] Connor, K et al. Failure of chloro-s-triazine-derived compounds to induce estrogen receptor-mediated responses *in vivo* and *in vitro*. *Fundam. Appl Toxicol* 30 (1996), pp. 93-101.

[156] Eil, C & Nisula BS. The binding properties of pyrethroids to human skin fibroblast androgen receptros and to sex hormone binding globulin. *J Steroid Biochem*. 35 (1990), pp. 409-414.

- Toxicity studies suggest that young, developing animals are particularly susceptible to adverse effects from pesticides. Animal studies also suggest that the effects of pesticides may be transmitted from generation to generation.
- Children are likely particularly susceptible to the acute and chronic effects of pesticides because of their immature systems, long period of development and their unique behaviour and diet that brings them into greater contact with sources of pesticides.
- Most data on human health effects comes from studies of those who handle pesticides, or from farming communities. Except for clinical information from accidental exposures, there are few epidemiological studies that specifically examine exposures to pesticides in children.
- Depending on the specific pesticide and duration and timing of exposure, pesticides have been associated with a variety of health outcomes in people. There is an association between pesticide exposure and reproductive effects such as decreasing fertility in both males and females, as well as increased risk of spontaneous abortion. Chromosomal abnormalities have been observed after exposure to some pesticides and this also has implications for reproduction. Developmental problems, including appearance of certain birth defects, *in utero* growth retardation and low birth weight have also been observed. There is recent startling evidence of neurobehavioural deficits in Mexican children heavily exposed to pesticides, confirming data from animal studies. There appears to be a higher risk for some childhood cancers such as leukemia and brain tumours associated with prenatal and early exposure to certain pesticides.
- When we assess the effects of pesticides on animals in the lab and the wild, there are other outcomes that are of concern, such as the potential for endocrine disruption, neurobehavioural problems and immune system and respiratory effects.
- While there are certainly gaps in our knowledge, when the weight of evidence from animal models, acute human exposures and epidemiology is considered collectively, the potential for health problems from pesticides respresents an unacceptable risk to humans, and children in particular.

9.4 PESTICIDE REGULATION

As noted in Section 9.1 above, this case study focuses on a review of the activities of the federal government's Pest Management Regulatory Agency (PMRA). The discussions of Risk Assessment and the implementation of the *Food Quality Protection Act* in the United States are particularly relevant to this case study.

Also as noted in Section 9.1.4 above, the following review, despite its length, focuses only on the Pest Management Regulatory Agency (PMRA) and therein, on issues critical to pesticide regulation and the protection of children's health. This review addresses the PMRA risk assessment and risk management processes with respect to new pesticide registrations, the review of pesticides already registered and the evaluation of formulants. It also addresses the PMRA's consideration of pest management alternatives and the management of information. Since the case study was completed in December of 1999, reference to Chapter 4 is necessary for discussion of more recent developments with respect to the PMRA's policy on the use of risk assessment and its proposals for pesticide re-evaluation.

Detailed recommendations are made with respect to improving the transparency and effectiveness of regulating pesticides to protect children's health. Many of the recommendations have to do with the detailed steps necessary to implement a wide range of unfulfilled government commitments with respect to pesticides management. To reiterate, these unfulfilled commitments include the fact that the PMRA has so far failed to:

- adequately implement the Toxic Substances Management Policy;
- develop a regulatory policy on formulants;
- develop a national compliance policy;
- develop a re-evaluation policy and a comprehensive program of pesticide re-evaluation;
- develop a pesticide risk reduction policy;
- produce Proposed Regulatory Decision Documents (PRDD) for proposed registration, re-evaluation and special review decisions;
- create a national database on pesticide use;
- require mandatory reporting of adverse effects by registrants;
- support the integration of pest management with the broader goal of environmental sustainability including setting targets and establishing workplans for the reduction of pesticide use in all sectors.

The analysis that follows addresses these and additional issues from which 45 recommendations arise. The last five of these recommendations have to do with both political will and resources. The federal government's stated commitment to the well-being of Canadian children is hollow if it does not address the undeniable risks of current levels of pesticide exposure.

9.5 THE PEST MANAGEMENT REGULATORY AGENCY

Pesticide regulation in Canada is primarily a function of the federal government, which determines whether a pesticide may be used in this country. The provinces exercise control over the sale and use of federally-approved pesticides. In addition, municipal governments regulate pesticide use on lands and within buildings that they own or control. Increasingly, municipalities are responding to local concerns and are seeking to control pesticide use on privately-owned municipal land, as well.

In 1990, the Pesticide Registration Review Team, a multistakeholder group charged with studying and making recommendations to improve the federal pesticide regulatory system, issued its *Recommendations for a Revised Federal Pesticide Management Regulatory System (hereinafter, The Blue Book)*. The federal government response, a 1994 publication entitled, *Government Proposal for the Pesticide Management Regulatory System (hereinafter, The Purple Book),* outlined its plans for the implementation of Blue Book recommendations. One such recommendation was the creation of a government agency that would facilitate pesticide regulation by a single government department. This recommendation was satisfied in 1995 with the establishment of the Pest Management Regulatory Agency (PMRA), which reports to the Minister of Health.[157]

The Agency's goal is to protect human health and the environment while supporting the competitiveness of agriculture, forestry, other resource sectors and manufacturing.[158] It is responsible for providing safe access to pest management tools while minimizing the risks to human and environmental health. The PMRA administers the *Pest Control Products Act*[159] for Health Canada and sets food Maximum Residue Levels for pesticides on food under the *Food and Drugs Act*.[160] The Agency's specific roles include, but are not limited to the following:

- processing registration applications;
- conducting risk, efficacy and value assessments for potential registrants;
- determining Maximum Residue Limits for pest control products;
- developing effective information and communications;
- reviewing public comments;
- auditing compliance and enforcing the *Pest Control Products Act*;
- coordinating and monitoring the implementation of policies;
- developing risk-reduction policies for all use sectors; and
- identifying areas where research is needed.[161]

The Agency is organized into five divisions:

- The Submission Management and Information Division manages and tracks submissions and conducts scientific screening of potential registrants.
- The Product Sustainability and Co-ordination Division undertakes efficacy, sustainability and value assessments.
- The Health Evaluation Division provides expertise on human health hazards, risk assessment and risk mitigation. It conducts toxicology evaluation and exposure assessments.
- The Environmental Assessment Division provides expertise on environmental hazards, risk assessment and risk mitigation. It conducts assessments of the environmental fate and effects of pest control products.
- The Alternative Strategies and Regulatory Affairs Division directs the development, review and

[157] PMRA. *Strategic Plan 1998-2003* (undated) http://www.hc.sc.gc.ca/pmra-arla/stratp-e.html [hereinafter *PMRA Strategic Plan*].

[158] PMRA. *Overview Document* (undated) [hereinafter *PMRA Overview Document*].

[159] *Pest Control Products Act*, R.S.C. 1985, c. P-9.

[160] *Food and Drugs Act*, R.S.C. 1985 c. F-27.

[161] *PMRA Strategic Plan, op.cit.*

assessment of policies, regulations, programs and legislative amendments, including those related to sustainable pest management.[162]

Several groups advise the PMRA. The Economic Management Advisory Committee includes representatives from among the manufacturers and users of pest control products that are economically impacted by PMRA decisions. The Committee provides advice to the PMRA on mechanisms to improve efficiency and cost effectiveness. The Pest Management Advisory Council includes representatives of pesticide manufacturers, users, and environmental and health groups, as well as individuals with appropriate expertise. It makes recommendations regarding PMRA management, priorities and strategies. It also acts as a forum for the exchange of ideas and advice. The PMRA Policy Council includes the PMRA Executive Director, and the Assistant Deputy Ministers of Agriculture and Agri-Food, Environment, Fisheries and Oceans, Health, Industry and Natural Resources. It provides a forum for the exchange of information and advice between federal government departments and the PMRA. Finally, the Federal - Provincial - Territorial Committee on Pest Management and Pesticides includes provincial and territorial government representatives. It promotes information exchange, the provision of advice and the harmonization of appropriate programs and policies.[163]

The PMRA has committed to fully implementing the regulatory reforms that were identified by the Pesticide Registration Review Team, by the year 2003. Its first strategic objective in that process is to protect health, safety and the environment from the risks of pesticides through the use of sound, progressive science including innovative approaches to sustainable pest management. The PMRA will reportedly meet this objective by strengthening its risk management framework, incorporating the consideration of sustainability into that framework, ensuring that registered pest control products meet current safety standards through re-evaluation and special review, developing innovative approaches to sustainable pest management and ensuring that pest control products are used legally and according to label instructions, among other strategies.[164]

A further strategic objective is to establish an open, transparent and participatory regulatory process. The Agency aims to achieve this objective by establishing a clear regulatory framework, developing an open and transparent decision-making process, soliciting public input on major regulatory decisions and inviting stakeholder participation in regulatory development.

The final objective is to effectively manage the human and financial resources of the PMRA which is to be achieved through a number of initiatives including, but not restricted to work sharing with international partners, increased electronic dependence and the implementation of sound financial management practices.[165]

9.6 THE PEST CONTROL PRODUCTS ACT

The PMRA's authority for pesticide regulation is found in the *Pest Control Products Act*,[166] an act that

[162] *PMRA Overview Document, op.cit.*

[163] PMRA. *Registration Handbook*. 1998. http://www.hc-sc.gc.ca/pmra-arla/hndbk-e.html [hereinafter *PMRA Registration Handbook*].

[164] *PMRA Strategic Plan, op.cit.*

[165] *Ibid.*

[166] *Pest Control Products Act*, R.S.C. 1985, c. P-9.

has been the subject of a lengthy process of prospective amendment. Proposals for legislative amendments were announced by the government in 1995 and are outlined in the government's 1994 *Purple Book*. The primary objectives of the reforms are to enhance health and environmental protection and to increase the openness and transparency of pesticide regulation. The Pest Management Advisory Council is now in discussion with the PMRA regarding the proposed amendments. The *PCPA* amendment process is not covered in any detail in this report.[167]

The existing *Pest Control Products Act* establishes the pesticide registration process and dictates that only registered pesticides may be used in Canada. The regulations to the act specify that in order to approve a pesticide for registration, the registering authority must be of the opinion that:

1) the pesticide's use will not lead to *an unacceptable risk of harm* (emphasis added) to:
(i) things on or in relation to which the control product is intended to be used, or
(ii) public health, plants, animals or the environment; and
2) the product has merit or value for the purposes claimed, when the control product is used in accordance with label directions.[168]

The burden of proof in the registration process lies with the applicant, who must provide sufficient information to allow the PMRA Registrar to determine the safety, merit and value of the product for which registration is sought.[169] However, the act does not define its standard of *unacceptable risk of harm*. Moreover, a clear process, with explicit criteria for determining what constitutes unacceptable risk, has never been laid out,[170] thereby permitting considerable discretion in the assessment of the statutory requirements.

Applicants for whom registration is denied may appeal the decision to an administrative tribunal.[171] The public is denied a corresponding right of appeal when a registration is granted. Once registered, a product retains this status for five years at which point a registrant may apply for renewal. This renewal is generally a *pro forma* exercise which requires little more than confirmation that the product formulation is consistent with documents on register with the PMRA.[172]

Registration of a product may be suspended or canceled by the PMRA when the safety, merit or value of the product is no longer acceptable. The registrant may appeal a suspension or cancellation, in which case the minister must appoint a review board and hold a hearing. The board prepares a report, including recommendations, which it files with the minister. The minister has final power regarding registration of the product.[173] Review boards have been utilized three times. The most recent was in 1985 to hear *Monsanto's* appeal regarding the banning of its herbicide *Alachlor,* one of the pesticides tested by the infamous Industrial Bio-Test Laboratories, indicted in the United States for fraudulent health and safety

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[167] For more information see http://www.hc-sc.gc.ca/pmra-arla/future-e.pdf .

[168] *Pest Control Products Regulations*, C.R.C., c. 1253, ss. 18(c) and (d).

[169] *Ibid.*, s. 9(1).

[170] *Report of the Commissioner of the Environment and Sustainable Development to the House of Commons.* Minister of Public Works and Government Services Canada, 1999 http://www.oag-bvg.ca , *op.cit.* [hereinafter *Report of the Commissioner*].

[171] SOR/92-585, s. 2(F).

[172] *PMRA Registration Handbook, op.cit.*

[173] *Pest Control Products Regulations*, C.R.C., c. 1253.

testing on over 100 pesticides. The *Alachlor* review board recommended reinstatement of *Alachlor's* registration despite finding that the herbicide was a potential human carcinogen. The board also overstepped its authority by basing its findings on *Alachlor* in terms of comparisons and assessments of the commercial viability of its alternative, *Metolachlor*, a pesticide that it had not reviewed in any detail. The review board's report was heavily criticized. In 1988, the Minister of Agriculture issued a decision to maintain the ban on *Alachlor*.[174]

Recommendations

1. The *Pest Control Product Act's* core test for judging the acceptability of a pesticide (*unacceptable risk of harm*) should be specifically defined so that it can be applied in a transparent and consistent manner throughout the risk assessment-risk management process. An essential amendment to the Act, to complement Recommendation 5 below, is to designate persistent and bioaccumulative substances as presenting an unacceptable risk of harm.

2. The *Pest Control Products Act* should be amended to include a requirement to act in a precautionary manner, for example, when the weight of evidence points to the potential for "unacceptable risk of harm". In keeping with this approach, Canada should follow Sweden's lead with legislative amendments to specify inherent characteristics of pesticides that justify de-registration including criteria such as very high acute toxicity, endocrine disruption, probable human carcinogenicity, and neurotoxicity all of which should be considered synonymous with "unacceptable risk of harm."

3. To more effectively implement Recommendations 6 - 31 below, the PMRA should publish a guideline to make its risk assessment and risk management process more transparent. The guideline should include detailed descriptions of its decision-making process including the manner in which children's health interests are taken into account. It may be necessary that the guideline be legislated in the form of a regulation under the *Pest Control Products Act*, in order the ensure that it is implemented.

4. The public should be placed on an equal footing with industry regarding the appeal of a registration decision. To do so, the public must be granted the authority to challenge the approval for registration of pest control products.

Note that several additional recommendations noted in the sub-sections below will involve additional amendments to the *Pest Control Products Act*.

9.7 PMRA AND THE TOXIC SUBSTANCES MANAGEMENT POLICY

The 1995 Toxic Substances Management Policy (TSMP) is a federal government initiative to guide the management of toxic substances (also discussed in Chapter 6). It applies to all substances that are subject to federal regulation. Under the Policy, toxins are categorized as following either Track 1 or Track 2. Track 1 substances are "CEPA-toxic" or equivalent; i.e., they are persistent, bioaccumulate and are primarily the result of human activity. The long-term goal of the TSMP regarding Track 1 substances is their virtual elimination.

Track 2 substances are those that are of concern because of their potential to harm the environment or human health, but which fail to meet all of the Track 1 criteria of CEPA-toxicity: persistence;

[174] See more detailed accounted in: Estrin D. and Swaigen J. *Environment on Trial: A Guide to Ontario Environmental Law and Policy*. 1993, pp. 630-1.

bioaccumulation; and predominantly anthropogenic production. The TSMP aims to control Track 2 substances by preventing or minimizing their release through all stages of their life cycles.[175] Essentially all pesticides can be considered as Track 2 substances since they require some management framework in terms of use and exposure to the public.

The Track 1 list currently includes 12 chemicals, 9 of which are pesticides.[176] Most of the Track 1 pesticides have been used in Canada. All of them are no longer allowed for use although some may enter the country on imported food, flowers, etc., and of course via the movement and cycling of persistent pollutants in the global environment. Notably however, three Track 1 chemicals are or may be found in several commonly used Track 2 pesticides as contaminants generally due to problems with the manufacturing process. The worst example is pentachlorophenol, a commonly used wood preservative for which the manufacturing process unavoidably creates dioxins, furans and hexachlorobenzene (HCB).[177] In other examples, HCB contamination can occur in the pesticides Atrazine and Chlorothalonil, both commonly used across Canada. Dioxin contamination can occur in 2,4-D, Mecoprop and MCPA, also commonly used pesticides. Further, the pesticide Dicofol, registered as an ingredient in 13 pesticide products across Canada is contaminated with DDT, an ingredient used in its manufacture. And finally, the pesticides Endosulfan and Chlopyralid, also in common use in Canada, can be contaminated with HCB or PCBs. As part of a global campaign to eliminate persistent organic pollutants (POPs), some groups have called for the registration of these POPs-contaminated pesticides to be cancelled.[178]

In implementing the TSMP, the PMRA reports that it will assess whether new pest control products are candidates for Track 1 or Track 2 classification. According to the PMRA's 1999 *Strategy for Implementing the TSMP,* new products containing Track 1 active ingredients or formulants will be denied registration. Significantly, exceptions to this rule include emergency use, critical need situations and situations where significant risk reduction can be achieved. The PMRA has not set out which situations this wide range of exemptions embodies. Similar exemptions exist for allowing the approval of new products that contain Track 1 substances as microcontaminants.

Currently-registered products will reportedly also be screened to identify those that contain Track 1 substances. While the focus is on Track 1 substances in active ingredients and formulants, the PMRA implementation plan also states that it will review current levels of microcontaminants in pest control products for their continued acceptability. Virtual elimination is identified as a long term goal for Track 1 substances. More immediate actions that may be taken include strengthening partnerships with industry and users, including efforts to reduce use, and consideration of the possible replacement of chemicals of concern. The PMRA states that it will also use the results of its screening activities to assist in the setting of priorities for re-evaluation and special review.

According to the PMRA, its current management practices meet the TSMP requirements for Track 2

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[175] PMRA. *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. 1999. Document No. Dir99-03, http://www.hc- sc.gc.ca/pmra-arla/qpubs2-e.html.

[176] The list includes dioxins, furans and PCBs and the pesticides: Aldrin, Chlordane, Dieldrin, DDT, Endrin, Heptachlor, Hexachlorobenzene, Mirex and Toxaphene.

[177] Like many other pesticides requiring reevaluation, Pentachlorophenol has languished on the PMRA re-evaluation shelf since 1992 - see Section 9.9 below).

[178] World Wildlife Fund, Inuit Circumpolar Conference, Inuit Tapirisat of Canada, *POPs in CANADA: Persistent Pollutants, Persistent Threats*. Map, March, 2000.

substances.[179] However, most of this chapter disputes this claim. Given the problems discussed in detail below with respect to existing (currently registered) pest control products, formulants, sustainable pest management and information issues, it is doubtful that current PMRA practices satisfy the TSMP requirement to prevent or minimize Track 2 substance release through life cycle management.

In his 1999 audit, the Commissioner of the Environment and Sustainable Development found that application of the TSMP to pesticide regulation has been limited. The PMRA lacks detailed plans for the removal of substances that are identified for virtual elimination, as well as plans to prevent or minimize releases of pesticides that are identified for life cycle management. The Commissioner recommended that the PMRA identify specific substances subject to life cycle management and that it develop and apply strategies for implementing its management approach.[180]

Recommendation

5. The PMRA should fulfill its commitment to incorporate the TSMP in pesticide regulation. This activity should include immediate bans (or de-registrations) on pesticides which are persistent and bioaccumulative (Track 1 substances) without wasting time and resources on re-evaluation. In keeping with this approach, the PMRA should immediately revise its TSMP Implementation Policy to eliminate the ability to register Track 1 pesticides and to cancel registration of pesticides contaminated with persistent organic pollutants pursuant to the TSMP.

9.8 THE REGISTRATION PROCESS: NEW PRODUCTS

9.8.1 Introduction

The process for determining whether a pest control product is safe for registration has come under review, globally. A number of international initiatives have been developed to coordinate national efforts in this area. The NAFTA Technical Working Group on Pesticides, of which Canada is a member, proposes to develop a common data submission format and a coordinated review process among its membership. The realization of these objectives will require the harmonization of data requirements, relevant test protocols, data submission and study report formats, data review and risk assessment practices, regulatory decision making, and administrative processes and procedures.[181] Similarly, the Organisation for Economic Co-operation and Development's Pesticide Programme works to develop and harmonize test guidelines and assessment methods.[182]

Currently, registration of new pest control products in Canada involves three steps:

i. a decision is made as to whether the pesticide is safe for registration;
ii. a maximum residue limit is established for the product that sets out the maximum quantity of pesticide residue permitted on food products; and finally,

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[179] *Ibid.*

[180] *Report of the Commissioner, op.cit.*

[181] NAFTA Technical Working Group on Pesticides. *A North American Initiative for Pesticides: Operation of the NAFTA Technical Working Group on Pesticides*. November, 1998. http://www.hc-sc.gc.ca/pmra-arla/qinter2-e.html .

[182] For a description of current projects, see PMRA. *PMRA Table of Current OECD Pesticide Projects*. February 1999. Document No. OECD99-01. http://www.hc-sc.gc.ca/pmra-arla/qinter-e.html .

iii. any use restrictions necessary to minimize the risks associated with the pesticide's use are established and must be printed on the product label.

These three processes are described, in turn, in sections 9.8.2, 9.8.3 and 9.8.4, below.

This approach to pesticide registration suffers from a number of significant shortcomings which are addressed in the case study recommendations. Some of the more glaring deficiencies include the PMRA's failure to aggregate pesticide exposure from all media, and its failure to consider the potential cumulative and synergistic effects of exposure to multiple pesticides (all pesticides are considered in isolation from each other and from other toxic substances). These flaws are set out in detail in the discussion below.

9.8.2 Registration

In order to determine whether a pest control product is safe for use and should therefore be registered in Canada, the PMRA carries out product risk assessments.[183] These assessments are carried out on a chemical-by-chemical basis, as new pest control products are submitted for registration. Two risk assessments are undertaken by the PMRA for each new product: one considers the hazards to human health caused by exposure to the pesticide; the other assesses the environmental hazards associated with the pesticide's use.

Each risk assessment involves two major steps. First, any hazards associated with use of the product are identified and assessed. This process is described below in section 9.8.2.1. Secondly, the potential exposure of humans and the environment to the pest control product is estimated, as described in section 9.8.2.2. The hazards and expected exposure levels associated with a pesticide are then used to make a determination about its safety. The PMRA states that its risk assessments for new products include a specific consideration of children and their unique characteristics.[184]

Following completion of the risk assessments, a value assessment of the pest control product is also conducted. This is described in section 9.8.2.3 below. The outcome of all of these assessments is a decision regarding whether to register the pest control product. What remains unclear in PMRA documentation however, is the relative importance that the PMRA assigns in the registration decision-making process to the three determining factors of risk to human health, environmental risk, and pest control product value.

Regulations under the *Pest Control Products Act*[185] specify the range of information required by the PMRA in order to complete the assessments identified above. Information requirements vary depending on the nature of the product, the manufacturing process and the submission (whether it is a new registration or an amendment). Generally, the applicant must submit scientific studies addressing:

- pest control product effectiveness;
- occupational safety;

[183] Risk assessment is discussed more fully in Chapter 4.

[184] Letter from Christine Norman, Acting Head, Occupational Exposure Assessment Section, PMRA to Canadian Environmental Law Association, May 26, 1999 [hereinafter *PMRA Letter*].

[185] *Pest Control Products Act*, R.S.C. 1985, c. P-9.

- safety to host plant, animal, or the article in relation to which the product is to be used;
- effects to non-target organisms;
- pest control product and residue persistence, retention and movement;
- analysis methods for detecting the control product and its residues in food, feed and the environment;
- detoxification or neutralization methods;
- disposal methods for the control product and its empty packages;
- the stability of the product during storage and display;
- analysis methods for detecting the active ingredient; and
- the compatibility of the control product with other products.[186]

These statutory requirements are supplemented in practice with the requirement for studies of bystander exposure.[187] Where the control product is intended for use on foods for human consumption, the applicant must also provide the results of animal tests that consider the risks of the control product or its residues, to human health.[188] In practice, this requirement has been extended to all pest control products, regardless of whether they are used in connection with food commodities.[189]

9.8.2.1 The Risk Assessment Process: Hazards

Depending on the nature of the pesticide and the application, the PMRA states that its information requirements regarding human health risks could include studies of acute, short-term and long-term toxicity, carcinogenicity, reproductive toxicity, teratology, genetic toxicity, metabolism and toxicokinetics, neurotoxicity, immunotoxicity and endocrine disrupter potential. To provide guidance to registrants regarding which studies are required, the PMRA has characterized pesticides according to their use. Sample pesticide use-site categories (USCs) include Greenhouse Food Crops, Stored Food and Feed, and Indoor Hard Surfaces. Each USC has an associated list of required and conditionally-required data that are set out in data-code (DACO) tables.[190]

Testing for endocrine disruption potential, immunotoxicity and developmental neurotoxicity are not required for all pest control products.[191] According to the PMRA, it uses a two-tiered testing system. Only when certain indicators appear in the core toxicology tests are these more specialized tests required.[192] The PMRA has not made clear, however, how this testing system operates, including an identification of the triggers for additional testing requirements.

In addition, it is not clear whether the PMRA's data requirements test for all potential endpoints or whether the tests that are required are adequate to gauge the risk of causing these endpoints. This is

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[186] *Pest Control Products Regulations*, C.R.C., c. 1253, s. 9(2)(b)(i) to (xi).

[187] *PMRA Letter*, *op.cit.*

[188] *Pest Control Products Regulations*, C.R.C., c. 1253, s. 9(2)(b)(i).

[189] *PMRA Letter, op.cit.*

[190] PMRA. *Organizing and Formatting a Complete Submission for Pest Control Products*. 1998. Document No. Pro98-02. http://www.hc-sc.gc.ca/pmra-arla/qpubs2-e.html [hereinafter *PMRA Submission*].

[191] See *Ibid.*, and PMRA Data Code Tables.

[192] *PMRA Letter, op.cit.* and Personal Communication, Christine Norman, Acting Head, Occupational Exposure Assessment Section, PMRA. June 10, 1999.

particularly important with respect to tests that assess the risks to children's health. For example, the PMRA reports that its neurotoxicity tests are being refined to better investigate the effects of pesticides on neurodevelopment.[193] Even the Minister of Health recognizes the limitations of current PMRA testing requirements: "[a]lthough the current toxicology package allows for an assessment of the potential for endocrine disruption, it is recognized that these test methods can be enhanced to include additional endpoints and that more specific methods need to be developed."[194]

The PMRA evaluates the required studies and makes a judgement regarding the pesticide's safety. Two assessments are involved. The first gauges the risk to human health from occupational and bystander exposure to pesticides. The second considers the risks from exposure to pesticide residues on food and in drinking water. Significantly, the combined risks to human health from these two sources of exposure (occupational/bystander and food/water) are never considered. In other words, the combined or cumulative effects of different sources of exposure to a particular pesticide are never examined by the PMRA. In addition, the effects of cumulative exposure to multiple products with common mechanisms of toxicity are not considered in the PMRA's risk assessment process.[195] This means that all determinations regarding safe exposure levels consider each pesticide in isolation. For example, the herbicide Sulfosulfuron has been found to be carcinogenic to animals. However, the PMRA has concluded that the toxin should pose no carcinogenic risk to humans as long as human intake is below the threshold concentration needed to cause damage. Consequently, the pesticide has been approved for registration, in the absence of a consideration of whether exposure to other chemicals, which may have similar mechanisms of action, would put human intake over the cancer threshold.[196]

To gauge the risk to human health from occupational and bystander exposure, the PMRA identifies the most appropriate no observed adverse effect level (NOAEL) reported in the studies. Choosing which NOAEL is appropriate is based on considerations such as the route and duration of exposure, the species that were tested in toxicity studies and the endpoint of toxicological concern. The PMRA does not explain how this decision-making process takes place.

Once chosen, the NOAEL is divided by uncertainty factors to account for data limitations and response variability.[197] According to the PMRA, additional uncertainty factors are applied beyond the traditional 100-fold uncertainty factor (which accounts for inter- and intra-species difference) to account for severity of endpoint and lack of data.[198] The adjusted NOAEL is intended to quantify a safe level of exposure.

The PMRA next considers the risk posed by exposure to pesticide residue in food and drinking water. The PMRA reports that the most appropriate NOAEL is divided by a safety factor, typically of 100. The PMRA has not set out whether the same NOAEL is used in occupational/bystander exposure assessments and food residue assessments. Nor does the PMRA explain how it determines which safety factor to apply to the NOAEL. This calculation results in the derivation of the acceptable daily intake (ADI). The

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[193] *PMRA Letter, op.cit.*

[194] Letter from the Honourable Allan Rock, Minister of Health, to Julia Langer, World Wildlife Fund, June 29, 1998.

[195] PMRA. *Presentation Materials on Submission Review and Decision-Making and the FQPA*. February 1999 [hereinafter *PMRA Presentation Materials*].

[196] PMRA. *Proposed Regulatory Decision Document: Sulfosulfuron*. 1998. Document No. PRDD98-01 http://www.hc-sc.gc.ca/pmra-arla/qpubs2-e.html [hereinafter *PMRA Sulfosulfuron PRDD*].

[197] *PMRA Overview Document, op.cit.*

[198] *PMRA Presentation Materials*, *op.cit.*

ADI is the amount of pesticide that toxicologists consider safe for humans to consume every day, for a lifetime. The ADI is used to set maximum residue limits for the pesticide, described below in section 9.8.3.

According to the PMRA, risk assessments for carcinogens are based on the weight of the scientific evidence. The assessments involve an evaluation of the entire data package.[199] The PMRA does not describe how this process is undertaken.

The PMRA reports that the increased sensitivity of the young (especially infants and children), as well as pregnant women, are considered during the risk assessment process to provide additional protection where warranted.[200] However, the PMRA fails to set out under which conditions this additional protection would be warranted or what form it would take.

In addition to the human health assessment described above, the PMRA assesses the environmental risk of using the pesticide. The PMRA examines reports of scientific investigations regarding environmental fate and toxicity, including effects on non-target species. Based on this information, the no observed effect concentration (NOEC) for the pesticide is determined by the PMRA.[201] The NOEC is intended to quantify a safe level of exposure.

Recommendations

6. The PMRA should set out exactly how its two-tiered system of testing requirements functions. The trigger points for additional testing requirements should be made explicit.

7. Several toxicity tests that are currently conditionally-required should become standard requirements. This includes developmental neurotoxicity testing on young animals, which is particularly important for gauging risks to children's health. Similarly, tests for endocrine disruption that are protective of children should be made a standard PMRA test requirement.

8. There is a need for a detailed examination of the toxicity tests required by the PMRA in order to assess their adequacy. An investigation should be undertaken regarding whether the PMRA requires testing for all potential endpoints and whether the tests that are required are adequate to gauge the risk of causing these endpoints.

9. The PMRA should consider the potential effects on human health of occupational/bystander and food/drinking water exposures on an aggregated basis.

10. The PMRA should consider the potential effects on human health of cumulative exposures to pesticides that act via common mechanisms of toxicity.

11. The PMRA should describe how it chooses a NOAEL for occupational/bystander assessments and food residue assessments from the available alternatives.

12. The PMRA should set out how it determines which uncertainty factors to apply to the occupational/bystander and food residue NOAELs.

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[199] *PMRA Overview Document, op.cit.*

[200] PMRA. *PMRA Position on FQPA Science Policies*. 1998.

[201] *PMRA Overview Document, op.cit.*

13. The PMRA should adopt a requirement similar to that found in the U.S. *Food Quality Protection Act,*[202] mandating the application of an uncertainty factor with a minimum value of 10 in order to account for potential pre- and post-natal developmental toxicity and the incompleteness of toxicity and exposure data for children. The uncertainty factor could have a higher value in situations of relatively high uncertainty regarding toxicity and children's exposure.

14. The PMRA should explain precisely how it incorporates considerations regarding the increased sensitivity of the young and pregnant women into its risk assessments and should set out under which conditions it considers additional protection for these groups to be warranted.

15. The PMRA should set out precisely how its risk assessments are undertaken for potentially cancer-causing pesticides.

9.8.2.2 The Risk Assessment Process: Exposure

In addition to assessing the toxicological hazards posed by a particular pesticide, the PMRA estimates the exposure of Canadians to the pesticide. It then compares this expected exposure level to the safe exposure level determined through the hazards assessment, in order to gauge whether use of the pesticide will be safe.

Information regarding expected human exposure levels to a pest control product must be submitted to the PMRA by the registrant. This information includes values for occupational and bystander exposure. The adjusted occupational/bystander NOAEL that is described in section 9.8.2.1 is divided by this estimated exposure level to determine the pesticide's margin of safety (MOS). A MOS of 100 is typically considered acceptable to account for variability in response to pesticide exposure, both within species (differences between adults and children) and between species.[203]

Information regarding expected pesticide residue levels in food and drinking water is also considered and is compared to the ADI that is derived through the process described in section 9.8.2.1. This information is used to set maximum residue limits for the pesticide, as described in section 9.8.3 below.

In addition to data regarding human exposure, information in support of an environmental exposure assessment must be provided by the registrant. These data are used to generate an expected environmental concentration (EEC) for the substance. The most sensitive test species NOEL is then compared to the EEC in the form of a ratio. According to the PMRA, many factors determine how large this ratio must be in order for the risk to be judged acceptable.[204] However, the PMRA does not describe what these factors are, their relative weights and how they are applied. Such clarification is essential to know whether the PMRA adequately accounts for uncertainty and gaps in data and for the unique exposure circumstances of children.

As part of a movement to harmonize their regulatory approaches, the EPA and the PMRA are working together to develop Standard Operating Procedures (SOPs) for residential exposure assessments and a

[202] *Food Quality Protection Act*, Pub. L. No. 104-170, 110 Stat. 1489 (1996).

[203] *PMRA Overview Document, op.cit.*

[204] *Ibid.*

harmonized post-application exposure guideline.[205]

Recommendation
16. The PMRA should set out which factors it considers when making determinations regarding how large the ratio between the NOAEL for the most sensitive test species and the EEC must be in order for the risks associated with a pesticide to be judged acceptable, as well as their relative weight, and the manner in which they are applied.

9.8.2.3 Value Assessment

Finally, the PMRA considers the value of registering the applicant's product by examining economics (the value of the product to the sector) and sustainability (contribution to integrated pest management; comparison to alternative products and practices). The value assessment also considers efficacy, that is, whether the use of the product contributes to pest management and whether the application rates are the lowest possible to effectively control the target pest.[206]

The PMRA fails to describe how its value assessments are used in pest control product registration decisions and in particular, the weight these assessments are given relative to the risk assessments undertaken by the PMRA.

Recommendation
17. The PMRA should set out how the results of its value assessment are used in the regulatory decision-making process.

9.8.3 Maximum Residue Limits (MRLs)

If a pesticide is intended for use on, or affecting, food commodities, the maximum residue limit (MRL) of the pesticide on food products must be determined as part of the registration process. MRLs are set by the Food Residue Exposure Assessment Section of the Health Evaluation Division of the PMRA, under authority of the *Food and Drugs Act*.[207] This work takes place at the same time as the hazard, exposure and value assessments described above.

Limits are established for parent pesticides as well as any degradation products, metabolites or impurities that are of toxicological concern. Together these compounds are termed the residue of concern (ROC). The applicant is required to develop analytical methods to identify all of the components of the residue of concern.[208]

Applicants are obligated to submit the scientific data necessary to assess whether any residues will result from proposed pest control product use and to determine a MRL. Required information includes:

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[205] PMRA. *The PMRA Position on FQPA Science Policies*. 1999.

[206] *PMRA Overview Document, op.cit.*

[207] *Food and Drugs Act*, R.S.C. 1985 c. F-27.

[208] PMRA. *Residue Chemistry Guidelines*. 1998. Document No. Dir98-02. http://www.hc-sc.gc.ca/pmra-arla/qpubs2-e.html. [hereinafter *PMRA Residue Chemistry Guidelines*].

- the results of plant and animal metabolism studies that determine the metabolic fate, translocation and deposition of the active ingredient after application to plants or administration to livestock;
- pesticide residue in water, fish and irrigated crops following direct application to water;
- pesticide residues in food and feed that result from the treatment of food and feed handling establishments;
- residue deposition in meat, milk, poultry and eggs;
- residues on and in plant material following pesticide exposure;
- data regarding whether residues in raw commodities degrade, reduce or concentrate during food processing; and
- data to assess whether pesticide residues are stable during the storage of analytical samples.[209]

The PMRA also relies on information regarding the relative consumption of various crops in the Canadian diet. This information is used to guide pesticide testing requirements. Crops that constitute a greater proportion of Canadians' diet require a higher number of crop residue trials. These trials measure the type and amount of residue left on a particular crop, growing in a variety of locations, when a pesticide is applied according to label directions.

To set an MRL, the registrant proposes a value which, based on field trial data, reflects the maximum residue level that could occur on food at the point of sale. The MRL must include all components of the ROC and should reflect residue values on the raw agricultural commodity. The MRL should be large enough to include any residue values that could reasonably be expected, and should not be an average value.[210]

The proposed MRL is then used to generate potential daily intake (PDI) estimates of pesticide residue, based on food and drinking water consumption patterns.[211] To estimate consumption patterns, the PMRA reports that it relies on the 1996 US Department of Agriculture Continuing Survey of Food Intakes by Individuals.[212] In addition, as part of a movement to harmonize its pesticide regulatory approach with that of the US Environmental Protection Agency (EPA), the PMRA reports that it has adopted the computer-based probabilistic models used by the EPA to assess dietary exposure. The PMRA has stated that it intends to harmonize as far as possible with the EPA on the use of models (including probabilistic models) to generate better estimates of drinking water exposure. Finally, the PMRA reports that it plans to begin aggregating dietary and non-dietary exposure data..[213]

The MRL is accepted on condition that the PDI will not exceed the pesticide's acceptable daily intake (ADI). According to the PMRA, residue consumption assessment includes consideration of different consumption patterns, including those of children.[214]

If the PDI exceeds the ADI, the PMRA applies use restrictions, such as approving the pesticide for fewer crops, imposing lower application rates, or increasing the time between spraying and harvest, in order to

[209] *Ibid*.

[210] *Ibid.*

[211] *PMRA Overview Document, op.cit.*

[212] Personal Communication, Danielle Prevost, Information Officer, PMRA. September 30, 1999.

[213] PMRA. *The PMRA Position on FQPA Science Policies*. 1999.

[214] *PMRA Overview Document, op.cit.*

lower the PDI.[215]

A serious limitation of this process is the fact that the exposure estimate only considers pesticide intake from food and water sources. Other sources, such as soil and dust, are significant for children. In addition, no consideration is made of the cumulative intake of pesticides that act via similar mechanisms of toxicity.

The NAFTA Technical Working Group on Pesticides reports that it plans to take steps to minimize trade problems resulting from different maximum residue limits for commodities that are traded among the three member countries. Concern has been expressed that in harmonizing MRLs among trading partners, there will be pressure to weaken Canadian MRLs in order to place them in line with the least stringent standards of its trading partners. The outcome could be universally weak standards.[216]

Recommendations

18. Pesticide intake via soil and dust should be included in exposure estimates.

19. The PMRA should consider cumulative exposure to multiple pesticides that act via similar mechanisms of toxicity in its risk assessments.

20. The PMRA should ensure that the negotiation of MRLs between trading partners is a transparent process and that the strength of Canada's MRLs is not compromised.

9.8.4 Use Restrictions[1]

Use restrictions may be employed as an additional risk management tool for new pest control products that are approved for registration via the process describe above. These restrictions are used to manage pesticide exposure in order to ensure that it does not exceed the pesticide's acceptable daily intake. The restrictions can prohibit product use on certain crops, vary post application intervals including the interval between the last application and harvest, vary application rates and frequencies, prohibit the use of the product around environmentally sensitive areas and impose restrictions related to conditions such as wind speed at the time of use. Any measures determined to be necessary in order to bring the risks associated with a pesticide within acceptable limits must be set out, in detail, on the product label.[218]

Use restrictions can be employed as a primary method of risk management. For example, the herbicide Sulfosulfuron has been found to be very toxic to non-target terrestrial and aquatic plants, and it is reported that spray drift and run off following application have the potential to significantly affect terrestrial and aquatic plant habitat. The PMRA's management solution for this potentially significant source of contamination is to require the establishment of a buffer zone of 30 m between sprayed areas and sensitive terrestrial areas, and a zone of 6 m between sprayed areas and the edge of sensitive aquatic

[215] Personal Communication, Christine Norman, Acting Head, Occupational Exposure Assessment Section, PMRA, October 6, 1999. See also next section, 9. 8.4, for discussion of pesticide use restrictions.

[216] Canadian Environmental Law Association, *The Environmental Implications of Trade Agreements*, CELA Brief No. 231, August, 1993.

[217] Use restrictions may be imposed by provincial pesticide regulators, as well. The division of responsibilities over pesticides between the federal and provincial governments is described in Chapter 3.

[218] PMRA. *Regulatory Decision Making*. January 1998.

areas, as well as label instructions not to spray prior to forecasted rain.[219]

Given the high toxicity of many pest control products to non-target organisms, and high level of reliance that can be placed on the applicator to minimize the associated risks, it is vital that the PMRA effectively monitor and enforce use restrictions. Yet the PMRA has failed to adequately fulfill this role, as described in Section 9.12.2 below.

In its 1994 Purple Book commitments, the government pledged to legislate strengthened *Pest Control Product (PCPA)* enforcement provisions and to develop a national compliance policy.[220] According to the PMRA, it currently employs a number of strategies for ensuring compliance with the *PCPA*. Inspections are used for educational purposes and to assess compliance. PMRA inspectors can also undertake an investigation when they suspect *PCPA* infractions. An investigation involves information gathering and evaluation, and appropriate enforcement measures.
The range of possible enforcement measures include:

- *registration cancellation or suspension*
- *education letters*: if there is a problem but no infraction, or when the infraction cannot be attributed to the person in question
- *notice of violation warnings*: if an infraction is detected for the first time and has not caused significant harm
- *imposition of violation penalties*: if a previous warning has been issued, or the infraction presents a risk, etc.
- *prosecution*: in more serious situations.[221]

The PMRA has not developed a national compliance policy.[222] In his 1999 report, the Commissioner of the Environment and Sustainable Development assessed the PMRA's enforcement record. Incredibly, the Commissioner reported that the PMRA has the equivalent of a mere 44 officers to inspect farms, food processing plants, commercial application facilities, retail outlets, pesticide registrants and formulators, lawn care companies, and others, *nationwide.* Not surprisingly, the Commissioner found that, "[t]he PMRA does not know the extent to which users comply with directions on pesticide labels."[223] The Commissioner found that inspections are primarily undertaken in response to known or suspected violations, and are not used to systematically monitor compliance.[224]

In addition, the Canadian Food Inspection Agency, the government agency responsible for all federally-mandated food inspection, reports that the rate of pesticide MRL exceedance on domestic crops tripled between 1991 and 1998. This increase is the result of several practices including: application of a pesticide to a crop for which it is not approved, application of more than recommended amounts of pesticide and the application of a pesticide too close to the harvest.[225]

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[219] *PMRA Sulfosulfuron PRDD, op.cit.*

[220] *PMRA Strategic Plan, op.cit.*

[221] PMRA. *Compliance and Enforcement Policy Guideline*. 1998. Document No. B98-01. http://www.hc-sc.gc.ca/pmra-arla/qpubs3-e.html .

[222] Personal Communication, Danielle Prevost, Information Officer, PMRA. September 30, 1999.

[223] *Report of the Commissioner, op.cit.*, at 4-30.

[224] *Ibid.*

[225] Eli Neidert and Glenn Havelock, Canadian Food Inspection Agency. *Report on Levels and Incidences of Pesticide Residues in Selected Agricultural Food Commodities Available in Canada During 1994-1998.*

Within the context of clearly inadequate inspection and enforcement capacity, heavy reliance upon pesticide label instructions and restrictions to avoid pesticide risks to human and environmental health, is a poor risk management strategy.

Recommendation

21. The PMRA should reduce the reliance on pesticide label instructions and restrictions for the management of pesticide risk to human and environmental health and in the interim, given the importance of label compliance, the PMRA should improve its inspection and enforcement operations to ensure appropriate pesticide use. The PMRA must not hesitate to apply the full range of enforcement penalties that are available to it, in order to guarantee compliance. Enhanced enforcement should be guided by a national compliance policy, which the PMRA committed itself to develop in its 1994 *Purple Book*.

9.9 EXISTING (CURRENTLY REGISTERED) PEST CONTROL PRODUCTS

The discussion thus far has focused on products that are new to the regulatory system. Although the data requirements for these new pest control products have improved with time, over 300 of the 500 active ingredients found in currently-registered pest control products were approved prior to 1981, and more than 150 others were originally registered pre-1960.[226] Health and environmental standards were less stringent and scientific methods less reliable when these pesticides were registered for use. For example, until recently, estimates of pesticide exposure through food consumption relied on a 1975 Department of National Health and Welfare study, *Nutrition Canada Food Consumption Patterns Report*. Incredibly, according to this outdated study, no significant differences existed between the diets of infants and the general population, with the exception of oats.[227] This information is clearly inaccurate.[228]

Although registration of existing products expires every five years, registration renewal is a formality and is routinely given as a matter of course. The only inquiry that takes place at the time of re-registration considers whether the product label information and formulation ingredients are consistent with those that are held on file by the PMRA. No consideration is given as to whether these older products satisfy current assessment requirements or whether their MRLs are within current ADI levels.[229]

The PMRA committed itself, in its *Strategic Plan*, to remedy this problem by means of a comprehensive program of pesticide re-evaluation.[230] The Agency defines re-evaluation as the assessment and reconfirmation of the acceptability of older compounds in light of modern technology and scientific standards.[231] This language reveals a bias towards maintaining the *status quo* and upholding the registration status of older pesticide products.

November, 1998.

[226] *Report of the Commissioner, op.cit.*

[227] *PMRA Residue Chemistry Guidelines, op.cit.*

[228] See section 9.2.3.2 above.

[229] *PMRA Registration Handbook, op.cit.*

[230] Pesticides may be re-evaluated at any time to ensure their safety, under authority of the *Pest Control Products Regulations*, s. 19.

[231] *PMRA Strategic Plan, op.cit.*

The PMRA's re-evaluation commitment is to review registered products and their maximum residue limits to ensure that they meet current safety standards. Its goal is to re-evaluate all products registered as of December 31, 1994, by 2005/6.[232] It proposes to do this in coordination with the United States Environmental Protection Agency and the European Union, through shared pesticide reviews. The rationale is to save time and resources, and to eliminate the potential for trade difficulties resulting from differential pesticide standards among these trading partners. In particular, the PMRA plans to draw heavily from US data reviews.[233]

In certain circumstances, the PMRA can also undertake a "special review" of an existing pest control product.[234] These reviews are initiated when specific concerns about a product, based on new evidence or regulatory action taken in other countries, indicate that there may be a significant risk of harm to human health, safety or the environment, or that the product is no longer efficacious. In contrast to re-evaluation, which is meant to be undertaken on all older pesticides in order to assess compliance with current risk assessment requirements, special reviews are carried out in response to indications that there may be a problem with a particular pesticide. The PMRA concluded a special review of Carbofuran in 1998 after concerns were expressed regarding its effects on wildlife. To date this is the only special review that the PMRA has initiated,[235] although it has indicated that it plans to review pest control products containing the organochlorine insecticide *Lindane*.[236]

The Commissioner of the Environment and Sustainable Development examined pesticide re- evaluation and special review in his 1999 Report.[237] He noted that the federal government has formally recognized the need for pesticide re-evaluation for over 13 years but has failed to meet its long-standing commitment to implement a re-evaluation program. Prior to the creation of the PMRA, Agriculture Canada made commitments to re-evaluate priority pesticides that were not fulfilled. Similarly, the PMRA was charged in 1995 with the development and implementation of a pesticide re-evaluation program. Despite these commitments, the Commissioner found that:

> [t]here is no clearly delineated process that identifies steps to be followed in undertaking re-evaluations or special reviews, the roles of each of the various participants, the criteria to be used in making decisions, and the respective accountabilities.[238]

In contrast, the US legislated a pesticide re-evaluation requirement in 1988 that has resulted in a number of pesticide use de-registrations.[239]

The PMRA has committed no budgetary allowances to re-evaluation. Instead, funds for this endeavour are to come from efficiencies in other areas of PMRA's functions. Specifically, resources that result from

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[232] Pest Management Advisory Council. *Draft Meeting Report*. April 16, 1999.

[233] *PMRA Strategic Plan, op.cit.*

[234] Under authority of s. 19 of the *Pest Control Products Regulations*.

[235] *Report of the Commissioner, op.cit.*

[236] PMRA. *Special Review of Pest Control Products Containing Lindane*. 1999. Document No. SRA99-01. http://www.hc-sc.gc.ca/pmra-arla/qpubs2-e.html .

[237] *Report of the Commissioner, op.cit.*

[238] *Ibid*., at 3-32.

[239] *Ibid.*

efficiencies and cost savings are to be shifted from the area of new product evaluation.[240] It is unclear exactly what this means. Moreover, revenues generated this way have been much lower than PMRA predictions, resulting in delays in re-evaluation activities. A study comparing government expenditures on the registration of new products versus the re-evaluation of old products found that Canada lags behind the US, UK and Australia in its financial commitment to re-evaluation.[241]

In his report, the Commissioner concluded that:

> Canada's track record for the re-evaluation of pesticides [is] one of inaction and unfulfilled commitments" and that, "[w]ithout an effective re-evaluation program, there is no assurance that Canadians are not being exposed to unacceptable risk.[242]

The Commissioner recommended that the PMRA develop and implement a program of re- evaluation that identifies priorities and a schedule for completion, and that the PMRA develop and document the processes to be followed for pesticide re-evaluations and special reviews. The processes should include a clear definition of responsibilities, timelines and reporting. In addition, the Commissioner recommended that priorities for re-evaluation should be determined in consultation with other government departments including Environment Canada, Health Canada, Natural Resources Canada, Fisheries and Oceans, as well as other stakeholders.[243]

Recommendations[244]

22. The PMRA should expeditiously complete on-going re-evaluations including several that were initiated close to 20 years ago, such as for pentachlorophenol.[245]

23. The PMRA should fulfill its commitment to establish a comprehensive pesticide re-evaluation and special review policy that includes responsibilities, methods for reporting and systems of accountability. The special review process should clearly set out the conditions necessary to trigger a special review. The PMRA should establish a re-evaluation program that sets out priorities and firm deadlines.

See also: Recommendation number 44, in section 9.13 below.

9.10 FORMULANTS

In addition to active ingredients, which are the substances that cause harm to a pest, many pesticides contain ingredients called formulants or inerts. These substances are added for a number of reasons such as to facilitate application or enhance effectiveness, and can often represent over 90% of a pesticide formulation. The concern with formulants is that many are toxic substances. In fact, some substances that are used as formulants in one pesticide product are the active ingredient in others. Some have been

[240] *Strategic Plan, op.cit.*

[241] *Report of the Commissioner, op.cit.*

[242] *Ibid*., at 3-31.

[243] *Ibid.*

[244] See also Recommendations for Sustainable Pest Management, Section 9.11 below.

[245] *Report of the Commissioner, op.cit.*The re-evaluation of pentachlorophenol was initiated in 1992.

classified as hazardous air and water pollutants (naphthalene)[246] and others are known carcinogens (crystalline silica, ethylbenzene).[247] Still others have been linked to birth defects (ethylbenzene),[248] central nervous system disorders (xylene),[249] and damage to internal organs (chlorobenzene, toluene).[250]

In its *Blue Book* of 1990, the Pesticide Registration Review Team recommended that the federal government develop a regulatory policy on formulants and in its 1994 response, the government committed the PMRA to develop such a policy.[251] Despite this commitment, the PMRA does not have a written policy regarding the regulation of pesticide formulants. Moreover, the PMRA's progress in addressing formulant safety is constrained by resource restrictions.[252] In practice, the PMRA closely follows the U.S. Environmental Protection Agency (EPA) approach to formulant regulation. The PMRA reports that it is currently developing a formulant policy that will also be based on EPA work.[253]

9.10.1 EPA Regulation

The EPA's policy on pesticide inerts took effect in 1987. On the basis of toxicity, it characterized the existing 1200 pesticide inerts as belonging to one of 4 lists:

- List 1: Inerts of toxicological concern based on carcinogenicity, adverse reproductive effects, neurotoxicity, other chronic effects, developmental toxicity, ecological effects and the potential for bioaccumulation. There were initially approximately 50 substances on this list; there are now 8.
- List 2: Potentially toxic inerts/high priority for testing. Many are structurally similar to those known to be toxic. There were initially approximately 60 substances on this list.
- List 3: Inerts of unknown toxicity. Inerts are placed on List 3 when there is no basis for listing them on any of the other three lists. Initially there were approximately 800; there are now 1500 listed substances.
- List 4: Inerts of minimal concern. There were initially approximately 300 listed substances.[254]

The composition of these lists has changed as substances were found to no longer be present in pesticide products, were reassigned to other lists, were reclassified as active ingredients or as their use was phased out. Inert classification can change at any time as new information becomes available.[255]

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[246] Northwest Coalition for Alternatives to Pesticides. *Worst Kept Secrets: Toxic Inert Ingredients in Pesticides*. January, 1998.

[247] Are "Inert" Ingredients in Pesticides Really Benign? In: *Journal of Pesticide Reform*, Summer 1999, Vol. 19, No. 2.

[248] *Ibid.*

[249] Northwest Coalition for Alternatives to Pesticides, 1998, *op.cit.*

[250] Hammond, M., Citizens for Alternatives to Pesticides. *Pesticide Bylaws: why we need them; how to get them*. 1995.

[251] *PMRA Strategic Plan, op.cit.*

[252] Facsimile document from Doreen Riedel, Evaluation Officer, PMRA, August 6, 1999.

[253] Personal Communication, Doreen Riedel, Evaluation Officer, PMRA, June 29, 1999.

[254] http://www.epa.gov/opprd001/inerts .

[255] Facsimile document from Doreen Riedel, Evaluation Officer, PMRA, August 6, 1999.

The EPA's regulatory efforts initially focused on List 1. It has taken a number of steps to better regulate these compounds including: encouraging registrants to substitute inerts on Lists 1 and 2 with other inerts; requiring that List 1 substances be included on product labels; and requiring that inerts of toxicological concern that remain in products are subject to data call-ins, that is, that registrants be required to provide the EPA with adequate toxicity and exposure data, as well as data on environmental fate, ecological effects and residue chemistry, to permit the EPA to assess product safety.[256]

The EPA has completed its assessment for the majority of current List 1 substances. It is now undertaking a similar assessment of List 2 substances, including a data call-in. In addition, the EPA has begun toxicological and ecological assessments to support reclassification determination for List 3 inerts. In the interim, use of these substances, including the 1500 List 3 formulants of unknown toxicity, continues.[257] In addition to these activities regarding existing formulants, the EPA requires that a minimal data set and scientific review be undertaken for all new inert ingredients.[258]

The Northwest Coalition for Alternatives to Pesticides (NCAP) is critical of the EPA's progress in reducing the dangers from toxic inert ingredients since the 1987 launching of its inert policy. This group found that a high number of inerts on the EPA's lists are what the NCAP calls "active inerts." These inerts have been, or continue to be registered for use in pest control products as active ingredients. Because these substances must be registered for use as active ingredients, the EPA necessarily has significant toxicity information on these substances. Yet 70% of the active inerts used at the time of the NCAP's inquiry were categorized as List 3 substances, that is, substances of *unknown* toxicity, with the associated lenient regulatory requirements.

In addition, using the US EPA inert lists of 1995, the NCAP found that a high number of inerts, including List 3 inerts, are considered hazardous air and/or water pollutants under the US *Clean Air* and *Clean Water Acts.* Several inerts, some of which are List 3 inerts, are classified as extremely hazardous substances under the US *Superfund Amendments and Reauthorization Act.* Another group of inerts, many of which are once again found on List 3, have been identified as occupationally-hazardous substances by the US Occupational Safety and Health Administration. Moreover, a number of listed inerts, the majority of which are found on List 3, include substances identified by the International Agency for Research on Cancer (IARC) and the US National Toxicology Program as known or suspected carcinogens. In 1987, when the EPA inerts policy was introduced, a number of chemicals such as bitumens, butylated hydroxyanisole and potassium bromate had been identified by the IARC as possible carcinogens. Coal tar was a known carcinogen at the time. Ten years later, these substances remained on List 3. Moreover, because inerts are not tested for carcinogenicity, it is impossible to know how many more List 3 inerts are possible carcinogens.

The NCAP has concluded that based on the identified hazards of List 3 substances described above, it is dubious whether the EPA's policy of encouraging pesticide manufacturers to replace List 1 and List 2 substances with List 3 substances will be any more protective of human and environmental health. NCAP calls for full ingredient disclosure on all pesticide products and extensive toxicity testing on the end use product, which would include any inert ingredients.[259]

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[256] http://www.epa.gov/opprd001/inerts/fr52.htm .

[257] http://www.epa.gov/opprd001/inerts/lists.html .

[258] http://www.epa.gov/opprd001/inerts/fr52.htm

[259] Northwest Coalition for Alternatives to Pesticides, 1998, *op.cit.*

9.10.2 PMRA Regulation

The PMRA largely follows the EPA approach to formulant regulation. However, the PMRA does not have comprehensive data regarding which formulants are in Canadian-registered products, and which of these are found on the EPA inerts lists. Failing adequate categorization of Canadian-registered formulants, it is doubtful that these substances are being effectively regulated. The PMRA reports that it is addressing this critical information gap.[260]

Under current PMRA practice, those formulants that are identified as EPA List 1 substances are only permitted for use in Canada when there are no substitutes for these substances, or when there is a negligible potential for exposure to these formulants. List 1 formulants may also be approved for use in certain use site categories. Registrants must request a waiver to use List 1 formulants and they must list these substances, as well as their concentrations, on their product labels.[261]

According to the PMRA, this has not always been the practice with List 1 substances, which were not as tightly screened in the past. Moreover, in practice, use of List 1 formulants may not always respect regulatory restrictions. For example, List 1 formulants may not consistently be listed on product labels. The PMRA reports that it is currently addressing this problem.[262]

In 1998, the Ottawa-based Campaign for Pesticide Reduction (CPR!) obtained a PMRA list of the over 4700 formulants present in pesticides registered in Canada. According to this group, only 2.4% of the substances present on the PMRA list are categorized by the EPA as known or possible toxins. The remainder are classified as being of unknown toxicity.[263] Given the known hazards associated with a large number of List 3 inerts, which are described above, these substances should be more tightly regulated. Continued use of those List 3 substances for which there is limited data regarding potential adverse effects should be prohibited. It is unclear what work the PMRA is undertaking to address the gaps in information that exist regarding the safety of these substances.

In addition to the individual formulants that are identified on the EPA lists, many pest control products contain formulant mixtures. These mixtures are often sold under a trade name and their constituents are not disclosed. Most formulant producers are American. Canadian producers of pesticide active ingredients purchase formulants from these companies or from their Canadian partners. In most cases, the pesticide registrant is not aware of the composition of the formulant mix; it is merely added to the active ingredient and offered for sale. The composition of these formulant mixtures is generally considered to be confidential business information.

Consequently, in effect, the EPA does not list these mixtures on its inerts lists and it does not disclose their composition to third parties, including the PMRA. The EPA has access to this information through its legislated right to demand such information from suppliers. There is no corresponding legal obligation in Canada.[264] Consequently, in effect, the PMRA has been forced to seek this information from U.S. formulant producers.

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[260] Facsimile document, Doreen Riedel, Evaluation Officer, PMRA, August 9, 1999.

[261] *Ibid.*

[262] *Ibid.*

[263] Campaign for Pesticide Reduction. *Pesticide Watch*. Vol 2, Issue 1. April 1998.

[264] Personal Communication, Doreen Riedel, Evaluation Officer, PMRA, June 29, 1999.

The PMRA also manages individual formulants that are not included on the EPA inerts lists. When a non-EPA-listed substance is identified in a Canadian-registered product, a reviewer searches on-line databases for toxicity information on the formulant. The PMRA reports that once its Formulants Policy is in place, it will be able to obtain this information directly from the manufacturer. It is proposed that the PMRA will require the same data as are currently required by the EPA for formulants. These include 90-day oral and dermal toxicity, genotoxicity and ecotoxicity studies. The results of these studies are used to determine whether long term studies are also required for risk assessments.[265]

In the meantime, PMRA documentation indicates that the required testing on non-EPA listed formulants is minimal.[266] According to PMRA documents, toxicological testing is undertaken on pesticide active ingredients and on "end-use products," which are the final formulation of the active ingredient combined with any formulants. PMRA toxicological testing requirements for end-use products, which capture the potential adverse effects of formulants, are far less stringent than those for active ingredients. In fact, in a recent Decision Document regarding the registration of the herbicide Sulfosulfuron, the PMRA stated that the environmental impact of a pesticide is assessed through studies on the product active ingredient. The PMRA may then request studies on the formulated product, on a case-by-case basis, if there are reasons for concern. In the case described, no environmental toxicity studies of the final mixture were required.[267] In contrast to testing requirements on the active ingredient, no long-term animal toxicology or special studies (includes multigeneration-reproductive, teratogenicity, genotoxicity and neurotoxicity tests) are required on the end-use product.[268] Moreover, examining the data requirements for specific Use Site Categories,[269] there are far fewer environmental toxicity data requirements for end-use products than for active ingredients. In addition, all of the end-use product data are conditionally, and not mandatorily required.

The PMRA states that it is concerned about the additional costs that will be imposed on pesticide manufacturers when they are forced to make changes to their pesticide registrations due to revisions in formulant requirements.[270]

With the exception of List 1 substances and petroleum distillates, the names of other formulants present in a pesticide need not be disclosed on the product label.[271]

Recommendations

24. The PMRA should expeditiously fulfill its commitment and complete development of its policy on formulants. The PMRA should release its policy to the public for comment and revision. Once completed, the PMRA should effectively implement and enforce its policy. The policy should set out how the PMRA will use the EPA formulant classification system and toxicological database. The policy should also include an explicit enumeration of rigorous testing requirements for new and non-EPA-listed

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[265] Facsimile document from Doreen Riedel, Evaluation Officer, PMRA, August 6, 1999.

[266] See, for example, Use Site Data-code Tables and *PMRA Submission*, *op.cit.*

[267] *PMRA Sulfosulfuron PRDD, op.cit.*

[268] *PMRA Submission, op.cit.*

[269] Livestock for Food and Terrestrial Food Crops.

[270] Personal Communication, Doreen Riedel, Evaluation Officer, PMRA, June 29, 1999.

[271] *Registration Handbook, op.cit.* and Facsimile transmission from Doreen Riedel, Evaluation Officer, PMRA, August 6, 1999.

formulants. These requirements should be effectively enforced.

25. The PMRA should immediately complete its assessment of formulants in Canadian-registered pesticides in order to determine which are on the EPA lists and which are not. This is a vital precursor to effective pesticide regulation.

26. The PMRA should more effectively regulate the use of List 3 formulants of known or suspected toxicity. The PMRA should aggressively investigate the safety of List 3 formulants that truly are of unknown toxicity. In accordance with the precautionary principle, use of these formulants should be prohibited until their potential effects are understood.

27. All formulants should be listed on pest control product labels. The requirement to include List 1 substances on product labels should be more aggressively enforced.

28. The PMRA should make active use of the re-evaluation process to assess the safety of formulants that until now, have not been rigorously considered.

29. The PMRA should be granted legislative authority to demand formulant composition information from registrants. It is unacceptable that acquisition of this information is contingent on the good will of U.S. formulant suppliers.

30. The PMRA should expedite its work on the identification and risk assessment of non-EPA-listed formulants that are present in products registered in Canada. Pesticide registrants should be required to provide the PMRA with adequate data to assess the toxicological hazard of such formulants.

31. In his next report, the Commissioner of the Environment and Sustainable Development should investigate the adequacy of PMRA measures to ensure the safety of pest control product formulants.

See also: Recommendation 45, in section 9.13 below.

9.11 SUSTAINABLE PEST MANAGEMENT

In its 1990 *Blue Book*, the Pesticide Registration Review (PRR) Team recommended that the government establish a Pest Management Promotion Office. The office was intended to harmonize pest management with the goal of environmental sustainability, including the development of targets and work plans for the reduction of pesticide use. In its 1994 response to the PRR Team's recommendations, the government committed itself to the establishment of an Alternatives Office within the PMRA in order to fulfill this objective including, in particular, the development of a pesticide risk reduction policy.[272]

An Alternative Strategies and Regulatory Affairs Division has since been created within the PMRA. It is charged with encouraging the development and adoption of sustainable pest management systems. Its functions include providing leadership and support in the development of policies, programs and projects related to sustainability.[273]

According to the PMRA, pest management systems that are compatible with sustainable development are

[272] *PMRA Strategic Plan, op.cit.*

[273] *Ibid.*

those that:

- meet society's needs for human health protection, food and fibre production and resource utilization;
- conserve or enhance natural resources and the quality of the environment for future generations; and
- are economically viable.[274]

An important component of sustainable pest control is integrated pest management (IPM). IPM aims to prevent pest problems from occurring and eliminate or reduce reliance on chemical pesticides. Some components of IPM can include cultural strategies such as good farming methods, the use of pest-resistant crop varieties, adapting planting times, maintaining soil fertility and nutrient balance, and preserving biodiversity. A further strategy is to ensure the presence of natural pest enemies.

Integrated Pest Management definitions and practices vary, and herein lies the problem. "Classical" IPM, applied in conventional agricultural systems, allows the use of pesticides in some instances. In contrast, IPM that is part of sustainable agricultural systems strictly adheres to the use of ecologically-sound management practices. Whether this includes chemical pesticide use, in tightly restricted conditions, is controversial. This form of IPM sees economic factors as being secondary to ecological integrity, even if the result is diminished profit margins. It also involves redesigning agricultural systems so that they are ecologically sound in terms of energy, water, mineral and biotic cycles, as well as being as pest-stable as possible.[275]

The danger with these divergent visions is that they are all advanced, by different groups, under the name of IPM. The result is that IPM has lost meaning. This is particularly dangerous when regulators, whose intentions are to make subtle, if any real change to the status quo, commit to implementing IPM. Reliance on the ambiguous IPM concept permits these agencies to put off instituting the type of real change that is necessary in order to move towards true sustainability in agricultural practices.

According to the PMRA, IPM aims to ensure that pesticide application takes place only when warranted, at the most appropriate time, and that the benefits of pesticide use are maximized by being undertaken as part of a larger, integrated strategy that includes non-pesticide tools. This approach is intended to reduce the adverse health and environmental effects of pesticides and to slow the development of pest resistance to pest control products.

The PMRA elements of IPM include:

- identifying potential pest organisms;
- monitoring pest and beneficial organism populations, pest damage, and environmental conditions;
- managing ecosystems to prevent organisms from becoming pests;
- using injury thresholds in making control decisions;
- reducing pest populations to acceptable levels using strategies that may combine biological, cultural, mechanical, behavioural and, when necessary, chemical controls; and
- evaluating the effects and efficacy of pest management strategies.[276]

According to the PMRA, it facilitates the use of sustainable pest management approaches in Canada

[274] http://www.hc-sc.gc.ca/pmra-arla/adifs-e.html .

[275] Integrated Pest Management: A Second Look. *Journal of Pesticide Reform*. Winter 1998, Vol. 8, No. 4.

[276] http://www.hc-sc.gc.ca/pmra-arla/adifs-e.html .

through a number of initiatives including:

- moving from regulation on a product-by-product basis, to a systems approach that incorporates risk reduction and integrated pest management;
- facilitating access to new technologies such as reduced-risk and biopesticide products;
- product labeling for resistance management;
- participation in international risk reduction projects through NAFTA and the OECD, including multilateral sustainable pest management projects and the OECD Pesticide Risk Reduction Activities in Canada survey; and
- the development of national strategies for sustainable pest management for particular commodities and sectors.[277]

The final initiative above is undertaken through voluntary IPM Partnership Projects. These projects include the participation of grower organizations, pesticide manufacturers, federal government departments, provinces, research establishments and non-governmental organizations. Working groups are established to develop, communicate and monitor the adoption of IPM strategies for particular crops and pests. IPM Partnership Projects aim to identify innovative approaches to pest management, facilitate access to new technology and technology transfer, incorporate current research, and highlight emerging research needs. Project areas include the Colorado potato beetle, canola, and urban landscapes, among others.[278]

The steps undertaken in the establishment of an IPM Partnership Project include:

- the identification of stakeholders;
- the establishment of a working group that includes all interested parties;
- the selection of a smaller steering group;
- the gathering of technical information;
- the development of an IPM program and documents;
- the publication and dissemination of the IPM program; and
- the undertaking of follow-up activities such as an assessment of the program's effectiveness.[279]

The PMRA's vision of IPM merely tinkers with the status quo. Its focus is on reducing the risks associated with chemical pesticides and fails to question the more fundamental issue of how to reduce our dependence on these toxic agents. In addition, this extremely limited version of Integrated Pest Management is used by the PMRA as a reactive tool, once a control product has been registered. According to the Environment Commissioner, PMRA IPM initiatives, "lack focus and clear goals and are largely reactive."[280] Moreover, IPM application takes place on a voluntary basis and on a small scale. The principles upon which IPM is based do not guide the pesticide registration process. Apart from ensuring that the least pesticide necessary is applied, which should be an automatic pesticide use restriction, it appears that considerations of integrated pest management are not included in the registration process.

[277] http://www.hc-sc.gc.ca/pmra-arla/adpst1-e.html .

[278] *Ibid*.

[279] *Ibid*.

[280] *Report of the Commissioner, op.cit.*

Integrated pest management considerations should be included in the re-evaluation process. For example, should less toxic or non-chemical alternatives exist, a pesticide should be de- registered.

Not only has the PMRA failed to implement a genuine and effective IPM program, it has not fulfilled its commitment to develop a risk reduction policy. The Commissioner of the Environment and Sustainable Development recently reported that rather than implement an agency-wide strategy to guide the integration of risk reduction measures into its activities, the PMRA deals with each pesticide individually. Furthermore, the PMRA does not assess which pesticides pose the greatest risk, in order to set management priorities. In contrast, many other countries have established programs and policies that focus on reducing the use and risks of pesticides. The US Department of Agriculture, for example, has set the goal of establishing 70% of US agricultural land under IPM by the year 2000.[281] The Commissioner recommended that the PMRA develop, in consultation with other federal departments and in conjunction with the provinces, a national pesticide risk reduction strategy. The strategy should inform new pesticide registration, existing pesticide re-evaluation and special review, and Agency programs for promoting pesticide alternatives.[282]

Some commentators argue that a risk reduction policy, should the PMRA ever develop one, is an inadequate strategy for dealing with the dangers inherent in pesticide use. Instead of reducing the risks associated with pesticide use, they advocate a strategy to reduce reliance on pesticides. This approach is certain to reduce exposure to pesticides and their dangers, and avoids the lengthy pesticide-by-pesticide approach that would be necessary in a risk reduction approach.[283]

Recommendations

32. The PMRA should develop a pesticide reduction policy and should apply its policy to all PMRA decisions and activities including as a first priority the reduction of pesticides important in children's diets and in use categories of most relevance to children's exposure circumstances including parks and institutional facilities geared primarily to children.

33. The PMRA should reassess its IPM program and make the establishment of sustainable agricultural practices the goal of this program. The program should have, as its focus, the reduction of chemical pesticide use. IPM considerations should be integrated into all stages of pesticide decision-making including a consideration, in the registration process, of whether lower risk or non-chemical alternatives exist, in some cases preempting the need for new registrations. Once registered, pest control product use should be guided by the principles of integrated pest management.

34. The PMRA should do more to facilitate the widespread adoption of IPM. The PMRA should develop a national policy, with clear goals, and a sustainable funding program in order to fulfill this goal.

9.12 INFORMATION

9.12.1 Public Access to Information

[281] *Ibid.*

[282] *Ibid*.

[283] Facsimile document, Julia Langer, World Wildlife Fund, July 5, 1999.

Public access to information regarding pesticide safety and the pesticide regulatory process is limited. The public is not notified when a registration, re-evaluation or other regulatory process begins.[284] Access to the information upon which regulatory decisions are based is also restricted.

Virtually all of the information that the PMRA uses in its regulatory decision-making processes, including pesticide formulations (ingredients) and the results of health and environmental toxicity studies, originates with the manufacturer. The *Pest Control Products Act* is silent on the issue of public access to this information. Consequently, the *Access to Information Act*[285] applies. Under this Act, public access to corporate information can be denied if the information is classified as confidential business information which includes:

- financial, commercial, scientific or technical information that is confidential;
- information the disclosure of which could reasonably be expected to result in material financial loss or gain to a third party or that could prejudice the competitive position of the third party; and
- trade secrets.[286]

The Act does not define "trade secret." In order to preempt abuse of these provisions, section 20 provides that if disclosure would be in the public interest as it relates to public health, public safety or the protection of the environment, and if the public interest in disclosure out weighs the importance of non-disclosure in financial terms, the government may disclose confidential information, with the exception of trade secrets.[287]

Pesticide manufacturers claim that the information that they are required to supply to the PMRA is confidential business information and the PMRA treats it as such. Consequently, the public has no access to information regarding the composition of pest control products, including the presence and relative quantities of formulants, contaminants or by-products, or their potential hazards. Only the name of the product's active ingredient appears on the label.[288] Similarly, access to hazard information, which is derived from the toxicological studies undertaken by potential registrants, is limited. This restriction includes information regarding the product's toxicity, persistence and bioaccumulative potential, routes of exposure and environmental fate.[289] The public should have access to basic information that is essential to an understanding of the risks posed by pesticide exposure including disclosure of all pest control product ingredients.

The PMRA claims that its policy of restricting public access to pesticide information is mandated by the *Access to Information Act*. However, its policy of non-disclosure was established prior to the enactment of this statute.[290] Moreover, the Act authorizes the disclosure of information regarding public health and

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[284] Campaign for Pesticide Reduction. *Pesticides: The Right to Know*. Fact Sheet. (undated).

[285] *Access to Information Act*, R.S.C. 1985, c. A-1.

[286] *Ibid*., s.20(1).

[287] *Ibid.*, s.20(6).

[288] See section 9.10 on formulants for a description of the limited exceptions.

[289] Davies, Katherine. *The Right to Know About Chemical Pesticides: A Discussion Paper,* prepared for the Canadian Labour Congress and the Campaign for Pesticide Reduction (undated), and Campaign for Pesticide Reduction. *Pesticides: the Right to Know Fact Sheet* (undated).

[290] Davies, Katherine. *The Right to Know About Chemical Pesticides: A Discussion Paper,* prepared for the Canadian Labour Congress and the Campaign for Pesticide Reduction (undated).

environmental concerns under section 20, described above. It is for precisely those reasons set out in section 20 that affected members of the public seek to have pesticide formulation and hazard information released. Given the explicit allowance in the Act for public availability of health and environment-related information, the continued treatment of pesticide formulation and hazard information as confidential business information is questionable.

In its 1990 *Blue Book*, the PRR Team recommended that Proposed Regulatory Decision Documents (PRDDs) be prepared for all proposed registrations of new active ingredients and for registrations that may result in substantially increased pesticide use or exposure. In response, the government committed to the production of PRDDs for proposed registration, re-evaluation and special review decisions. The government directed that PRDDs include the risk and value assessments upon which regulatory decisions are based. The public is then afforded the opportunity to comment on PRDDs.[291] The PMRA is to respond to public comments and release its decision in a Regulatory Decision Document. If the decision is favourable, the pesticide can then be registered or re-registered, as the case may be.

The PMRA does not produce the PRDD. Rather, the only PRDDs produced have been with the explicit agreement of the registrant. Content can therefore be controlled by the registrant.[292] PRDDs are not released without the authorization of the pesticide manufacturer[293] and the PMRA has not set out how it utilizes public comments to strengthen PRDDs and the regulatory decision-making process.

Upon registration, therefore, public access to information regarding a pesticide is limited to the product label and the PRDD, if one has been prepared.

Recommendations

35. The PMRA should ensure that the public has access to basic information that is essential to an understanding of the risks posed by pesticide exposure. Information availability requires that:

a) The PMRA disclose all pest control product ingredients and provide access to all information upon which registration and other regulatory decisions are based;
b) If necessary, the public health and environmental protection provisions in the Access to Information Act be invoke; and
c) Public notification mechanisms regarding the initiation and status of new regulatory decisions be developed.

36. The PMRA should fulfill its commitment regarding PRDD production, making the documents as comprehensive as possible. The PMRA should clearly set out its policy for the incorporation of public comments and concerns regarding PRDDs.

9.12.2 Research and Monitoring: The Fate and Effects of Pesticide Use

While the PMRA has decision-making power over pesticide use, responsibility for pesticide research and

[291] *PMRA Strategic Plan, op.cit.*

[292] Personal Communication, Julia Langer, World Wildlife Fund. June 14, 1999. See also PMRA web site http://www.hc-sc.gc.ca/pmra-arla

[293] Personal Communication, Christine Norman, Acting Head, Occupational Exposure Assessment Section, PMRA, June 10, 1999.

monitoring rests with the research-oriented federal departments such as Environment Canada and the Department of Fisheries and Oceans. Environment Canada, for example, spent approximately $1.3 million on pesticide research and monitoring in 1997/8. This research, regarding the fate and effects of pesticides, is relevant to product re-evaluation, special review and risk reduction activities. Despite the importance of this work to PMRA operations, the PMRA does not cooperate effectively with the research-oriented departments. A system for the sharing of research findings and the setting of research priorities between departments has not been established.[294]

For example, in the past, Environment Canada has requested information from the PMRA that is necessary to guide its pesticide research. However, relying on the *Access to Information Act*, the PMRA claims that this information is confidential business information and refuses to share it with its regulatory counterparts. In an attempt to resolve this problem, Environment Canada and the PMRA signed a 1998 memorandum of understanding setting out their respective roles and responsibilities. Implementation of this memorandum has barely begun. A similar memorandum of understanding exists between the PMRA and the Department of Fisheries and Oceans. This document remains unsigned as a result of unresolved conflicts between the departments.[295]

In his recent audit, the Commissioner of Environment and Sustainable Development recommended that the PMRA, Environment Canada and the Department of Fisheries and Oceans implement their memoranda of understanding. This should include the development of a plan to guide research and monitoring, the exchange of results, and the consideration of results during regulatory decision-making. The Commissioner further recommended that the PMRA ensure that its registration decisions do not conflict with other federal legislation. When such conflicts do occur, the Agency should consult with other departments prior to making a registration decision.[296]

Noting that there is no pesticide monitoring in many parts of the country, the Commissioner further recommended that the PMRA, Environment Canada, the Department of Fisheries and Oceans, Health Canada, and Natural Resources Canada, together with other partners, identify monitoring needs for pesticides and develop and maintain an inventory of current monitoring programs, to be used to determine information gaps that need to be filled.[297]

Recommendation
37. The PMRA and its research and monitoring counterparts should establish and implement a plan for the collaborative gathering, sharing and use of vital pesticide information.

9.12.3 Adverse Effects Reporting

Reports regarding adverse effects resulting from pesticide use are an important source of information on previously-assessed pest control products. The Pesticide Registration Review Team recommended, in 1990, that registrants be required to report information indicating that a pest control product may cause unreasonable adverse effects on human health, safety or the environment.[298] Legislation in the U.S.

[294] *Report of Commissioner, op.cit.*

[295] *Ibid.*

[296] *Ibid.*

[297] *Ibid.*

[298] *PMRA Strategic Plan, op.cit.*

requires manufacturers to provide the government with any reports it may receive regarding unexpected adverse effects resulting from pesticide use.[299] However, the *Pest Control Products Act* has no such requirement.

The federal government, in its 1994 *Purple Book*, committed to establishing an adverse effects reporting requirement.[300] The government has not yet fulfilled this commitment. Such a requirement should be established, as should an effective system of information exchange and a central database for this critical information. The reporting requirement should apply to doctors and should include information regarding affected individuals' occupation and place of residence. It must be recognized however that reporting of adverse effects by physicians is not a simple matter. In a busy practice it can be difficult to file such reports even for more routine situations such as adverse effects of medications. Some physicians may not even know reporting forms exist or where they should be submitted or may not consider the effort worthwhile. For pesticides, reports may arise as they do currently from accidental exposures but more subtle effects that are difficult to substantiate or for which associations may be hypothetical are unlikely to be reported. The British Medical Association made useful observations and recommendations on this matter in its report, *Pesticides, Chemicals and Health.*[301] The BMA states that physicians have an important role to play in providing guidance on the hazards of toxic chemicals but that they require sufficient training to recognize symptoms of exposure. The non-specific nature of symptoms underscores both the difficulty of the physician's task and the need for increased training in basic toxicology as well as the opportunity to update and refresh their existing toxicological training.[302]

Recommendation

38. The federal government should fulfill its commitment and legislate an adverse effects reporting requirement that explicitly includes information regarding the adverse effects of pesticide exposure on children. To be effective this reporting system requires first that:

a) effort is placed on ensuring the education of primary care health-care practitioners (i.e., family physicians, pediatricians, emergency room physicians, obstetricians and midwives, nurse practitioners and social workers about the health effects, both acute and chronic, of pesticides on children in order that they can better clinically detect these cases; and
b) a central registry be established, federal or provincial, of adverse clinical responses to pesticides, in an attempt to gather appropriate data.

9.12.4 Pesticide Use Database

The Pesticide Registration Review Team identified the need for a national database of information on pesticide sales. In response, the government committed the PMRA to implement such a database. However, the Commissioner of the Environment and Sustainable Development recently reported that of OECD member states, Canada is one of only two nations that do not collect data on pesticide sales. The Commissioner noted that,

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[299] *Report of the Commissioner, op.cit.*

[300] *PMRA Strategic Plan, op.cit.*

[301] British Medical Association, *The BMA Guide to Pesticides, Chemicals and Health* (Edward Arnold, London 1992).

[302] Recommendations on this matter are contained in Chapter 2.

[w]ithout such data, Canada has no ability to measure amounts of pesticides used and released into the environment. This information is needed to monitor the risks to health, safety, and the environment and to measure the extent to which lower-risk pesticides and non-pesticide alternatives are being adopted.[303]

The PMRA reports to be working on the establishment of such a database.[304]

Recommendation
39. The PMRA should promptly establish an enforced pesticide sales and use reporting requirement and a pesticide database. The database should be organized by active ingredient and should include detailed information regarding the quantities and locations of pesticide sales and use. Particular emphasis should be placed on reporting information relevant to assessing the effects of pesticide use on children. This information should inform pesticide regulatory decision-making and must be publicly accessible.

9.12.5 WHMIS

The Workplace Hazardous Material Information System (WHMIS) is designed to secure the right of workers to know about hazardous materials that are present in the workplace. WHMIS is legislated under the Federal *Hazardous Products Act*[305] and includes requirements for hazardous material labeling, the preparation and provision of material safety data sheets (MSDSs), which include a list of hazardous ingredients and their toxic properties, and worker education and training programs. Under WHMIS, hazard information cannot be claimed as confidential business information and there are ingredient disclosure requirements. WHMIS requirements also include a public right to know component. Users of controlled products can request the toxicological data upon which the MSDS is based.

Pesticides are exempted from WHMIS requirements and the *PCPA* does not require the preparation of MSDSs. Consequently, people that work with pesticides are in the anomalous position of being denied access to information regarding the formulation and hazards of the chemicals to which they are exposed. In 1990, the Sectoral Committee on Pesticides, which is composed of workers, industry and government representatives, recommended to the Parliamentary Standing Committee on Consumer and Corporate Affairs and Government Operations that WHMIS requirements be applied to pesticides, including the requirements that MSDSs be provided by pesticide suppliers for pesticides intended to be used in the workplace, that pesticide suppliers disclose the presence of formulants, and that pesticide labels should conform to WHMIS standards, among other recommendations.[306] These recommendations have not been realized. Because of the possible transgenerational effects on the children of occupationally-exposed parents, WHMIS requirements are important not only to workers, but also to their children.[307]

Recommendation
40. The anomalous situation of WHMIS requirements not being applied to pesticides requires correction. Because of the possible transgenerational effects on the children of occupationally-exposed parents,

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[303] *Report of the Commissioner, op.cit.* at 4-30.

[304] *PMRA Strategic Plan, op.cit.*

[305] *Hazardous Products Act*, R.S.C. 1985, c. H-3.

[306] Davies, Katherine. *The Right to Know About Chemical Pesticides: A Discussion Paper*, prepared for the Canadian Labour Congress and the Campaign for Pesticide Reduction, (not dated).

[307] See Section 9.3.3.2 above.

WHMIS requirements are important not only to workers, but also to their children. WHMIS requirements for Material Safety Data Sheets (MSDSs) must be applied to pesticide suppliers for pesticides intended for use in the workplace. Pesticide suppliers should also be required to disclose the presence of formulants, and pesticide labels should conform to WHMIS standards.

9.13 POLITICAL WILL AND FUNDING

The federal government's stated commitment to the well-being of Canadian children in the recently established National Children's Forum is laudable. This commitment is hollow however if it does not ensure that adequate resources exist to regulate toxic chemicals, including pesticides, in a manner protective of children's health. The following recommendations are made to ensure the implementation of the preceding recommendations those that precede

Recommendations

41. In recognition of the greater exposure and sensitivity in children to the toxic effects of pesticides, the federal government's National Children's Forum must allocate the necessary resources to honour longstanding domestic and international commitments to improving legal and policy tools, including application of the precautionary principle, to protect children from toxic substances, including pesticides.

42. The many recommendations noted above have significant resource implications in six major areas, including: 1) legislative amendments; 2) additional requirements in risk assessment and risk management procedures; 3) the re-evaluation of existing pesticides; 4) research and monitoring; 5) inspection and enforcement; and 6) development/refinement of guidelines and policy in key areas including risk assessment and risk management, the Toxic Substances Implementation Policy, formulants, integrated pest management, etc. Accordingly, for federal budget calculations, the PMRA should be required to prepare a detailed accounting of the resources necessary to implement these recommendations including an indication of short, medium and longer term priorities.

43. In setting priorities for the implementation of unfulfilled commitments and other necessary objectives for improving the pest management regulatory system, immediate attention and resources should be given to re-evaluation of existing pesticides, implementation of the precautionary principle, development of a formulants policy, and development and promotion of sustainable pest management alternatives.

44. In the establishment of an adequate and guaranteed resource base for the pesticide re-evaluation program, funding for re-evaluation must not be made contingent on the generation of funds from efficiencies created in other areas.

45. In the development of a policy on formulants, the PMRA should not be guided in the development of its formulant policy solely by the costs that would be borne by registrants for potential amendments to their registrations.

9.14 CONCLUSIONS

The potential for the health of children in Ontario[308] to be affected by pesticides is undeniable. Definitive

[308] While the focus of this study is Ontario, the results of this case study are applicable to all Canadian children.

proof of harm will never be available; not unless human children are made the subjects of controlled experiments investigating the effects of long-term, low dose exposure to the full range of pesticides encountered in their daily lives. Ethically, such experiments would not be condoned. However, in this context, it is exceptionally troubling to conclude that a multitude of uncontrolled experiments on the effects of long-term, low-dose exposure to pesticides on children's health is occurring *by default* as pesticide use continues in a wide variety of applications. It is equally disturbing that pesticide companies have renewed and expanded the practice of using human "volunteers" to determine human NOAELs in attempts to avoid more stringent regulation (see Section 4.4.3 of Chapter 4).

This report summarizes a broad array of observational studies from the peer-reviewed scientific literature[309] documenting the known or suspected health effects of pesticides. Possible health outcomes are extremely serious and in some cases life threatening. The literature points to the increased likelihood of damage to childrens' immune, endocrine, nervous and reproductive systems, as well as various cancers. Although more research needs to be done, this does not exonerate pesticides as human toxins, especially since children are far more vulnerable to pesticides than adults. For numerous reasons documented herein, both exposure and sensitivity to pesticides is greater in children than adults. Not only is there potential for harm, but in all likelihood some Canadian children are now enduring the negative effects of pesticides.

For instance, evidence suggests that the immune systems of Inuit children are being jeopardized by exposure to many persistent chemicals, including DDE (a by-product of the pesticide DDT) through their mothers' breast milk and through their traditional diet. Children in agricultural areas may also be at risk of cognitive deficits (nervous system damages) without obvious clinical symptoms of pesticide exposure. Pesticide use in the home puts children and pregnant women and their babies at risk of health problems, including cancer and reproductive problems in later life. Children from poorer families, living in older housing, and children with chemical sensitivities or immune system problems are also more likely to be affected by pesticides. Lastly, many commonly used pesticides can be detected in our food supply, frequently at levels that would not be safe for young children.The cumulative effects of being exposed to many different pesticides over a lifetime represents an unacceptable risk to all Canadian children.

Moreover, this investigation reveals that children's health is at risk because of the inherent weaknesses of the Canadian regulatory system governing pesticides and the lack of capacity to implement existing laws and policies. It is clear that children's health is at risk because of an inadequate regulatory system, a system the federal government promised to fix as far back as 1994. This study finds that the great majority of prior commitments remain unfulfilled. In addition to numerous unfulfilled commitments on matters highly significant to children's health protection, this review found serious shortcomings in the fundamental aspects of work conducted by the PMRA. In particular, the inaccessibility, lack of clarity and contradictory nature of the PMRA's risk assessment and risk management process is of significant concern. This problem is in addition to the more fundamental shortcomings of risk assessment in general as discussed in Chapter 4.

Put starkly, this review concludes that Canadians don't really have a regulator for pesticides. Rather, Health Canada has set up the Pest Management Regulatory Agency to be not much more than a "customer service department" for the pesticides industry. Children are being impacted by pesticides as

[309] The evidence gathered here is intentionally and overwhelmingly from the peer-reviewed scientific literature, government reports or from the proceedings of conferences presenting the results of scientific inquiry; all of which is, as much as is possible and as far as can be determined, indepedent of funding from companies involved in either the sale of pesticides or the evaluation of pesticides on behalf of the pesticide industry.

the federal government is knowingly refusing to act or delaying action to make legislative changes and spend the necessary resources.

The study provides 45 recommendations covering a broad range of regulatory issues, including:

- Changes to the *Pest Control Products Act.* For example: clarifying the core test for judging the acceptability of a pesticide; ensuring use of the precautionary approach when the weight of evidence suggests a potential unacceptable risk of harm; and enhanced citizen rights to appeal a registration decision.

- Implementation of the Federal *Toxic Substances Management Policy* including immediate bans (or de-registrations) on pesticides which are persistent (stay in the environment a long time) and bioaccumulative (accumulate in fat cells) without wasting resources on re-evaluation.

- Revisions to the registration process for new products to ensure a broader array of impacts on children is taken into account including developmental neurotoxicity and endocrine disruption and impacts from cumulative exposures to pesticides.

- Implementation of a detailed regulatory policy on pesticide formulants.

- Improved inspection and enforcement by the Pest Management Regulatory Agency (PMRA) to ensure appropriate pesticide use.

- Development and application by the PMRA of a Sustainable Pest Management Policy to reduce overall pesticide use.

- Improvements to public access to information that is essential to the understanding of the risks posed by pesticides exposure.

Finally, several recommendations are made to ensure the political will and resources necessary to do the job are in place and applied on a priority basis to urgent and overdue matters. It is also crucial that the resources necessary to honour both unfulfilled commitments and additionally necessary measures to regulate pesticides are not exclusively tied to "cost-recovery" mechanisms. It is perverse for the federal government to insist that the numerous shortcomings of its regulation of pesticides must be paid for by revenues obtained from the approval of new pesticides or the achievement of "efficiencies" in other areas of the PMRA. This department is in need instead of both significant expansion and, more important, re-orientation towards a mind-set that gives first priority to health promotion and prevention of harm.

9.15 CONSOLIDATED LIST OF RECOMMENDATIONS

The Pest Control Products Act

1. The Pest Control Product Act's core test for judging the acceptability of a pesticide (unacceptable risk of harm) should be specifically defined so that it can be applied in a transparent and consistent manner throughout the risk assessment-risk management process. An essential amendment to the Act, to complement Recommendation 5 below, is to designate persistent and bioaccumulative substances as presenting an unacceptable risk of harm.

2. The Pest Control Products Act should be amended to include a requirement to act in a precautionary manner, for example, when the weight of evidence points to the potential for "unacceptable risk of harm." In keeping with this approach, Canada should follow Sweden's lead with legislative amendments to specify inherent characteristics of pesticides that justify de-registration including criteria such as very high acute toxicity, endocrine disruption, probable human carcinogenicity, and neurotoxicity all of which should be considered synonymous with "unacceptable risk of harm."

3. To more effectively implement Recommendations 6 - 31 below, the PMRA should publish a guideline to make its risk assessment and risk management process more transparent. The guideline should include detailed descriptions of its decision-making process including the manner in which children's health interests are taken into account. It may be necessary that the guideline be legislated in the form of a regulation under the Pest Control Products Act, in order the ensure that it is implemented.

4. The public should be placed on an equal footing with industry regarding the appeal of a registration decision. To do so, the public must be granted the authority to challenge the approval for registration of pest control products.

Implementation of the Toxic Substances Management Policy

5. The PMRA should fulfill its commitment to incorporate the TSMP in pesticide regulation. This activity should include immediate bans (or de-registrations) on pesticides which are persistent and bioaccumulative (Track 1 substances) without wasting time and resources on re-evaluation. In keeping with this approach, the PMRA should immediately revise its TSMP Implementation Policy to eliminate the ability to register Track 1 pesticides and to cancel registration of pesticides contaminated with persistent organic pollutants pursuant to the TSMP.

The Risk Assessment Process: Hazards

6. The PMRA should set out exactly how its two-tiered system of testing requirements functions. The trigger points for additional testing requirements should be made explicit.

7. Several toxicity tests that are currently conditionally-required should become standard requirements. This includes developmental neurotoxicity testing on young animals, which is particularly important for gauging risks to children's health. Similarly, tests for endocrine disruption that are protective of children should be made a standard PMRA test requirement.

8. There is a need for a detailed examination of the toxicity tests required by the PMRA in order to assess their adequacy. An investigation should be undertaken regarding whether the PMRA requires testing for all potential endpoints and whether the tests that are required are adequate to gauge the risk of causing these endpoints.

9. The PMRA should consider the potential effects on human health of occupational/bystander and food/drinking water exposures on an aggregated basis.

10. The PMRA should consider the potential effects on human health of cumulative exposures to pesticides that act via common mechanisms of toxicity.

11. The PMRA should describe how it chooses a NOAEL for occupational/bystander assessments and food residue assessments from the available alternatives.

12. The PMRA should set out how it determines which uncertainty factors to apply to the occupational/bystander and food residue NOAELs.

13. The PMRA should adopt a requirement similar to that found in the U.S. Food Quality Protection Act, mandating the application of an uncertainty factor with a minimum value of 10 in order to account for potential pre- and post-natal developmental toxicity and the incompleteness of toxicity and exposure data for children. The uncertainty factor could have a higher value in situations of relatively high uncertainty regarding toxicity and children's exposure.

14. The PMRA should explain precisely how it incorporates considerations regarding the increased sensitivity of the young and pregnant women into its risk assessments and should set out under which conditions it considers additional protection for these groups to be warranted.

15. The PMRA should set out precisely how its risk assessments are undertaken for potentially cancer-causing pesticides.

The Risk Assessment Process: Exposure

16. The PMRA should set out which factors it considers when making determinations regarding how large the ratio between the NOAEL for the most sensitive test species and the EEC must be in order for the risks associated with a pesticide to be judged acceptable, as well as their relative weight, and the manner in which they are applied.

Value Assessment

17. The PMRA should set out how the results of its value assessment are used in the regulatory decision-making process.

Maximum Residue Limits

18. Pesticide intake via soil and dust should be included in exposure estimates.

19. The PMRA should consider cumulative exposure to multiple pesticides that act via similar mechanisms of toxicity in its risk assessments.

20. The PMRA should ensure that the negotiation of MRLs between trading partners is a transparent process and that the strength of Canada's MRLs is not compromised.

Use Restrictions

21. The PMRA should reduce the reliance on pesticide label instructions and restrictions for the management of pesticide risk to human and environmental health and in the interim, given the importance of label compliance, the PMRA should improve its inspection and enforcement operations to ensure appropriate pesticide use. The PMRA must not hesitate to apply the full range of enforcement penalties that are available to it, in order to guarantee compliance. Enhanced enforcement should be guided by a national compliance policy, which the PMRA committed itself to develop in its 1994 Purple Book.

Existing (Currently-Registered) Pest Control Products

22. The PMRA should expeditiously complete on-going re-evaluations including several that were initiated close to 20 years ago, such as for pentachlorophenol.

23. The PMRA should fulfill its commitment to establish a comprehensive pesticide re-evaluation and special review policy that includes responsibilities, methods for reporting and systems of accountability. The special review process should clearly set out the conditions necessary to trigger a special review.

The PMRA should establish a re-evaluation program that sets out priorities and firm deadlines.

Formulants

24. The PMRA should expeditiously fulfill its commitment and complete development of its policy on formulants. The PMRA should release its policy to the public for comment and revision. Once completed, the PMRA should effectively implement and enforce its policy. The policy should set out how the PMRA will use the EPA formulant classification system and toxicological database. The policy should also include an explicit enumeration of rigorous testing requirements for new and non-EPA-listed formulants. These requirements should be effectively enforced.

25. The PMRA should immediately complete its assessment of formulants in Canadian-registered pesticides in order to determine which are on the EPA lists and which are not. This is a vital precursor to effective pesticide regulation.

26. The PMRA should more effectively regulate the use of List 3 formulants of known or suspected toxicity. The PMRA should aggressively investigate the safety of List 3 formulants that truly are of unknown toxicity. In accordance with the precautionary principle, use of these formulants should be prohibited until their potential effects are understood.

27. All formulants should be listed on pest control product labels. The requirement to include List 1 substances on product labels should be more aggressively enforced.

28. The PMRA should make active use of the re-evaluation process to assess the safety of formulants that until now, have not been rigorously considered.

29. The PMRA should be granted legislative authority to demand formulant composition information from registrants. It is unacceptable that acquisition of this information is contingent on the good will of U.S. formulant suppliers.

30. The PMRA should expedite its work on the identification and risk assessment of non-EPA-listed formulants that are present in products registered in Canada. Pesticide registrants should be required to provide the PMRA with adequate data to assess the toxicological hazard of such formulants.

31. In his next report, the Commissioner of the Environment and Sustainable Development should investigate the adequacy of PMRA measures to ensure the safety of pest control product formulants.

Sustainable Pest Management

32. The PMRA should develop a pesticide reduction policy and should apply its policy to all PMRA decisions and activities including as a first priority the reduction of pesticides important in children's diets and in use categories of most relevance to children's exposure circumstances including parks and institutional facilities geared primarily to children.

33. The PMRA should reassess its Integrated Pest Management program and make the establishment of sustainable agricultural practices the goal of this program. The program should have, as its focus, the reduction of chemical pesticide use. IPM considerations should be integrated into all stages of pesticide decision-making including a consideration, in the registration process, of whether lower risk or non-chemical alternatives exist, in some cases preempting the need for new registrations. Once registered, pest control product use should be guided by the principles of integrated pest management.

34. The PMRA should do more to facilitate the widespread adoption of Integrated Pest Management.

The PMRA should develop a national policy, with clear goals, and a sustainable funding program in order to fulfill this goal.

Public Access to Information

35. The PMRA should ensure that the public has access to basic information that is essential to an understanding of the risks posed by pesticide exposure. Information availability requires that:

a) The PMRA disclose all pest control product ingredients and provide access to all information upon which registration and other regulatory decisions are based;
b) If necessary, the public health and environmental protection provisions in the Access to Information Act be invoke; and
c) Public notification mechanisms regarding the initiation and status of new regulatory decisions be developed.

36. The PMRA should fulfill its commitment regarding PRDD production, making the documents as comprehensive as possible. The PMRA should clearly set out its policy for the incorporation of public comments and concerns regarding PRDDs.

Research and Monitoring

37. The PMRA and its research and monitoring counterparts should establish and implement a plan for the collaborative gathering, sharing and use of vital pesticide information.

Adverse Effects Monitoring

38. The federal government should fulfill its commitment and legislate an adverse effects reporting requirement that explicitly includes information regarding the adverse effects of pesticide exposure on children. To be effective this reporting system requires first that:

a) effort is placed on ensuring the education of primary care health-care practitioners (i.e., family physicians, pediatricians, emergency room physicians, obstetricians and midwives, nurse practitioners and social workers about the health effects, both acute and chronic, of pesticides on children in order that they can better clinically detect these cases; and
b) a central registry be established, federal or provincial, of adverse clinical responses to pesticides, in an attempt to gather appropriate data.

Pesticide Use Database

39. The PMRA should promptly establish an enforced pesticide sales and use reporting requirement and a pesticide database. The database should be organized by active ingredient and should include detailed information regarding the quantities and locations of pesticide sales and use. Particular emphasis should be placed on reporting information relevant to assessing the effects of pesticide use on children. This information should inform pesticide regulatory decision-making and must be publicly accessible.

Workplace Hazardous Materials Information System (WHMIS)

40. The anomalous situation of WHMIS requirements not being applied to pesticides requires correction. Because of the possible transgenerational effects on the children of occupationally-exposed parents, WHMIS requirements are important not only to workers, but also to their children. WHMIS requirements for Material Safety Data Sheets (MSDSs) must be applied to pesticide suppliers for pesticides intended for use in the workplace. Pesticide suppliers should also be required to disclose the presence of formulants, and pesticide labels should conform to WHMIS standards.

Political Will and Funding

41. In recognition of the greater exposure and sensitivity in children to the toxic effects of pesticides, the federal government's National Children's Forum must allocate the necessary resources to honour longstanding domestic and international commitments to improving legal and policy tools, including application of the precautionary principle, to protect children from toxic substances, including pesticides.

42. The many recommendations noted above have significant resource implications in six major areas, including: 1) legislative amendments; 2) additional requirements in risk assessment and risk management procedures; 3) the re-evaluation of existing pesticides; 4) research and monitoring; 5) inspection and enforcement; and 6) development/refinement of guidelines and policy in key areas including risk assessment and risk management, the Toxic Substances Implementation Policy, formulants, integrated pest management, etc. Accordingly, for federal budget calculations, the PMRA should be required to prepare a detailed accounting of the resources necessary to implement these recommendations including an indication of short, medium and longer term priorities.

43. In setting priorities for the implementation of unfulfilled commitments and other necessary objectives for improving the pest management regulatory system, immediate attention and resources should be given to re-evaluation of existing pesticides, implementation of the precautionary principle, development of a formulants policy, and development and promotion of sustainable pest management alternatives.

44. In the establishment of an adequate and guaranteed resource base for the pesticide re-evaluation program, funding for re-evaluation must not be made contingent on the generation of funds from efficiencies created in other areas.

45. In the development of a policy on formulants, the PMRA should not be guided in the development of its formulant policy solely by the costs that would be borne by registrants for potential amendments to their registrations.

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Appendix 1: DOCUMENT "KEY"

This document "key" is provided to assist the reader with the numerous abbreviations made, throughout the text, to several key reference materials.

The Blue Book
*Recommendations for a Revised Federal Pesticide Management Regulatory System,*Pesticide Registration Review Team, 1990.

The Purple Book
Government Proposal for the Pesticide Management Regulatory System. (Federal Government response to "the Blue Book"). 1994.

PMRA Letter
(Letter from Christine Norman, Acting Head, Occupational Exposure Assessment Section, PMRA to Canadian Environmental Law Association, May 26, 1999)

Report of the Commissioner
Minister of Public Works and Government Services Canada. *Report of the Commissioner of the Environment and Sustainable Development to the House of Commons.* (1999) http://www.oag-bvg.ca

PMRA Submission
PMRA. *Organizing and Formatting a Complete Submission for Pest Control Products*. (1998) Document No. Pro98-02. http://www.hc-sc.gc.ca/pmra-arla/qpubs2-e.html

PMRA Overview Document
PMRA. *Overview Document* (undated)

PMRA Sulfosulfuron PRDD
PMRA. *Proposed Regulatory Decision Document: Sulfosulfuron*. (1998) Document No. PRDD98-01 http://www.hc-sc.gc.ca/pmra-arla/qpubs2-e.html

PMRA Registration Handbook
PMRA. *Registration Handbook*. (1998) http://www.hc-sc.gc.ca/pmra-arla/hndbk-e.html

PMRA Strategic Plan
PMRA. *Strategic Plan 1998-2003* (undated) http://www.hc.sc.gc.ca/pmra-arla/stratp-e.html