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Taking Uncertainty Seriously: From Permissive Regulation to Preventative Design in Environmental Decision Making

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Abstract

This paper contrasts two paradigms of environmental regulatory decision making, "permissive regulation" and "preventative design," with respect to their treatment of scientific and legal uncertainty and the allocation of legal standards and burdens of proof. "Permissive regulation," which is the predominant approach in Canada, suffers two types of statistical errors. A type I error occurs when, for example, a pollution control device is unjustly imposed on an industry. A type II error occurs when no action is taken to control an industry when, in fact, damage is taking place. Concern to prevent type I errors often leads to type II errors. Attempts to resolve these problems through incremental changes in legislation and policy have generally failed. This article illustrates the scientific and regulatory problems associated with 'permissive regulation" through an analysis of environmental common law, legislation, and regulation. Protection of environmental quality requires regulatory decision making rooted in the principles of precautionary, preventative action that tends to minimize costly type II errors. With the "preventative design" approach now being used in several jurisdictions, the regulatory burden of proving harm is shifted from regulators to the polluters who must demonstrate safety. European and American initiatives as well as international agreements illustrate the historical development and implementation of this "preventative design" perspective. This article suggests that Canadian legislation and regulations be written with this approach.

Keywords

Factory and trade waste--Law and legislation; Pollution--Law and legislation; Science and law

TAKING UNCERTAINTY SERIOUSLY: FROM PERMISSIVE REGULATION TO PREVENTATIVE DESIGN IN ENVIRONMENTAL DECISION MAKING©

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This paper contrasts two paradigms of environmental regulatory decision making, "permissive regulation" and "preventative design," with respect to their treatment of scientific and legal uncertainty and the allocation of legal standards and burdens of proof. "Permissive regulation," which is the predominant approach in Canada, suffers two types of statistical errors. A type I error occurs when, for example, a pollution control device is unjustly imposed on an industry. A type II error occurs when no action is taken to control an industry when, in fact, damage is taking place. Concern to prevent type I errors often leads to type II errors. Attempts to resolve these problems through incremental changes in legislation and policy have generally failed. This article illustrates the scientific and regulatory problems associated with "permissive regulation" through an analysis of environmental common law, legislation, and regulation.

Protection of environmental quality requires regulatory decision making rooted in the principles of precautionary, preventative action that tends to minimize costly type II errors. With the "preventative design" approach now being used in several jurisdictions, the regulatory burden of proving harm is shifted from regulators to the polluters who must demonstrate safety. European and American initiatives as well as international agreements illustrate the historical development and implementation of this "preventative design" perspective. This article suggests that Canadian legislation and regulations be written with this approach.

Cet article compare deux paradigmes concernant la prise de décision en matière de règlementation environnementale : la «règlementation permissive» et le «modèle préventif», quant à leur traitement de l'incertitude légale et scientifique et quant à l'allocation de normes légales et de fardeaux de preuve. La «règlementation permissive», comme méthode prédominante au Canada, est marquée par deux types d'erreurs statistiques. Une erreur de type I a lieu quand, par exemple, un dispositif de contrôle de la pollution est imposé injustement à une industrie. Une erreur de type II se manifeste par manque de contrôle d'une industrie causant des dommages à l'environnement. En général, les tentatives visant à résoudre ces problèmes en accroissant la quantité de lois et de politiques ont échoué. En analysant la common law, les lois, et les règlements en droit environnemental, cet article montre les problèmes scientifiques et règlementaires que pose la «règlementation permissive».

Pour protéger l'environnement, la prise de decision en matière de règlementation devrait s'axer sur des principes d'action préventive, qui tend à réduire les erreurs coûteuses de type II. Plusieurs juridictions utilisent maintenant une approche préventive; le fardeau de preuve règlementaire est transféré aux pollueurs qui doivent démontrer la sécurité de leur processus. Les initiatives européennes et américaines ainsi que les accords internationaux illustrent le développement historique et la mise en place de la perspective du «modèle préventif». Cet article propose que les lois et règlements canadiens soient écrits selon cette approche.

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I. INTRODUCTION

In the past decade, the growing scale and impact of the industrial use of hazardous substances have raised concerns in Canada and around the world. After decades of widespread usage, compounds once thought to be harmless, like polychlorinated biphenyls (PCBs), dioxins, and chloro-fluorocarbons (CFCs), have become household names because of increasing evidence of their serious and, in some cases, potentially catastrophic effects.[1] Many industrial activities and by-products have followed a pattern of an initial judgement of safety, followed by uncertainty and circumstantial evidence of harm, acrimonious debate, and finally hard evidence of detrimental effects. With the dramatic increase in recent years in the use of artificial chemical substances, a regulatory approach that permits specific discharges of industrial by-products, subject to an "acceptable" limit that is based on uncertain scientific information, may no longer be adequate for assuring acceptable environmental quality.

In this paper, we shall examine this situation and the challenge that it poses for Canadian law. Of particular concern is the pattern of scientific inference and legal regulation that underlies our current control strategy for industrial pollution. This pattern has focused largely on what we know, rather than what we do not know; that is, it has emphasized cause-and-effect relationships that can be demonstrated between substances and the environment, and not relationships that may exist but which, despite extensive scientific testing, remain hidden. This pattern applies to more than just toxic substances. Failure to detect an effect when one exists is a common problem associated with the widely used, discharge-based regulatory approach in Canada, the approach that we call "permissive regulation." Although this problem also pervades other sectors, such as fisheries management and timber harvesting, it has been rarely acknowledged by scientists, legislators, environmental decision makers, or the judiciary in Canada. In contrast, a new regulatory approach oriented to the character of the whole industrial process, an approach that we call "preventative design," is being developed in other jurisdictions to deal with precisely this problem. To contrast these approaches, we must have an understanding of the

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[1] These potential effects are suspected at the large-scale environmental level (CFCs depleting the global ozone layer, or carbon dioxide (CO_2) leading to the greenhouse effect) and also frequently on small scales. See, for example, J.E. Cummins, "Extinction: The PCB Threat to Marine Mammals" (1988) 18:6 Ecologist 193.

scientific basis of contemporary regulation, of the regulatory character of present Canadian law, and of the new initiatives being taken elsewhere.

II. SCIENTIFIC UNCERTAINTY IN ENVIRONMENTAL REGULATION

The regulatory framework for environmental protection in Canada has been widely noted as placing an onerous burden on those seeking to protect the environment, the effect of which is a perhaps unintended but, nonetheless, *de facto* bias in favour of industrial freedom of action.[2] More specifically, the tradition of making legal inferences (including, most importantly, the allocation of the burden of proof) is often so restrictive that, despite strong suspicions of harm, clear environmental degradation or damage to human health must occur before legal action can be taken.

This regulatory situation reflects, in part, a lack of attention to "statistical power" (a critical component of scientific experimental design), which describes in mathematical terms the probability of an experiment or monitoring programme actually detecting an effect where one exists.[3] Most scientific environmental studies that fail to detect an effect of some action or substance do not evaluate the level of statistical power even though it may be very low for a variety of reasons.[4] Yet

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[2] These concerns are expressed, for example, in D. Estrin *et al.*, eds., *Environment on Trial: A Citizen's Guide to Ontario Environmental Law* (Toronto: Canadian Environmental Law Research Foundation, 1974); D.P. Emond, *Environmental Law and Policy: A Retrospective Examination of the Canadian Experience* (Ottawa: Royal Commission on the Economic Union and Development Prospects, 1985); J.F. Castrilli, "Control of Toxic Chemicals in Canada: An Analysis of Law and Policy" (1982) 20 Osgoode Hall L.J. 322; and T.F. Schrecker, *Political Economy of Environmental Hazards* (Ottawa: Law Reform Commission of Canada, 1984).

[3] The extent of this judicial neglect has been made apparent by a recent computer analysis of several decades of American judicial decision making. Over that time, the concept was addressed only three times at the district, appeals, and Supreme Court levels: S.E. Fienberg, ed., *The Evolving Role of Statistical Assessments as Evidence in Courts* (New York: Springer-Verlag, 1989) at 8. For one consideration of statistical power in judicial decision making, see R. Goldstein, "Two Types of Statistical Errors in Employment Discrimination Cases" (1985-86) 26 Jurimetrics J. 32 at 35.

[4] These reasons are discussed in detail below. For a survey of this situation, see R.M. Peterman, "Statistical Power Analysis Can Improve Fisheries Research and Management" (1990) 47 Can. J. Fish. Aquat. Sci. 2 at 4 [hereinafter "Statistical Power Analysis"]. For papers noting the common absence of statistical power analysis from studies, see C.A. Toft & P.J. Shea, "Detecting Community-Wide Patterns: Estimating Power Strengthens Statistical Inference" (1983) 122 Am. Nat. 618; R.H. Green, "Power Analysis and Practical Strategies for Environmental Monitoring" (1989) 50 Envtl. Res. 195; D.F. Parkhurst, "Statistical Hypothesis Tests and Statistical Power in Pure and Applied Science" in G.M. von Furstenberg, ed., *Acting Under Uncertainty: Multidisciplinary Conceptions* (Boston: Kluwer Academic, 1990) 181; and R.M. Peterman, "The Importance of

because statistical power has rarely been evaluated, some past decisions were not justified. The decisions to license various pesticides on the strength of only limited conclusions, which are now known to be wrong, serve as one example.[5] Because so many causal links are scientifically unprovable in the legal sense of "cause in fact," this situation has led some (especially American) commentators to question whether toxic substances can be well regulated without restructuring the rules concerning the burden of proof.[6] What this restructuring might involve has scarcely been considered in the legal literature, especially in Canada.[7]

Reporting Statistical Power: The Forest Decline and Acidic Deposition Example" (1990) 71 Ecology 2024 [hereinafter "The Importance of Reporting Statistical Power"]. See also J.P. Hayes, "The Positive Approach to Negative Results in Toxicology Studies" (1987) 14 Ecotox. & Envtl. Safety 73. Hayes notes at 73 that, in the field of toxicology, negative results (or failure to detect an effect) "often lead to the (sometimes invalid) inference that a suspected toxicant does not significantly deleteriously affect organisms or biological systems," and that such results may have an important influence on decisions regarding the regulation of toxic substances.

5 See, for example, the U.S. Environmental Protection Agency, *Suspended, Cancelled and Restricted Pesticides*, 5th ed., by the Office of Compliance Monitoring, Office of Pesticides and Toxic Substances (Washington, D.C.: 1990).

6 See T.W. Koelling, "The Burden of Proof in Environmental and Public Health Litigation" (1981) 49 U. Mo. Kan. City L. Rev. 207; H.A. Latin, "The 'Significance' of Toxic Health Risks: An Essay on Legal Decisionmaking Under Uncertainty" (1982) 10 Ecology L. Q. 339; T. Page, "A Generic View of Toxic Chemicals and Similar Risks" (1978) 7 Ecology L.Q. 207 [hereinafter "A Generic View"]; and T. Page, "A Framework for Unreasonable Risk in the Toxic Substances Control Act" in W.J. Nicholson, ed., *Management of Assessed Risk for Carcinogens, Annals of the New York Academy of Sciences*, vol. 363 (New York: New York Academy of Sciences, 1981) 145 [hereinafter "A Framework"]. For a recent survey of the issue, see A.C. Flournoy, "Legislating Inaction: Asking the Wrong Questions in Protective Environmental Decisionmaking" (1991) 15 Harv. Envtl. L. Rev. 327.

7 A notable exception to this is the landmark study by P. Muldoon & M. Valiante, *Toxic Water Pollution in Canada: Regulatory Principles for Reduction and Elimination With Emphasis On Canadian Federal and Ontario Law* (Calgary: Canadian Institute for Resources Law, 1989). Recently, the West Coast Environmental Law Research Foundation published an excellent critique and proposal: C. Sandborn, W.J. Andrews & B. Wylynko, *Preventing Toxic Pollution: Toward a British Columbia Strategy* (Vancouver: 1991).

A. *Uncertainty in Statistical Procedures*

There are two contrasting approaches to making scientific inferences from uncertain information. The most common approach aims to minimize the probability of incorrectly *concluding that there is an effect when one actually does not exist*. In the scientific and statistical literature, this is referred to as a "type I" error.[8] Such an error could lead to a regulatory "false positive" in which an agency erroneously concludes that a cause-effect relationship exists and imposes unnecessary restrictive regulations. The second, much rarer, approach aims to minimize the probability of incorrectly *concluding that there is no effect when one actually exists*; that is, a "type II" error. This approach to uncertainty in scientific inference attempts to minimize the chances of a regulatory "false negative" occurring, in which case regulations that should be imposed are not because it is incorrectly assumed that no effect exists.[9]

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[8] W.J. Dixon & F.J. Massey, Jr., *Introduction to Statistical Analysis*, 4th ed. (Toronto: McGraw-Hill, 1983) at 87. See also Parkhurst, *supra* note 4, *passim*.

[9] When designing an experiment to determine whether a substance or industrial activity has a detrimental effect on the environment or public health, standard research methodology uses data to evaluate quantitatively two different hypotheses. Traditionally, the null hypothesis (H_0) refers to the hypothesis that there is *no* effect; the alternative hypothesis (H_A) is that there *is* an effect. The relevant data are analyzed to see if they reject, or are consistent with, the null hypothesis. If the data are not consistent with the null hypothesis, then it is rejected.

Four possible outcomes exist for the hypothesis test, depending on the true "state of nature" and the type of decision made by the researcher. If the true state of nature is that the substance *does not* have a detrimental effect (null hypothesis is actually true) and the researcher *does not* reject the null hypothesis (Table 1, Box 1), then no error is made. However, given this true state of nature, a type I error (Table 1, Box 2) occurs if the researcher, incorrectly finding the data to be inconsistent with the null hypothesis, rejects H_0 and concludes that the alternative hypothesis—that there is an effect—is true. This leads to a "regulatory false positive."

Alternatively, if the true state of nature is that the substance *does* have a detrimental effect (null hypothesis is actually false), and the researcher *does* reject the null hypothesis (Table 1, Box 4), then a correct decision has been made. In contrast, a type II error occurs in situations in which the substance truly does have a detrimental effect, but the researcher fails to reject the null hypothesis and concludes that there is no effect (Table 1, Box 3). This leads to the "regulatory false negative."

TABLE 1

Decision Table for Hypothesis Testing
(Associated probabilities are in parentheses)[10]

	Decision	
True State of Nature	Reject H_0	Do not reject H_0
Null hypothesis true (there is no effect)	Box 2 Type 1 Error False Positive (*alpha*)	Box 1 No Error (1-*alpha*)
Null hypothesis false (there is an effect)	Box 4 No Error (1-*beta*)	Box 3 Type II Error False Negative (*beta*)

In environmental management, scientific data are gathered on hypotheses and subjected to a statistical analysis, after which some inference is drawn concerning the null hypothesis. Most standard statistical inference procedures aim to minimize the chance of committing type I errors. Scientists have traditionally been quite conservative about making type I errors, choosing small values for the probability (called *alpha*[11]) that an apparent cause-effect link found in the data could be explained by chance alone (*i.e.*, that the observed effect could have been generated by chance alone if the null hypothesis (H_0) were true). This *alpha* value is usually equal to 0.05; that is, there would be a 5 per cent chance of obtaining results as observed if the null

[10] After Toft & Shea, *supra* note 4.

[11] *Alpha* represents a probability ranging from 0 to 1 of committing a type I error. The conservative attitude reflects a scientific tradition of wanting to minimize the chance of mistakenly concluding that the process or substance being studied has some effect. By choosing a small value for *alpha* there is a low probability that they will incorrectly reject H_0 and accept H_A. Thus, an *alpha* value of 0.05 means that there is only a 5 per cent chance that the researcher may be incorrect in rejecting H_0, *i.e.*, that the researcher may have committed a type I error.

hypothesis were true. Some toxicological studies set *alpha* as low as 0.01. If the statistical analysis of the data produces a probability of obtaining the results under H_0 (P value) *less than* the pre-set *alpha* value, the results are said to be "statistically significant" and the researcher rejects H_0 and accepts the alternative hypothesis (H_A) that there is an effect.

Of greater significance to our discussion, however, is when the statistical analysis gives a P value *greater than* the preset *alpha* value. Here the researcher fails to reject the null hypothesis of no effect; however, most scientists go further and actually conclude that the observations are due to chance alone, and that the null hypothesis is true.[12] This conclusion (which is especially common when non-scientists contemplate the implications of technical studies) is usually unjustified and may be dangerous because it can lead to a type II error—the belief that there is no effect when one actually exists—as explained below.

Statistical procedures exist for computing the probability of a type II error[13] but, as discussed above, scientists are not often aware of them. This probability of a type II error is symbolized as *beta* which, like *alpha*, ranges between 0 and 1. A low *beta* value (for example, 0.1) means that there is a low probability (10 per cent chance in this case) of making a type II error. Because statistical power is, by definition, 1.0-*beta*, this experiment would have "high power," or a 90 per cent chance of detecting the effect if it exists at some specified level. Conversely, a high *beta* value (for example, 0.6) indicates a high probability (60 per cent chance) of making a type II error. This experiment would have only a 40 per cent chance of detecting the specified effect; that is, it would have a low power. Note that if decision makers wish to be as careful about averting type II errors as they are now about averting type I errors, the desired *beta* should be the same as the preset *alpha*, usually 0.05. Therefore, they should set the desired statistical power at 0.95. However, there is, as yet, no generally agreed upon level for *beta*, but a value of 0.1 or less is clearly advisable.

Statistical power is a function of four variables: sample size (a larger sample size increases power); sample variance (which includes natural variability in the sample and measurement error—lower variance

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12 The difference between "failing to reject" and "accepting" H_0 is critical, of course, as the former conclusion means that the evidence was simply unable to reject H_0, whereas the latter suggests that the data conclusively show H_0 to be true.

13 For detailed discussion of these procedures, see Dixon & Massey, *supra* note 8; B.J. Winer, *Statistical Principles in Experimental Design*, 2d ed. (Toronto: McGraw-Hill, 1971); and J. Cohen, *Statistical Power Analysis for the Behavioral Sciences*, 2d ed. (Hillsdale, N.J.: Lawrence Erlbaum, 1988) at c. 1.

gives higher power); effect size (the larger the true effect for which one is testing, the higher the power); and *alpha*.[14] This last variable is particularly important because it points to a trade-off between type I and type II errors for a given experimental design. That is, if a scientist is rigorous in minimizing the probability of making a type I error and sets a very low *alpha*, the power of the experiment will *automatically be reduced*, all else being equal.[15] In short, *alpha* and *beta* are inversely related—there is usually a trade-off between the probability of making type I and type II errors. Therefore, by trying to minimize the chance of making a type I error, scientists are inadvertently increasing the chances of missing some effect. The only way to reduce the effects of this inverse relation is by increasing the sample size or by improving the experimental design to increase statistical power.

This trade-off is critical and must be accounted for when making regulatory environmental decisions. For instance, imagine that a toxicologist especially wants to prevent making false claims about the mortality rate of test animals caused by a particular pesticide. If an especially low *alpha* value of 0.01 is set so as not to have more than a 1 per cent chance of incorrectly finding an adverse effect, then any P value calculated from the experimental data that is greater than 0.01 would mean that the researcher would not conclude that an effect exists, and may conclude that one does *not* exist. In other words, the more cautious the experimenter is to avert type I errors (or, to put it another way, to prevent finding an "innocent" pesticide "guilty"), the higher the chance of making a type II error (that is, of letting a harmful pesticide "go free"). Unfortunately, in such situations in most fields of medical and environmental research, scientists fail to calculate *beta*[16] and regularly assert that there is no effect without also stating the probability of

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[14] See "Statistical Power Analysis," *supra* note 4, for a complete discussion of the relations between these variables and statistical power. Peterman works through a hypothetical example of a statistical analysis and type I and type II errors at 3-5.

[15] See Cohen, *supra* note 13; and "The Importance of Reporting Statistical Power," *supra* note 4 at 2026.

[16] See A. Endo, "Determination of sample sizes for the screeing [*sic*] test of teratogenecity" (1976) 14 Terat. 238 (abstr.); M. Yasuda, "The Importance of Type II Error in Toxicological Studies" (1979) 4 J. Toxicol. Sci. 288 (abstr.); T. Tachibana & S. Kiyono, "Safety Evaluation of Compounds and Statistical Type II Error" (1980) 20 Congen. Anom. 157; W. Stucky & H.D. Unkelbach, "Testing Transition Rates in Generalized Binomial Models" (1980) 22 Biom. J. 725; Toft & Shea, *supra* note 4; and C.G. Brown *et al.*, "The Beta Error and Sample Size Determination in Clinical Trials in Emergency Medicine" (1987) 16 Annals of Emerg. Med. 183.

error.[17] Because scientists rarely think of statistical power, law makers and regulators are not aware of its serious implications, a situation which has resulted in many instances of serious, sometimes irreversible, environmental degradation.

B. *Uncertainty in Research Procedures*

Despite considerable scientific data about the dynamics of natural and human-disturbed environmental systems, large gaps in our understanding still exist. Because of the complexity of most ecological systems, it is sometimes difficult either to identify causes of past observations or to forecast future responses to a proposed activity. Many features of ecological systems can increase the variance of data so as to reduce the statistical power of a study, thus posing interpretive difficulties for regulators who depend on scientific studies.[18]

1. Laboratory studies

Because researchers often fail to report that studies have low statistical power, tests that supposedly identify a no-adverse-effect level may be misleading.[19] For example, controversy has long surrounded the

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[17] See "Statistical Power Analysis," *supra* note 4 at 5. In a survey of several recent volumes of two prominent fisheries science journals, it was found that of 160 papers, with at least one occurrence of not rejecting a null hypothesis, there were 142 assertions of no effect. Only 3 of these papers mentioned statistical power (the probability of correctly detecting an effect if one exists).

[18] Variability and uncertainty in natural ecological systems may result from differences among age groups, individual responses to disturbances, variable responses to disturbances in different spatial locations, lag times between disturbances and effects, cumulative and synergistic effects, biomagnification, and unknown mechanisms of responses (nonlinear and threshold responses). Biomagnification refers to the process by which toxins are absorbed by living tissues, and because of their resistance to change, accumulate in greater concentrations in animals than in their food. This can in turn lead to progressively greater concentrations of toxins at higher levels of the food chain. Synergism refers to the process by which two or more pollutants released separately into the environment may act together, or may combine to form a new substance, resulting in harmful effects that are greater than the sum of the effects of their component parts. Cumulative effects refers to the results of several individual environmental developments. Thresholds of response are those levels at which a response, in terms of measurable harm to a species or ecosystem, is detected. In some instances these mechanisms of response exhibit a linear relationship between dose and response. In others, a nonlinear or exponential dose-response curve is seen. For many toxins the nature of the dose-response curve remains uncertain, thus creating regulatory difficulties.

[19] See K.G. Brown & L.S. Erdreich, "Statistical Uncertainty in the No-Observed-Adverse-Effect-Level" (1989) 13 Fund. & Applied Toxic. 235, for a discussion of how decision makers can be misled by results from experiments designed to estimate the highest dose of a chemical that shows

application of the results of animal studies for carcinogenicity to human beings, although authoritative reviews of this controversy have affirmed the reliability of such extrapolations.[20] Laboratory studies of industrial chemicals have also been criticized because only a limited number of the components of an ecosystem can be tested for in the laboratory, and then only under a limited range of conditions.[21] Tests which use one chemical compound at a time, over a limited range of concentrations, may overlook important cumulative or synergistic effects. Other studies may focus on a substance's effects on the mortality of an indicator species at a single stage of its life,[22] thereby neglecting both the sub-lethal (chronic) and cumulative effects on that particular species, and the potential effects on species of different trophic levels. Thus, for example, the use of indicator species to provide both qualitative and quantitative characterizations of ecosystem quality "may be an example of over-emphasis on a criterion of legal relevance and statistical precision over criteria of comprehensiveness and realism, in order to satisfy requirements of the legal process."[23]

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no adverse effect. They note that such experiments focus on reducing the incidence of type I, false positive, errors but not type II, false negative, errors.

[20] This controversy stems from scepticism of the high doses which are typically administered and the high sample sizes that are required for proper testing. In contrast, see Toxic Substances Strategy Committee, *Toxic Chemicals and Public Protection: A Report to the President* (Washington, D.C.: USGPO, May 1980) at 125-33 [hereinafter *Toxic Chemicals*]. One of the conclusions of this committee, which included eighteen United States federal agencies, was that "established test protocols, which include administration of high test doses to animals, sometimes by a route different than the expected human exposure route, are appropriate and scientifically valid test methods for identifying human carcinogens," as cited in J.F. Castrilli & T. Vigod, *Pesticides in Canada: An Examination of Federal Law and Policy* (Ottawa: Law Reform Commission of Canada, 1987) at 23.

[21] See M.R. Gelpe & A.D. Tarlock, "The Uses of Scientific Information in Environmental Decisionmaking" (1975) 48 S.Cal. L. Rev. 371 at 403, for a complete discussion of the methodological difficulties in extrapolating from laboratory data to natural ecosystems.

[22] In Canada, for instance, testing requirements in the *Pulp and Paper Effluent Regulations*, SOR/92-269, sch. I, written pursuant to the *Fisheries Act*, R.S.C. 1985, c. F-14, require that fish of a species that frequents the waters into which effluent is being discharged should be used for toxicity testing of mill effluent. Schedule I of the Regulations also designates rainbow trout and *Daphnia magna* as the two indicator species to be used in assessing the toxicity of the effluent. The assumption is that toxic responses in these species act as indicators for other species and whole ecosystems. However, "species vary greatly in their tolerance to pollution, and most toxicity studies use fairly pollution-tolerant species" as they are easier to maintain under stressful laboratory conditions: See R.W. Howarth, "Determining the Ecological Effects of Oil Pollution in Marine Ecosystems" in S.A. Levin *et al.*, eds., *Ecotoxicology: Problems and Approaches* (New York: Springer-Verlag, 1989) 69 at 71.

[23] H.A. Regier, "Commentary" in *Cumulative Environmental Effects: A Binational Perspective* (Ottawa: Supply and Services Canada, 1989) 49 at 50. Regier comments on the scientific perspective on the cumulative environmental effects on freshwater systems, at a workshop held by the Canadian Environmental Assessment Research Council and the United States National

The possibility of synergistic reactions among chemical compounds in the environment creates additional hardships for decision makers because they make predictions difficult. Some substances may have insignificant toxic effects when analyzed individually but may be significantly toxic when combined. One example of synergistic and nonlinear interactions among chemicals involves the air pollutants benzo(a)pyrene and benzo(a)anthrocene. Both are carcinogenic on mouse skin, but their potency is increased one thousandfold in the presence of n-dodecane which, by itself, is non-carcinogenic.[24] These are all potential sources of type II errors.

2. Field studies

Field studies are also subject to inherent uncertainties. Natural ecosystems exhibit such a high degree of complexity in structure and function that they are difficult to study.[25] Where there is more than one pathway for the same function in a community, the potential effect of a human disturbance that interferes with only one of these pathways may be masked,[26] while a later disturbance affecting remaining pathways may have an observable effect—an effect which may be difficult to trace to its source.[27] Unfortunately, proper experimental design (such as the use of "replicates," or duplications at different locations[28]) is often difficult to

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Research Council Board on Basic Biology in Toronto, Ontario, 4-7 February 1985.

24 See "A Generic View," *supra* note 6 at 221.

25 See Gelpe & Tarlock, *supra* note 21 at 396-407, for a discussion of the complexity of natural ecosystems, threshold effects, and the difficulties of using laboratory and field studies to describe these systems.

26 For example, a predator at the top of the food chain may have several sources of food. When one source becomes extinct, because of some anthropogenic disturbance, there may be no observed effects on the predator population. However, the resilience of the ecosystem to future disturbances may have been weakened as there are now fewer prey species to support the predator. Serious depletion of the predator population will result if the remaining prey species suffer subsequent disturbances; for example, if they are overharvested. Another aspect of community resilience that can mask cause-effect relationships is the phenomenon of threshold responses. For example, in the hypothetical predator-prey relationship described above, the removal of a third prey species may cause the predator population to crash when no responses were detectable after the earlier removal of one or two prey species. This is because the third species became critical once the first two were removed.

27 C.S. Holling, "Resilience and Stability of Ecological Systems" (1973) 4 Annual Rev. of Eco. and System. 1 at 5.

28 Replicates allow the scientist to control for variables that could affect responses to the experimental treatments. For example, spatial replicates of different experimental treatments (types of manipulations) allow the scientist to control for variables associated with the natural

achieve where confounding effects (those that cannot be controlled for) associated with other variables in the study ecosystem cannot be eliminated. Type II errors thus occur frequently as a result of hidden resilience in ecological community structures, time-lags, threshold responses, synergistic effects, and the limited ability of researchers to conduct well-designed field experiments and long-term studies.

3. Epidemiological studies

Epidemiological studies also may have low statistical power[29] as a result of several associated problems. For example, sample sizes are usually low, and controlling external factors (such as exposure to toxins other than the one being studied) may be difficult. A researcher may not be able to make clear associations between exposure to a carcinogen and health effects for a large cohort[30] of workers or residents because of difficulties in determining exact exposure levels. Epidemiologists are also restricted in their ability to perform follow-up studies and, hence, to establish cause-effect relationships, because of the long latency periods characteristic of most carcinogens. Studies usually require that a researcher monitor the study group over a twenty- to thirty-year period. During this time, it is not uncommon for many individuals to leave the cohort,[31] thus reducing the sample size of the affected population. Since statistical power is directly related to sample size, this inevitably lowers the power of the study and reduces the probability of detecting an effect. In addition, there may be more than one causative agent for the observed effect, creating difficulties in correlating observable health effects with exposure to any given toxin.

In summary, intrinsic variability in natural ecosystems, cumulative and synergistic effects, confounding factors, large inherent uncertainty, and the prevalence of low statistical power in laboratory,

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environment. Without proper replicates it may be impossible to distinguish responses to human manipulation from natural variation in the study ecosystem.

29 T.A. Brennan, "Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous-Substance Litigation" (1988) 73 Cornell L. Rev. 469 at 506, discusses the problems of epidemiological studies in demonstrating statistically significant associations between certain chemical carcinogens and clinical outcomes. See also P.H. Schuck, *Agent Orange on Trial: Mass Toxic Disasters in the Courts* (Cambridge, Mass.: Harvard University Press, 1986) at 236, for a discussion of the role of low power in epidemiological evidence in the Agent Orange trials.

30 A cohort is a group of individuals having a statistical factor in common in an epidemiological, biological, or demographic study.

31 This may occur, for example, by death from other causes, migration to another geographical area, or a change of employment that removes a worker from the source of exposure being studied.

field, and epidemiological studies make it difficult to establish clearly cause-effect relationships between certain substances or processes and eventual environmental degradation and endangerment of public health. These problems amplify the concern over the lack of recognition of type II errors in science, policy, and the law. This concern is magnified when one appreciates the potential costs of such errors.

C. *The Costs of Uncertainty*

Type I and type II errors impose a number of economic and social costs. Regulatory false positives derived from type I errors lead a regulatory agency to bear the unnecessary administrative and monitoring costs of implementing and enforcing stricter environmental standards. Industry must pay, both in monetary expenditures and loss of competitiveness, to install unnecessary emission control devices or secondary treatment facilities, especially where these have to be retrofitted. In addition, jobs may be lost through the closure of plants that are unable to adapt profitably.

Direct monetary costs of type I errors can be especially high in the case of an entire industry within a large jurisdiction. In response to stricter regulation of the pulp and paper industry, for example, a report by the Council of Forest Industries (COFI) in British Columbia suggested that the potential cost of installing technologies to meet one proposed standard for the discharge of absorbable organic halogens (2.5 kg per tonne of pulp) in all mills in the province would be one billion dollars, with a stricter standard (1.5 kg) costing an additional six-hundred million dollars.[32]

In contrast, regulatory false negatives resulting from type II errors may result in high monetary costs of a different and potentially more serious type: environmental clean-up costs, loss of earnings and jobs in other industries incidentally affected by pollution, and costs associated with human health effects. Indeed, failing to regulate a dangerous pollutant over a long period may lead to an irreversible resource loss or a decline in environmental quality, as well as monetary losses which could be much higher than the more specific costs of a type I error. One example of a regulatory false negative was the incorrect conclusion that organochlorines in pulp mill effluents posed no danger to the marine environment and human health on Canada's west coast.

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32 Council of Forest Industries of British Columbia, *Sustainable Development and the B.C. Pulp and Paper Industry* (Vancouver: COFI, 1990) at 26.

However, in 1989, the federal Department of Health and Welfare closed several fisheries for crab, prawn, and shrimp because of dioxin contamination from pulp and paper mill effluents.[33] The costs of the error included the loss of revenues from commercial fisheries and associated employment, and the accumulated human health effects of a still unknown, but potentially large, magnitude. Indeed, when type II errors permeate both pollution regulations and resource management generally (for example, in the calculation of fisheries quotas), the costs in declining ecosystem productivity and sustainability can be enormous and irreversible.

With persistent toxic contaminants, type II errors may, in the long run, be more costly than type I errors that would impose potentially unnecessary clean technology. Of course, such comparisons are of a hypothetical nature, and quantitative data on the relative costs of type I and type II errors are usually not available. Nevertheless, some qualitative comparisons are possible. The lengthy debate over the role of CFCs in the destruction of the ozone layer, with all of its consequences,[34] indicates the potential scale of this regulatory problem. Although banned for use in aerosols in the United States in the early 1970s, the emphasis on averting type I errors and the general lack of concern for the seriousness of type II errors led to a continuous increase in the usage of CFCs in a variety of products until the late 1980s. Even the adoption in September 1987 of the *Montreal Protocol on Substances that Deplete the Ozone Layer*[35] (since signed by 46 countries) only committed participating countries to a gradual, phased-in reduction and elimination schedule, despite worldwide anxiety over the impact on the environment, and the (as yet, unquantifiable) costs to human health and industry.

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33 See M. Campbell, "7 BC Fisheries ordered closed after poisons found in shellfish" *The [Toronto] Globe and Mail* (24 November 1989) A1; and "B.C. Fisheries Shut Down" (1989) 19:48 Ottawa Letter 382. (The Ottawa Letter is the newsletter of the federal Parliament.) For a discussion of these closures, which were expanded on 29 November 1991, see M. Waldichuk, "Dioxin Pollution near Pulpmills" (1990) 21 Marine Poll. Bull. 365.

34 See generally, F.S. Rowland, "Chlorofluorocarbons and the Depletion of Stratospheric Ozone" (1989) 77 Amer. Sci. 36.

35 The Protocol was adopted by the Conference of Plenipotentiaries on the Protocol on Chlorofluorocarbons to the Vienna Convention for the Protection of the Ozone Layer, held in Montreal from 14 to 16 September 1987: 26 I.L.M. 1544. The protocol is important as it represents the first multi-level agreement to restrict the use of substances in order to prevent future environmental damage. However, several authors have suggested that the reduction schemes are inadequate because of broad concessions to potential signatories. See T.C. Faries, "Clearing the Air: An Examination of International Law on the Protection of the Ozone Layer" (1990) 28 Alta. L. Rev. 818; and I. Elrifi, "Protection of the Ozone Layer: A Comment on the Montreal Protocol" (1990) 35 McGill L.J. 415.

This slow response reflects an important practical fact: decision makers have difficulty in taking remedial action when new data expose a problem in a well-established product or practice. When irreversible damage has already occurred, corrective action is impossible; but even when future damage can be prevented by remedial action, corporations and labour groups—which would bear the costs of retrofitting—demand that the government provide hard evidence of detrimental effects.

The costs of the two types of regulatory errors are often incurred by different parties, and this too has a significant effect on regulatory orientation. The costs of regulatory false positives are immediate and are paid directly by industry and government. Though these costs may be passed on to the consumer, they will still affect the industry's competitiveness. The costs of false negatives, however, may result in economic externalities, the costs of which are borne by other economic sectors, the general public, and the environment. This phenomenon of "diffuse costs and concentrated benefits" skews the process of decision making because those most directly affected by stricter standards, *i.e.*, industrial interests, have a clear and immediate interest in informing government of the specific costs of action.[36] In contrast, those representing the general environmental and public interest must organize disparate groups and, even then, may only be able to point to uncertain, long-term costs imposed unevenly on a diverse and, as yet, unrepresented variety of future interests.

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36 W.F. Sinclair, in "Controlling Effluent Discharges from Canadian Pulp and Paper Manufacturers" (1991) 17:1 Can. Pub. Pol. 86 at 98-99, comments on the state of pulp and paper regulation in Canada:

> [T]here is considerable incentive for government representatives to accept industry claims of economic hardship in order to avoid the perceived risks associated with causing economic and social dislocation. However, there are no incentives for industry to accept government demands for reductions in effluent discharges unless environmental authorities are prepared to reject the often exaggerated claims of economic hardship by industry, and are willing to prosecute.

D. *Conclusion: The Trade-off Between Certainty and Uncertainty*

As noted briefly above, many studies dealing with environmental and health issues suffer from low statistical power. As well, in any given situation, a trade-off exists between the probabilities of making a type I and type II error because of the inverse relationship between *alpha* and *beta* values. Thus, a decision-making process which requires certainty has a high probability of having undesired effects as a result of uncertainty. This regulatory situation parallels the judicial context where the use of the high standard of proof in a criminal prosecution ("beyond a reasonable doubt") makes it less likely that an innocent person will be convicted (type I error) than if the lesser civil standard ("on the balance of probabilities") were applied. Inevitably, however, the stricter standard of proof creates a greater probability of letting a guilty person go unconvicted (type II error) than if the lesser standard of proof were used. This clear analogy between scientific research and criminal prosecutions has meant that the regulation of hazardous substances and activities generally occurs only when there is clear evidence that a hazard actually exists. This is the basis of the regulatory paradigm of "permissive regulation." Yet, as in criminal prosecutions, such high standards in environmental regulation may be creating many cases in which activities are not as restricted as they should be.

III. UNCERTAINTY AND CAUSATION IN CANADIAN ENVIRONMENTAL LAW

Problems of identifying causal links in the face of uncertainty are increasingly pervasive in environmental and legal matters today. For example, the statistical/legal analysis presented here is relevant to the impact of acid rain on forests; to the impact of fishing on declining fish populations; to CO_2 and CFC emissions and their effect on the atmosphere; and to the effect of clearcutting on wildlife populations and biological diversity. However, we are concerned with only one aspect of this larger group of problems: the regulation of environmental pollution.

The concepts of "burden" and "standard" of proof are the legal complements to scientific procedures for evaluating uncertainty. The *burden* of proof refers to the responsibility to adduce evidence before a fact finder in order to establish a particular hypothesis. This includes both a primary burden of ultimate persuasion, and a secondary burden (the so-called evidentiary burden[37]) to adduce evidence on any specific fact in issue. While the primary burden is fixed in both civil and criminal proceedings, the secondary burden alternates between the defendant and the plaintiff/prosecution throughout any trial, civil or criminal, according to who is less likely to meet that burden with regard to any particular fact in issue. The *standard* of proof refers to the strength of the evidence which must be adduced to establish a particular hypothesis. Civil cases are decided on a balance of probabilities; in criminal cases, the stricter standard of "beyond a reasonable doubt" is applied. As discussed below, the permissive character of Canada's environmental regulatory system is evident in the traditional allocation of the burden of proof, and in the standard of proof applied in both the common law and statutory regulation.

A. *Proof of Harm Under the Common Law*

Private citizens may have recourse to a number of common law causes of action to protect both their own private interests and, indirectly, those of the environment. These include the torts of private and public nuisance, riparian rights, trespass, negligence, and strict liability. Of all the causes of action, however, only a public nuisance action might lead to a remedy for environmental damage *per se* (usually through the intervention of the Attorney General[38]), as all the other causes of action require the plaintiff to establish that a personal, proprietary interest has been affected. In such civil actions, the burden of proof is on the plaintiff to show that, on a balance of probabilities, health and/or private property has suffered as a result of the defendant's actions. Environmental protection through the common law occurs as a by-product of such civil actions. The plaintiff may seek compensation by way of damages or may ask the court to grant an injunction to prevent a potential, or ongoing, wrong. Thus, the common law achieves

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[37] R. Cross, *Evidence*, 5th ed. (Toronto: Butterworths, 1979) at 87, defines the evidentiary burden of proof as "the obligation to show, if called upon to do so, that there is sufficient evidence to raise an issue as to the existence or non-existence of a fact in issue, due regard being had to the standard of proof demanded of the party under such obligation." The Law Reform Commission of Canada noted that the burden of producing evidence refers to the responsibility a party has to produce some evidence of an asserted fact to avoid a ruling by the judge that the existence of the fact cannot be considered. Law Reform Commission of Canada, *Burdens of Proof and Presumptions* (Study No. 8) by the Law of Evidence Project (Ottawa: July 1973) at 43-67.

[38] For the "public interest" exception whereby a private complainant may be granted standing, see *Minister Finance of Canada* v. *Finlay*, [1986] 2 S.C.R. 607.

environmental protection either by granting an injunction to deter the defendant from allowing the wrong to continue or by requiring payment, both of which act as deterrents to others who may undertake similar actions.[39]

Important differences between various causes of action exist. For example, in a private nuisance action, proving that an action had a certain detrimental effect may not be enough to establish the defendant's liability, as the "social utility of the conduct complained of must be weighed against the significance of the injury caused and the value of the interest sought to be protected."[40] Of special concern, however, is the problem of establishing a causal link between the defendant's activity and the probable environmental harm to the plaintiff. Proving this connection is especially problematic where relief is sought before the consequences manifest themselves.[41] Here, too, important differences exist between various causes of action. For example, while an action in trespass is often pleaded in conjunction with an action in nuisance, once a trespass has been established, the harm is *prima facie* wrongful, and the defendant is obliged to prove justification or excuse.[42] This effective reversal of the onus has found expression in the case of *Cook* v. *Lewis*,[43] where the plaintiff was struck by birdshot immediately after the two defendants discharged their guns. The jury concluded that the plaintiff was struck by a shot fired by one of the two defendants, but was unable to determine which one. The Court concluded that, once the culpability of one of the two defendants had been established,

39 The difficulties of getting an injunction are legion. For a summary of the applicable principles, see *Hipwell* v. *Virden (Town of)*, [1987] 47 M.R. 25 at 33 [hereinafter *Hipwell*]. For a general survey of the state of the law, see E.J. Swanson, "The Common Law: New Developments and Future Trends" in D. Tingley, ed., *Into the Future: Environmental Law and Policy for the 1990's* (Edmonton: Environmental Law Centre, 1990) at 79.

40 *Royal Anne Hotel* v. *Ashcroft*, [1979] 2 W.W.R. 462 at 467-68 (B.C.C.A.), McIntyre J.A.

41 In *Waste Not Wanted Inc.* v. *R.* (1987), 2 C.E.L.R. 24 at 48 (N.S.) [hereinafter *Waste Not Wanted Inc.*], Collier J. stated that the "legal test is whether the plaintiff has shown that it is reasonably likely a failure, causing harm to occupiers, will occur. It is not for the defendants to show, with certainty, that failure, and the possible consequences foreseen by Mr. Brown, will not occur." See also *Cantwell* v. *Minister of the Environment* (1991), 6 C.E.L.R. 16 (N.S.), a case concerning the proposed Point Aconi thermal plant in Nova Scotia. In that case, MacKay J. concluded that concern about co_2 does not in itself determine that the emission has any potentially harmful effects.

42 A. Linden, *Canadian Tort Law*, 4th ed. (Toronto: Butterworths, 1988) at 247.

43 [1951] S.C.R. 830 [hereinafter *Cook*].

> the onus is then shifted to the wrongdoer to exculpate himself ... The onus attaches to culpability, and if both acts bear that taint, the onus or prima facie transmission of responsibility attaches to both, and the question of the sole responsibility of one is a matter between them.[44]

As discussed below, if more broadly applied, this principle could have important implications for the judicial reform of the common law.

More generally, however, merely establishing causation has proven to be a significant obstacle to success. For example, with regard to an action in negligence, not only must it be established that the plaintiff's damage was caused by the conduct of the defendant, the conduct of the defendant "must [also] be a proximate cause of the loss, or stated in another way, the damage should not be too remote a result of the defendant's conduct." Further, the plaintiff "must not be guilty of contributory negligence."[45] This raises the need to overcome the host of scientific problems discussed in the previous section.

These difficulties in establishing a causal link between the defendant's activity and probable environmental harm are best illustrated by the case of *Palmer* v. *Nova Scotia Forest Industries*.[46] In this case, the Court dismissed the plaintiffs' application for an injunction to stop the defendant from spraying herbicides 2,4-D and 2,4,5-T, which contain dioxins, over their lands. A major difficulty in establishing a causal link between the application of the herbicides and the adverse health effects was the time-lag in the manifestation of effects,[47] even though a large volume of scientific evidence and expert testimony was submitted to the Court, demonstrating that cancer and other adverse health effects could be caused by even a small amount of dioxin. In finding against the plaintiffs, the Court clearly affirmed that the "complete burden of proof, of course, rests upon the plaintiffs throughout for all issues asserted by them,"[48] especially with respect to prospective damage. With regard to the scientific evidence, Nunn J. noted that "there are opposing views, and [that] the whole field is not without some uncertainty," concluding that the plaintiffs had failed to meet the burden of proof because the evidence did "not even come close to establishing any probability ... of risk to health to warrant the granting

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44 *Ibid.* at 833.

45 Linden, *supra* note 42 at 89.

46 (1983), 60 N.S.R. (2d) 271 [hereinafter *Palmer*].

47 *Ibid.* at 298. Dr. S. Daum, an expert witness for the plaintiffs, testified that "one difficulty in making any assessment [regarding the carcinogenicity of dioxin in the herbicide] is the latency period which, on average, is 20 years and may extend to 40 or even 50 years."

48 *Ibid.* at 347.

of *quia timet* injunctive relief."[49] Nunn J. found that safe exposure levels to carcinogens *can* be determined, and that positive test findings of cancer in animals cannot be generalized to humans because of the high doses administered to these animals.[50]

Above all, the Court's analysis reflects the scientific orientation discussed above by its exclusive concern to avoid making the type I error of incorrectly ascribing a causal relationship where one might not exist. At no time did either counsel or Judge Nunn investigate the statistical power of the expert studies presented that *failed* to show any adverse effect of dioxins. Instead, accepting the allocation of the burden of proof on the plaintiff, the Court merely restated the prevailing judicial attitude that "if science itself is not certain, a court cannot resolve the conflict and make the thing certain."[51]

Strict liability in the common law removes some of the difficulties in proving causation by requiring the plaintiff only to establish the *actus reus*, and not the negligence of the defendant. Despite the earlier focus of strict liability on cases of non-natural uses of land, in *Cruise* v. *Niessen*[52] (a case involving aerial spraying of pesticides), the rule was applied to ordinary or common practices which involve inherently dangerous substances. When the pesticide is shown to have escaped from the property of the defendant on to that of the plaintiff (the *actus reus* is established), the burden shifts to the defendant to establish a defence for his actions. Strict liability thus facilitates establishing a causal link but, as discussed below, serious obstacles prevent this cause of action from developing very far under present Canadian law.

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[49] *Ibid.* at 350-51. In contrast, Castrilli & Vigod, *supra* note 20 at 23 have criticized the decision because "a number of conclusions made by the Court appear to run counter to principles that have been widely supported in the scientific community, expert committees and international agencies." This reasoning was, however, affirmed in the 1987 Ontario case of *Waste Not Wanted Inc.*, *supra* note 41, and in the 1987 Manitoba case of *Hipwell*, *supra* note 39.

[50] *Palmer*, *supra* note 46 at 352. Both of these conclusions are contradicted in a 1980 Report to the President by eighteen United States federal agencies. See *Toxic Chemicals*, *supra* note 20 and accompanying text on laboratory studies.

[51] *Palmer*, *supra* note 46 at 348. See, however, *Farrell* v. *Snell*, [1990] 2 S.C.R. 311 [hereinafter *Farrell*], where the defendant in a malpractice suit was required to adduce evidence to rebut an inference of negligence drawn from the plaintiff's evidence, even though the burden of proof remained with the plaintiff. This case, however, differs from the *Palmer* decision in that visible harm had occurred, and the only issue was the attribution of blame.

[52] [1978] 1 W.W.R. 688.

B. *Proof of Environmental Harm in Statutory Law*

Regulation of environmental pollution in Canada involves literally hundreds of federal and provincial statutes. A comprehensive review of these statutes is beyond the scope of this section, which focuses on the character of the regulatory process that permeates a range of federal and provincial statutes.

The primary federal statutes involved in the control of environmental, especially toxic, pollution are the *Fisheries Act*,[53] the *Canada Water Act*,[54] the *Pest Control Products Act*,[55] the *Motor Vehicle Safety Act*,[56] and the *Canadian Environmental Protection Act*,[57] which replaces the *Environmental Contaminants Act*,[58] the *Ocean Dumping Control Act*,[59] the *Clean Air Act*,[60] and Part III of the *Canada Water Act*.[61] The *Fisheries Act* has long been the government's major instrument for protecting water quality by regulating the discharge of

53 *Supra* note 22.

54 R.S.C. 1985, c. C-11.

55 R.S.C. 1985, c. P-9. This *Act* provides for banning the use, production, or import of particular substances, as does the *Food and Drugs Act*, R.S.C. 1985, c. F-27, and the *Atomic Energy Control Act*, R.S.C. 1985, c. A-16.

56 R.S.C. 1985, c. M-10. Vehicle emission standards are set under this *Act*.

57 S.C. 1988, c. 22 [hereinafter *CEPA*].

58 R.S.C. 1985, c. E-12, now repealed. This *Act* was the primary federal legislation throughout the 1980s regulating specific classes of toxic substances. See *Chlorobiphenyl Regulations*, No.1, C.R.C. 1978, c. 564; *Chlorofluorocarbons Regulations*, COR/80-254; *Mirex Regulations*, SOR/78-891; *Polybrominated Biphenyls Regulations*, SOR/79-351; and *Polychlorinated Terphenyls Regulations*, SOR/79-369. These are now all regulated under Schedule I of the *CEPA*.

59 R.S.C. 1985, c. O-2, now repealed.

60 S.C. 1970-71-72, c. 47, now repealed. This *Act* set out unenforceable emission guidelines for a variety of industries including mining, asphalt paving, cement manufacturing, incinerators, thermal power plants, wood pulping, and so on. Several sets of regulations to protect human health were also promulgated which are now administered under the *CEPA*. These include *Asbestos Mining and Milling National Emission Standards Regulations*, C.R.C. 1978, c. 405; *Chlor-Alkali Mercury National Emission Standards Regulations*, C.R.C. 1978, c. 406; *Secondary Lead Smelter National Emission Standards Regulations*, C.R.C. 1978, c. 412; and *Vinyl Chloride National Emission Standards Regulations*, SOR/79-299.

61 R.S.C. 1985, c. C-11. While this *Act* allows the government to focus on maintaining water quality objectives through designations of water quality management areas (ss. 4, 5, and 11), it has not yet made any such designations.

miscellaneous "deleterious substances" by specific industrial sectors.[62] This *Act* allows the Minister of Environment to require modifications of plans for new operations which might lead to regulatory violations.[63]

The statutory regulation of toxic substances at both the federal and provincial levels imposes onerous legal and non-legal burdens. Even before regulatory action is initiated, many federal statutes place an onerous non-legal burden on the government agency. For example, the Canadian federal *Environmental Contaminants Act*[64] mandated anyone importing or manufacturing a chemical compound for the first time to disclose information regarding the danger which it might pose to human health or the environment. However, in order for such information to be required, the substance had to be included on the Schedule of Prescribed Substances, which itself required the government agencies to believe that a substance was entering or will enter the environment "in a quantity or concentration or under conditions that they have reason to believe constitute or will constitute a significant danger to human health or the environment."[65] In essence, someone had to demonstrate with statistically significant experimental data that an effect was likely to exist. This was such a difficult task (as we have seen) that the agency never invoked section 4(1)(c) of the *Act* and, thus, never imposed systematic testing requirements.[66]

The *CEPA* was passed with much fanfare by the federal government as a vehicle both to monitor and control toxic substances and to bring miscellaneous related statutory functions under one comprehensive statute to allow the government to shape industrial practices affecting environmental quality. The *CEPA* provides for a tiered approach to the classification and regulation of toxic substances. At the first stage, in consultation with provincial governments, representatives of labour and industrial sectors, and associations concerned with environmental and health matters, the Ministers compile a Priority Substances List, specifying substances "in respect of which the

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62 See *Chlor-alkali Mercury Liquid Effluent Regulations*, C.R.C. 1978, c. 811; *Metal Mining Liquid Effluent Regulations*, C.R.C. 1978, c. 819; *Petroleum Refinery Liquid Effluent Regulations*, C.R.C. 1978, c. 828; *Potato Processing Plant Liquid Effluent Regulations*, C.R.C. 1978, c. 829; and *Pulp and Paper Effluent Regulations*, SOR/92-269.

63 *Fisheries Act*, *supra* note 22, s. 27(2).

64 1974-75-76, c. 72 [hereinafter *ECA*], s. 4(6). This *Act* was repealed in 1988 by s. 147 of the *CEPA*.

65 *ECA*, *ibid.* s. 4(1).

66 E.W. Keyserlingk, *Crimes Against the Environment* (Ottawa: Law Reform Commission of Canada, 1985) at 41, note 32.

Ministers are satisfied priority should be given in assessing whether they are toxic or capable of becoming toxic."[67] The second stage is to assess the toxicity of these substances through a process of data collection.[68] If the Minister decides that the substance meets the requirements for designation as a toxic substance, as outlined in the definition of a toxic substance,[69] it is added to the List of Toxic Substances.[70] After that, regulations *may* be written[71] at the discretion of the Minister.[72]

Throughout this process, the burden still remains squarely on the government to establish that a particular substance warrants regulation before regulations will be implemented. However, a major change in the *CEPA* over the *ECA* is the inclusion of the word "may" in the definition of toxic substances in the *CEPA*. This wording suggests that the evidence required to show toxicity does not necessarily have to satisfy rigorous conditions of certainty. Section 11 of the *CEPA* states that

> a substance is toxic if it is entering or may enter the environment in a quantity or concentration
> (a) having or that *may* have an immediate or long-term harmful effect on the environment;
> (b) constituting or that *may* constitute a danger to the environment on which human life depends; or
> (c) constituting or that *may* constitute a danger in Canada to human life. [emphasis added]

By recognizing the existence of scientific uncertainty, the *CEPA* allows the Minister more freedom to make cautious decisions than was

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67 *CEPA*, *supra* note 57, s. 12.

68 *Ibid.* s. 15. Section 15 details the process of collecting data and conducting investigations respecting the nature of the substance; its presence in the environment and its effect on the environment or on human life or health; its potential for dispersal and persistence; its ability to bioaccumulate; methods of controlling the presence of the substance in the environment; methods of testing for its presence, development, and use of alternatives to the substances; quantities, uses, and disposal of the substance; and methods of reducing the amount used, produced, or released into the environment.

69 *Ibid.* s. 11.

70 *Ibid.* s. 33. The Governor in Council must be "satisfied that a substance is toxic on the recommendation of the Ministers."

71 *Ibid.* s. 34.

72 With regard to those substances that were included on the Priority Substance List in February 1989, the Department of the Environment (C. Gaz. 1989.I.544) stated that

> each substance that has been selected ... will undergo an assessment of whether or not it is "toxic" and it should not be assumed that regulations will be required for each substance merely because it has been selected for investigation ... If a substance is determined to be "toxic," the Ministers will indicate their intentions with regard to recommending regulations.

available under the *ECA*. The Minister can thus add a substance to the List of Toxic Substances and write regulations, even if there is some uncertainty as to the extent of harm that may be caused. The risk of making a type II error can thus be reduced. Despite the less restrictive definition of a toxic substance, however, few regulations have been passed under the *CEPA*. Whether the potentially preventative approach in the *Act* will actually be translated into regulations remains an open question.[73]

Creation of regulations is only one step in the process. When one tries to *enforce* these regulations similar problems of scientific uncertainty and causation recur. Canadian environmental legislation classifies most pollution offences as quasi-criminal, regulatory offences. In theory, prosecution of the regulatory offence does not require the Crown to show that the accused intentionally caused or allowed pollution to occur, only that a certain limit has been exceeded, and that the accused was responsible.[74] The standard of proof required to discipline polluters should, therefore, be eased. In practice, however, this is often not the case.

In the Canadian regulatory system, guidelines and objectives (rather than legally enforceable standards) are commonly used. Thus, one cannot merely show that the limits have been exceeded, but that the discharge has violated some statutory definition of "pollution." As recently noted in a paper for the Law Reform Commission of Canada, the result in such situations is that the "difference between conviction and acquittal in pollution prosecutions is often the Crown's ability (or lack thereof) to prove that a deposit or emission qualifies as pollution as defined in legislation or regulations."[75]

But such problems apply more broadly, as an examination of the practice under the federal *Fisheries Act* reveals. One of the most

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[73] In fact, in August 1988, the Priority Substance Advisory Panel recommended that fifty substances, or groups of substances, be included on the Priority Substance List. The forty-four substances that were actually listed (C. Gaz. 1989.I.545) were divided into three groups according to the planned completion of assessment reports. Only nine substances were included in Group 1 of that list, those requiring the most immediate action. Assessment was scheduled to be completed by the end of 1992, but as of June 1993, only ten of the substances on the list had been assessed. The only regulations for substances on the list are for *Pulp and Paper Mill Effluent Chlorinated Dioxins and Furans* (SOR/92-267) and for the related *Pulp and Paper Mill Defoamer and Wood Chips* (SOR/92-268). In addition, the use of the word "may" in American statutes has led to a variety of judicial interpretations. See Flournoy, *supra* note 6 at 341-44.

[74] K. Webb, *Pollution Control in Canada: The Regulatory Approach in the 1980s* (Ottawa: Law Reform Commission of Canada, 1988) at 34-39.

[75] *Ibid.* at 39. Webb's examples are primarily drawn from the *Fisheries Act*.

influential pieces of legislation for environmental protection in Canada, section 36(3) of the *Act*, contains a blanket prohibition against "the deposit of a deleterious substance of any type in water frequented by fish." This section has been used widely to prevent environmental degradation. However, sections 36(4) and 36(5) of the *Act* set prescribed levels for specific pollutants. Although they seem to give greater precision and efficacy to the regulatory process, in practice, these provisions counterbalance, and potentially diminish, the strength of the broader prohibition by shifting from *prevention* of environmental harm to *permission* for some prescribed quantity of industrial discharges.

There have certainly been numerous convictions under the *Fisheries Act*, but the permissive regulatory structure of offences has created an onerous evidentiary burden for prosecutors. Essentially, the prosecution must establish four elements of the offence contained in section 36(3) of the *Act*: (1) that the accused person or corporation was responsible for the deposit, (2) that a deposit occurred, (3) that the deposit was a deleterious substance, and (4) that it was deposited into waters frequented by fish.[76] In *R.* v. *Irving Pulp and Paper Ltd.* (No. 1),[77] the accused was charged with depositing a deleterious substance, pulp mill waste, into the Saint John River. The specific testing procedure for determining toxicity, prescribed in Schedule D of the *Pulp and Paper Effluent Regulations*, was not followed by government authorities. Instead, a newer procedure was used, and these test results were introduced into evidence. This resulted in acquittal on the basis that, even though the substance discharged was generally considered to be deleterious for the purposes of the *Act*, the testing procedures used did not satisfy the requirements of the *Pulp and Paper Effluent Regulations*.[78] In a later appellate level case, *R.* v. *Doman Forest Products*,[79] the Court held that although the levels of the chemical were considered lethal to trout and extremely toxic to salmon in minute quantities, the trial judge still had doubts regarding deleteriousness because no witness had said

76 See A.R. Thompson & H. Rueggeberg, "Science, Inference and the Law: The Ultimate Fish Story" in C.D. Levings, L.B. Holtby & M.A. Henderson, eds., *Proceedings of the National Workshop on Effects of Habitat Alteration on Salmonid Stocks, Canadian Special Publication of Fisheries and Aquatic Sciences* 105 (Ottawa: Supply and Services, 1989) at 167.

77 (1976), 2 F.P.R. 78 (N.B. Prov. Ct.) [hereinafter *Irving* (No. 1)].

78 *Ibid.* at 81.

79 (1982), 3 F.P.R. 326. This appeal was dismissed in light of a possible alternative explanation "for the presence of chemical and pH levels at various stages throughout the discharge system" (327-28) and because of the absence of sufficient evidence at trial.

"at what level the liquid became deleterious."[80] Thus, the trial judge "had a reasonable doubt as to whether or not the concentration of the chemical in the liquid pumped out of the sump was deleterious to fish,"[81] and the Crown appeal was dismissed.

As these and other cases[82] demonstrate, many actions brought under section 36(3) of the *Fisheries Act* have been frustrated by the technical requirements of establishing the "deleteriousness" of a substance; that is, that there was a causal link between the polluting activity and the alleged harm. Proof "beyond a reasonable doubt" that a substance is deleterious is difficult to establish, however, when there is no documented evidence of fish kills or actual impairment of fish habitats. Without this evidence, the prosecution must rely on other sub-lethal indices of harm. As we have seen, this allows some doubt as to the link between the discharge and the harm to the fish.[83]

The regulatory process under the federal *Fisheries Act* thus requires that the Crown establish the essential elements of a "pollution" offence rather than the simple fact that the accused was not in compliance with regulatory standards. Even where such pollution is also provincially regulated by a system of waste discharge permits, which implement federal standards, a discharge that does not comply with provincial permit conditions is not, according to the *Fisheries Act*, automatically regarded as deleterious to the protected resource. Thus, Canadian federal legislation, as it is currently applied, does little to recognize the great uncertainties inherent in scientific environmental and health research. With the enormous difficulties in meeting the legal standard and burden of proof, we may be committing numerous type II errors without yet realizing it.

Provincial regulation of pollution offences through the enforcement of permit conditions face similar problems. For example, the British Columbia *Waste Management Act*,[84] section 3(2), states that

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80 *Ibid.* at 327.

81 *Ibid.* at 328.

82 See, for example, the conflicting decisions of *R.* v. *Imperial Oil Enterprises Ltd.* (1978), 2 F.P.R. 155 (N.S. Mag. Ct.); and *R.* v. *MacMillan Bloedel (Alberni) Limited* (1979), 2 F.P.R. 182 (B.C.C.A.).

83 The testing procedures for toxicity, upon which decisions of deleteriousness are most often based, usually do not recognize that a substance can be deleterious without having acute toxic effects. Chronic and sub-lethal effects, such as impaired reproductive ability or reduced life expectancy, often are not considered sufficient evidence of deleteriousness. See Webb, *supra* note 74 at 40.

84 S.B.C. 1982, c. 41.

"no person shall introduce waste into the environment in such a manner or quantity as to cause pollution," but then allows, in section 3(3), "the disposition of waste in compliance with a permit, approval, order or the regulations, or with a waste management plan approved by the minister." These sections reflect the permissive regulatory approach at the provincial level, a standard pattern across the country. Waste disposal is defined as a strict liability offence[85] under the *Act*,[86] but the permissive nature of provincial legislation again demands proof that a discharge fits the statutory definition of "waste" and that the accused, in allowing the discharge, was not in compliance with permit conditions. As at the federal level, prosecution of an offence under section 3 of B.C.'s *Act* is subject to strict requirements to establish causation; requirements which can significantly impede successful litigation.[87]

The Ontario case of *Re Canada Metal Company Ltd. and Macfarlane*[88] provides a good example of the difficulties into which these legal restrictions lead. In that case, stop orders issued by the Director of the Ontario Ministry of the Environment under the *Environmental Protection Act*[89] were quashed by the Ontario Supreme Court, because the Ministry could not satisfactorily demonstrate a causal link between lead emissions from the two accused firms and the incidence of high lead blood levels in the surrounding area. An affidavit of the Director of the Air Management Branch cited an engineer's report that "levels of [lead were] considerably in excess of those found in normal urban environments." This evidence was later dismissed by the Court on the basis that the words "considerably in excess of those found in a normal urban environment" had no evidentiary value since, "there [was] no evidence as to what the lead levels [were] in a normal environment, let

85 Strict liability offences, in a criminal law context, result in criminal liability without the necessity of proving that the accused intended to commit the wrongful act. Therefore, the Crown need only prove the elements of the offence, at which time the onus shifts to the accused to establish either that the offence occurred without its consent, knowledge or acquiescence, or that there was due diligence. In a tort context, fault by the defendant need not be established.

86 *Supra* note 84 at s. 5.3. The section is subject to strict requirements of proof, including *inter alia* a determination that the substance is "waste," and that the waste constituted "pollution" in the manner and quantity in which it was introduced to the environment.

87 Interview with Frances Gordon, British Columbia Crown Prosecutor (8 October 1990) Vancouver, British Columbia.

88 (1974), 1 O.R. (2d) 577 (Ont. H.C.).

89 R.S.O. 1990, c. E-19. Section 8(1) allows such orders where there are "reasonable and probable grounds ... that a source of contamination is discharging into the natural environment any contaminant that constitutes ... an immediate danger to human life [and] health."

alone what the deponent in his own mind regard[ed] as a normal urban environment."[90]

Contrary to this general pattern, the federal *Pest Control Products Act*[91] attempts a more preventative approach, reducing the risk of type II errors by requiring an industry to show that the products it proposes to market or use are safe before they may be registered and marketed.[92] As the Minister who introduced the original Bill noted in the House, the increased use of, and the great concern over, the potentially harmful pesticides called for "a broader authority for regulation than in the past."[93] The regulations written pursuant to the *Act* state that, in the Minister's "opinion," the use of the pesticide must not "lead to an unacceptable risk of harm ... to public health, plants, animals or the environment."[94]

However, in effect, the *Act* defines as "safe" anything that has not been demonstrated as constituting an "unacceptable risk of harm," which is not itself defined in the *Act* or regulations. Furthermore, in assessing this risk of harm, the *Act* does not specify any improvement in standard testing procedures, which do not presently require the reporting of a study's statistical power when results fail to reject the null hypothesis. Under the *Act*, "absolute safety is not what must be shown, or indeed is being shown by applicants."[95] Instead, the standard of proof applied when demonstrating safety is more oriented to providing the decision maker with a risk-benefit calculation; that is, the expected risks of using the chemicals are measured against the expected benefits.[96] This risk-based, reversed standard for industries to get *approval* of pesticide applications is less stringent than the traditional standard

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[90] *Supra* note 88 at 589.

[91] R.S.C. 1985, c. P-9.

[92] Sections 6(i) and 9(2)(a)(i) to (xi) of the *Pest Control Products Regulations*, C.R.C. 1978, c. 1253, require the applicant to provide the Minister with scientific test studies and results regarding: control product effectiveness; occupational safety and exposure; effects on host plant, animal, article, or non-target organism; control product and residue persistence, retention, and movement; analysis methods for detecting the control product and its residues; detoxification or neutralization methods; disposal methods; and information regarding the storage, display, stability, and compatibility of the product with other products.

[93] The Honourable H.A. Olson, in *House of Commons Debates* (14 January 1969) at 4275, as quoted in Castrilli & Vigod, *supra* note 20 at 42.

[94] *Pest Control Products Regulations*, *supra* note 92, para. 18(d)(ii).

[95] Castrilli & Vigod, *supra* note 20 at 53.

[96] See generally, "A Generic View," *supra* note 6 for a discussion of risk-benefit analysis in the context of the regulation of toxic substances. See also, "A Framework," *supra* note 6, which considers the regulatory framework for such an evaluation.

imposed on agencies which are *prosecuting* offences. In the former case, actual *safety* need not be shown whereas, in the latter case, actual *harm* must be shown "beyond a reasonable doubt," and with no balancing of risks and benefits. While the general approach of the *Act* is thus more preventative than that of other legislation, the test used to determine "safety" fails to account adequately for scientific uncertainty—to the benefit of greater industrial freedom of action. This increases the risk of making type II errors, which could lead to harm.

The problem evidenced by the *Pest Control Products Act* is not an easy one to overcome so long as regulators are still ultimately required to make a determination of the "risk of harm" for particular substances entering the surrounding environment. Whether it is the *Environmental Contaminants Act*, the *Fisheries Act*, the B.C. *Waste Management Act*, or other legislation, the pattern is the same. Furthermore, the calculations of damage to the environment are usually very limited in scope. Even the *CEPA* and the regulations presently being drafted under it demonstrate a continuing "inability to look beyond the end of an effluent pipe to the surrounding ecosystem."[97] Another critic of the new *CEPA* regulations for dioxins and furans commented that "[a]ttempting to control the deposition of a deleterious substance simply by setting a limit on its *concentration* in an effluent pipe [rather than the total amount being discharged] is meaningless from an ecological standpoint, and scientifically unjustifiable."[98] In other words, what is important is how much is being discharged, the resultant concentration levels in various parts of the environment, and the overall results. In short, as Muldoon and Valiante concluded in their study of toxic water pollution in Canada, new preventative approaches are developing internationally, but

> [d]espite [the] *CEPA*, much of the existing regime with respect to federal environmental pollution control remains unmodified or only slightly modified ...

[97] J.B. Sprague, "Comments on Proposed Federal Regulations for Control of Water Pollution From Pulp and Paper Mills" (J.B. Sprague Associates, 1990) at 2. Sprague is a noted toxicologist and co-author of the Municipal and Industrial Strategy of Abatement (MISA) report on pulp and paper mill pollution. See Expert Committee on Kraft Mill Toxicity, "Stopping Water Pollution at Its Source: Kraft Mill Effluents in Ontario" by N. Bonsor, N. McCubbin & J.B. Sprague (Toronto: Pulp and Paper Sector of MISA, Ontario Ministry of the Environment, April 1988).

[98] Rawson Academy of Aquatic Sciences, *Briefing Document on the Proposed Federal Regulations under the Canadian Environmental Protection Act dealing with Dioxin and Furan Discharges from Pulp and Paper Mills* (Ottawa: 1990) at 7.

> Instead, the existing emphasis on attempting to find ways and means of dealing with wastes already created seems well entrenched.[99]

IV. PERMISSIVE REGULATION: THE PARADIGM IN CRISIS

Underlying the legislation and common law described above is a way of thinking about the control of toxic pollution that is largely taken for granted. This is the "paradigm" of permissive regulation, which permits discharges into, or activities in, a receiving environment, some of which may occur only to a specified limit which purportedly reflects "safe" levels. The problems associated with the paradigm are evident in the common but ill-considered and incorrect assumptions about how the environment assimilates waste, how scientific research is done, how reliable the results of such research are, and how regulatory agencies operate. These problems undermine the paradigm on both theoretical and practical levels, and lead to growing criticism of permissive regulation worldwide. Though increasingly voiced in Canada, these criticisms point to the need for a new theory of regulation and a new practical approach to the implementation of controls.

A. *The Assumption of Assimilative Capacity*

The permissive regulation paradigm is based on the philosophy of what might be called the "assimilative capacity" theory of pollution control. Under this theory, "allowable" levels of polluting behaviours, or levels of discharge into the receiving environment, are permitted in accordance with the central assumption that the environment has an enduring capacity to assimilate these prescribed levels of pollutants without harm. With the increasing experience of the environmental "surprises"[100] referred to above, this approach has, in recent years, come under mounting international criticism by governments, non-governmental organizations, and international regulatory bodies.

In a 1986 report on hazardous waste reduction, the United States Office of Technology Assessment (USOTA) outlined a basic criticism of the assimilative capacity approach that has been independently taken up by many others:

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99 *Supra* note 7 at 33 and 78.

100 See C.S. Holling, "The resilience of terrestrial ecosystems: local surprise and global change" in W.C. Clark & R.E. Munn, eds., *Sustainable Development of the Biosphere* (New York: University of Cambridge Press, 1986) 292.

> American environmental protection efforts emphasize control and cleanup of pollution by hazardous substances after they are generated and no longer serve a productive function ... The cost of controlling that waste totals many billions of dollars annually. Usually, hazardous industrial wastes are not destroyed by pollution control methods. Rather, they are put into the land, water, or air where they disperse and migrate. The result is that *pollution control for one environmental medium can mean that waste is transferred to another medium.* [This] regulatory system sanctions the generation of certain amounts of waste, and these can accumulate to environmentally unacceptable levels when postpollution control discharges from many generators enter the environment.[101] [emphasis added]

Muldoon and Valiante have made a similar critique in the Canadian context and point to five structural changes needed in the regulatory framework. These changes require the shift from: (1) a medium-specific to cross-media approach, (2) a waste-management to a reduction-of-toxic-use-at-the-source approach, (3) a focus on allowable concentrations to one on absolute load reductions, (4) point-source to non-point-source pollution control, and (5) inter-jurisdictional regulation to an ecosystem approach.[102]

B. *The Assumption of Scientific Knowledge*

Underlying the assumption of assimilative capacity is a corresponding assumption that we are, in some way, basing our regulations and allowable limits on firm scientific knowledge. It is not necessary to review in detail the statistical and research problems discussed above, but it is useful here to consider how these problems restrict our ability to actually protect environmental quality on a scientific basis. Indeed, the range of problems are so great that the very character of the regulatory process as "scientific" must be called into question.

First, is the sheer scale of the regulatory problem. There are presently some 30,000 to 45,000 industrial emissions and effluents that remain unassessed with regard to toxicity, and between 500 and 1,000 new chemicals that are introduced each year.[103] When regulation occurs on a substance-by-substance basis (as is common with the current permissive approach), a huge diversity of chemicals necessarily escapes regulation, including a large number of new substances introduced

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101 "Serious Reduction of Hazardous Waste: For Pollution Prevention and Industrial Efficiency" (Washington, D.C.: USOTA, 1986) at 11 (Summary) and 29.

102 *Supra* note 7.

103 (1989) 19:8 Ottawa Letter 56.

annually. This is so, at least partly, because the amount of testing required to determine whether a chemical is dangerous enough to regulate is prohibitively expensive and time-consuming.[104]

In addition to the huge number of chemicals in use, it is difficult to set criteria for determining which of those substances require priority action. The generally accepted criteria are toxicity, persistence, and bioaccumulation. However, because of the concerns discussed earlier, these are rendered quite subjective as guides to identifying what to regulate and what thresholds of harm should be set.

Testing has historically focused on acute toxicity, rather than on sub-lethal, chronic, or cumulative effects, so that the database of scientific knowledge in the latter areas is extremely limited. Yet, as one critic noted in relation to Canadian regulations under the *CEPA*, for many highly toxic substances, "it is their chronic effects and their potential to cause severe damage over the longer term at sub-lethal levels of exposure that is cause for concern and serious regulatory prohibitions."[105] At the final stages of the regulatory process, without such data on regulated substances, prosecutors trying to establish environmental damage must rely on the testimony of toxicological and epidemiological expert witnesses, whose testimony is based on a variety of scientific studies. Unfortunately, these studies deal with "issues of causality in terms of statistical probabilities [and] [t]raditionally, the courts have been reluctant to accept probabilistic evidence as showing causation."[106]

It is in this realm of hidden relationships that surprising results are so often experienced, given the temporal and spatial latencies associated with so many cause-effect relationships. For example, in the case of carcinogenesis, the latency period between exposure to a cancer-causing substance and the appearance of a tumour may range between five and forty years. Koelling, among others, notes that authorities estimate that 60 to 90 per cent of all cancers are caused by environmental factors, but that it is difficult to establish direct causal

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[104] See generally, J. Swaigen, "Procedure in Environmental Regulation" in P. Finkle & A. Lucas, eds., *Environmental Law in the 1980s: A New Beginning, Proceedings of a Colloquium* (Calgary: Canadian Institute of Resources Law, 1982). The colloquium was held in Banff, British Columbia, 27-29 November 1981.

[105] Rawson Academy of Aquatic Sciences, *supra* note 98 at 4 (also see this document regarding proposed regulations of dioxins and furans under *CEPA*). More generally, see P.A. Johnston *et al.*, "Effluent Complexity, Ecotoxicological Response and Regulatory Implications" (1990) Envtl. Poll. 1-ICEP.1 570.

[106] J. Trauberman, "Statutory Reform of 'Toxic Torts': Relieving Legal, Scientific, and Economic Burdens on the Chemical Victim" (1983) 7 Harv. Envtl. L. Rev. 177 at 198.

agent-effect linkages because of the lengthy latency periods of many carcinogens.[107] Chronic effects that result from long-term, low-level exposure to toxic or hazardous substances often go undetected until considerable damage has been done.[108] Even when the potential harm is large but subject to some uncertainty (as in the cases of the widely used defoliant Agent Orange[109] and pulp mill effluents[110]), or when the proximate sources of the damage are not easily established, or when the

107 Koelling, *supra* note 6 at 207. See also Trauberman, *ibid.* at 180.

108 Chronic or sub-lethal effects are numerous. For example, the pesticide residue DDE induced the thinning of eggshells and reproductive failure in cormorants in Lake Michigan in 1964, and herring-gulls, cormorants, and common terns in Lake Ontario between 1963 and 1970: M. Gilbertson, "Epidemics in Birds and Mammals Caused by Chemicals in the Great Lakes" in M.S. Evans, ed., *Toxic Contaminants and Ecosystem Health: a Great Lakes Focus* (New York: J. Wiley & Sons, 1988) 133.

In general, chronic environmental or ecosystem effects can include impaired reproductive ability, birth defects, reduced food conversion efficiency, spatial disorientation in affected species, and changes in species composition in community structures that alter the dynamics among predators and prey species. For a general discussion of these issues, see M.A. Kamrin, *Toxicology* (Chelsea, Michigan: Lewis, 1988) at 35ff.

109 Agent Orange was originally thought to be a model herbicide, but was later found to impose significant risk and danger to the environment and to human health. The danger, which was suspected as early as the late 1960s, is caused by a by-product of an intermediate stage of the manufacturing process that remains in the final product only in trace amounts. This chemical, 2,3,7,8 tetrachlorodibenzo-p-dioxin (TCDD), is one of the organochlorine chemical family and has been described as "perhaps the most toxic molecule ever synthesized by man": A. Galston, Chairman, Department of Biology, Yale University, (interview), as cited in Schuck, *supra* note 29 at 18. On this topic, see generally, S.A. Skene, I.C. Dewhurst & M. Greenberg, "Polychlorinated Dibenzo-p-dioxins and Polychlorinated Dibenzofurans: The Risks to Human Health. A Review" (1989) 8 Human Toxic. 173.

110 Pulp mill effluents from mills using chlorine-bleaching technologies contain a large number of organochlorines including TCDD and TCDF. TCDF (2,3,7,8-tetrachlorodibenzofuran) is approximately one-tenth as toxic as the dioxin, but its prevalence in pulpmill effluent is about ten times that of the dioxin. The complex chemicals associated with pulp mill effluent, for example, are now the subject of considerable scientific scrutiny and public concern because of their high toxicity and the significant damaging effects they cause in aquatic ecosystems in concentrations as low as 1 part per billion (ppb) in mill effluent. Yet the toxic effects of dioxins and furans on the environment have been suspected from as early as the 1960s, and their presence in pulp mill effluent has been known since 1983 when concentrations of greater than 50 parts per thousand (ppt) were discovered by the U.S. Environmental Protection Agency in fish downstream from several mills in Wisconsin: C. Van Strum & P. E. Merrell, *No Margin of Safety: A Preliminary Report on Dioxin Pollution and the Need for Emergency Action in the Pulp and Paper Industry* (Washington: Greenpeace USA, 1987). Nevertheless, it was not until dioxins were detected in sludge samples from Ontario pulp mills in 1986 and a number of shellfish fishing areas in B.C. were closed in 1989 because of contamination, that regulation of these substances became a priority with federal and provincial governments in Canada. See Waldichuk, *supra* note 33. As he concludes, at 366, "[t]he haunting question remains: How many other substances are being inadvertently produced by industry that we are not yet aware of or that we cannot measure with our present state of analytical technology?"

delay between exposure and effect is large, regulation may be delayed pending the availability of more conclusive evidence.[111]

In this light, it is not surprising that the courts have often cited intervening causes, remoteness, and foreseeability as reasons to deny liability in such cases. This is especially a problem in industrialized areas, where several point sources of the same or different pollutants may contribute to the causation of the same disease.[112] The denial of a claim on such bases may occur "even though it is generally accepted that excessive exposure to the pollutant is unhealthy."[113] Whatever the obstacle, the courts' denial of liability in these terms points to the inherent difficulties of demonstrating causation when spatial and temporal latencies exist. As was evident in the *Palmer* decision discussed above,[114] judges make such decisions after scientific experts are queried on the possibility of making type I errors, but they are rarely queried about type II errors. Biased decision making in favour of possible polluters can thereby result.

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111 For a review of this problem in American Legislation see Flournoy, *supra* note 6 at 330ff.

112 Trauberman, *supra* note 106 at 181, points out that

> toxic tort plaintiffs must explain a disease's etiology, or manner in which the hazardous substance caused the condition. In cases involving chronic health effects, however, any of numerous factors may be the cause of the condition. Furthermore, because the relative contribution of genetic makeup and external environment to human health is difficult to determine, discerning the extent to which environmental contaminants contribute to any particular illness may be likewise difficult.

113 R.J. Roberts & J.L. Sullivan, "The Role of the Technological Expert in Complex Environmental Litigation" (1976) 54 Can. Bar Rev. 65 at 93. They noted, at 81, that

> these problems can arise in a variety of contexts, for example, showing that air, water or noise pollution from the defendant's operation and not the operations of his neighbours caused the injury; showing that an oil slick which damaged beaches or property came from a particular ship; or showing that health problems resulted from the defendant's pollution and not from disease.

In the much discussed case of *Allyn* v. *United States*, 461 F.2d 810 (U.S. Ct. of Claims 1972) at 817, the court rejected the plaintiff's claim that he had been harmed in his work (as distinct from his personal life) because he "failed to prove that his duties ... caused him to be 'exposed to dangerously high concentrations' ... 'which [were] likely to cause serious disease.' " The case illustrates the limitations of science in determining at what level exposure to substances begins to have toxic effects and, even when toxic effects are shown, the difficulty of establishing the causal connection and effect of one of several sources of exposure.

114 See text accompanying notes 45-50.

C. *The Assumption of Effective Regulation*

The assumption of assimilative capacity when science is uncertain has led to serious practical problems for government agencies in the implementation of permissive regulatory strategies. For instance, the success of any regulatory system based on a substance-by-substance approach is dependent on access of the regulatory agency to high levels of funding, expert staffing, and sufficient research and enforcement facilities. The vast number of chemicals to be tested for toxicity and monitored in industrial effluents, in addition to the large number and types of individual industrial operations subject to regulation, create difficult practical problems for regulatory agencies.

For example, in place of independent government testing and monitoring programmes, regulatory agencies often rely on industry research and even self-policing.[115] This puts the government at a disadvantage because the industry is then "uniquely well supplied with information on product and process characteristics, abatement technology and costs, production and effluent volumes, and numerous other variables."[116] In one well-documented example, American investigators found that test results produced by IBT Laboratories, which were used as a basis for regulatory approval of more than 100 pesticides in the United States and Canada, were "invalid for reasons ranging from sloppy experimental procedure to apparent outright fabrication."[117] Even where industry testing is honestly undertaken, agencies may not have sufficient resources or access to the raw data to allow them to evaluate properly the experimental design and the statistical power of the results.

The combination of the above factors—the problematic assumption of assimilative capacity, the limited scientific understanding of environmental effects, and constrained agency resources—has created a situation in which the environment is effectively treated as a free good. This leads to externalization of the true costs of industrial production through the degradation of environmental quality and an increase in public health risks. Yet, in attempting to correct this after the fact, private citizens and public regulators may confront significant

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[115] A standard procedure, for example, is to have the industry conduct its own monitoring and submit the results to the regulatory agency, which itself only occasionally checks the discharges directly. Castrilli & Vigod, *supra* note 20, discuss this problem more fully.

[116] Schrecker, *supra* note 2 at 12.

[117] *Ibid.* at 12-13.

transaction costs, including the costs of litigation, negotiation, and regulation. Avoiding these costs leads to economically inefficient outcomes which may favour polluters. For example, where a Crown prosecutor weighs the costs of litigation against its potential benefits, pollution may not be penalized until the harm to individuals exceeds their transaction costs. Given the uncertainty of litigation, this cost is higher, and the inefficiency greater, than necessary. For example, because causation must usually be "proven," the plaintiff is often faced with the potentially prohibitive financial burden of conducting scientific research and obtaining expert testimony, and this is in addition to the already high costs of any legal action. These practical problems are inherent in the *post factum*, reactive character of the permissive regulatory strategy.

In Canada, this situation has encouraged a strategy based on negotiated, rather than enforced, compliance between industry and government. One prominent Canadian commentator has noted that

> the rules of environmental regulation are never clearly stated or certain, except in a purely symbolic sense. Instead the norms of conduct are the subject of negotiation and renegotiation between the regulator and the regulated right down to the moment of compliance and noncompliance. In this sense, rules stated in statutes or regulations are merely points of departure for negotiating modifications of behaviour ...
>
> The significant point is that no matter how normative measures are expressed in a statute—whether as policy guidelines or as command prohibitions—the end result in the case of environmental regulation is a bargaining process.[118]

Negotiations between the stakeholders in environmental regulation (government, industry, and the public) as the basis for *setting standards* may be an effective approach, so long as all affected parties are involved in the process and the ability of government to force technological development is not compromised.[119] With the inclusion of a clause in the new federal pulp and paper regulations that allows mills to delay compliance from 1993 to 1995 under special circumstances—over

118 A.R. Thompson, *Environmental Regulation in Canada: An Assessment of the Regulatory Process* (Westwater Research Centre, 1980) at 33-34.

119 In the absence, however, of strong public interest representation in such negotiations, the implementation of standards based on the "best available technology" may be compromised by industry's paramount concerns for economic and technical feasibility, leading instead to standards which reflect only the "best practicable technology." For a discussion of this in the pulp and paper industry, see W.F. Sinclair, *Controlling Pollution From Canadian Pulp and Paper Manufacturers: A Federal Perspective* (Ottawa: Environment Canada, 1990). See also generally, P.A. Victor *et al.*, *Environmental Protection Regulation: Water Pollution, and the Pulp and Paper Industry* (Technical Report No. 14) (Ottawa: Economic Council of Canada, 1981). See also D.B. La Pierre, "Technology-Forcing and Federal Environmental Protection Statutes" (1977) 62 Iowa L. Rev. 771.

objections by environmental interest groups—the acceptability of this approach among the stakeholders is far from complete. Negotiation as the basis for *ensuring compliance* is, however, even more problematic, as it may politicize what should be a predictable enforcement process, ultimately making compliance voluntary. This tends to be the case where a continuous negotiating process costs less for the industry than actually complying with existing regulations.[120] In British Columbia, this strategy led to the widespread granting of exceptions to compliance. Under section 11 of the B.C. *Waste Management Act* and the *Special Waste Regulations*,[121] the government manager has extensive powers to amend permits and approvals "on his own initiative where he considers it necessary, or on application by a holder of a permit or ... an approval." In addition, the Minister may issue a variance order if he believes "that a person should have temporary relief from the requirements of an order, permit, approval, licence or waste management plan."[122] With no public notice requirement for a permit amendment or a variance order, permit applicants and government officials can quietly negotiate lower standards.

The results of this procedure have not been encouraging, even for those few chemicals which are subject to regulatory standards. Of 122 direct discharge pulp and paper mills in Canada in 1985, a nationwide compliance survey indicated that 26 (21 per cent) were not in compliance with national biological oxygen demand (BOD) standards, 47 (39 per cent) were not in compliance with total suspended solids (TSS) standards, and 83 (68 per cent) were out of compliance with toxicity requirements.[123] In British Columbia, a 1989 survey indicated that 21 out of 22 mills in the province were in violation of their permits—and the one mill that was listed as being in compliance was operating under a

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120 F. Anderson *et al.*, in *Environmental Improvement Through Economic Incentives* (Baltimore: Johns Hopkins University Press, 1977) at 16, point out that, from the point of view of industry negotiators, "the benefits of delay are typically so great in comparison with the costs of complying that there is little incentive for voluntary compliance."

121 B.C. Reg. 63/88.

122 *Waste Management Act*, *supra* note 84, s. 13.

123 Sinclair, *supra* note 119 at 294.

variance order.[124] Another study[125] indicated that, for the period between January 1985 and May 1987, in two Waste Management Branch (WMB) regions in British Columbia, 63 per cent of all class 1 permits[126] were out of compliance over half the time that inspections were made. However, the most stringent action taken was the writing of a letter requesting a meeting with industry representatives to discuss ways of bringing the violating plants into compliance.[127] In the last few years, under public pressure, more sizable fines have been assessed in British Columbia.[128]

In conclusion, the regulatory paradigm underlying Canadian pollution legislation is critically weakened by a number of problems: its assumption of the environment's assimilative capacity, its failure to

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124 West Coast Environmental Law Research Foundation Newsletter, Special Pulp Pollution Edition: Pulp Pollution Campaign Update (1990) 14:4 at 5. Similarly, in a recent study entitled *Report on the 1989 Industrial Direct Discharges in Ontario*, 93 of 170 industrial plants exceeded their average monthly limits for environmental discharges. See M. Mittelstaedt, "Major Ontario companies exceeded pollution limits" *The [Toronto] Globe and Mail* (13 July 1991) A3.

125 R.M. Brown & T.M. Rankin, "Persuasion, Penalties and Prosecution: The Treatment of Repeat Offenders Under British Columbia's Occupational Health and Safety and Pollution Control Legislation" (1988) Faculty of Law, University of Victoria at 20-29 [forthcoming in the U.B.C. Law Rev.].

126 The Ministry of the Environment Procedural Manual places permits in one of four compliance-impact groups. Class 1 consists of permits that are in "significant non-compliance" and that are also causing a "high environmental impact." Non-compliance refers to the degree, in terms of both frequency and severity, to which the permit's quality and quantity parameters are exceeded. Environmental impact refers to the effect on the receiving environment (both potential and actual harm). Class 3 permits are also in significant non-compliance but have low environmental impact. Class 2 and 4 permits are listed as being in compliance with high and low environmental impact respectively. See Brown & Rankin, *ibid.* at 20-22.

127 The Procedural Manual assigns a high priority to the enforcement of Class 1 permits. The escalation of responses to be taken by WMB officials is as follows: writing the permittee and requesting suggestions for remedial action; meeting with company representatives to explore remedies; escalation to a more senior level meeting; issuance of a ticket; and, only in the last resort, prosecution. L. Kolankiewicz, "Compliance with Pollution Control Permits in the Lower Fraser Valley, 1967-1981" (1986-87) 72 B.C. Stud. 28, also notes this general trend of non-compliance and negotiation.

128 Province of British Columbia, Ministry of the Environment, Lands and Parks, News Release "Environmental Charges and Fines Announced" (4 September 1992). In the 1990-91 fiscal year, 466 charges were laid, and $1,059,051 in fines were levied for 244 convictions. In 1991-92, a total of 469 charges were laid with only 154 convictions. However, the average fine level had increased, with a total of $1,032,500 in fines. See also Sandborn *et al.*, *supra* note 7 at 49.

In July 1992, the B.C. provincial government introduced a new fee structure for waste management permits under the *Waste Management Act*. The new fee structure reflects both the quantity and quality of pollutants in the discharge. However, the fee structure is only intended to raise sufficient funds to compensate for the administration and monitoring of permits and does not fully reflect the environmental costs of the discharges. See *Waste Management Permit Fees Regulation*, 432/82 and Order in Council No. 1264, 30 July 1992.

acknowledge the implications of scientific uncertainty, and its unrealistic expectations of regulatory agencies. In short, such a system of regulation does not ensure long-term environmental quality as it was designed to do but, instead, inefficiently employs agency resources to facilitate the externalization of the environmental and social costs of industrial production.

V. PRECEDENTS FOR INCREMENTAL REFORM

In response to the difficulties experienced with permissive regulation, many national governments and international regulatory bodies have begun to shift from the *control* of pollution to varying degrees of pollution *reduction*. In addition to alternative approaches, however, the potential exists for incremental reforms within the framework of permissive regulation itself.

A. *Lowering the Standard of Proof*

A number of precedents exist in common law tort actions where the standard of proof has been lowered to protect environmental values and public health. American courts have shown a particular willingness to accept uncertain scientific information as sufficient to establish a fact on "the preponderance of the evidence."

1. Creation of risk as evidence

In *Wilsonville* v. *SCA Services, Inc.*,[129] the Illinois Supreme Court stated that "there can be no doubt but that it is highly probable that the chemical-waste-disposal site will bring about a substantial injury," and that "if a court can prevent any damage from occurring, it should do so."[130] Ryan J., in his concurring comments, stated that "there are situations where the harm that is potential is so devastating that equity should afford relief even though the possibility of the harmful result occurring is *uncertain or contingent*."[131] Since many types of harm that have potentially severe consequences are also characterized as having a

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[129] 426 N.E. 2d 824 (Ill. 1981).

[130] *Ibid.* at 836-837.

[131] *Ibid.* at 842 [emphasis added].

low probability of occurrence, application of the traditional standard of proof may lead to downplaying the likelihood and thus the potentially high costs of the defendant's actions on society. Lowering the standard of proof, by accepting evidence of "creation of risk," allows the courts to make decisions which minimize judicial subjectivity when confronted with uncertain proof of causation;[132] to avoid serious harm which may have only a small probability of occurrence; and, at the same time, to achieve broader societal values.

In *Allen* v. *United States*,[133] a case arising out of the 1963 nuclear tests in Utah, the Court held that statistical evidence may be relied on to create an inference of a causal link despite the lack of direct causal evidence:

> Where the injuries are causally indistinguishable, and where experts cannot determine whether individual injury arises from culpable human cause or non culpable natural causes, evidence that there is an increased incidence of the injury in a population following exposure to defendant's risk creating conduct may justify an inference of "causal linkage."[134]

English courts too have considered the "creation of risk" as evidence of causation in cases where there were multiple potential causes of injury for which the court was unable to establish independent contributions. In the oft-cited case of *McGhee* v. *National Coal Board*,[135] the court granted the plaintiff relief on the grounds that the action of the defendant "materially increased the risk ... on a balance of probabilities."[136] By thus accepting "creation of risk" as sufficient proof of causation, the standard of proof was lowered and a *prima facie* case was established, shifting the burden of proof onto the defendant. The result was that the plaintiff "succeeded without proof that more probably

132 See generally, L.D. Silver, "The Common Law of Environmental Risk and Some Recent Applications" (1986) 10 Harv. Envtl. L. Rev. 61, who suggests, at 96-97, that historically the "common law's experience with environmental risks highlights the absence of an objective approach to deal with uncertainty ... The objective complexity of decision making in the face of uncertainty has reduced our description of the process to a subjective simplicity—the hunch."

133 588 F. Supp. 247 (1984).

134 *Ibid.* at 253.

135 [1972] All E.R. 1008 (H.L.) [hereinafter *McGhee*].

136 *Ibid*. at 1013. In this case, an employee was exposed to brick dust with a risk of dermatitis at the worksite and was put at risk for an additional period of time because the employer failed to provide after-work shower facilities. Experts were unable to determine the relative contributions to the total risk of the two causes, and the Court could make no useful distinction between a source contributing to the *risk of the disease* and a source contributing to the *disease itself*.

than not it was [the defendant] that had caused his injury."[137] Although not following *McGhee*, the recent Supreme Court of Canada case of *Farrell* reached essentially the same result by drawing an inference of causation adverse to the defendant despite the lack of clear proof, which the defendant was then unable to rebut.[138] There is, however, considerable uncertainty as to how far the judiciary will allow this approach to develop.[139]

In effect, risk-benefit analysis alters what needs to be proven by relieving the plaintiff of demonstrating that the occurrence of harm is more probable than not. Instead, the plaintiff need only show both that there exists a mere risk of harm, and that the costs of that risk to the plaintiff outweigh the benefits to the defendant. Similarly, in enforcing regulatory standards, substituting a "risk-benefit analysis" approach for a damage-oriented, punitive approach could effectively lower the standard of proof by allowing the plaintiff to establish merely that the expected costs of potential environmental degradation that *could* be induced are greater than the expected benefits. A common approach to calculating the expected costs and benefits of proposed activities is to measure the possible cost of environmental degradation multiplied by the probability of occurrence, against the expected benefit of a new technology or development multiplied by the probability that there will be a benefit.[140]

The risk-benefit approach has been applied in a number of environmental cases in the United States. In *Reserve Mining Co.* v.

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[137] J.G. Fleming, "Probabilistic Causation in Tort Law" (1989) 68 Can. Bar Rev. 661 at 669.

[138] *Supra* note 51. In this case, the plaintiff had suffered an eye injury after being operated on by the defendant. Although direct causation could not be established, the Court found that the evidence adduced by the plaintiff was sufficient to support an inference of causation, based on common sense, despite the absence of medical proof. In *Farrell*, the Court effectively reduced the standard of proof on the plaintiff which allowed the Court to draw an inference on the facts adverse to the defendant but without shifting the burden of proof to the defendant. In *McGhee*, however, the Court stated that the plaintiff had *prima facie* proven his case, thus shifting the burden of proof to the defendant. As the Court in *Farrell* noted, at 330, "[t]he legal or ultimate burden remains with the plaintiff, but in the absence of evidence to the contrary adduced by the defendant, an inference of causation may be drawn, although positive or scientific proof of causation has not been adduced."

[139] Recent decisions in the United Kingdom and Australia diverge in their treatment of these issues, leading J.G. Fleming, "Probabilistic Causation in Tort Law: A Postscript" (1991) 70 Can. Bar Rev. 136 at 141, to remark that "[w]e are awaiting the next move in the causality game."

[140] See, for example, the American *Toxic Substances Control Act* (Pub. L. No. 94-469, 90 Stat. 2003 (1976)) which provides, at c. 6(c)(1), that decisions to prevent certain risks from chemical substances will be based upon a balancing of the risks against the benefits of substances and the economic consequences of regulation. This approach is discussed in "Risk-Benefit Analysis and Technology-Forcing Under the *Toxic Substances Control Act*" (1977) 62 Iowa L. Rev. 942 at 948.

Environmental Protection Agency,[141] an injunction was sought against the discharge of mine tailings containing asbestos fibres into Lake Superior—the community's drinking water supply. Availability of injunctive relief depended on the applicability of the "imminent hazard" provision under the Federal *Water Pollution Control Act*. Scientific evidence was inconclusive on the key issue of whether the discharge would cause increased rates of cancer in the community, so the Court decided that the "concepts of potential harm, whether they be assessed as 'probabilities and consequences' or 'risk and harm' necessarily must apply."[142] Applying a risk-benefit analysis, the Court interpreted "endangerment" to mean a *threat* of risk of harm, rather than a risk of harm itself, and the injunction was upheld even though it was not possible to conclude that "the probability of harm was more likely than not."[143] This decision was cited in *Ethyl Corp.* v. *Environmental Protection Agency*,[144] where the Court upheld EPA regulations requiring a reduction of lead components in fuel, based on the determination that there was a "significant risk" to public health, without requiring proof of either actual or even probable harm.

Kuster argues that a more general application of risk-benefit analyses to prove causation, and a resultant lowering of the standard of proof, should depend on a court's analysis of three issues: (1) the seriousness of the potential injury in terms of both the extent and the type of harm, (2) the benefits of the activity and the effects of a damage award or injunction on these activities, and (3) the degree of uncertainty in the scientific information introduced as evidence.[145] This latter factor must then be balanced against the results of the inquiries regarding the seriousness of harm and its possible benefits. Essentially, an activity associated with serious harm or low benefits would require a less certain, *i.e.*, lower, standard of proof of causation. Nevertheless, problems remain in estimating costs and benefits as many of the variables in a risk assessment are unquantifiable, and the probabilities of occurrence of different outcomes, as well as the range of possible outcomes, may not

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[141] 514 F.2d 492 (8th Cir. 1975).

[142] *Ibid. at 520.*

[143] *Ibid.* The injunction was allowed with the provision that the company must have a "reasonable" time to abate the discharges. This decision takes a more precautionary regulatory approach in order to protect public health against the potential for adverse effects, a decision which was consistent with the preventative purpose of the federal *Act*.

[144] 541 F.2d 1 (D.C. Cir. 1976).

[145] B.W. Kuster, "Toxic Substance Contamination: The Risk-Benefit Approach to Causation Analysis" (1980) 14 J. of L. Ref. 53 at 63-64.

be known with any degree of certainty. In addition, treatment of intangible costs, intergenerational effects, and synergistic and cumulative effects assessment are difficult, given the uncertainties involved.

Despite these limitations, the risk-benefit approach has important implications for the Canadian environmental regulatory framework, which have not allowed for the "creation of risk" as adequate proof of an offence. For instance, causing harm to the receiving environment is not directly prohibited under the B.C. *Waste Management Act*, even though this may be the intent of the *Act*. The focus instead is on preventing unauthorized discharges which cause pollution. In this regard, the prosecution must establish that the discharge fits the statutory definition of pollution—"the presence in the environment of substances or contaminants that substantially alter or impair the usefulness of the environment"[146]—rather than just demonstrating the creation of a risk as sufficient proof of this element of the offence.

Similarly, for offences under sections 35(1) and 36(3) of the *Fisheries Act* the standard of proof would be lowered if it were sufficient to establish that an accused's activity put a fish habitat at risk. Indeed, the standard and burden of proof required to establish elements of an offence under the *Fisheries Act* have been somewhat relaxed through the use of inferences.[147] It is yet to be seen whether risk of harm will be sufficient to regulate substances under *CEPA*, although the phrase "may have an immediate or long-term harmful effect on the environment" in section 11 of the *Act* could well be interpreted in this way. Finally, the International Joint Commission has recently proposed that governments adopt a "weight of evidence" approach to "the identification and virtual elimination of persistent toxic substances"[148] in the Great Lakes.

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146 *Waste Management Act*, *supra* note 84, s. 1.

147 Thompson & Rueggeberg, *supra* note 76 at 167, note that provisions in the *Fisheries Act* "in some cases reverse the onus of proof, in others change the standard of proof to a balance of probabilities, and in still others, obviate the need for assessing the weight of evidence by deeming that certain inferences are facts."

148 Sixth Biennial Report on Great Lakes Water Quality, (1992) at 21-22. As the Commissioners note, at 21-22, "[c]ritics have attempted to find flaws with individual studies in order to discredit findings and conclusions about persistent toxic substances. While limitations to study design may exist, this does not necessarily invalidate the findings and conclusions when considered in a weight-of-evidence context."

2. The right to environmental quality

In the United States, a number of states have enacted legislation that specifically seeks to secure a right to environmental quality by lowering the standard of proof and, on some issues, by shifting the burden onto the defendant. Similar to the judicial acceptance of "creation of risk," acts like the *Michigan Environmental Protection Act*[149] alter the standard and burden of proof rules. The plaintiff may establish a *prima facie* case by showing that the defendant's actions are merely likely to harm the environment. The burden of proof then shifts to the defendant, who must show that his or her conduct was reasonable "by way of an affirmative defence, that there is no feasible and prudent alternative ... and that such conduct is consistent with the promotion of the public heath, safety and welfare in light of the state's paramount concern for the protection of its natural resources."[150] The *MEPA* defines a violation as the "impairment" of a "natural resource," but the *Act* does not establish a threshold which must be met by the plaintiff, thus making it possible for the courts to apply the statute flexibly. The *MEPA* also allows the court to "determine the validity, applicability and reasonableness of the standard," and, if the court decides that a standard is deficient, it may "direct the adoption of a standard approved and specified by the court."[151]

Establishing the affirmative defence may be onerous for the defendant. Abrams argues that "[i]f a low level of environmental harm satisfies the threshold, defendants will be forced to explore alternative courses of action in a greater range of cases."[152] If so, this could be a

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149 Mich. Comp. Laws Ann. 691.1201-.1207 (West Supp. 1977) [hereinafter *MEPA*]. The *MEPA* is discussed in detail here as an early example of this type of legislation. Similar laws were subsequently adopted in other states. See generally, D.L. Alessi, M.J. Wright & M.P. Treiber, "Shifting the Burden of Proof in State Environmental Protection Acts: A Blessing to Environmental Plaintiffs" (1978) 8 Envtl. L. 851; and R.H. Abrams, "Thresholds of Harm in Environmental Litigation: The *Michigan Environmental Protection Act* as a Model of a Minimal Requirement" (1983) 7 Harv. Envtl. L.R. 107. Cases filed under the *MEPA* have dealt with a wide range of activities including several different types of air pollution, atomic energy generation, fish and game management, land use, land drainage and construction, mining operations, oil and gas leasing, park management, road development, shoreline protection, wetlands protection, solid waste disposal, stream channelization, toxic substances, water management, water pollution, and municipal treatment systems. For an overview of cases under the *MEPA*, see D.K. Slone, "The Michigan Environmental Protection Act: Bringing Citizen-Initiated Environmental Suits into the 1980's" (1985) 12 Ecology L.Q. 271.

150 *MEPA*, s. 3(1).

151 *Ibid.* ss. 2(2)(a) and 2(2)(2b).

152 *Supra* note 149 at 116.

significant step toward a more preventative and less legalistic approach to environmental protection. In assessing alternatives, economic criteria must not determine the outcome. Rather, it should be shown that there are unique non-economic problems which preclude the selection of other alternatives.[153] As Abrams notes:

> If, as advocated, an exceedingly low threshold is employed under *MEPA*, litigants and courts alike will often find that the crux of litigation is the alternatives issue. In fact, this is salutary: the focus becomes how best to improve decisionmaking instead of a nit-picking debate about how much harm will ensue.[154]

This single technique of emphasizing alternative processes encourages the courts to make innovative decisions in spite of scientific uncertainty about causal relationships, thus reducing the potential costs to society and to the environment by minimizing type II errors. Such an approach has not yet made an appearance in Canadian legislation.

B. *Shifting the Burden of Proof*

A few common law precedents exist in which the traditional allocation of the burden of proof has been reversed so that the defendant had to prove that he was not the cause of the injury. The theory of "alternate liability," as set out in *Cook*,[155] applies in situations in which there is more than one possible defendant or cause of harm. As discussed above, the negligence of the two defendants had been established, but the plaintiff could not prove which one was at fault and, therefore, caused the injury. The court reversed the burden so as to require each defendant to absolve himself by showing on a balance of probabilities that he was not to be held responsible for the injury. In other words, the defendants were given the task of proving that their actions were not harmful.

The applicability of the alternative liability rule to environmental regulatory issues is, however, limited since it requires that harm already have occurred, that there is a proven and limited number of possible causes of the harm, and that the negligence of the defendants has been established. The overall burden on the prosecution is thus still high,

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153 In fact, the *Minnesota Environmental Rights Act*, § 116B at § 116B.04, explicitly rejects consideration of economic factors as rebutting a *prima facie* case or as serving as an affirmative defence. Abrams, *supra* note 149 at 116, discusses specific cases which "confirm the stringency of the requirements for establishing a successful affirmative defense."

154 *Supra* note 149 at 117.

155 *Supra* note 43.

especially in quasi-criminal regulatory environmental offences where the higher standard of proof beyond a reasonable doubt is still applied. In such cases, each defendant would only need to raise a doubt that points to one of the others as the cause of harm to make it difficult to convict any of the defendants.

Going beyond the alternative liability rule is the common law tort standard of strict liability where "[a]nyone having care or control of a substance likely to do harm [is] to be held strictly liable for the consequences should it escape."[156] Strict liability, which does not reverse the burden of proof but removes the burden of establishing the defendant's negligence, has been explicitly recognized in some environmental protection acts in Canada.[157] For instance, under the "Ontario Spills Act"[158] the costs of clean-up are subject to absolute liability rules, and strict liability is applied to loss or damage from spills. Plaintiffs are not required to show that the defendant was at fault or was negligent in allowing the spill, but the "due diligence defence" is open to the defendant once the offence has been shown. The decision of the Supreme Court of Canada in the case of *R.* v. *Sault Ste. Marie*[159] formally established that the regulatory pollution offence is indeed a strict liability offence.

In *Sault Ste. Marie*, the Court identified three bases for liability: (1) the *mens rea* offence, in which some positive state of mind such as intent or knowledge or recklessness must be proved by the prosecution; (2) the strict liability offence, in which it is not necessary for the

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156 Swanson, *supra* note 39 at 89.

157 P.N. Nemetz, "Federal Environmental Regulation in Canada" (1986) 26 Nat. Resources J. 551 at 581, points out that the type of liability and burden of proof vary by jurisdiction and statute. However, most legislation is not explicit on the interpretation of liability and the due diligence defence is commonly assumed. Nemetz discusses, at 582, specific provisions for absolute liability under the Ontario "Spills Bill," the federal *Arctic Waters Pollution Prevention Act*, R.S.C. 1985, c. A-12, and the Manitoba *Fishermen's Assistance and Polluter's Liability Act*, S.M. 1970, c. 32.

158 *Environmental Protection Act*, R.S.O. 1980, c. 141, Part IX. The most far-reaching strict liability legislation in this area is the American *Comprehensive Environmental Response Compensation and Liability Act* (the Superfund Act), 42 U.S.C. 9601-9657.

159 [1978] 2 S.C.R. 1299 [hereinafter *Sault Ste. Marie*]. In that case, the accused had an agreement with a private company, Cherokee Disposal and Construction Co. Ltd., for the disposal of the city's garbage. The waste disposal method caused nearby bodies of water to become polluted. The contracted company was convicted of a breach of s. 32(1) of the *Ontario Water Resources Act*, R.S.O. 1970, c. 332. The question before the Court in *Sault Ste. Marie* was whether the city was also guilty of an offence under that section. Section 32(1) of the *Ontario Water Resources Act* prohibits discharging, causing to be discharged, permitting to be discharged, or depositing materials into a body of water or on the shore or bank thereof, or in such place that might impair the quality of the water.

prosecution to prove the existence of *mens rea* (instead, the prosecution must establish a *prima facie* case that the act occurred—it then being left to the accused to avoid liability by proving that all reasonable care was taken by exercising "due diligence"); and (3) offences of absolute liability, where it is not open to the accused to show an absence of fault as a defence. Again, however, judicial obstacles prevent the seemingly stricter approach from having the desired effect in environmental cases. In this case it was clearly established that a discharger who violates the terms of a licence or permit may defend itself by showing that due diligence was exercised. This can be established, for instance, by showing that equipment did not perform according to design specifications or that reasonable care was exercised by ordering and installing pollution control equipment. Once the occurrence of the offence has been successfully established by the prosecution, the defendant may establish the due diligence defence on the balance of probabilities, which is relatively easy[160] in comparison with the prosecution's subsequent task of rebutting the defence beyond a reasonable doubt.[161] While the strict liability offence does shift some of

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160 In proving *actus reus*, the Crown's case "must be based on a single act or a narrowly time-limited series of acts" and thus the prosecution is restricted to an extremely narrow range of evidence. This is not the case for the defence of due diligence. As noted by Swaigen, *supra* note 104 at 97:

> [W]hile the Crown is restricted to prosecuting for such narrowly circumscribed activities, the defendant is free to put in issue a wide array of circumstances if it feels this will help to establish due diligence. To illustrate, if the Crown charges a company with committing a single air pollution incident, it would then be open to the company to prove the general expenditure of funds on pollution abatement, and instructions issued to employees over several years. The company could launch an inquiry into its labour-management relations over a period of years in an attempt to show that the employees had been instructed in the methods of avoiding pollution but were uncooperative ... [The] cumulative effect [of such evidence] may well convince the Court that on the balance of probabilities the company had exercised due diligence to prevent the incident, unless the Crown can rebut it.

161 To rebut the defence, more sophisticated and extensive investigations are required to determine whether a company actually took all possible precautions to avert the pollution. This can be a formidable task considering that the defendants usually have exclusive access to information regarding their actions to prevent the pollution. As Swaigen, *ibid.* at 94, notes:

> [P]ollution inspectors trained to take samples of toxic materials and trace a pollution trail to its source, will now also have to establish who gave the orders that led to the pollution, who carried them out, what supervision was provided, how the equipment was maintained, and many other matters that could only be ascertained by taking statements, scrutinizing documents, auditing financial records, and dissecting the relationships within corporations and between interlocking corporations.

the legal burden onto the polluter,[162] the extensive investigation and the use of expert witnesses required to rebut the due diligence defence add to the expense and difficulty of prosecuting a strict liability offence.

Finally, strict liability offences have been challenged under section 11(d) of the *Canaadian Charter of Rights and Freedoms*,[163] which provides the right "to be presumed innocent until proven guilty," and under section 7 of the *Charter*, the "right to life, liberty and security of the person ... in accordance with the principles of fundamental justice." With respect to section 7 challenges, while it is generally held that to prevent punishment of the *morally innocent*,[164] proof of subjective intent (*mens rea*) is necessary, the decision in *Sault Ste. Marie* indicates that, for public welfare offences, the defence of due diligence or reasonable mistake of fact provides adequate protection for the morally innocent. Moreover, because regulatory offences are generally part of a larger system of administration that permits certain behaviours under controlled conditions, it can be assumed that by agreeing to the conditions of regulation there is a tacit intent to comply.[165]

It may be more difficult, however, for strict liability offences to remain consistent with the requirement of presumption of innocence set out in section 11(d) of the *Charter*. Here, the Crown must prove all of the essential elements of the offence beyond a reasonable doubt. The Supreme Court of Canada has been inconsistent on the onus which this creates, but the trend seems to be to find elements of the strict liability offence contrary to the *Charter*.[166] In the recent case of *R.* v. *Wholesale*

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162 The accused must establish due diligence based on the objective standard of the reasonable person in the circumstances (*R.* v. *Ellis-Don* (1990), 24 A.C.W.S. (3d) 188). The standard of care is based on the seriousness of the risk of harm, so that a greater possibility of a more serious risk of harm requires that more precautions be taken (*R.* v. *Placer Developments Ltd.* (1983), 13 C.E.L.R. 42 (Y. Terr. Ct.)).

163 *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11. [hereinafter *Charter*].

164 *Sault Ste. Marie*, *supra* note 159 at 1326.

165 See K.R. Webb, "Regulatory Offences, the Mental Element and the *Charter*: Rough Road Ahead" (1989) 21 Ottawa L. Rev. 419, especially at 449. Webb argues, at 453, that "an objective negligence standard is justifiable when it is part of a regulatory regime because advertence, the full *mens rea* mental element, has been reasonably attributed to the regulated accused as a pre-condition to that accused being permitted to engage in a certain activity."

166 This issue had previously split the Supreme Court of Canada in the cases of *R.* v. *Holmes*, [1988] 1 S.C.R. 914 [hereinafter *Holmes*]; *R.* v. *Whyte*, [1988] 2 S.C.R. 3 [hereinafter *Whyte*]; and *R.* v. *Schwartz*, [1988] 2 S.C.R. 443 [hereinafter *Schwartz*]. In *Holmes* and *Schwartz*, the Court held that requiring the accused to establish a defence on the balance of probabilities did not violate s. 11(d) as the Crown satisfied its duty once it had successfully proven the essential elements of the offence. In *Whyte*, Dickson C.J. held that the distinction between the elements of the offence and those of

Travel Group Inc,[167] the Supreme Court of Canada was virtually unanimous in its supportive approach to corporate *Charter* standing and remedial entitlement, which will inevitably add support to corporate interests in what appears to be a new trend in challenging state regulatory activities.[168] However, on the more controversial issue of the constitutionality of the due diligence defence, the Court held, by a very thin majority,[169] that the strict liability offence created in *Sault Ste. Marie*

the defence is irrelevant to the s. 11(d) issue. He stated that the real concern is whether an accused may be convicted when a reasonable doubt exists.

167 [1991] 3 S.C.R. 154 [hereinafter *Wholesale Travel*]. On appeal to the Supreme Court, the issues were: (1) whether a corporation has the capacity to invoke *Charter* protection in the regulatory process, (2) whether the retraction provisions in the impugned sections of the *Competition Act* (R.S.C. 1985, c. C-34) were unconstitutional, and (3) whether the due diligence defence contained in the *Act* infringed the presumption of innocence as guaranteed by ss. 7 and 11(d) of the *Charter*.

In the Ontario Court of Appeal (*R.* v. *Wholesale Travel Group Inc.* (1990), 70 O.R. (2d) 545) Tarnopolsky J.A., for the majority, held that the imposition "of a persuasive burden on the accused to prove that he or she acted with due diligence violates s. 11(d) because it permits conviction despite a reasonable doubt as to the culpability of the accused."

168 See generally, C. Tollefson, "Case Comment: *R.* v. *Wholesale Travel Group Inc.*" (1992) 71 Can. Bar Rev. 369.

169 Two judges held that the due diligence provisions were constitutionally sound, three held that the provisions infringed s. 11(d) but were sustained by s. 1 of the *Charter*. The remaining four judges would not have upheld the due diligence provision, arguing that they were unconstitutional under both ss. 11(d) and 1. The majority of the Court viewed the strict liability offence as an "essential means of enforcing public policy without which the state's regulatory capacity would be substantially reduced." See Tollefson, *ibid.* at 374.

The Court was in agreement on the first two requirements of the test set out in *R.* v. *Oakes*, [1986] 1 S.C.R. 103 [hereinafter *Oakes*]. This case states, at 105-06, that when the state is attempting to justify a limit on a right to freedom under s. 1 of the *Charter*, it must follow a procedure, which involves the application of four criteria: (1) the objective of the impugned provision must be of sufficient importance to warrant overriding a constitutionally protected right or freedom; (2) the means chosen to achieve the objective must be "rationally connected" to the objective and not arbitrary, unfair, or based on irrational considerations; (3) the means chosen must impair the right or freedom in question as "little as possible" to accomplish the objective; and (4) the means chosen must be such that their effects on the limitation of rights and freedoms are proportional to the objective.

Iacobucci J., speaking for the majority in *Wholesale Travel*, at 258, held that, with respect to the third requirement of *Oakes*, the alternative means available to Parliament of achieving the objective (the use of a "mandatory presumption of negligence" following from proof of the *actus reus*) would

> shift to the accused the burden of simply raising a reasonable doubt as to due diligence and would not thereby allow the effective pursuit of the regulatory objective. It would leave the Crown the legal burden of proving facts largely within the peculiar knowledge of the accused ...
>
> [S]uch an alternative would in practice make it virtually impossible for the Crown to prove public welfare offences ... and would effectively prevent governments from seeking to implement public policy through prosecution.

would be maintained. It is important to note that the reverse onus provisions of strict liability regulatory offences, as created in *Sault Ste. Marie*, came within a narrow margin of being constitutionally erased.[170] Should this decision be reversed in the future, the difficulties previously experienced in prosecuting a strict liability offence will be amplified. In general, then, while incremental reforms to lower the standard or shift the burden of proof in both the common law and statutory provisions are possible, Canadian initiatives in this area are few and encounter serious legal obstacles, despite the clear policy justification for such a shift.

VI. STRUCTURAL REFORM THROUGH PREVENTATIVE DESIGN

The lack of judicial innovation in Canada to overcome intractable problems of establishing causation is an example of the impediments to effective environmental protection within the existing regulatory and judicial framework. More important still are the technical and scientific problems that regulators who rely on "end-of-pipe" solutions face daily. One international commentary summarized these problems as follows:

> (a) end-of-pipe abatement tends to transfer pollution from one medium to another, where it may either cause equally serious environmental problems or even end up as an indirect source of pollution to the same medium;
> (b) although not as expensive as remediation of environmental damages, end-of-pipe abatement contributes significantly to the costs of production processes and products;
> (c) end-of-pipe abatement of pollution requires regulation through control legislation which is often costly and cumbersome, and leads to potentially inefficient regulatory structures;
> (d) end-of-pipe abatement technology represents a significant technological market with an associated economic inertia which works against the reduction of pollution at the source.[171]

As to the fourth requirement in the *Oakes* test, Iacobucci J. concluded, at 267-68, that since "the regulated activity and the public welfare offence are a fundamental part of Canadian society," and "the means chosen impair the right guaranteed by s. 11(d) as little as is reasonably possible, the effects of the reverse onus on the presumption of innocence are proportional to the objective."

170 Tollefson, *supra* note 168 at 370, note 6, points out that the Supreme Court has been asked to overrule *Sault Ste. Marie* on *Charter* grounds twice in the five months since *Wholesale Travel* was handed down. In both cases, the invitation was declined for reasons in *Wholesale Travel*. It is inevitable that more challenges to the constitutionality of *Sault Ste. Marie* will be brought.

171 T. Jackson & P.J. Taylor, "The Precautionary Principle & the Prevention of Marine Pollution" (Paper presented to the First International Ocean Pollution Symposium, Puerto Rico, April 1991) at 35. The authors are members of the London Dumping Convention's (LDC's) Scientific Group on Dumping.

Thus, for example, the solution for improving local air quality, tall stacks, was a major source of acid rain. Similarly, technologies to remove heavy metals from effluent streams or particulate matter from tall stacks merely transferred the pollution to landfills in the form of sludges or flyash, which may then leach into the surrounding water table. These control problems have, of course, been exacerbated by the dramatically rising scale of the problem. As one study of American toxic regulations has noted, "in 1940, the entire U.S. economy produced less than 1 million tons of synthetic organic chemicals. By 1987, 125 million tons of synthetic organics were produced—a 12,500 percent increase."[172]

Overcoming both the inherent contradictions of permissive regulation and the escalating pollution problem requires a new regulatory approach which does not merely treat waste once it has been generated, but deals with it at its source through new production processes. A range of terms have been used to describe this new approach, such as waste minimization, waste reduction, toxics use reduction, best available technology, and clean production. Toxics use reduction, for example, is defined as

> changes in production processes, products or raw materials that reduce, avoid, or eliminate the use of toxic or hazardous substances and the generation of hazardous byproducts per unit of production, so as to reduce overall risks to the health of workers, consumers or the environment without shifting risks between workers, consumers or parts of the environment.[173]

Several precedents exist for such structural reforms, and an examination of them provides us with a detailed model for a "preventative design" strategy. Such a strategy takes a "precautionary approach" to preventing type II errors by creating a presumption of harm and translates this presumption into a comprehensive new procedure and administrative framework for regulation of the entire production process.

A. *Precedents for Structural Reform*

Historically, initial demands for a more precautionary approach arose from the deteriorating state of the shared rivers and enclosed seas of northern Europe. In the North Sea, for example, surprising

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172 W. Ryan & R. Schrader, *An Ounce of Toxic Pollution Prevention: Rating States' Toxics Use Reduction Laws* (National Enironmental Law Center (Boston) and the Center for Policy Alternatives (Washington, D.C.), 1991) at 3.

173 *Ibid.* at 4.

events—massive algal blooms which caused serious damage to fisheries, marine mammal epidemics, die-offs, and a rising incidence of fish diseases—escalated in the 1980s despite the absence of clear cause-and-effect explanations. In the mid-1980s, new concepts such as "low waste/non-waste and low-emission/non-emission technologies" were being considered to deal with an emerging crisis.[174] A number of national governments, notably those of Germany and the Netherlands, began to move toward a more preventative or "precautionary" approach[175] with new legislation that sought to encourage waste prevention and clean technology. These goals have been promoted through licensing and siting requirements for waste management facilities, operational standards, and the wide use of economic incentives such as pollution charges and direct financial support for research, development, and implementation of so-called clean technologies.

For example, in 1986, amendments to the *Waste Disposal Act*[176] in the Federal Republic of Germany established, for the first time, the prevention and reduction of waste as a national policy: no pollution permit could be issued unless the applicant had demonstrated that all possibilities for waste minimization had been exhausted.[177] Legislation provides for the development of catalogues of alternative technologies and uniform technical standards for various industrial sectors. Similarly, the Netherlands has put in place an overall strategy to improve waste management and to encourage waste minimization, including financial support for the development and implementation of new waste minimization technologies and better industrial "housekeeping" practices. The overall goal of these systems is to internalize the costs of "pollution and waste control into the production methods so that compliance with pollution and waste limitations becomes a normal and necessary part of maintaining an efficient operation."[178]

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174 For a detailed discussion of this history, see L. Bass *et al., Protection of the North Sea: Time for Clean Production* (Rotterdam: Erasmus Centre for Environmental Studies, 1990).

175 For an early elucidation of the precautionary approach, see V. Dethlefsen, "Marine Pollution Mismanagement: Towards the Precautionary Concept" (1986) 17:2 Marine Poll. Bull. 54.

176 7 June 1972 Bundesgesetzblatt (BGBl.I) 1410.

177 See A.C. Williams, "A Study of Hazardous Waste Minimization in Europe: Public and Private Strategies to Reduce Production of Hazardous Waste" (1987) 14 Envtl. Affairs 165 at 177; and "Economic Instruments for Environmental Protection" (1989), Organisation for Economic Co-Operation and Development (OECD), Paris. The OECD study reviews a variety of economic instruments (pollution charges, subsidies, deposit-refund systems, market systems, and enforcement incentives) in several European countries and the United States.

178 Williams, *ibid.* at 195.

Similarly, in the United States, early signs of a new approach were evident by the mid-1980s. The 1984 Hazardous and Solid Waste Amendments to the *Resource Conservation and Recovery Act*[179] outlined a national policy on waste management, which stated that "wherever feasible, the generation of hazardous waste, is to be reduced or eliminated as expeditiously as possible." Included in the amendments were requirements that firms using or manufacturing toxics must report their efforts to reduce the volume and toxicity of waste prior to treatment. In 1986, the United States Office of Technology Assessment (USOTA) released a landmark report which advocated shifting government policy from pollution control to waste reduction.[180] This report argued that pollution prevention is superior to pollution control as it: (1) benefits the government because less waste will enter the environment and thus the risk of mismanagement and costs of environmental treatment and remediation will be reduced, (2) benefits companies through reduced waste treatment expenses, and (3) benefits society because it conserves materials and slows the depletion of nature's virgin resource base.[181]

This cause has been taken up most aggressively at the state, rather than the federal, level, with the 1989 Massachusetts *Toxic Use Reduction Act*[182] setting the U.S. national standard.[183] In response to substantial public interest pressure from the National Toxics Campaign,[184] the new legislation establishes a statewide goal of reducing toxic waste generation by 50 per cent by 1997. Its approach is to shift the domain of intervention

> up into the production process where decisions traditionally have been management prerogatives well hidden from public review ... [The approach] relies more on government-mandated planning, goal-setting and performance standards coupled with government technical assistance and financial incentives.[185]

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179 Pub. L. No. 98-616, 98 Stat. 3221.

180 *Supra* note 101.

181 *Ibid.* at 14-15.

182 Mass. Gen. Laws Ann. § 21 I (West 1993) [hereinafter *TURA*]. For discussions of the *Act*, see K. Geiser, "Toxics Use Reduction and Pollution Prevention" (1990) New Sol. 1; and Sandborn *et al.*, *supra* note 7 at 86-89.

183 For a comparison of ten different state laws, see Ryan & Schrader, *supra* note 172.

184 See generally, S. Lewis & M. Kaltofen, "From Poison to Prevention: A White Paper on Replacing Hazardous Waste Facility Siting With Toxics Reduction" (Boston, The National Toxics Campaign Fund, 1989).

185 Geiser, *supra* note 182 at 1-2.

To achieve this, the *Act* requires initiatives on four fronts: "administrative reorganization, toxics use reduction planning, creation of a research and training institute, and state-mandated performance standards for targeted industrial sectors."[186] The first initiative requires the state to establish an Office of Toxics Use Reduction Assistance and Technology[187] to coordinate the shift in policy. Toxics use reduction[188] is to be encouraged by requiring firms which manufacture or use any substance on a special chemical substance list[189] to file annual chemical inventories[190] by production unit, and to indicate their progress in pollution reduction by keeping score under formalized "use reduction" and "waste reduction" indices. Beginning in 1994, these firms have been required to prepare "toxics use reduction plans"[191] which are to be updated every two years. The plans must include information on past and projected changes in toxic chemical use, assessments of available technologies or chemical substitutes that would reduce toxic chemical use, and schedules for the introduction of economically feasible reduction technologies or practices.

Under the third initiative, the state will establish a Toxics Use Reduction Institute,[192] the first of its kind in the United States, dedicated solely to encouraging and assisting industries in the reduction of toxic chemical use and toxic waste generation. The Institute is mandated to develop ways of substituting safer materials for the toxic substances presently used and generated by manufacturing processes.

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186 *Ibid.* at 6.

187 See the *TURA*, *supra* note 182 at § 7.

188 Toxics use reduction is defined in § 1 of the *TURA*, *ibid.* as

> in-plant changes in production processes or raw materials that reduce, avoid, or eliminate the use of toxic or hazardous substances or generation of hazardous by-products per unit of production, so as to reduce risks to the health of workers, consumers, or the environment, without shifting risks between workers, consumers, or the environment.

It is to be achieved through the following methods: input substitution; product reformulation; production unit redesign, modification, or modernization; improved operation and maintenance of production unit equipment and methods; and recycling, reuse, or extended use of toxics. Further, "toxics use reduction shall not include or in any way be inferred to promote or require incineration, transfer from one medium of release or discharge to other media, off-site or out-of-production unit waste recycling, or methods of end-of-pipe treatment of toxics as waste."

189 See the *TURA*, *supra* note 182 at § 9. The basis for this list is the Toxic Chemical list defined in § 313 of the American *Emergency Planning and Right-to-Know Act* (Pub. L. No. 99-499, 1986). The list will be expanded over the first four years of administering the *TURA*.

190 See the *TURA*, *supra* note 182 at § 10.

191 *Ibid.* § 11.

192 *Ibid.* § 6.

The Institute acts as a clearinghouse for information on source reduction and clean technologies. Finally, the *TURA* grants authority to the state to target specific industrial sectors[193] where it appears that new technologies or practices could achieve significant source reduction. The state can set performance standards to pressure firms to achieve these high levels of reduction.

In October 1990, the American federal government passed the *Pollution Prevention Act*[194] which also sets out a national policy on pollution prevention and source reduction. The preamble states that

> pollution should be prevented or reduced at source ... Pollution that cannot be prevented should be recycled in an environmentally safe manner ... and disposal or other release into the environment should be employed only as a last resort.

The *Act* is intended to improve Environmental Protection Agency (EPA) data collection systems and the dissemination of information regarding the reduction of toxic emissions in all media, and to assist the government in providing information on, and technical assistance for, source reduction. Under the *Pollution Prevention Act*, the Administrator of the EPA will establish an office that will develop and implement a strategy to promote source reduction;[195] investigate methods of coordinating, streamlining, and improving public access to data collected under existing environmental statutes; develop an inventory of existing data; and consider developing consistent report formats, nomenclature and data storage and retrieval systems.[196] This office will also establish liaison groups with industry, public interest groups, state source reduction programme officials, and an Advisory Panel of technical experts.[197] In addition, the Administrator of the EPA will establish a Source Reduction Clearinghouse to compile information on management, technical, and operational approaches to source reduction.[198] The Clearinghouse will serve as a centre for source reduction technology transfers and will promote the adoption of source reduction technologies through extensive education programmes. Although the *Act* does not include regulatory provisions, it is intended to encourage preventative action by establishing a national policy of waste

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193 *Ibid.* § 14.

194 42 U.S.C.S. 13101 *et. seq.*

195 *Ibid.* § 4.

196 *Ibid.* §§ 4, 5.

197 *Ibid.* § 5.

198 *Ibid.* § 6.

reduction through the exchange of information and the establishment of a hierarchy of waste management solutions—with source reduction as the preferred option, and disposal as a last resort.

Both conceptually and in practice, Canadian legislative policy lags far behind these initiatives. Internationally, the International Joint Commission (of which Canada is a co-member with the United States) has, since 1978, articulated in its Great Lakes Water Quality Agreement the goal of "zero discharge" for persistent toxic pollutants.[199] To help achieve this, in 1990, the Commission called for a reverse onus provision so that a chemical should be assumed to be harmful unless demonstrated otherwise.[200] Nationally and provincially, however, despite the fact that 3.5 million tonnes of hazardous wastes are generated annually by Canadian industry, "there is neither an explicit national policy nor legislative provisions promoting source reduction."[201] Meanwhile, many provincial governments remain within the old regulatory paradigm, still proposing procedures, such as that recently put forward by British Columbia, for the use of the "best available *control* technology" (BACT) [emphasis added].[202] A recent strategy presently under consideration in British Columbia does, however, contemplate a more preventative approach in the future.[203]

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199 See the *Great Lakes Water Quality Agreement of 1978*, signed at Ottawa, 22 November 1978, and the Phosphorus Load Reduction Supplement, signed 7 October 1983. Zero discharge is articulated in Annex 12. For a current discussion of this, see *A Prescription for Healthy Great Lakes: Report of the Program for Zero Discharge* (Toronto: Canadian Institute for Environmental Law and Policy, February 1991) [hereinafter *A Prescription for Healthy Great Lakes*].

200 Fifth Biennial Report on Great Lakes Water Quality, Part II, (1990), 21. In its Sixth Biennial Report, *supra* note 148 at 2 and 3, the Commission noted that we "have not yet virtually eliminated, nor achieved zero discharge, of any persistent toxic substance" so that it "is time to ask whether we really want to continue attempts to *manage* persistent toxic substances ... [or] begin to *eliminate* and *prevent* their existence in the ecosystem in the first place" [emphasis in original].

201 Muldoon & Valiante, *supra* note 7 at 74. In its 1990 Green Plan, the federal government has called for the "virtual elimination of discharges of persistent toxic substances into the environment." The policy does not address the need for source reduction and is still subject to the existing drawn-out screening procedures under the *CEPA*. See *Canada's Green Plan For a Healthy Environment* (Ottawa: Supply and Services Canada, 1990) at 43.

202 *Waste Discharge Criteria Based on (BACT) Best Available Control Technology* (Victoria: Ministry of Environment, Lands and Parks, 1991). For a critique of this draft proposal, see WCELRF newsletter, 15:5 (12 February 1991).

203 New regulations require the elimination of organochlorines in pulp mill effluent by 31 December 2002. As of 31 December 1995, the interim discharge limit will be 1.5 Kg of AOX per tonne of pulp produced. See *Pulp Mill and Pulp and Paper Mill Effluent Control Regulations*, B.C. Reg. 470/90. Permittees may be exempted from the interim limit if a plan and timetable is submitted to the Waste Management Branch (WMB) Director for the elimination of AOX on or before 31 December 2000. Not suprisingly, these regulations are opposed by industry and are being

B. *Preventative Design: A Model*

While the challenge to the assumption of assimilative capacity was initiated in a few European countries in the mid-1980s, under prodding from international non-governmental organizations (NGOs) and individual states,[204] several international bodies, such as the Oslo and Paris Commissions,[205] began reforming their regulatory approach because they recognized that it was necessary to act upon the scientifically based presumption of a causal link "even when there is no conclusive evidence of a causal relationship between the inputs and the effects."[206] Thus, the 1990 Ministerial Declaration of the Third International Conference on the Protection of the North Sea states that the Ministers will "take action to avoid potentially damaging impacts of substances that are persistent, toxic and liable to bioaccumulate even where there is no scientific evidence to prove a causal link between emissions and effects."[207]

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implemented gradually with the assistance of a professional mediator and through a broad participatory negotiation process.

204 See, for example, the submission by the lead international NGO in this area, Greenpeace International, "A Critical Analysis of the Assimilative Capacity Approach," to the Thirteenth Meeting of the London Dumping Convention (LDC) Scientific Group on Dumping, International Maritime Organisation, Document No. LDC/SG/13/8/2 (London, 1990). Submissions by several national delegations to the LDC's 13th meeting in April 1990 were also critical of the assimilative capacity approach to protecting the marine environment. See, for example, Germany's "Remarks on the Assessment of Data and the Principle of Precautionary Action," Doc. LDC/SG 13/8/1.

205 See the (Oslo) Convention for the Prevention of Marine Pollution by Dumping from Ships and Aircraft, 1972, 11 I.L.M. 262, and the (Paris) Convention for the Prevention of Marine Pollution from Land-Based Sources, 1974, 13 I.L.M. 352. These regional European commissions, hereafter referred to as OSCOM and PARCOM, share a common secretariat and together provide the regulatory framework for national legislation and international coordination for the environmental protection of the north-east Atlantic, including the heavily contaminated North Sea. Their member states include, *inter alia*, France, Germany, the Netherlands, Sweden, and the United Kingdom.

206 On the Principle of Precautionary Action, PARCOM Recommendation 89/1 of 22 June 1989 at Art. 2, 2 (a). This approach led, for example, to that organization's banning all industrial waste dumping at sea.

207 *Ministerial Declaration of the Third International Conference on the Protection of the North Sea* (The Hague: International Maritime Organisation (IMO), 7-8 March 1990) at 5. Participation in the conference included the Ministers, responsible for the protection of the North Sea and the rivers entering the North Sea, from Belgium, Denmark, Norway, Sweden, the Netherlands, the Federal Republic of Germany, the French Republic, Switzerland, Great Britain, and the European Community. This approach contrasts, for example, with the federal *Pulp and Paper Effluent Regulations* in Canada, which ignore both persistence and cumulative effects in the receiving environment by setting permissible levels of discharge in units of pollution *per unit of production* (*e.g.*, 1.5 kg AOX per tonne of pulp), thus increasing the overall level of discharges in direct proportion to increases in the levels of production.

Acceptance of such an approach is now widespread in the international regulatory community.[208] In August 1990, for example, the United Nations Environment Program's (UNEP) Governing Council endorsed a comprehensive approach to hazardous waste management, which

> *[a]ppeals* to governments and appropriate international forums taking economic costs into consideration to consider alternative clean production methods—including raw material selection, product substitution, and clean production technologies and processes—as a means of implementing a precautionary approach in order to promote production systems which minimize or eliminate the generation of hazardous wastes and optimize use of raw materials, water and energy, for example through recycling.[209]

In June 1989, the European Contracting Parties of the Oslo Commission (OSCOM) adopted a policy to reduce and terminate the dumping of all industrial wastes into the marine environment.[210] This decision represents both a sweeping application of the precautionary principle to hazardous and other wastes, and a new approach to making such decisions. It states:

> that the dumping of industrial wastes in the North Sea shall cease by 31 December 1989, and in other parts of Convention waters by 31 December 1995, ... except[ing] ... those industrial wastes for which it can be shown to the Commission through the Prior Justification Procedure (PJP) both that there are no practical alternatives on land and that the materials cause no harm in the marine environment.

In developing a model for preventative design, two elements stand out: a new philosophical base, the "precautionary principle," which replaces the assumption of assimilative capacity; and a practical strategy

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208 Two authors, active in the negotiations, K.C. Stairs & P.A. Johnston in their article "The Precautionary Action Approach to Environmental Protection" (1991) 1-ICEP.1 Envtl. Poll. 473, cite, at 475, the following fora which have adopted the precautionary approach: the North Sea Ministerial Conferences; the UNEP Governing Council; the Paris and Oslo Commissions; the Barcelona Convention; the Nordic Council's International Parliamentarian Conference on Pollution of the Seas; the Nordic Council of Ministers; the European Community (EC) Parliament; the European Economic Community (EEC) (the June 1990 "Environmental Imperative"); the Bergen Conference (ECE) Ministerial Declaration; and the Vienna Convention on the Protection of the Ozone Layer. See also J. Cameron & J. Abouchar, "The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment" (1991) 24 B.C. Int'l & Comp. L. Rev. 1. The authors, at 14 and 20, argue that the wide acceptance of the precautionary principle in national and international instruments indicates its emergence as customary international law.

209 UNEP Governing Council, Second Special Session, Nairobi, Kenya, 1-3 August 1990, Decision No. SS.II/4 at 41.

210 Convention for the Prevention of Maritime Pollution by Dumping From Ships and Aircraft (Fifteenth Meeting of the Oslo Commission (OSCOM)), *On the Reduction and Cessation of Dumping Industrial Wastes at Sea*, Decision 89/1 (Dublin, 14 June 1989).

for implementation, which includes such processes as the "prior justification procedure."

1. The precautionary principle and statistical power

The essential reference point of the preventative design approach is the precautionary principle.[211] This principle was first developed in Germany (*vorsorgenprinzip*), but was formalized as an operational legal principle in the Ministerial Declaration of the Second International Conference on the Protection of the North Sea in 1987. In it, the ministers

> accept the principle of safeguarding the marine ecosystem of the North Sea by reducing pollution emissions of substances that are persistent, toxic and liable to bioaccumulate at source by the use of the best available technology and other appropriate measures. This applies especially when there is reason to assume that certain damage or harmful effects on the living resources of the sea are likely to be caused by such substances, *even when there is no scientific evidence to prove a causal link between emissions and effects ("the principle of precautionary action")*.[212] [emphasis added]

A regulatory approach based on this principle highlights the uncertainty of scientific information by recognizing the necessity to act with caution even when causal links between emissions and effects have not been proven. An inherent component of the preventative design approach is that the burden of proof should not be on the environmental agency to demonstrate harm conclusively, but rather on the prospective polluter to demonstrate a lack of harm.

This early formulation of the principle clearly covers substances that are "persistent, toxic, and liable to bioaccumulate," but it has also been expanded in more recent formulations. For example, the Nordic Council's Conference on Pollution of the Seas refers more broadly to the need for an effective precautionary approach: we must "[eliminate and prevent] pollution emissions where there is reason to believe that damage or harmful effects are likely to be caused, even where there is inadequate or inconclusive scientific evidence to prove a causal link

211 For an early discussion of the concept, see Dethlefsen, *supra* note 175. The author, at 56, attributes the introduction of this concept to W. Kohlhammer (1980), Rat von Sachverstandigen fur Umweltfragen, Umwelt-probleme der Nordsee, Sondergutachten, Stuttgart.

212 1988, 27 I.L.M. 835 at 840.

between emissions and effects."[213] This refers not merely to toxic substances, but to any "pollution emissions."

This broad definition of the precautionary principle has not been without its detractors, who have argued that "acceptance of the precautionary principle is entirely an administrative and legislative matter and has nothing to do with science"[214] and should, therefore, be restricted to clearly dangerous substances which are known to be toxic, persistent, and bioaccumulative. Some scientists have challenged the precautionary principle for its avowed lack of statistical rigor because it implies that one presumes an effect to exist despite the lack of statistically significant evidence of that effect.[215] Essentially, it is argued that standard, classical statistical methods must be used, and that the result must be statistically significant before one concludes that an effect exists. This challenge, although put forward by several scientists, again reveals the widespread failure to recognize the *concepts* of type II errors and statistical power, let alone the equally rigorous procedures of statistical power analysis.[216] While power analysis may not have been applied explicitly to the marine pollution cases that led to the precautionary principle, the underlying concerns of that principle specifically parallel those of type II errors and statistical power. Thus, a major theme of the precautionary principle is the control not merely of toxic substances, where the toxicity (or persistence or bioaccumulative character) has already been demonstrated, but of *any substances*, whose "safety" has not yet been demonstrated.

Indeed, in reviewing the debate about the principle, it can be seen that its advocates argue in precisely these terms—even though, by not referring to statistical power, they too may be unaware of the concept or, at least, of its importance. Two commentators argue that the precautionary principle has "considerable scientific rigour" with a

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213 Nordic Council's Conference on Pollution of the Seas, Copenhagen, 1989. This conference included members of parliament from Belgium, Canada, Czechoslovakia, Denmark, Germany, Finland, Iceland, Ireland, the Netherlands, Norway, Poland, Sweden, Switzerland, Union of Soviet Socialist Republics, United Kingdom, and the autonomous territories of Faroe Island, Greenland, and Aland Island.

214 J.S. Gray, "Statistics and the Precautionary Principle" (April 1990) 21 Marine Poll. Bull. 174.

215 In addition to Gray, extensive debate has occurred within the LDC's Scientific Group on Dumping where, according to one report, "[a]ttitudes varied from annoyed incomprehension to something that seemed to negate the role of science in policy making": Jackson & Taylor, *supra* note 171 at 3.

216 R.M. Peterman & M. M'Gonigle, "Statistical Power Analysis and the Precautionary Principle" (1992) 23:5 Marine Poll. Bull. 231.

broader applicability to any polluting discharge, because "it protects against initiating discharges of potentially harmful substances in the absence of adequate information. Current practices can only be effective as part of a process of retrospective damage limitation."[217] The explicit use of statistical power analysis should, however, help to resolve this debate by providing the requisite scientific underpinning for the principle's broader application to any discharges (indeed, any industrial activities at all) the environmental impacts of which are uncertain.

For example, where a scientific study has failed to reject the null hypothesis of no effect of some substance, one can calculate statistical power *a posteriori*, *i.e.*, the probability that a specified magnitude of effect, if present, could have been detected statistically given the sample size used, experimental design, and other related information.[218] If power were low (less than 0.95) for that specified size of effect, claims of harmlessness should not be taken seriously since the test was too weak to detect that effect and there is, therefore, a chance that harm could occur in the future. However, if the null hypothesis of no effect were not rejected, and if power were acceptably high (0.95 or greater) for detecting the specified effect size, statements concerning the lack of the specific type and magnitude of harm tested for should be given weight. However, such conclusions of no harm would apply only under the specific conditions tested. In many instances, it is impossible to conduct separate tests for the full range of anticipated types of harm. This is because of the possibility of synergistic and cumulative effects, the wide range of types and life stages of organisms exposed, and the great variety of potentially harmful effects associated with some activities. We outlined these problems with typical experimental studies earlier in this paper.

Thus, those wanting to discharge some substance could be required to (1) conduct tests that cover a wide range of conditions in which that substance could be anticipated to be potentially harmful, (2) show that there is no harmful effect in any of the tests, and (3) show in all of the tests that statistical power is high (*e.g.*, > 0.95). Clearly, discharges would not be permitted if at least one type of unacceptable harmful effect was found. Depending on the relative costs of type I and type II errors, precautionary action regarding the discharge may be appropriate when tests are conducted for all anticipated harmful effects, no harmful effects are found, and statistical power is low (*e.g.*, < 0.95).

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217 P. Johnston & M. Simmonds, "Precautionary Principle" (1990) 21:8 Marine Poll. Bull. 402.

218 See *supra* notes 8-16.

In this way, precautionary action could be placed in a more objective and rigorous framework to identify situations in which it is justified. This approach is necessary because there have been numerous cases (discussed above) in which substances, assumed to be safe, have turned out to be harmful, and the costs of type II errors have been great.

In their discussion, Jackson and Taylor begin to acknowledge this latter point when they note:

> it is clear to us that the [precautionary] principle can and should be logically extended to any potentially harmful substance. It should not be forgotten that CFCs were once classified as harmlessly non-toxic and do not bioaccumulate, yet their persistence and chemical properties have the capacity for massive perturbation of the global ecosystem.[219]

The precautionary principle thus presumes that any regulatory procedure should begin with a presumption against the discharge of wastes unless the proponent can adequately demonstrate that harm is not likely to occur. Where tests are conducted to assess whether a discharge is or will be harmful, statistical power analysis is relevant for designing experiments, *before* they are implemented, that will have a high probability of detecting a specified level of effect, if it exists. If field or experimental data fail to show such an effect, *a posteriori* power analysis can indicate the probability of detecting that size of effect. If power is high, discharges *might* be permitted; if not, discharges *might* be prevented, depending on the relative costs of errors. These principles for action would add an important and essential element to all legislative approaches, especially those that shift the burden of proof onto industry to show that their products or processes are "safe."

2. Prior justification procedure

With the precautionary principle replacing the assumption of assimilative capacity as the scientific foundation for environmental regulation, a new procedure for translating this into practice is necessary. The use of statistical power analysis above is only one element of a possible strategy for implementing procedures. Although such procedures will clearly vary from jurisdiction to jurisdiction, the

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219 *Supra* note 171 at 31-32. With this in mind, they formulate, at 32, what they call "the principle of precautionary action": "The release into the environment of unnatural substances or natural substances in unnaturally large quantities should be avoided so far as is ecologically sensible." This definition puts a lot of weight on the phrase "ecologically sensible" which the authors define in light of varying degrees of likely harm.

so-called prior justification procedure (PJP) being developed in a number of international fora (especially OSCOM) provides a useful model of the necessary framework and institutional components applicable internationally, including in Canada. (Some similarities to several of the national procedures discussed above exist.) In addition to its recognition of the limits of the assimilative capacity approach, PJP involves governments in a regulatory process which seeks to overcome the practical limitations of testing and enforcement imposed on environmental agencies by the paradigm of permissive regulation.

The PJP consists of a series of steps with which an applicant for a permit to dispose of waste at sea must comply. Figure 1[220] illustrates a generic schematic relationship of this procedure. The application may be rejected at several stages as it passes through the schematic framework in an itinerate manner. The first hurdle to pass through is a "Prohibition Box" (Box 1). Wastes and waste sources on this list are known to be hazardous enough to be prohibited on the basis of the application of sound waste management principles.[221] If an application passes through the prohibition stage, it goes to the first assessment stage (Boxes 2 and 3) conducted by the Regional Offices of Technology Assessment (ROTA).

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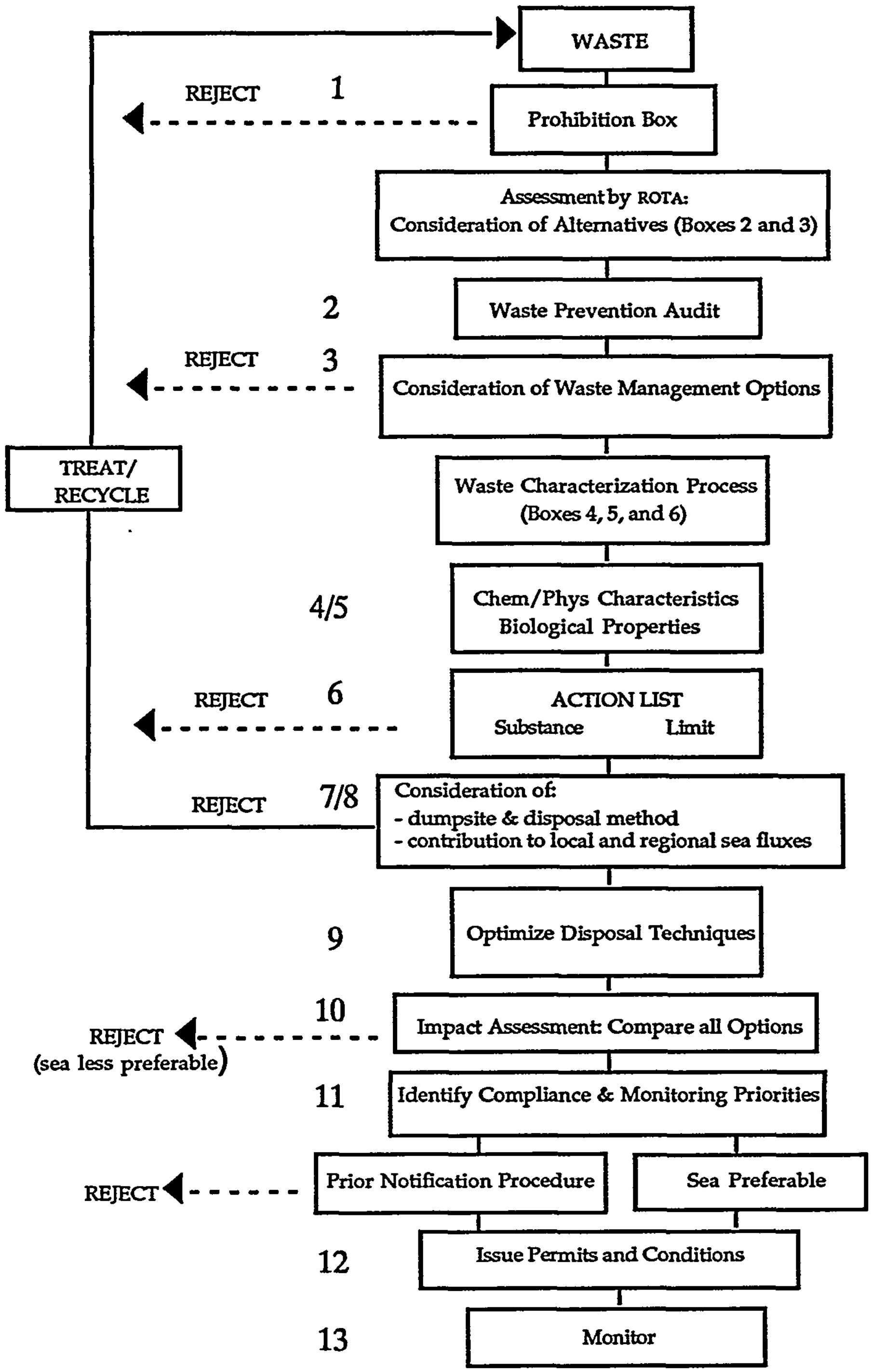
220 This figure is based on the permit framework of OSCOM and that presently being considered by the LDC under its so-called New Assessment Procedure (NAP). See the *Report to the Oslo Commission: Justification for the Issue of Permits for the Dumping of Industrial Wastes at Sea* (12-14 June 1989); and the International Maritime Organisation, *Consideration of the Report of the Third Meeting of the Ad Hoc Group of Experts on the Annexes to the London Dumping Convention* Doc. No. LDC/SG 13/2 at Annex 3 (London: 28 February 1990).

An application for disposal at sea may be rejected at six stages of the process. Applicants are required to perform waste prevention audits (Box 2), consider alternative waste management options (Box 3), and supply information regarding the character of the waste (Boxes 4, 5, and 6). The disposal method and effects on the regional seas are also taken into consideration when an application is reviewed. Finally, all proposed alternatives are compared and a permit is granted only if the sea is the preferred option. Any convention member country may object to an application through the Prior Notification Procedure. This is further discussed below.

221 In addition to known hazardous products, it may be possible to regulate substances on the basis of their inherent chemical structure; that is, to shift the basis of regulation away from proof of adverse effects to the likelihood of such effects given the inherent structure of the discharged substance.

FIGURE 1: The Prior Justification Procedure



ROTA take on a critical function in the decision framework, assessing permit applications, and providing information on the technological factors and economic considerations of pollution prevention through source reduction and clean technologies. ROTA review applications in terms of the character of the waste, the degree to which waste reduction and prevention occurs at the source, and the availability of technologically feasible alternatives to disposal. This is a two-step process consisting of a so-called waste prevention audit followed by a consideration of waste management options. The waste prevention audit is required of any new applicant or existing permit holder on a regular basis[222] and must describe: (1) the types, amount, and relative hazard of wastes generated; (2) details of the production process and of the sources of waste within that process; and (3) the feasibility of techniques of waste prevention through clean technologies. In general, information submitted in the application must include the investigation results of (1) alternative production and recycling processes; (2) separation of critical waste components by cleaning procedures; (3) destruction of the waste or its critical components; (4) economic considerations of options mentioned in (1) and (2); and (5) the environmental consequences and health risks of different options. If the required audit reveals that opportunities exist for waste prevention at the source, the applicant must formulate and implement a waste prevention strategy, including specific waste reduction targets and provisions for further audits to monitor progress towards these targets. Permit issuance or renewal is subject to compliance with this requirement.

The application must also indicate that a full range of waste management options has been considered. PJP establishes a so-called hierarchical approach to waste minimization based on the following prioritization: (1) waste prevention; (2) on-site recycling; (3) re-use; (4) destruction of hazardous constituents; (5) treatment to reduce or remove the hazard; and (6) disposal into land, air and water. Disposal—that is, permitted discharge—is the last option available. In comparing alternatives, some of the factors that must be taken into account are the projected emissions of pollutants (into all media); the risk of accidental emissions; the potential for control over both projected and accidental emissions; the projected effect on indigenous species; the risk of greater harm than projected; the risk of contamination of water supplies and the food chain; the potential for control over these risks; and, finally, the potential for remedial action in cases of contamination.

222 OSCOM permits must be reviewed every three years.

This hierarchy reflects a negative view of the permissive regulatory approach that has historically relied on the last waste management option of disposal. Indeed, it is interesting to note that risk-benefit analysis and environmental impact assessment, to the extent that they are evaluating discharges of effluents, the safety of which has not been "proven," are relegated near the bottom of the hierarchy.

The waste must be fully characterized with respect to its origin, the amount to be disposed of, the frequency of disposal, and the chemical, physical, and biological properties (Boxes 4, 5 and 6). In addition, the applicant must characterize the proposed disposal method and disposal area, and assess the risk to the environment (Boxes 7 and 8). If, on the basis of the information provided, ROTA decide that alternatives are available which have not been considered, or if the assessment of the impact of alternatives indicates that the proposed form of disposal is not a preferable option, then the application is rejected at this stage. The final stage at which an application may be rejected is through the Prior Notification Procedure which allows for other states to object to, or comment on, the proposed disposal operation. An objection must state what alternatives are available or why the proposed operation is considered harmful, and must be supported by scientific argument.

In addition to the strong presumption against ocean disposal in OSCOM's PJP, the regulatory framework of OSCOM shifts the onus onto the applicant, who must then conduct the necessary research and provide sufficient information on the key factors which constrain the use of alternatives. The role of an independent office of technology assessment is thus central to the procedure. This structure inherently encourages state-of-the-art source reduction and stimulates governments into a technology-forcing role—in other words, regulation by preventative design. Furthermore, although there is no reversal of the "burden of proof" in a judicial sense, the administrative permit procedure is rooted in a presumption against disposal, imposing on the applicant a duty to provide the necessary evidence. Moreover, the common problems of poor or incomplete industry reporting are reduced by the PJP's provision for "external review."

3. Clean production

Unlike the paradigm of permissive regulation, which is rooted in the assumption of an almost limitlessly accommodating environment, preventative design is driven by the recognition that our industrial processes must ultimately fit within a sustainable, and limited, environmental context. So long as this was not recognized, substantive goals for industrial regulation were not necessary. Given the mounting problems discussed above, this is clearly no longer possible. Those countries and international institutions leading the way in the development of a new regulatory paradigm recognize this situation, and the need which it imposes on the decision maker to shift, from reliance upon an endless process of discharging pollutants, to designing a substantive end-point for regulatory intervention—clean production.

Economic instruments play an important role in the industrial transition to the clean production technologies that are implicit in the PJP. The "polluter pays" principle was first endorsed by the member countries of the Organisation for Economic Co-operation and Development (OECD) in 1972. At this time, it was agreed in principle that environmental policies should reflect a commitment to an internalization of the costs of pollution prevention and control measures in such a way that a more rational use of scarce environmental resources is encouraged. The "polluter pays" principle requires that the polluter bear the expense of pollution prevention and control by factoring it into the overall cost of production in the same way that the costs of raw materials, energy, and labour are accounted for. In general, however, under the permissive approach, such instruments as "effluent charges" have not been oriented to achieving efficiently an absolute reduction in pollution levels, but more to allocating discharges efficiently among specific competing industries.

Without some end-point in mind, however, the charging process still produces an "inefficient" utilization of scarce capital and environmental resources. On the one hand, the permissive approach to environmental pollution is expensive. As Muldoon and Valiante remark:

> As regulation becomes more stringent and complex, it becomes more expensive for government to develop standards, evaluate permit applications and enforce compliance, and for industry ... "because it requires substantial investment in control equipment, which uses substantial amounts of energy and other resources to operate and creates residues that are costly to treat or dispose of."[223]

Despite such costs, this pattern of regulation has resulted in massive economic externalities, especially when remediation costs are included, such as the $6 billion estimated over the next thirty years to contain and

223 *Supra* note 7 at 66, quoting P. Muldoon & M. Valiante, *Zero Discharge: A Strategy for the Regulation of Toxic Substances in the Great Lakes Ecosystem* (Toronto: Canadian Environmental Law Research Foundation, 1988) at 43.

clean up just four of the largest leaking dumps on the American side of the Niagara River.[224] On the other hand, advocates of "clean production" point to numerous examples of profitable industrial transition,[225] while independent analysts often dismiss industry arguments (as in the Canadian pulp and paper industry[226]) that they cannot afford to clean up. Indeed, with some countries clearly moving ahead with a policy of industrial clean production, failure to pay the full costs of production when other industries are doing so is not merely poor business planning, but might even be considered an unfair subsidy which could jeopardize the international competitiveness of the industry.[227]

Under the preventative approach, economic incentives are used more broadly to foster clean production. Clean production is

> a conceptual and procedural approach to production that demands that all phases of the life-cycle of a product or of a process should be addressed with the objective of prevention or the minimization of short and long-term risks to humans and to the environment.[228]

Clean production envisions a range of strategies including good housekeeping, on-site closed-loop recycling, input substitution, process modification, low-impact technologies, and product reformulation. Economic instruments can be used in any one of these areas, including penalizing the very use of toxic substances in the production process. For example, fees for the use of toxic substances are being implemented to finance progressive waste reduction initiatives created under

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224 See *A Prescription for Healthy Great Lakes*, *supra* note 199 at 7.

225 See, for example, D. Huisingh *et al.*, *Proven Profits from Pollution Prevention: Case Studies in Resource Conservation and Waste Reduction* (Washington: Institute for Local Self-Reliance, 1986).

226 See Sinclair, *supra* note 36 at 95- 96, who notes that "the vast majority of mills operating in Canada during 1988 could have adopted the latest in available effluent control [at a cost of $14 per tonne, and that this] ... would not pose a threat to any but the least efficient of those operating within the industry."

227 In his much-praised report on Canadian competitiveness, *Canada at the Crossroads: The Reality of a New Competitive Environment* (1991) at 58, M. Porter notes:

> Stringent standards and regulations for product performance and environmental impact can create and upgrade competitive advantage by pressuring firms to improve product and process quality ... With some exceptions, [Canadian] environmental standards have rarely been at the forefront of international practices, with the result that industries such as pulp and paper are having to undertake substantial investments simply to catch up.

228 Bass *et al.*, *supra* note 174 at 19.

legislation such as the Massachusetts *Toxic Use Reduction Act*.[229] Economic incentives also play an important role in achieving waste minimization goals in many European countries. Positive economic incentives, such as direct financial and technical assistance, are used to promote the development and implementation of clean technologies. Negative economic incentives are used to promote hazardous waste minimization by increasing the cost of waste production, treatment, and disposal. By being tied to a detailed analysis of the industrial processes in use, this approach is also more easily implemented as part of the permit procedure than the dominant Canadian system of judicially enforced fines for end-of-pipe permit violations.

VII. CONCLUSION

In this article, we have pointed out the frequent occurrence of uncertainty in scientific studies of causes and effects, and have discussed the concept of statistical power analysis as a means of quantifying the probability of the kind of error that is often ignored: failing to detect a specified effect when one is present. The prevalence of these type II errors in the past and their high cost has led us to re-examine Canada's model of environmental regulation in light of a more fully scientific approach. In contrast to the piecemeal approach to reforming the present paradigm of permissive regulation, the revolution in regulatory strategies, evident in a diverse number of multilateral agencies, state and national governments, points to a new paradigm which has gained wide international acceptance. Canadian legislation, regulatory action, and environmental decision making have yet to recognize this dramatic shift. To facilitate this transition in Canada, a new approach is needed.

This new approach is that of preventative design. The permissive model is no longer viable because it cannot work well in the face of the large uncertainties presently found. Its failure demands a comprehensive rethinking and restructuring of existing legislation, as well as a basic reorientation of judicial decision making. Standards must no longer be set without the recognition of uncertainty. Instead, the inescapable presence of uncertainty should lead to a shift of the

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229 *An Act to Promote Reduced Use of Toxic and Hazardous Substances in the Commonwealth*, House Bill No. 6161, Boston, 26 June 1989. See especially § 19. The fee structure requires payment of amounts consisting of a base fee, and additional amounts according to the number of employees and the amount of chemicals used.

regulatory burden onto those seeking to utilize, and profit from, our common environment's questionable assimilative capacity.

Rigorous science recognizes the need to account for uncertainty. The application of statistical power analysis to test design is a crucial step, and this formal recognition of uncertainty can become the foundation of the precautionary principle and the paradigm of preventative design. This model of regulation now has precedents to follow, including the Massachusetts *Toxic Use Reduction Act*, and OSCOM's Prior Justification Procedure. These precedents point to the importance of new management techniques (economic penalties are an essential tool) and agencies oriented to technology-forcing and industrial design. As the review of American legislation concludes, "[g]overnment action is needed to provide incentives and information to fundamentally change industry's focus on pollution control towards toxics use reduction."[230] Similarly, the judiciary must be more cognizant of the implications of scientific uncertainty in order to respond realistically and imaginatively to problems of causation. Reallocating the burden of proof from the environmental management agencies or public to the polluter, and setting appropriate standards of proof, are important ways to begin.

[230] Ryan & Schrader, *supra* note 172 at 6.