http://books.google.com/books?id=p8OC3HT6bmwC&printsec=frontcover#v=onepage&q=weight%20of%20the%20evidence&f=false

Protecting Public Health and the Environment: Implementing The Precautionary Principle

By: Carolyn Raffensperger

(Island Press © 1999)

Edited by Carolyn Raffensperger, Joel Tickner

…Criteria and Structure for Decision Making About Harm Under Uncertainty

"**A structure for operationalizing the Precautionary Principle needs to provide clear instructions to inform decision makers on how to weigh scientific and other evidence about the likelihood of harm**. Deciding whether there is enough evidence of potential or actual harm or take action is perhaps the most contentious aspect of the decision-making process. There are two important questions that must be asked in developing criteria and structure for precautionary decision making: First, does a legal regime for the Precautionary Principle establish some standard of proof of harm at which level precautionary action would taken?4; and what information should be included in decision making?

…**Decision making about associations or likelihood of harm under the Precautionary Principle should be based on a 'weight-of-evidence' approach, *rather than* on some quantitative probability of harm (as is the case with risk assessment approaches)**.

The weight-of-evidence approach to decision-making takes into account the cumulative weight of information from numerous sources that address the question of injury or the likelihood of injury to living organisms (IJC, 1995).5 Types of information that might be considered include observational studies, worker case histories, toxicological studies, exposure assessments, epidemiologic studies, and monitoring results. **Based on the weight of evidence, a determination is made as to whether an activity has caused or is likely to cause harm and the magnitude of that harm.6**

Lists of criteria for evaluating information on causal associations (cause-and-effect relationships) and potential harm have been proposed by numerous authors. These criteria guide the collection and analysis of information, as well as the questions asked by decision makers. (p.169)

…Some of the criteria address causal inference (such as the Hill criteria and those of the Massachusetts Weight-of-Evidence Committee) while others address magnitude of harm and considerations for weighing evidence of potential harm. (pp. 169-170)

The Massachusetts criteria, which were developed within an ecological risk assessment framework, provide some important criteria for assessing cause and effect relationships, but many of those criteria would require substantial quantitative evidence before such a relationship can be established, and this could undermine precautionary action.

The Dovers and Ludwig criteria indicate that a determination of causal association may not be necessary when an activity could potentially have irreversible, widely distributed, or multigenerational impacts. In other words, they address the 'decision-stakes' of a particular decision under uncertainty (Funtowicz and Ravetz, 1991).

The weight-of-evidence determination (or the determination of whether to allow an activity to continue or restrict it) would vary depending on the range and scale of impacts and the availability of alternatives (or other means) to prevent the hazard.

…The decision-making criteria and weight-of-evidence determinations can be incorporated into a decision tree/process type format. The analysis would consist of two parts. The first branch would deal with **existing hazards**. In this case if the weight of the evidence indicated actual or possible harm, preventive action would be taken. **Preventive action** would consist of stopping the activity, requiring an analysis of alternatives to the proposed activity, or undertaking mitigating measures. If ***insufficient evidence of harm*** was **available to arrive at a weight-of-evidence determination, the proponent of the activity would have the burden of providing evidence of no harm** (subject to independent evaluation). **If this evidence was simply not available and uncertainty remained, *precautionary measures*…would be taken**.

A second part of the analysis targets **new chemicals, products, or work activities**. **The initiator would conduct an initial impact statement**

identifying potential impacts of the activity, potential alternatives, and the proposed action. ***Precaution would serve as a default presumption* until the weight-of-evidence determination demonstrated that there was no safer alternative for the activity that would fulfill the needs of the initiator, and that there is a necessity for such activity – or that the activity posed *no real risk***. The weight of the evidence analysis would also identify potential adverse impacts of that activity and monitoring/investigation requirements for the initiator. (p. 170)

Depending on the level of uncertainty about cause-effect and the potential magnitude of the impacts of an activity, different levels of precautionary action might be warranted. **Different levels of evidence of harm could lead to different types of responses ranging from weak to strong precaution** (e.g., study requirements or substantive requirements, such as mitigation or alternative development). **For example, an activity for which we have only minimal evidence of harm and for which harm, if it were to occur, is minimal, would possibly lead to increased monitoring;7 an activity for which we have some evidence of harm would require preventive or remedial action and monitoring (depending on the magnitude of the problem); and an activity for which we are fairly certain of harm for which damage, should it occur, would be large or irreversible would be limited or prohibited**."(p. 171)

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http://sustainableproduction.org/precaution/back.brie.putt.html

Putting Precaution into Practice: Implementing the Precautionary Principle

By Joel Tickner, Sc.D.

Excerpted from: Tickner, Joel. **A Map Toward Precautionary Decision-making**. In Raffensperger, C. and J. Tickner, eds. 1999.**Protecting Public Health and the Environment: Implementing the Precautionary Principle**. Washington, DC: Island Press

..**Under a precautionary decision-making structure**, evidence of harm from multiple sources is considered, as well as evidence of alternatives to prevent harm and the magnitude of possible harm (severity, irreversibility, and scale) from an activity. The latter two

are considered just as important in the decision-making process as evidence of harm. In this regard, if there is information about safer alternatives or if the magnitude of potential harm from an activity is great, it may be possible to partially or entirely bypass the costly and often contentious determination of causality that is central to current decision-making structures. **For example, if an activity could cause wide-spread, irreversible harm or it could harm sensitive members of a population (for example children), it would be prudent to take action, even before reasonable evidence of harm has been accumulated.** At any rate, harm to a small number of people or a limited geographic area should be prevented before causal links are established, especially if alternatives are available. It is also necessary under a precautionary decision-making structure to consider uncertainty, indeterminacy (large scale uncertainty) and ignorance (what we might not know), which are rarely thoroughly evaluated under current structures. Large uncertainty about cause-effect relationships would favor action to prevent harm while further studying the problem. That is action taken in advance of certainty.

Decisions about the likelihood of harm are made under this structure based on a "weight of evidence" approach, taking into consideration all of the available information from various kinds of sources, the magnitude of impacts and availability of alternatives. **This differs from the current quantitative approach to decision-making that quantifies risk based on a limited amount of information**. ***A central aspect of this structure is the shifting burdens onto the proponents of potentially harmful activities to provide information on its safety, need for an activity, and availability of alternatives***. If reasonable scientific evidence and experience (in contrast to certainty) indicate that harm has or might occur, then the activity would be presumed harmful until proven otherwise.

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http://www.greens.org/s-r/23/23-17.html

***Synthesis/Regeneration* 23 (Fall 2000)**

Biodevastation

Precautionary Principle: Current Status and Implementation

*by **Joel Tickner**, Lowell Center for Sustainable Production, University of Massachusetts, Lowell, and Nancy Myers, **Science and Environmental Health Network***

...Science must better anticipate harm and identify solutions. This requires **qualitative methods in decision-making, that is, the exercising of good judgment. For example, a weight-of-evidence approach examines the cumulative sum of information, including common sense and experience**. ***We must develop decision-making approaches that go beyond examining risk and causality*** to consider the magnitude of potential harm, reversibility, temporal and spatial scales, vulnerable populations, need, and availability of alternatives.

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http://www.sehn.org/pdf/ppep.pdf
INT J OCCUP ENVIRON HEALTH 2000;6:270–280

Special Series

The Precautionary Principle and Environmental Policy Science, Uncertainty, and Sustainability

Precautionary Principle in International Law

CLAUDIA SALADIN, JD

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The precautionary principle is increasingly at the center of national and international debate over environmental and public health policy making. A broad range of individuals in the environmental and public health communities and in government are interested in the principle as a guiding principle of environmental and public health policy making that should inform all steps in the decision-making process.1 **The precautionary principle in the**

policy dialog is fairly clearly articulated; significant elements include:

• taking precautionary measures even if not all cause and effect relationships are fully understood;
• shifting the burden of proving safety onto the proponent of a potentially harmful activity;
• making environmental and public health decisions in an open, informed, and democratic way;
• examining the full range of alternatives to a particular activity; and
• relying on a weight-of-the-evidence approach, *rather than waiting for absolute certainty*.

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http://www.organicconsumers.org/Toxic/precautionarybook.pdf

THE PRECAUTIONARY PRINCIPLE IN ACTION: A HANDBOOK

First Edition

Written for the Science and Environmental Health Network

By Joel Tickner – Lowell Center for Sustainable Production Carolyn Raffensperger – Science and Environmental Health Network and Nancy Myers

...Step Five: Determine the course of action.

Take all the information collected thus far and determine how much precaution should be taken stopping the activity, demanding alternatives, or demanding modifications to reduce potential impacts. A useful way to do this is by **convening a group of people to weigh the evidence, considering the information on the range and magnitude impacts, uncertainties, and alternatives coming from various sources. The weight of evidence would lead to a determination of the correct course of action.**

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http://books.google.com/books?id=X_vS751dIAgC&pg=PA112&lpg=PA112&dq=precautionary+principle+%2B+weight+of+the+evidence&source=bl&ots=DDqN9p-xqb&sig=vXK3wElFI3MptGlcjMTxFDA2vOc&hl=en&sa=X&ei=6MuLUvXUGPKy4AOU94GADw&ved=0CDUQ6AEwAjgK#v=onepage&q=precautionary%20principle%20%2B%20weight%20of%20the%20evidence&f=false

Is It Safe?: BPA and the Struggle to Define the Safety of Chemicals

By Sarah A. Vogel

"In the broadest terms, **"weight of the evidence" is a methodology used in law and science to evaluate the persuasiveness of data**. In law, the strength of the evidence, or burden of proof, varies according to whether a case is a criminal or civil one. In a criminal case, the burden of proof for guilt is more demanding, requiring the weight of the evidence to be beyond a reasonable doubt, whereas in a civil case guilt rests on the preponderance of the evidence.

In science, however, models for assessing the weight of the evidence can vary considerably. Among the most frequently cited models for evaluating the evidence are Robert Koch's late nineteenth-century postulates for establishing a causal relationship in the study of infectious disease and Sir Bradford Hill's criteria for causality and correlation in the study of chronic disease…**Hill, a well-known British epidemiologist, outlined nine criteria for assessing the causal relationship between an exposure and a suspected effect in epidemiology, with particular attention to environmental hazards in the workplace**…***Hill's criteria for assessing correlation and causality*** **include the statistical strength of the association, consistency, specificity, temporality (exposure before outcome), plausibility, biological gradient (i.e., dose-response relationship), coherence, experiment, and analogy**.

…Drawing from ecological and social epidemiological models, the IJC Working Group integrated complex variables, such as multiple exposures, transgenerational exposures, bioaccumulation, and the long latency of disease, to present a fuller picture of where uncertainty existed and where there was evidence of serious effects. **This was a deliberate effort to develop a process to assess the weight of the evidence that would allow for precautionary decision making** in the face of uncertainty, a challenge posed not only by problems of ecological health but also by other complex scientific problems such as climate change.

…**The codification of the precautionary principle in these treaties [Montreal Protocol on Substances that Deplete the Ozone Layer in 1987 and the Third North Sea Conference in 1990]** demonstrated an emergent political acceptance, at least in European nations, of the notion that **in the face of ecological complexities, and given evidence of risks of irreversible environmental damage, some action or government intervention may be justified before a high burden of proof of causation can be met**.

Colborn's weight-of-the-evidence evaluation of Great Lakes wildlife research sought to integrate the precautionary approach into the evaluation of complex evidence. It evaluated evidence in multiple species and drew extensively on historical data. The pattern of evidence observed suggested that the most serious health problems and abnormalities didn't appear in adults but disproportionately affected young offspring."
(pp. 110-113)

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http://www.precaution.org/lib/ehp_kriebel.pdf
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The Precautionary Principle in Environmental Science

David Kriebel,1 Joel Tickner,1 Paul Epstein,2 John Lemons,3 Richard Levins,4 Edward L. Loechler,5 Margaret Quinn,1 Ruthann Rudel,6 Ted Schettler,7 and Michael Stoto8

"…**In this paper we examine the implications of the precautionary principle for environmental scientists**, whose work often involves studying highly complex, poorly understood systems, while at the same time facing conflicting pressures from those who seek to balance economic growth and environmental protection. In this complicated and contested terrain, it is useful to examine the methodologies of science and to consider ways that, without compromising integrity and objectivity, research can be more or less helpful to those who would act with precaution. **We argue that a shift to more precautionary policies creates opportunities and challenges for scientists to think differently about the ways they conduct studies and communicate results**.

…**Setting Type I and Type II Error Rates**

Errors due to sampling variability are routinely quantified. However, standard practice has led to a conservatism that perhaps hinders precautionary action. When a scientific investigation is designed to test a hypothesis, there are two kinds of errors that one seeks to minimize. **A Type I error is the mistake of concluding that a phenomenon or association exists when in truth it does not**...By convention, Type I (or alpha) errors are guarded against by setting that error rate low, usually at 5%. In other words, the finding must be so strong that there is less than a 5% probability that this result would have been seen by chance alone in a world in which no such phenomenon actually exists. In this case the result is called statistically significant (with the clear implication that one is supposed to believe it). **The Type II error, failing to detect something that actually does exist**, is, by convention, often set at 20% (although practical limitations of sample size often result in a substantially higher or lower Type II error).

Twenty percent of the time, a real phenomenon will be missed because the data were not strong enough to convincingly demonstrate its existence. There is an implicit bias here: the test is set up to be more cautious about falsely detecting something than about failing to detect something. Should Type I and TypeII error rates be set explicitly and a priori, depending on the purposes that the study is meant to serve?

Bayesian statistical methods promise a way out of these conundrums by shifting the focus from formal testing to calculating the weight of evidence provided by a particular study and the degree to which this study should shift a priori beliefs. At present, Bayesian methods are little used in practice, but research to make them more accessible and practical is now under way.
(pp. 873-874)

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http://www.consiliencejournal.org/index.php/consilience/article/viewFile/5/4

Reducing Uncertainty: The Need to Clarify the Key Elements of the Precautionary Principle

Aaron Holdway1

2. Level of evidence required to prove safety

Clarification and elaboration is also required on **the level of evidence required to avoid the invocation of the precautionary principle**. Many definitions are vague about how

much certainty must be demonstrated regarding a product or activity's safety. **For example, the UN World Charter for Nature refers to cases where threats are "not fully understood," and the SPS Agreement refers to cases where scientific evidence is "insufficient."** Does this mean that industrialists or potential polluters must show that their product or process is safe with complete certainty ("zero risk"), or beyond a shadow of a doubt, or beyond a reasonable doubt, or beyond the balance of probabilities, or some other measure? Definitions like the Rio Declaration, which refer to "lack of full scientific certainty" (emphasis added), overlook the fact that it is impossible to prove the "absence of harm."42 **If it is acknowledged that the standard should be "one of weight of evidence rather than of absolute proof,"43 it should be made clear which of the above degrees of evidence is required.**

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43 Kheifets, L. I., Hester, G. L., & Banerjee, G. L. (2000), *The precautionary principle and EMF: Implementation and evaluation*, Journal of Risk Research, 4(2), 113-125.

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http://people.reed.edu/~ahm/Courses/Reed-POL-372-2011-S3_IEP/Syllabus/EReadings/05.2/05.2.FosterVecchia2000-Risk.pdf

Science and the Precautionary Principle

Author(s): Kenneth R. Foster, Paolo Vecchia, Michael H. Repacholi
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Accessed: 12/07/2010 17:17

An issue of particular interest to scientists is the relation if, any, of the **[precautionary] principle** to science-based risk assessment. The principle was initially applied to environmental issues, such as ocean dumping of pollutants,that are characterized by sparse scientific data useful for making policy. Its use has now expanded to protection against environmental health risks,for which extensive toxicological and epidemiological data are often available, notwithstanding gaps and inconsistencies in the evidence. **The question arises how to reconcile the principle with the weight of evidence analysis typically used by scientists and health agencies. (p. 979)**

…**Clear guidelines are still lacking for the *weight of evidence* needed to trigger the principle, and for deciding which of the large range of precautionary measures** should be applied in given circumstances. Different standards of proof seem to be needed to invoke the principle than for other regulatory actions-but how much different are they? Can one justify using the principle to limit public exposure to RF energy to levels far below the threshold for established hazards to address public concerns on the basis of scientific data that major scientific review committees find unpersuasive of a hazard? Conversely how much evidence of safety should proponents of a new technology be required to provide? Such issues will generate endless controversy and, indeed, may only be settled by litigation(17)

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http://www.tufts.edu/~skrimsky/PDF/AJPH_WOE.PDF

The Weight of Scientific Evidence in Policy and Law

Sheldon Krimsky, PhD

Supplement 1, 2005, Vol 95, No. S1 | American Journal of Public Health Krimsky | Peer Reviewed | Public Health Matters | S129

The term **"weight of evidence" (WOE) appears in regulatory rules and decisions**. However, there has been little discussion about the meaning, variations of use, and epistemic significance of WOE for setting health and safety standards. **This article gives an overview of the role of WOE in regulatory science**, discusses alternative views about the methodology underlying the concept, and places WOE in the context of the Supreme Court's decision in ***Daubert v Merrell Dow Pharmaceuticals, Inc*** (1993). **I argue that whereas the WOE approach to evaluating scientific evidence is gaining favor among regulators, its applications in judicial processes may be in conflict with some interpretations of how the *Daubert* criteria for judging reliable evidence should be applied**. (Am J Public Health. 2005;95:S129–S136. doi: 10.2105/AJPH.2004.044727)

…**A distinction has been made between WOE and "strength of evidence" (SOE).**4 The latter **[SOE] is associated with the gravitas and relevance of information related to a specific indicator, such as the number of tumors produced in animals.** In contrast, **WOE includes all varieties of evidence, positive and negative, mechanistic and nonmechanistic, in vivo and in vitro, as well as human and animal studies**. ***In risk assessment, the trend has been to widen the lens of relevant empirical and theoretical evidence, thus moving from approaches that utilize "strength of evidence" to those that utilize WOE***. In this article I shall speak exclusively of WOE and assume that it encompasses the use of strength of evidence.

The WOE approach has been introduced into ecological risk assessment since the early 1990s in response to the need for better risk analyses of Superfund sites and impacted natural ecosystems.5,6 One consensus report on WOE defined it as "the process by which multiple measurement endpoints are related to an assessment endpoint to evaluate whether a significant risk of harm is posed to the environment."7