

August 24, 2004



Arthur G. Baggett, Jr., Chair  
Members of the Board  
State Water Resources Control Board  
P.O. Box 100  
Sacramento, CA 95812-0100

**Re: Comments on the July 2004 Draft "Water Quality Control Policy for Developing California's Clean Water Act Section 303(d) List Functional Equivalent Document"**

Bay Area  
Clean Water Agencies

Bay Planning Coalition

California Association  
of Sanitation Agencies

California Council for  
Environmental &  
Economic Balance

California Manufacturers  
& Technology Association

Chemical Industry  
Council

Contra Costa Council

Oakland Metropolitan  
Chamber of Commerce

Pacific Merchant  
Shipping Association

Sun Leandro  
Chamber of Commerce

Tri-TAC  
Sponsored by:  
League of California Cities  
California Association of  
Sanitation Agencies  
California Water Environment  
Association

Western States Petroleum  
Association

Craig S.J. Johns  
Executive Director

Dear Chairman Baggett and Members of the Board:

The Partnership for Sound Science in Environmental Policy (PSSEP) appreciates the opportunity to comment on the July 2004 "Draft Water Quality Control Policy for Developing California's Clean Water Act Section 303(d) List Functional Equivalent Document" (FED). PSSEP is an association of San Francisco area and statewide public and private entities – businesses, municipal wastewater treatment agencies, trade agencies and community organizations. Our members have been actively involved in the stakeholder process leading to this most recent draft, and have provided comments on previous drafts of the Listing Policy and FED.

Although PSSEP is interested in many aspects of the Listing Policy, as it will affect all of our members directly or indirectly, our comments are limited to a single issue that arises in Appendix B to the FED, "Responses To Comments." For the record, PSSEP supports the comments submitted by others from the regulated community, including those from the AB 982 PAG Regulated Caucus (dated August 24, 2004).

The single issue this letter focuses on is the apparent - - if implicit - - embrace by State Board staff of the so-called "Precautionary Principle." We say "apparent" and "implicit" because of the ambiguous language used by staff in claiming that, "The process undertaken to develop the [Listing] Policy, the draft Policy itself, and the FED embody the spirit of the [Precautionary Principle]. (FED, Appendix B at p. B-47.)

The validity of the "Precautionary Principle" has become a very controversial issue at various levels of government, and presents the State Board with an unnecessary challenge to adopting a policy for listing and delisting impaired waters in the state. We have enclosed some background information on the "Precautionary Principle" and why we strongly oppose its use.

According to the Responses to Comments, State Board staff received only three comments on the December 2003 draft Listing Policy that raised the "precautionary principle." (See, Appendix B at p. B-47 (Sheehan, L., O'Brien, L., and Wilson, R.)) Staff summarizes these collective comments as follows:

Arthur G. Baggett, Jr.  
Members of the State Board  
August 24, 2004  
Page 2

“The Precautionary Principle is intended to deal with uncertainty. It expresses the ‘safe’ way of handling uncertainty. The draft Policy takes an anti-precautionary approach and tolerates a high level of potential harm before taking action. It uses uncertainty as a rationale for inaction. It adopts the position that a water body is clean until proven dirty. It creates disincentive for dischargers to contribute to additional, much-needed monitoring, because such monitoring might be used to build the case that the water segment is, in fact, impaired.”

(FED, Appendix B at p. 47, Comment Numbers 51.5, 51.7, 51.8, 51.9, 105.5, and 219.1.)

The Responses provided by staff to these comments are troubling, and arguably suggest to the reader that the State Board has, in fact, adopted the “Precautionary Principle” as enunciated in the FED document. There are several reasons why PSSEP objects to the staff’s discussion of the “Precautionary Principle” in the FED. First, to our knowledge, the issue of whether the “Precautionary Principle” (in *any* of its various forms and definitions) should be the basis on which all State and Regional Board decisions are to be based, has never been discussed, let alone decided by the California Legislature, Cal/EPA or the State Board.

Second, staff refers to the so-called “Rio Declaration” - - and specifically Principle 15) - - from the Rio Conference on the Environment and Development as the basis for the Precautionary Principle. Staff further identifies “guidelines” adopted by the Commission of European Communities (CEC) that were intended to implement the precautionary principle. Finally, staff cites each CEC guideline, and explains how and why the Listing Policy is consistent with the guidelines. The reliance on the CEC guidelines is wholly inappropriate and should be removed entirely from a discussion about the Listing Policy. To our knowledge, these guidelines have never been discussed, let alone approved, by the State Board - - or *any* board, department or office within Cal/EPA.

Third, inclusion of the Precautionary Principle issues in the FED - - and specifically, reliance on the Rio Declaration and CEC guidelines - - will suggest that the State Board has formally adopted the Precautionary Principle, or at least based the Listing Policy on it. In turn, this suggestion will be further relied upon by certain advocates seeking to inculcate every Regional Board decision with the Precautionary Principle. For many reasons, this would be a serious mistake.

Fourth, the U.S. Commission on Ocean Policy recently considered *and rejected* using the precautionary principle as the basis upon which all ecosystem management decisions should be made. (See, “*Preliminary Report of the U.S. Commission on Ocean Policy, Governors’ Draft, Washington, D.C., April 2004,*” at pp. 35-36 (hereafter, “Ocean Policy Report”; excerpts enclosed, full report at: <http://www.oceancommission.gov>.) In issuing its Ocean Policy Report in April of 2004, the Commission noted that “the precautionary principle has been proposed by some parties as a touchstone for managers faced with uncertain scientific information.” (Ocean Policy Report at p. 35.) Yet, in rejecting the precautionary principle, the Commission also noted that, “[w]hile this may appear sensible at first glance, *its application could lead to extreme and often undesirable results.*” (Ocean

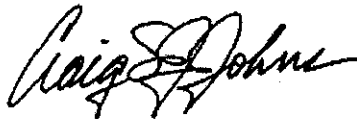
Arthur G. Baggett, Jr.  
Members of the State Board  
August 24, 2004  
Page 3

Policy Report at p. 35, emphasis added.) Instead, the Commission recommended "a more balanced *precautionary approach* that weighs the level of scientific uncertainty and the potential risk of damage as part of every management decision"

Fifth, any suggestion that the State Board has adopted or relied upon the "Precautionary Principle" as set forth in Principle 15 of the Rio Declaration, and the CEC guidelines, conflicts with the recent work of the Cal/EPA in developing its "Environmental Justice Action Plan." As recently as August 13, 2004, the Secretary for Cal/EPA released the latest draft of the Environmental Justice Action Plan, which calls for, among other things, the development of guidance on specific "precautionary approaches" appropriate for all of the Cal/EPA boards, departments and offices. It is no accident that the phrase, "precautionary approach" was used, as reliance on the "precautionary principle" was specifically rejected. Even the Cal/EPA Advisory Committee on Environmental Justice rejected inclusion of the term "*precautionary principle*" in its October 7, 2004 recommendations report because of the controversial nature of the principle and because of extensive public testimony that the Committee heard against the *precautionary principle*.

PSSEP respectfully requests the State Board to direct staff to remove the responses provided in Appendix B at pages B-47 through B-50 as they related to the "*Precautionary Principle*," the Rio Declaration, and the CEC guidelines for implementation of the *Precautionary Principle*.

Sincerely yours,



Craig S.J. Johns  
Executive Director

Enclosures

Cc: Mr. Terry Tamminen, Secretary, Cal/EPA  
Ms. Tam Doduc, Deputy Secretary, Cal/EPA  
Members, PSSEP



## What is the *Precautionary Principle*?

The *Precautionary Principle* is a relatively new regulatory approach increasingly being touted by many environmental, public health, and community-based organizations as a means to “fix” our current regulatory system to prevent harm to the environment or human health from new and existing products or activities. Although there is no widely accepted or widely used definition of the *Precautionary Principle*, the basic premise is that decision-makers should implement regulatory measures to prevent or restrict actions that may harm humans or the environment, even though there is incomplete scientific evidence to assess the significance of the potential harm.

The *Precautionary Principle* is sometimes represented as “erring on the side of safety” or “better safe than sorry.” The various definitions have significant differences in meanings and implications. The strong versions of the *Precautionary Principle* encourage decision-makers to take no action unless they are certain that it will do no harm. These strong versions do not allow for any risks and require proof that a product or activity is absolutely safe. The weaker versions of the *Precautionary Principle* usually state that a decision-maker does not have to have full certainty to justify prevention of something that may be harmful. These weaker versions may use risk assessment and scientific evaluation initially, but require the decision-maker to err on the side of caution if the information is incomplete. Below are some more commonly used definitions of the *Precautionary Principle*:

“When information about potential risks is incomplete, basing decisions about the best ways to manage or reduce risks on a preference for avoiding unnecessary health risks instead of on unnecessary economic expenditures.” (US EPA)<sup>1</sup>

“Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.” (Principle 15 of the Rio Declaration on Environment and Development, 1992.)<sup>2</sup>

When “potential adverse effects are not fully understood, the activities should not proceed.” (The United Nations World Charter for Nature.)<sup>3</sup>

“When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not established scientifically. In this context the proponent of the activity, rather than the public, should bear the burden of proof.” (Wingspread Declaration.)<sup>4</sup>

<sup>1</sup> <http://www.epa.gov/OCEPA/terms/pterm.html>

<sup>2</sup> <http://www.unep.org/Documents/Default.asp?DocumentID=78&ArticleID=1163>

<sup>3</sup> <http://www.un.org/documents/ga/res/37/a37r007.htm>

<sup>4</sup> <http://www.gdrc.org/u-gov/precaution-3.html>

**How does use of the *Precautionary Principle* differ from our current regulatory approach?**

Most regulatory decisions in the United States are based on scientific evidence and risk assessment. This system allows for the maximum benefits (improvements in the quality of products and/or life) while identifying and minimizing any potential hazard, both near and long term. It encourages innovation, economic growth and consumer power while minimizing consumer and environmental risk.

The *Precautionary Principle* represents a radical shift in how public policy is to be developed. It focuses on the *possibility* that technologies or actions could pose unique, extreme, or unmanageable risks, even after considerable testing has already been conducted. The *Precautionary Principle* fails to acknowledge that even when technologies introduce new risks, most confer net benefits — that is, their use reduces many other, often far more serious, hazards. Examples include blood transfusions, MRI scans, and automobile air bags, all of which offer immense benefits and only minimal risk.<sup>5</sup>

Although the United States has - - and should - - not formally adopted the *Precautionary Principle* as a regulatory system, it incorporates precautionary approaches in statute and guidelines. Regulatory evaluations commonly use extremely conservative assumptions and factors of safety to determine if or how a product can be used. These assumptions can include basing decisions on the impacts to high risks groups or the most sensitive species, adding factors of safety for unknown information and for future possible impacts, and similar types of conservative assumptions.

In addition, laws in this country put the burden of a safe product on the proponent of the activity in many instances. For example, within the United States food safety system, food processors are allowed to offer consumers only food that is safe. They may be held "strictly liable" if they fail to carry out their duty. "Strict liability" means that a processor who sells a food that causes injury to a consumer may be legally responsible even in the absence of actual knowledge of the product's hazard. The legal responsibility includes both the possibility of a private lawsuit by any injured consumers and the possibility of regulatory actions. Also, processors must have a reasonable basis for believing their products to be safe; they cannot simply assume this is so.<sup>6</sup>

**What are some concerns about the *Precautionary Principle*?**

The *Precautionary Principle* calls upon governments to impose regulatory measures based upon the barest potential of environmental or human harm. In other words, if a chemical substance *might* cause harm, it should be controlled or eliminated. If a new technological innovation *could* have unknown environmental effects, it should be prohibited. If a given action *could* harm a species that *might* be endangered, it should not be allowed. The *Precautionary Principle* may appeal viscerally to common-sense notions of safety, but its application will not produce a safer, cleaner world. Quite the opposite — the incorporation of the *Precautionary Principle* in environmental, health, and safety regulation is itself a threat to environmental protection and optimal safeguards for public health.<sup>7</sup>

<sup>5</sup> Conko, Gregory and Henry I. Miller, "The Perils of Precaution," Policy Review On-Line, Hoover Institution, June 2001. <http://www.policyreview.org/jun01/miller.html>

<sup>6</sup> Food and Drug Administration, U.S. Department of Agriculture. "United States Food Safety System, Precaution In U.S. Food Safety Decisionmaking: Annex II to the United States' National Food Safety System Paper," March 3, 2000. [www.foodsafety.gov/~fsg/fssyst4.html#a-intro](http://www.foodsafety.gov/~fsg/fssyst4.html#a-intro)

<sup>7</sup> Adler, Jonathan, "Dangerous Precaution: The precautionary principle's challenge to progress," National Review Online September 13, 2002. <http://www.nationalreview.com/adler/adler091302.asp>

The strongest definitions of the *Precautionary Principle* would require proof that no harm would be done by an action or product before it could be approved. Proving that an action would not harm anyone or anything now or in the future is impossible. Science cannot prove an absence of risk.

Implementing the weaker definitions of the *Precautionary Principle* would focus more effort on possible hazards, thus adding to regulation. Significant resources would be diverted to solve a possible hazard and “prove” no harm where science has not yet shown a hazard to exist. Regulators would be required to review a host of “possible” hazards rather than focusing on real and serious hazards. Regulatory schemes that divert attention, ingenuity, and money from real threats to minor risks, in the end, make us less safe.

The *Precautionary Principle* can also be used as a rhetorical weapon. Application of the *Precautionary Principle* has already elicited unscientific, discriminatory policies that inflate the costs of research, inhibit the development of new products, divert and waste resources, restrict consumer choice, and introduce new barriers to trade.<sup>8</sup>

The variations in the definitions and terms used within these definitions also lead to confusion and subjective application. For example, what are the limits, in terms of scientific uncertainty, of severity and irreversibility of consequences, over which the *Precautionary Principle* should apply? Without a clear understanding of the Principle, it will never be able to be implemented in a fair and consistent manner.

#### **Where has the *Precautionary Principle* been implemented and what are the outcomes?**

The *Precautionary Principle* is set forth in the European Union (EU) treaty and some other international treaties. The European Union is the most active in employing the *Precautionary Principle*, with Sweden and Germany taking the lead. In the United States, Hawaii, Massachusetts, Minnesota, and New Jersey are exploring the incorporation of the *Precautionary Principle* into policies and laws.

In California, the City and County of San Francisco has officially embraced the *Precautionary Principle* by resolution,<sup>9</sup> and the Los Angeles Unified School District has adopted it as part of its pest management program for schools.<sup>10</sup> Further, the California Environmental Protection Agency’s “Environmental Justice Advisory Committee” has considered (and rejected) a report that recommended incorporation of the *Precautionary Principle* in all policy and regulatory actions.<sup>11</sup>

The United States and Canada have seen the *Precautionary Principle* used in EU to restrict trade. The European Commission banned genetically modified (GM) food and hormone treated beef cattle produced in the United States and England citing the *Precautionary Principle*. Scientific evidence does not support that either of these technologies pose greater risks. Dozens of scientific bodies, including the

<sup>8</sup> Conko and Miller, *supra* note 5.

<sup>9</sup> San Francisco’s *Precautionary Principle* ordinance can be found at [http://sfgov.org/sfenvironment/aboutus/policy/legislation/precaution\\_principle.htm](http://sfgov.org/sfenvironment/aboutus/policy/legislation/precaution_principle.htm)

<sup>10</sup> Los Angeles Unified School District’s Integrated Pest Management Policy can be found at <http://www.calisafe.org/policy.htm>

<sup>11</sup> On October 14, 2003, California Environmental Protection Agency’s Interagency Working Group on Environmental Justice adopted by resolution “The Recommendations of the California Environmental Protection Agency (Cal/EPA) Advisory Committee on Environmental Justice to the Cal/EPA Working Group on Environmental Justice, Final Report,” September 30, 2003.

Resolution: <http://www.calepa.ca.gov/EnvJustice/Documents/2003/ResolutionIWG.pdf>.

Final Report: <http://www.calepa.ca.gov/EnvJustice/Documents/2003/FinalReport.pdf>

UK's Royal Society, the U.S. National Academy of Sciences, the World Health Organization and the American Medical Association, have performed analyses of the oversight that is appropriate for GM organisms (GMOs), with remarkable congruence in their conclusions:

- The newer molecular techniques for genetic improvement are an extension, or refinement, of earlier, far less precise ones;<sup>12</sup>
- Adding genes to plants does not make them less safe either to the environment or to eat;<sup>13, 14</sup>
- The risks associated with GMOs are the same in kind as those associated with unmodified and conventionally-modified organisms;<sup>15</sup> and
- Regulation should be based upon the risk-related characteristics of individual products, regardless of the techniques used in their development.<sup>16, 17</sup>

A scientific committee assembled by the World Trade Organization found that the European Commission's argument that the *Precautionary Principle* permits the restriction on imports of U.S. and Canadian beef treated with certain growth hormones was invalid for a number of reasons, including:

- The scientific studies cited by the Commission in its own defense do not indicate a safety problem when the hormones in question are used in accordance with good animal husbandry practices.
- EU health officials have expressed no concern about endogenous hormones that occur at higher levels in the un-castrated steers more common in Europe; and
- The European Union did not, at the time, ban growth hormones in the pork industry, where many European livestock operations are internationally competitive.<sup>18</sup>

In August 2002, the Zambian government refused to accept foreign food aid from the United States because it might have contained genetically modified (GM) food, despite a crippling food shortage that threatened to leave some two million people hungry in that country. Just one month before, the government of Zimbabwe announced a similar decision, but later allowed some GM food for famine relief. Contrary to scientific evidence and widespread use of GM foods in the United States, these southern African governments claimed the food was not safe enough to feed their people. Zambia's Information Minister claimed the decision reflected the "*Precautionary Principle*," because of alleged "uncertainties surrounding the likely consequences of consuming genetically modified food." Due to a hypothetical risk of foreign food, millions of Africans face a certain threat of starvation.<sup>19</sup>

<sup>12</sup> The Royal Society, "Genetically Modified Plants for Food Use," September 1998, p. 5. <http://www.royalsoc.ac.uk/policy/>

<sup>13</sup> *Id.*

<sup>14</sup> American Medical Association "Genetically Modified Crops and Food: Report 10 of the council on Scientific Affairs" pp. 11-16.

<sup>15</sup> National Academy of Sciences "Genetically Modified Pest-Protected Plants," *Science and Regulation* at p. 5. (2000)

<http://www.nap.edu/books/0309069300/html/>

<sup>16</sup> *Id.*

<sup>17</sup> World Health Organization "20 Questions on Genetically Modified (GM) Foods."

<http://www.who.int/foodsafety/publications/biotech/20questions/en>

<sup>18</sup> Conko, Gregory and Henry I. Miller, "Food Safety: The Precautionary Principle is the Wrong Approach," *European Affairs*, Spring 2001.

[http://www.europeanaffairs.org/archive/2001\\_spring/2001\\_spring\\_122.php4](http://www.europeanaffairs.org/archive/2001_spring/2001_spring_122.php4)

<sup>19</sup> Adler, *supra* note 7.

In the late 1980s, environmental activists were lobbying water authorities around the world, trying to convince them that carcinogenic byproducts of chlorination made drinking water a potential cancer risk. The Peruvian government saw this as a great way to save money, and it stopped chlorinating much of that country's drinking water. As a result, more than 1.3 million people contracted cholera and at least 11,000 died in one of Latin America's biggest cholera epidemics – all to save a handful of purely speculative cancer cases.<sup>20</sup>

It is, and will continue to be, difficult to assess the impacts of *Precautionary Principle* in world society. If something is never tried, both the benefits and risks will never be known, unless it is tried elsewhere and allowed to proceed. The cost of delay in the by The United States has some of the most rigorous approval processes for pharmaceutical drugs. While the FDA is supposed to guarantee the safety of new drugs brought to market, the costs of delay are often overlooked. In 1986, Dale H. Gieringer of the Decisions and Ethics Center at Stanford University reported, "The cost of a mere one-year delay in new-drug approval can be estimated at as much as 37,000-76,000 lives per decade -- several times the worldwide toll of all new-drug accidents."<sup>21</sup> For example, propranolol, the first Beta-blocker to be used extensively to treat angina and hypertension took three years longer to approve in the United States than in England. Approximately 10,000 Americans died every year for the three years it was against the law for their doctors to treat them with propranolol. Propranolol was finally approved in the US for minor uses in 1968, but was only approved in 1973 and 1976 for angina and hyper-tension respectively. The regulatory delay of this single drug may have been responsible for the death of more Americans than all other deaths from drugs in this century. Even so, the FDA came under severe criticism by Congress for "premature" approval of this valuable drug.<sup>22</sup> Although FDA has sped up its approval review from several years to six months in the last few years, this provides examples as to real costs of excess precaution.

### Recent Developments

The *Precautionary Principle* was one of the key issues addressed at the 2002 follow-up to the Rio summit, the World Summit on Sustainable Development (WSSD) in Johannesburg, South Africa. There, delegates debated amending the Rio Declaration Principle 15 definition by incorporating language stating the importance of governments adopting a precautionary approach in making regulatory decisions.

The world governments rejected this approach. Developing nations in particular were concerned that references to extreme interpretations of the *Precautionary Principle* would have an adverse effect on trade. The participating governments, including the United States, strongly supported the importance of a science-based approach to decision-making and the need to establish relationships between the science community and governments.

Paragraph 109 of the final WSSD text clearly and definitively addresses the desires of the world's nations to be cautious in decision-making but base decisions on science and not be bound by extreme interpretations of the *Precautionary Principle*. Paragraph 109 also establishes "science-based decision-making" as the preferred approach for making regulatory decisions. The final WSSD text reflects the thinking of those countries supporting a science-based approach to decision-making:

---

<sup>20</sup> Conko, Gregory, "The Precautionary Principle: Protectionism and Environmental Extremism by Other Means," International Society of Regulatory Toxicology and Pharmacology Workshop on The Precautionary Principle, June 20, 2002, Arlington, Virginia. <http://www.cei.org/gencon/027.03079.cfm>

<sup>21</sup> Tuccille, Jerome D., "FDA Reform.." <http://www.free-market.net/forums/main0210/messages/935960756.html>

<sup>22</sup> Ruwart, Dr. Mary J., "Protecting Ourselves to Death." <http://www.ruwart.com/Healing/chap6.html>



109 (f) Promote and improve science-based decision-making and reaffirm the precautionary approach as set out in Principle 15 of the Rio Declaration on the Environment and Development, which states: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

Recently, the Office of Management and Budget (OMB) recently released a report "Informing Regulatory Decisions" which includes a chapter on the current role of precaution in regulatory decision making, while explaining why precaution needs to be exercised wisely on a case-by-case basis.<sup>23</sup> There are some good conclusions to draw upon - for example the report states, "When applied appropriately, precautionary approaches can promote the protection of public health, safety and the environment by reducing potential threats. However, if precaution is taken to an extreme and rigidly applied, adverse impacts can occur."<sup>24</sup>

The report also concludes that the existing US regulatory approach already embeds a great deal of precaution, noting that, "Since the U.S. regulatory framework relies on an open and transparent system of delegated rulemaking with revisable regulations, the system is able to incorporate the best scientific advice at many steps in the process and respond to changes in information accordingly. This allows for an iterative process of information collection, risk assessment, and risk management when regulating emerging risks. In this iterative process, different levels of precaution are applied early on (when the scientific information is limited) and an appropriate reduction of precautionary consideration is applied as scientific knowledge and experience regarding risks, benefits, and costs increases."<sup>25</sup>

More recently, the U.S. Commission on Ocean Policy considered *and rejected* using the *Precautionary Principle* as the basis upon which all ecosystem management decisions should be made.<sup>26</sup> In issuing its Ocean Policy Report in April of 2004, the Commission noted that "the precautionary principle has been proposed by some parties as a touchstone for managers faced with uncertain scientific information."<sup>27</sup> Yet, in rejecting the *Precautionary Principle*, the Commission also noted that, "[w]hile this may appear sensible at first glance, *its application could lead to extreme and often undesirable results.*"<sup>28</sup> Instead, the Commission recommended "a more balanced *precautionary approach* that weighs the level of scientific uncertainty and the potential risk of damage as part of every management decision" which "can be explained as follows:

**Precautionary Approach:** To ensure the sustainability of ecosystems for the benefit of future as well as current generations, decision makers should follow a balanced precautionary approach, applying judicious and responsible management practices based on the best available science and on proactive,

<sup>23</sup> U.S. Office of Management and Budget, "Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities," Chapter 3, pp. 51-63. [http://www.whitehouse.gov/omb/inforeg/2003\\_cost-ben\\_final\\_rpt.pdf](http://www.whitehouse.gov/omb/inforeg/2003_cost-ben_final_rpt.pdf)

<sup>24</sup> *Id.* at p. 62.

<sup>25</sup> *Id.* at p. 62-63.

<sup>26</sup> See, "Preliminary Report of the U.S. Commission on Ocean Policy, Governors' Draft, Washington, D.C., April 2004" at pp. 35-36 (hereafter, "Ocean Policy Report"). <http://www.oceancommission.gov>

<sup>27</sup> *Id.* at p. 35.

<sup>28</sup> *Id.* (emphasis added)

Partnership for Sound Science in Environmental Policy

rather than reactive, policies. Where threats of serious or irreversible damage exist, lack of full scientific certainty shall not be used as a justification for postponing action to prevent environmental degradation. Management plans and actions based on this precautionary approach should include scientific assessments, monitoring, mitigation measures to reduce environmental risk where needed, and periodic reviews of any restrictions and their scientific bases."<sup>29</sup>

---

<sup>29</sup> *Id.* at p. 36.



## (Mis-) Applications of the *Precautionary Principle*

---

*The danger of not balancing the risk of an action to “improve” the environment (the Kyoto Protocol set forth different actions to help prevent global warming and green house impacts):*

A favorite Kyotoite prescription for curbing the greenhouse gas emissions alleged to be causing global warming is to ratchet-up the fuel economy standards for automobiles. However, Federal fuel economy mandates have already forced automakers to produce smaller, lighter, less crash-resistant cars. The result? An additional 2,000 - 4,000 highway deaths per year, according to John Graham of the Harvard School of Public Health.<sup>1</sup>

---

*Many times, technology provides the answers to potential hazards. As such, market forces play larger roles in solving the potential problems than policies.*

For some 200 years, Americans cut more trees than they planted. In the 1890s and early 20th century, conservationists warned that, in a few decades, all the forests would be gone. There would be no more wood to make homes. Houses would be so expensive only the very rich could afford them. In fact, America's forests have regenerated dramatically since 1920, and wood is plentiful. Government policies of course played a role in forest restoration, but market forces were more important.

Technological improvements in agriculture made it possible to grow more food on less land. This not only spared forests that did not need to be cleared to feed a growing population, it also allowed reforestation in areas such as the Northeast, where farming ceased to be profitable. Technological advances in construction and manufacturing allowed businesses and consumers to substitute other materials – such as metals and plastics – for wood. Coal, oil, natural gas, hydroelectricity, and nuclear power replaced wood as a fuel source. Private timber production became economical – so much so that, by 1993, an estimated 4 million trees were planted in the U.S. each day.<sup>2</sup>

---

<sup>1</sup> Lewis, Marlo Jr., Staff Director, National Economic Growth Natural Resources and Regulatory Affairs, U.S. House of Representatives Subcommittee on Speech to the Doctors for Disaster Preparedness. “Precautionary Foolishness,” July 1, 2000, [http://www.biotech-info.net/precautionary\\_foolishness.html](http://www.biotech-info.net/precautionary_foolishness.html)

<sup>2</sup> *Id.*

***The Precautionary Principle can be used as a reason to ignore scientific evidence as a way to create trade barriers.***

The European Commission has argued that the *Precautionary Principle* permits the restriction on imports of U.S. and Canadian beef from cattle treated with certain growth hormones. But a scientific committee assembled by the World Trade Organization (WTO) found that justification invalid for a number of reasons, including:

(1) Scientific studies cited by the Commission in its own defense did not indicate a safety problem when the hormones in question are used in accordance with good animal husbandry practices;

(2) European Union (EU) health officials had expressed no concern about endogenous hormones that occur at higher levels in the un-castrated steers more common in Europe; and,

(3) The EU did not, at the time, ban growth hormones in the pork industry, where many European livestock operations are internationally competitive.

Nevertheless, members of the European Commission still manage to claim that its restriction on hormone-treated beef is not intended to be a trade barrier.<sup>3</sup>

---

***The Precautionary Principle can easily lead to unfair application in order to protect self-interests.***

The EU's labeling mandate has covered any food or animal feed made from genetically modified organisms (GMOs), where residues of the novel gene or protein can be detected in the final product. Until July 2003, this meant that cooking oils from genetically modified corn, soy, or canola were exempt because the heat and friction from the crushing process tends to break apart DNA chains and break down proteins, making it impossible to tell the difference between GM and conventional. Now all food products containing more than 0.9% bioengineered ingredients in the finished item will have to be labeled, including oils.

What both the old and the new rule do not address are foods or feeds that are produced "with" is critical. Specifically exempted are products produced with the aid of genetically modified enzymes – including cheeses produced with the GM clotting agent chymosin, or beers and wines produced with GM yeasts – even though enzyme residues often can be detected in the final product.

Naturally, one is led to wonder how important the *Precautionary Principle* really is if consumers only need to be alerted to the genetic status of foods that come primarily from other countries. After all, if the *Precautionary Principle* just happens to exempt foods from industries where European producers have a competitive advantage, it doesn't seem like much of a principle.

---

<sup>3</sup> Conko, Gregory Director of Food Safety Policy, Competitive Enterprise Institute "The Precautionary Principle: Protectionism and Environmental Extremism by Other Means," presentation to the International Society of Regulatory Toxicology and Pharmacology Workshop on The Precautionary Principle, June 20, 2002, Arlington, Virginia <http://www.cei.org/gencon/027.03079.cfm>

What is intriguing about the GM labeling debate is that groups like *Greenpeace*, *Friends of the Earth*, and others have found nothing wrong with this double standard. Thus, when examined closely, it becomes obvious that most environmental groups have their own quirky double standards when it comes to precautionary regulation.

Consider pesticides. June 14, 2002 marked the 30th Anniversary of the EPA's ban on DDT. DDT was the original *bête noire* of the environmental movement, featured prominently in Rachel Carson's *Silent Spring*.

From the start, it should be acknowledged that DDT poses risks to birds and some fish. But when DDT was introduced as a commercial pesticide in the 1950s, it was a considerably safer technology than the arsenic-based pesticides that it all but replaced. After more than 60 years of testing, DDT has never been shown to pose any real threat to human health. And in the 28 countries around the world where DDT is still used in malaria control, it is an essential compound, saving literally tens of thousands of lives every year.<sup>4</sup>

The same cannot be said about either the copper-arsenate pesticide that preceded DDT or the pyrethrins and synthetic pyrethroids that have replaced it. Judged by environmentalist standards, both are hazardous to the environment and to humans. But the environmental movement has based its push for a global DDT ban on the *Precautionary Principle* – and strangely has argued that the existence of pyrethroid alternatives make such a ban practical.

But, if the *Precautionary Principle* was standard operating procedure in the 1930s when the insecticidal potency of DDT was first really understood, or in the 1940s when DDT was an indispensable tool for the allies during World War II, or in the 1950s when farmers began using it commercially, the old copper-and-arsenic-based Bordeaux Mixture for pest control might still be used.

Ironically, both copper-arsenate and pyrethrin pesticides are still used to this day in the organic agriculture that *Precautionary Principle* advocates hold as the pinnacle of consumer and environmental safety. They remain the darlings of the environmental movement because they are “natural” – mined from the earth in the first case, and refined from flowers in the second.<sup>5</sup>

---

***Taking precautionary actions without looking at the benefits can cause greater harm than the good that that the action is trying to do.***

The campaign by some environmentalists to rid society of chlorinated compounds has extended even to opposing the chlorination of drinking water. By the late 1980s, environmental activists were

---

<sup>4</sup> The following articles provide additional information on the life-saving aspects of DDT: World Health Organization (WHO) – Southern Africa Malaria Control “Malaria Vector Update... DDT- the Facts.” [http://www.fightingmalaria.org/pdfs/ddt\\_thefacts.pdf](http://www.fightingmalaria.org/pdfs/ddt_thefacts.pdf) <accessed 11/4/03>; Stolberg, Sheryl Gay, “DDT Target of Global Ban, Find Defenders in Experts on Malaria,” New York Times, Aug. 29, 2003. [http://www.malaria.org/DDT\\_NYTimes\\_29\\_VIII.html](http://www.malaria.org/DDT_NYTimes_29_VIII.html); Roberts, Donald R., et. al. “DDT, Global Strategies, and a Malaria Control Crisis in South America,” <http://www.cdc.gov/ncidod/eid/vol3no3/roberts.htm> <accessed 11/5/03>; Chlorine Chemical Council “Chlorine: Saving Lives Against Disease,” Chlorine Benefits News, Issue 1, Volume 1, February 2001. <http://c3.org/newsletter/cbn022101.html>

<sup>5</sup> Conko, *supra* note 3.

lobbying water authorities around the world, trying to convince them that carcinogenic byproducts of chlorination made drinking water a potential cancer risk.

The Peruvian government saw this as a great way to save money, and it stopped chlorinating much of that country's drinking water. Greenpeace got what it wanted, but more than 1.3 million people contracted cholera and at least 11,000 died in one of Latin America's biggest cholera epidemics – all to save a handful of purely speculative cancer cases.<sup>6</sup> In addition, due to the abrupt halt in tourism and agricultural exports, the outbreak cost the Peruvian economy US \$1,000 million in just 10 weeks. The total economic cost to Peru was more than three times the total national investment in water supply and sanitation improvements made in the 1980s.<sup>7</sup>

---

*Objective science is needed to best assess what real risks are. The Precautionary Principle offers no opportunity to balance real and perceived risk, and their related benefits and consequences.*

The removal of asbestos from schools in New York City was initially quite popular, in fact demanded by parents, even though experts believed that the risks were statistically small. As it happens, the risk of a child getting cancer from asbestos insulation was about 1/3 the risk of being struck by lightning. But when it was learned that the removal would cause schools to be closed for a period of weeks, and when the closing caused parents to become greatly inconvenienced, parental attitudes turned around, and asbestos removal seemed like a bad idea. When the costs of the removal became known, parents thought much more like experts, and the risks of asbestos seemed well worth tolerating.<sup>8</sup>

---

*Taking precautionary actions against scientific evidence can deprive society of life-saving tools.*

Anti-chlorine campaigners more recently have turned their attacks to phthalates - - liquid organic compounds added to certain plastics to make them softer. These soft plastics are used for important medical devices, particularly fluid containers, blood bags, tubing, and gloves, children's toys such as teething rings and rattles, and household and industrial items such as wire coating and flooring. Waving the banner of the *Precautionary Principle*, activists claim that phthalates "might" have numerous adverse health effects — even in the face of significant scientific evidence to the contrary. Governments have taken these unsupported claims seriously, and several formal and informal bans have been implemented around the world. As a result, consumers have been denied product choices, and doctors and their patients deprived of life-saving tools.<sup>9</sup>

---

<sup>6</sup> *Id.*

<sup>7</sup> World Health Organization, "Looking Back, Looking Ahead: Five Decades of Challenges and Achievements in Environmental Sanitation and Health," 2003, p. 7. [http://www.who.int/water\\_sanitation\\_health/hygiene/envsan/en/Lookingback.pdf](http://www.who.int/water_sanitation_health/hygiene/envsan/en/Lookingback.pdf)

<sup>8</sup> Sunstein, Cass R., "Beyond The Precautionary Principle - Chicago Public Law And Legal Theory Working Paper No. 38," University Of Chicago School of Law, January 2003.

<http://www.law.uchicago.edu/academics/publiclaw/resources/38.crs.precautionary.pl-lt.pdf>

<sup>9</sup> Miller, Henry I., and Gregory Conko, "The Perils of Precaution," Policy Review On-Line, Hoover Institution, June 2001. <http://www.policyreview.org/jun01/miller.html>

***Equal risks do not always get equal attention under the Precautionary Principle.***

People seem quite concerned about the risks associated with dioxin, but far less concerned about the statistically equivalent risks associated with *aflatoxin*, a carcinogen found in peanut butter. When aflatoxin does not trigger public concern, a large part of the reason is that the burdens of banning aflatoxin seem high and indeed intolerable; too many people would object to heavy regulation of peanut butter, a staple of school lunches and many diets for generations.<sup>10</sup>

---

***In most cases, new products are intended to improve on current products to make the product safer or more environmentally friendly. The Precautionary Principle allows one to overlook real risks for possible risks, thereby imposing unfair regulatory requirements.***

Some of the most successful of the gene-spliced crops, especially cotton and corn, have been constructed by splicing in a bacterial gene that produces a protein toxic to predatory insects, but not to people or other mammals. Not only do these gene-spliced corn varieties repel pests, but grain obtained from them is less likely to contain *Fusarium*, a toxic fungus often carried into the plants by the insects. That, in turn, significantly reduces the levels of the fungal toxin fumonisin, which is known to cause fatal diseases in horses and swine that eat infected corn, and esophageal cancer in humans. When harvested, these gene-spliced varieties of grain also end up with lower concentrations of insect parts than conventional varieties. Thus, gene-spliced corn is not only cheaper to produce but yields a higher quality product and is a potential boon to public health. Moreover, by reducing the need for spraying chemical pesticides on crops, it is environmentally friendly.

Other products, such as gene-spliced herbicide-resistant crops, have permitted farmers to reduce their herbicide use and to adopt more environment-friendly no-till farming practices. Crops now in development with improved yields would allow more food to be grown on less acreage, saving more land area for wildlife or other uses. And recently developed plant varieties with enhanced levels of vitamins, minerals, and dietary proteins could dramatically improve the health of hundreds of millions of malnourished people in developing countries. These are the kinds of tangible environmental and health benefits that invariably are given little or no weight in precautionary risk calculations.

In spite of incontrovertible benefits and greater predictability and safety of gene-spliced plants and foods, regulatory agencies have regulated them in a discriminatory, unnecessarily burdensome way. They have imposed requirements that could not possibly be met for conventionally bred crop plants.<sup>11</sup>

---

<sup>10</sup> Sunstein, *supra* note 8.

<http://www.law.uchicago.edu/academics/publiclaw/resources/38.crs.precautionary.pl-it.pdf>

<sup>11</sup> Miller and Conko, *supra* note 9.

---

*Some versions of the Precautionary Principle require that the need for a product be identified before risks should be allowed. We could miss out on important, useful and lifesaving technology this way.*

As American science writer Ronald Bailey points out, "When the optical laser was invented in 1960, it was dismissed as 'an invention looking for a job.' No one could imagine of what possible use this interesting phenomenon might be. Of course, now it is integral to the operation of hundreds of everyday products: it runs our printers, runs our optical telephone networks, performs laser surgery to correct myopia, removes tattoos, plays our CDs, opens clogged arteries, helps level our crop fields, etc. It's ubiquitous."<sup>12</sup>

Another example to consider is aspirin. If the hypothetical risks had been weighed against the hypothetical benefits, it is questionable whether the drug would ever have been licensed, according to Peter McNaughton, Sheild Professor of Pharmacology at the University of Cambridge. In his survey investigation on the effect of the *Precautionary Principle* on society, McNaughton argues that "this drug has considerable adverse side-effects, and would never be licensed today. The benefits, however, are enormous and growing - apart from the well-known treatment for inflammatory pain, there are uses in cancer, heart disease and prevention of deep vein thrombosis."<sup>13</sup>

Many of the benefits derived from aspirin could not have been anticipated. But also, as a result of the success of aspirin, many safer alternatives have been developed. In the course of scientific progress, there are endless examples of technologies that have served as bridges to new and better technologies.

History has shown us that, while scientific and technological progress may often introduce new risks, its general trajectory has been to reduce many other, more serious, risks. Examples are plentiful: including the development of vaccinations, organ transplantation, blood transfusion, the chlorination of drinking water, the use of pesticides, and much more.

The *Precautionary Principle* will not, therefore, make us any safer. But we could pay a very heavy price for taking it on board, by missing out on future social benefits that are unimaginable to us today.<sup>14</sup>

---

*The Precautionary Principle does not provide guidance as to the tradeoffs between human health and the environment.*

Take the use of pesticides. Society has relied on pesticides to better control disease-carrying insects like flies, mosquitoes, and cockroaches, and to protect crops. Clearly, pesticide use has significantly improved the health of scores of millions of people. But some pesticides have had side

---

<sup>12</sup> Ronald Bailey "Precautionary Tale," REASON Magazine, April 1999. <http://reason.com/9904/fe.rb.precautionary.shtml>

<sup>13</sup> Starr, Sandy, "Science, risk and the price of precaution," May 1, 2003. <http://www.spiked-online.co.uk/Articles/00000006DD7A.htm>

<sup>14</sup> Guldberg, Helene, "Challenging the Precautionary Principle," July 1, 2003. <http://www.spiked-online.com/Printable/00000006DE2F.htm>



effects on the environment, such as harming nontargeted species. The *Precautionary Principle* gives no guidance on how to make this tradeoff between human health and the protection of nonpest species.<sup>15</sup>

---

***Misinformation can lead to an unnecessary precaution. In many cases, the misinformation persists.***

There is no evidence that fireproofing chemicals in PVC mattresses produce toxic fumes which could be fatal to babies. This finding is embodied in the final report of the UK government-appointed expert group on cot death theories. The allegation of a link between flame-retardants and infant cot deaths was made by Roger Cook on ITV, one of England's major commercial television networks. The story caused much distress to mothers and, acting on the basis of the *Precautionary Principle*, retailers destroyed stocks of mattresses treated with flame-retardants worth hundreds of thousands of pounds. Even while this was later found to have been unnecessary, only *The Daily Telegraph* gave the same prominence to the authoritative findings which acquitted flame-retardants as they gave to the original scare.<sup>16</sup>

---

***Focusing on "possible harm" can cause real harm.***

In August, 2002, the Zambian government refused to accept foreign food aid, despite a crippling food shortage that threatened to leave some two million people hungry. In July, 2002, the government of Zimbabwe announced a similar decision. For each country the reason was the same: aid from the United States "could" contain genetically modified food. Despite the lack of any scientific evidence suggesting genetically modified crops pose any new threat to human health or the environment, these southern African governments claimed the food was not safe enough to feed their people. Zambia's Information Minister claimed the decision reflected the "*Precautionary Principle*," because of alleged "uncertainties surrounding the likely consequences of consuming genetically modified food."<sup>17</sup>

Zambia and Zimbabwe are not alone. The European Union also cites the *Precautionary Principle* as a basis for resisting the importation of genetically modified foods. If a chemical substance *might* cause harm, it should be controlled or eliminated. If a new technological innovation *could* have unknown environmental effects, it should not be permitted. If a given action *could* harm a species that *might* be endangered, do not allow it. The *Precautionary Principle* may appeal to common-sense notions of safety, but its application will not produce a safer, cleaner world. Quite the opposite — the incorporation of the *Precautionary Principle* in environmental, health, and safety regulation is itself a threat to environmental protection and optimal safeguards for public health.<sup>18</sup>

---

<sup>15</sup> Bailey, *supra* note 12.

<sup>16</sup> Chemical Industries' Association: "Cot Deaths Not Due to Fire Proofing Materials," April 1, 1999. [http://www.cia.org.uk/newsite/talking\\_points/tparticle.asp?id=104](http://www.cia.org.uk/newsite/talking_points/tparticle.asp?id=104)

<sup>17</sup> Paarlberg, Robert L., "African Famine, Made in Europe," *Wall Street Journal*, August 23, 2002. <http://www.foodsecurity.net/news/newsitem.php3?id=1886&tnews=news>; South Centre "Zambia Remains Firm Against GM-Maize Aid" <http://www.southcentre.org/info/southbulletin/bulletin41/bulletin41-10.htm> <accessed 11/6/03>

<sup>18</sup> Adler, Jonathan, "Dangerous Precaution: The Precautionary Principle's Challenge to Progress," National Review Online, September 13, 2002. <http://www.nationalreview.com/adler/adler091302.asp>

## What Price, *Precaution*?

In May of 2003, the London Royal Institution convened a meeting to discuss the *Precautionary Principle*, the seemingly new-obsession with its preeminency in policy decisions throughout the world, and the potential costs to society as we know it today. At the meeting, forty members of the international scientific community were asked to list what significant discoveries and achievements would have been *limited or prevented* if science, at the time, had been governed by the *Precautionary Principle*. Here are a few of those discoveries and achievements that would have been endangered<sup>1</sup>:

- Aspirin -** Considerable adverse side-effects. Aspirin deforms the unborn young of almost every animal species but humans.<sup>2</sup> The benefits, however, are enormous and growing - apart from the well-known treatment for inflammatory pain, there are uses in cancer, heart disease and prevention of deep vein thrombosis. As a result of the success of aspirin, many safer alternatives have been developed - for example, new generation COX2 inhibitors (Vioxx, Rofecoxib, etc).
- Airplanes -** Chance of crashing and hijack, sound and air pollution impacts.
- Trains -** Some argued that a man would die if he traveled at 30 miles per hour, and some of those who did journey reported sickness.
- Mobile phones -** May cause brain cancer, headaches, feeling tired or problems with sleeping. A study by a Swedish research group even suggested it could lead to Alzheimer's disease.
- Chlorine -** Poisonous gas added to drinking water, carcinogenic byproducts, caustic household cleaner, harmful if swallowed.
- Electricity -** In the 1990's, an average of more than 200 people were electrocuted in the United States each year from household electrical devices as lamps, switches, TVs, radios, washers, dryers and so on, with another 300 killed in some 40,000 electrical fires. Environmental impacts with the siting of power plants and transmission lines, and concerning the air and water pollutants, cannot be completely mitigated. **High-voltage power grids**, standard in the industrial world, would ever have been allowed to take shape - despite the fact that no serious evidence has ever emerged that low-frequency electromagnetic radiation is harmful.
- Digitalis -** Extracted from the foxglove plant (*Digitalis purpurea*). It is a highly toxic substance, and if the *Precautionary Principle* had operated in 1780 when it was discovered, its great beneficial effects on the heart would never have been advanced.

<sup>1</sup> Starr, Sandy, "Science, risk and the price of precaution," May 1, 2003. <http://www.spiked-online.co.uk/Articles/0000006DD7A.htm>

<sup>2</sup> Robertson, Richard T., et al., "Aspirin: Teratogenic Evaluation in the Dog," *Tetrology* 20: 313-320, 1979; Layton, William M., "An Analysis of Teratogenic Testing Procedures," *Congenital Defects*, Janerich, D.T., Skalko, R.G. and Porter, I.H., eds., pp. 205-217 (New York: Academic Press, 1974).

- Open-heart surgery – and organ transplants** – Killed a large number of recipients before it was regularly successful
- Penicillin-** Injected into a human after minimal testing on mice. The person died when more penicillin could not be produced. Later study found penicillin lethal to guinea pigs.
- Radiation –** Deadly at improper doses, can cause mutilation and cancer. No CT scans, brain imaging, or contrast agents.
- Vaccines -** The live vaccines carry a five percent risk of inflicting the disease. Jenner's experiments on vaccination would be condemned for transferring tissue across species, risking the creation of new human diseases. Use potentially deadly substance. Fear that some vaccines cause autism in children.
- Contraceptive Pill –** Believed to cause increased risk of some cancers in women, early forms linked to blood clots and strokes.
- Space travel to outer planets -** The use of radio isotope thermal generators (RTGs) is required for all spacecraft for the exploration of the outer planets since solar power is no longer effective. RTGs use radioactive material such as plutonium. This has generated some opposition because an accident on launch could contaminate the atmosphere.
- DDT –** May cause breast cancer, reduction in raptor population, bioaccumulation 'up the food chain'. DDT has saved millions of humans from dying of malaria and eradicated the disease from the entire Mediterranean region. Its inventor was awarded the Nobel Prize in medicine in 1948 for his discovery. National Academy of Sciences wrote in 1970: "To only a few chemicals does man owe as great a debt as to DDT."
- Green Revolution -** Randomly mutating seeds and selecting plants that had enhanced crop characteristics. There was no way of knowing with absolute certainty whether the random mutagenic process (done with gamma rays) would produce some kind of 'killer' crop, that could disrupt ecosystems or have a surreptitious harmful effect on people. The Green Revolution prevented widespread famine in large areas of Asia.
- Water supply and distribution -** Possibly allowed, but with strict (and expensive) controls on siting, and with rejection of specific applications. For example, the **Hoover Dam**, built primarily to control destructive habitat flooding and secondarily to produce electricity, would have the undesirable side-effect of encouraging growth in a pristine, unique, irreplaceable, priceless, delicate, biodiverse ecosystem.
- Air conditioning and refrigeration -** High electricity use and refrigerants like freon (Antarctic ozone thinning)
- Radar -** High-powered radar emits microwaves at sufficient intensity to harm or kill anyone standing directly in front of the antenna.
- Laser technology –** Fears it can cause chest infections, blindness and other serious health problems. At one point it was deemed "a solution looking for a problem." Today it is used for printers, optical telephone networks, surgery, CD players, and industrial tools.

U.S. COMMISSION ON  
OCEAN POLICY



**PRELIMINARY REPORT**  
OF THE U.S. COMMISSION ON OCEAN POLICY

**GOVERNORS' DRAFT**  
**APRIL 2004**

YOU MAY ELECTRONICALLY DOWNLOAD THIS DOCUMENT FROM THE  
U.S. COMMISSION ON OCEAN POLICY WEB SITE:  
[HTTP://WWW.OCEANCOMMISSION.GOV](http://www.oceancommission.gov)

THIS DOCUMENT MAY BE CITED AS FOLLOWS:  
PRELIMINARY REPORT OF THE U.S. COMMISSION ON OCEAN POLICY  
GOVERNORS' DRAFT, WASHINGTON, D.C., APRIL 2004

While determining appropriate new boundaries is necessary for ecosystem-based management, it is also important to maintain sufficient flexibility to manage on both larger and smaller scales when necessary. For example, air pollution problems must be dealt with on national and even international levels, while certain water pollution issues may need to be addressed on a small-scale watershed level. Managers should be able to adapt to the scale of different activities and the ecosystems they affect.

#### *Aligning Decision-making within Ecosystem Boundaries*

The current political and issue-specific delineation of jurisdictional boundaries makes it difficult to address complex issues that affect many parts of the ecosystem. Economic development in a coastal area may fall under the jurisdiction of several local governments, and natural resource management under the jurisdiction of one or more states, while pollution control and environmental monitoring of the same area may be overseen by several federal agencies. Yet water, people, fish, marine mammals, and ships flow continually across these invisible institutional borders.

Ecosystem-based management can provide many benefits over the current structure. The coordination of efforts within a specific geographic area allows agencies to reduce duplication and maximize limited resources. It also provides an opportunity for addressing conflicts among management entities with different mandates. Less obvious, but equally important, ecosystem-based management may engender a greater sense of stewardship among government agencies, private interests, and the public by promoting identification and connection with a specific area.

Finally, ecosystem-based management makes it easier to assess and manage the cumulative impacts of many different activities. For example, the U.S. Army Corps of Engineers' wetlands permitting program has been criticized for not evaluating cumulative impacts in its review of individual dredge-and-fill permits. A true ecosystem-based management approach would ameliorate this fragmented approach.

While ecosystem-based management is being attempted in some places on a limited basis, applying it broadly and successfully will take time and effort. In particular, the transition to such management will require explicit recognition of the uncertainty of current information and understanding. This uncertainty creates risks. One widely accepted guideline for managing in the face of uncertainty and risk is to adopt a precautionary and adaptive approach.

#### *Precautionary and Adaptive Management*

Scientific uncertainty has always been, and will probably always be, a reality of the management process. Because scientists cannot predict the behavior of humans or the environment with 100 percent accuracy, managers cannot be expected to manage with complete certainty. Nevertheless, scientists *can* provide managers with an estimate of the level of uncertainty associated with the information they are providing. Managers must incorporate this level of uncertainty into the decision-making process, support the research and data collection needed to reduce the uncertainties, and be prepared to adapt their decisions as the information improves.

The *precautionary principle* has been proposed by some parties as a touchstone for managers faced with uncertain scientific information. In its strictest formulation, the precautionary principle states that when the potentially adverse effects of a proposed activity are not fully understood, the activity should not be allowed to proceed. While this may appear sensible at first glance, its application could lead to extreme and often undesirable results. Because scientific information can never fully explain and predict all impacts, strict adoption of the precautionary principle would prevent most, if not all, activities from proceeding.



In contrast to the precautionary principle, the Commission recommends adoption of a more balanced *precautionary approach* that weighs the level of scientific uncertainty and the potential risk of damage as part of every management decision. Such an approach can be explained as follows:

**Precautionary Approach:** To ensure the sustainability of ecosystems for the benefit of future as well as current generations, decision makers should follow a balanced precautionary approach, applying judicious and responsible management practices based on the best available science and on proactive, rather than reactive, policies. Where threats of serious or irreversible damage exist, lack of full scientific certainty shall not be used as a justification for postponing action to prevent environmental degradation. Management plans and actions based on this precautionary approach should include scientific assessments, monitoring, mitigation measures to reduce environmental risk where needed, and periodic reviews of any restrictions and their scientific bases.

According to this approach, scientific uncertainty—by itself—should neither prevent protective measures from being implemented nor prevent uses of the ocean. Managers should review the best available science and weigh decisions in light of both the level of scientific uncertainty and the potential for damage. When the level of uncertainty is low and the likelihood of damage is also low, the decision to proceed is clearly supported. At the other extreme, when the level of uncertainty is high and the potential for irreversible damage is also high, managers should clearly not allow a proposed action to proceed. In the real world, managers will most likely face decisions between these two extremes, where the correct outcome will require balancing competing interests, using the best available information despite considerable uncertainty, and imposing some limits or mitigation measures to prevent environmental damage. After a decision is made, managers must continue to gather the information needed to reduce uncertainty, periodically assess the situation, and modify activities as appropriate.

#### *Goals and Objectives for Ecosystem-based Management Plans*

As with any major, complex undertaking, ecosystem-based management should be guided by clear, measurable goals and objectives. These goals should cover multiple uses and should be based on a combination of policy judgments, community values, and science. Although good science is essential for solving problems and scientists should advise managers about the consequences of various courses of action, science cannot determine the “best” outcome in the absence of clearly identified management goals. The setting of goals and objectives will depend on a blending of values and information.

Where multiple desirable but competing objectives exist, it is not possible to maximize each. For example, both recreational boating and marine aquaculture are potential uses of nearshore marine waters. Both provide benefits and costs to society, and both have impacts on the environment that can be lessened with proper planning. However, these activities can also conflict with each other: a large-scale aquaculture operation would prevent access by recreational boaters to certain waters. Science can inform managers of the potential positive or negative impacts of each activity but cannot ultimately determine whether to favor aquaculture or boating. Instead, a community judgment must be made, weighing the value of each activity against its potential impacts.

Ecosystem-based management will lead to better decisions that protect the environment while balancing multiple uses of ocean areas. Managers will need to work with the scientific community to develop the information and understanding needed to support such complex decisions. But the critical process of setting goals to guide management will require active participation by many different stakeholders with divergent views. This will be difficult to achieve without changes to the existing governance system.







August 24, 2004

Arthur G. Baggett, Jr., Chair  
Members of the Board  
State Water Resources Control Board  
P.O. Box 100  
Sacramento, CA 95812-0100

Bay Area  
Clean Water Agencies

Bay Planning Coalition

California Association  
of Sanitation Agencies

California Council for  
Environmental &  
Economic Balance

California Manufacturers  
& Technology Association

Chemical Industry  
Council

Contra Costa Council

Oakland Metropolitan  
Chamber of Commerce

Pacific Merchant  
Shipping Association

San Leandro  
Chamber of Commerce

Tri-TAC  
Sponsored by:  
League of California Cities  
California Association of  
Sanitation Agencies  
California Water Environment  
Association

Western States Petroleum  
Association

Craig S.J. Johns  
Executive Director

**Re: Comments on the July 2004 Draft "Water Quality Control Policy for Developing California's Clean Water Act Section 303(d) List Functional Equivalent Document"**

Dear Chairman Baggett and Members of the Board:

The Partnership for Sound Science in Environmental Policy (PSSEP) appreciates the opportunity to comment on the July 2004 "Draft Water Quality Control Policy for Developing California's Clean Water Act Section 303(d) List Functional Equivalent Document" (FED). PSSEP is an association of San Francisco area and statewide public and private entities - businesses, municipal wastewater treatment agencies, trade agencies and community organizations. Our members have been actively involved in the stakeholder process leading to this most recent draft, and have provided comments on previous drafts of the Listing Policy and FED.

Although PSSEP is interested in many aspects of the Listing Policy, as it will affect all of our members directly or indirectly, our comments are limited to a single issue that arises in Appendix B to the FED, "Responses To Comments." For the record, PSSEP supports the comments submitted by others from the regulated community, including those from the AB 982 PAG Regulated Caucus (dated August 24, 2004).

The single issue this letter focuses on is the apparent - - if implicit - - embrace by State Board staff of the so-called "Precautionary Principle." We say "apparent" and "implicit" because of the ambiguous language used by staff in claiming that, "The process undertaken to develop the [Listing] Policy, the draft Policy itself, and the FED embody the spirit of the [Precautionary Principle]. (FED, Appendix B at p. B-47.)

The validity of the "Precautionary Principle" has become a very controversial issue at various levels of government, and presents the State Board with an unnecessary challenge to adopting a policy for listing and delisting impaired waters in the state. We have enclosed some background information on the "Precautionary Principle" and why we strongly oppose its use.

According to the Responses to Comments, State Board staff received only three comments on the December 2003 draft Listing Policy that raised the "precautionary principle." (See, Appendix B at p. B-47 (Sheehan, L., O'Brien, L., and Wilson, R.)) Staff summarizes these collective comments as follows:

Arthur G. Baggett, Jr.  
Members of the State Board  
August 24, 2004  
Page 2

"The Precautionary Principle is intended to deal with uncertainty. It expresses the 'safe' way of handling uncertainty. The draft Policy takes an anti-precautionary approach and tolerates a high level of potential harm before taking action. It uses uncertainty as a rationale for inaction. It adopts the position that a water body is clean until proven dirty. It creates disincentive for dischargers to contribute to additional, much-needed monitoring, because such monitoring might be used to build the case that the water segment is, in fact, impaired."

(FED, Appendix B at p. 47, Comment Numbers 51.5, 51.7, 51.8, 51.9, 105.5, and 219.1.)

The Responses provided by staff to these comments are troubling, and arguably suggest to the reader that the State Board has, in fact, adopted the "Precautionary Principle" as enunciated in the FED document. There are several reasons why PSSEP objects to the staff's discussion of the "Precautionary Principle" in the FED. First, to our knowledge, the issue of whether the "Precautionary Principle" (in *any* of its various forms and definitions) should be the basis on which all State and Regional Board decisions are to be based, has never been discussed, let alone decided by the California Legislature, Cal/EPA or the State Board.

Second, staff refers to the so-called "Rio Declaration" - - and specifically Principle 15) - - from the Rio Conference on the Environment and Development as the basis for the Precautionary Principle. Staff further identifies "guidelines" adopted by the Commission of European Communities (CEC) that were intended to implement the precautionary principle. Finally, staff cites each CEC guideline, and explains how and why the Listing Policy is consistent with the guidelines. The reliance on the CEC guidelines is wholly inappropriate and should be removed entirely from a discussion about the Listing Policy. To our knowledge, these guidelines have never been discussed, let alone approved, by the State Board - - or *any* board, department or office within Cal/EPA.

Third, inclusion of the Precautionary Principle issues in the FED - - and specifically, reliance on the Rio Declaration and CEC guidelines - - will suggest that the State Board has formally adopted the Precautionary Principle, or at least based the Listing Policy on it. In turn, this suggestion will be further relied upon by certain advocates seeking to inculcate every Regional Board decision with the Precautionary Principle. For many reasons, this would be a serious mistake.

Fourth, the U.S. Commission on Ocean Policy recently considered and rejected using the precautionary principle as the basis upon which all ecosystem management decisions should be made. (See, "Preliminary Report of the U.S. Commission on Ocean Policy, Governors' Draft, Washington, D.C., April 2004," at pp. 35-36 (hereafter, "Ocean Policy Report"; excerpts enclosed, full report at: <http://www.oceancommission.gov>.) In issuing its Ocean Policy Report in April of 2004, the Commission noted that "the precautionary principle has been proposed by some parties as a touchstone for managers faced with uncertain scientific information." (Ocean Policy Report at p. 35.) Yet, in rejecting the precautionary principle, the Commission also noted that, "[w]hile this may appear sensible at first glance, *its application could lead to extreme and often undesirable results.*" (Ocean

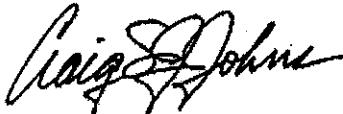
Arthur G. Baggett, Jr.  
Members of the State Board  
August 24, 2004  
Page 3

Policy Report at p. 35, emphasis added.) Instead, the Commission recommended "a more balanced *precautionary approach* that weighs the level of scientific uncertainty and the potential risk of damage as part of every management decision"

Fifth, any suggestion that the State Board has adopted or relied upon the "Precautionary Principle" as set forth in Principle 15 of the Rio Declaration, and the CEC guidelines, conflicts with the recent work of the Cal/EPA in developing its "Environmental Justice Action Plan." As recently as August 13, 2004, the Secretary for Cal/EPA released the latest draft of the Environmental Justice Action Plan, which calls for, among other things, the development of guidance on specific "precautionary approaches" appropriate for all of the Cal/EPA boards, departments and offices. It is no accident that the phrase, "precautionary approach" was used, as reliance on the "precautionary principle" was specifically rejected. Even the Cal/EPA Advisory Committee on Environmental Justice rejected inclusion of the term "*precautionary principle*" in its October 7, 2004 recommendations report because of the controversial nature of the principle and because of extensive public testimony that the Committee heard against the *precautionary principle*.

PSSEP respectfully requests the State Board to direct staff to remove the responses provided in Appendix B at pages B-47 through B-50 as they related to the "*Precautionary Principle*," the Rio Declaration, and the CEC guidelines for implementation of the *Precautionary Principle*.

Sincerely yours,



Craig S.J. Johns  
Executive Director

Enclosures

Cc: Mr. Terry Tamminen, Secretary, Cal/EPA  
Ms. Tam Doduc, Deputy Secretary, Cal/EPA  
Members, PSSEP





## What Price, *Precaution*?

In May of 2003, the London Royal Institution convened a meeting to discuss the *Precautionary Principle*, the seemingly new-obsession with its preeminency in policy decisions throughout the world, and the potential costs to society as we know it today. At the meeting, forty members of the international scientific community were asked to list what significant discoveries and achievements would have been *limited* or *prevented* if science, at the time, had been governed by the *Precautionary Principle*. Here are a few of those discoveries and achievements that would have been endangered<sup>1</sup>:

- Aspirin -** Considerable adverse side-effects. Aspirin deforms the unborn young of almost every animal species but humans.<sup>2</sup> The benefits, however, are enormous and growing - apart from the well-known treatment for inflammatory pain, there are uses in cancer, heart disease and prevention of deep vein thrombosis. As a result of the success of aspirin, many safer alternatives have been developed - for example, new generation COX2 inhibitors (Vioxx, Rofecoxib, etc).
- Airplanes -** Chance of crashing and hijack, sound and air pollution impacts.
- Trains -** Some argued that a man would die if he traveled at 30 miles per hour, and some of those who did journey reported sickness.
- Mobile phones -** May cause brain cancer, headaches, feeling tired or problems with sleeping. A study by a Swedish research group even suggested it could lead to Alzheimer's disease.
- Chlorine -** Poisonous gas added to drinking water, carcinogenic byproducts, caustic household cleaner, harmful if swallowed.
- Electricity -** In the 1990's, an average of more than 200 people were electrocuted in the United States each year from household electrical devices as lamps, switches, TVs, radios, washers, dryers and so on, with another 300 killed in some 40,000 electrical fires. Environmental impacts with the siting of power plants and transmission lines, and concerning the air and water pollutants, cannot be completely mitigated. **High-voltage power grids**, standard in the industrial world, would ever have been allowed to take shape - despite the fact that no serious evidence has ever emerged that low-frequency electromagnetic radiation is harmful.
- Digitalis -** Extracted from the foxglove plant (*Digitalis purpurea*). It is a highly toxic substance, and if the *Precautionary Principle* had operated in 1780 when it was discovered, its great beneficial effects on the heart would never have been advanced.

<sup>1</sup> Starr, Sandy, "Science, risk and the price of precaution," May 1, 2003. <http://www.spiked-online.co.uk/Articles/00000006DD7A.htm>

<sup>2</sup> Robertson, Richard T., et al., "Aspirin: Teratogenic Evaluation in the Dog," *Tetrolgy* 20: 313-320, 1979; Layton, William M., "An Analysis of Teratogenic Testing Procedures," *Congenital Defects*, Janerich, D.T., Skalko, R.G. and Porter, I.H., eds., pp. 205-217 (New York: Academic Press, 1974).

- Open-heart surgery – Killed a large number of recipients before it was regularly successful and organ transplants**
- Penicillin-** Injected into a human after minimal testing on mice. The person died when more penicillin could not be produced. Later study found penicillin lethal to guinea pigs.
- Radiation –** Deadly at improper doses, can cause mutilation and cancer. No CT scans, brain imaging, or contrast agents.
- Vaccines -** The live vaccines carry a five percent risk of inflicting the disease. Jenner's experiments on vaccination would be condemned for transferring tissue across species, risking the creation of new human diseases. Use potentially deadly substance. Fear that some vaccines cause autism in children.
- Contraceptive Pill –** Believed to cause increased risk of some cancers in women, early forms linked to blood clots and strokes.
- Space travel to outer planets -** The use of radio isotope thermal generators (RTGs) is required for all spacecraft for the exploration of the outer planets since solar power is no longer effective. RTGs use radioactive material such as plutonium. This has generated some opposition because an accident on launch could contaminate the atmosphere.
- DDT –** May cause breast cancer, reduction in raptor population, bioaccumulation 'up the food chain'. DDT has saved millions of humans from dying of malaria and eradicated the disease from the entire Mediterranean region. Its inventor was awarded the Nobel Prize in medicine in 1948 for his discovery. National Academy of Sciences wrote in 1970: "To only a few chemicals does man owe as great a debt as to DDT."
- Green Revolution -** Randomly mutating seeds and selecting plants that had enhanced crop characteristics. There was no way of knowing with absolute certainty whether the random mutagenic process (done with gamma rays) would produce some kind of 'killer' crop, that could disrupt ecosystems or have a surreptitious harmful effect on people. The Green Revolution prevented widespread famine in large areas of Asia.
- Water supply and distribution -** Possibly allowed, but with strict (and expensive) controls on siting, and with rejection of specific applications. For example, the **Hoover Dam**, built primarily to control destructive habitat flooding and secondarily to produce electricity, would have the undesirable side-effect of encouraging growth in a pristine, unique, irreplaceable, priceless, delicate, biodiverse ecosystem.
- Air conditioning and refrigeration -** High electricity use and refrigerants like freon (Antarctic ozone thinning)
- Radar -** High-powered radar emits microwaves at sufficient intensity to harm or kill anyone standing directly in front of the antenna.
- Laser technology –** Fears it can cause chest infections, blindness and other serious health problems. At one point it was deemed "a solution looking for a problem." Today it is used for printers, optical telephone networks, surgery, CD players, and industrial tools.

U.S. COMMISSION ON  
OCEAN POLICY



**PRELIMINARY REPORT**  
OF THE U.S. COMMISSION ON OCEAN POLICY

**GOVERNORS' DRAFT**  
**APRIL 2004**

YOU MAY ELECTRONICALLY DOWNLOAD THIS DOCUMENT FROM THE  
U.S. COMMISSION ON OCEAN POLICY WEB SITE:  
[HTTP://WWW.OCEANCOMMISSION.GOV](http://www.oceancommission.gov)

THIS DOCUMENT MAY BE CITED AS FOLLOWS:  
PRELIMINARY REPORT OF THE U.S. COMMISSION ON OCEAN POLICY  
GOVERNORS' DRAFT, WASHINGTON, D.C., APRIL 2004

While determining appropriate new boundaries is necessary for ecosystem-based management, it is also important to maintain sufficient flexibility to manage on both larger and smaller scales when necessary. For example, air pollution problems must be dealt with on national and even international levels, while certain water pollution issues may need to be addressed on a small-scale watershed level. Managers should be able to adapt to the scale of different activities and the ecosystems they affect.

#### *Aligning Decision-making within Ecosystem Boundaries*

The current political and issue-specific delineation of jurisdictional boundaries makes it difficult to address complex issues that affect many parts of the ecosystem. Economic development in a coastal area may fall under the jurisdiction of several local governments, and natural resource management under the jurisdiction of one or more states, while pollution control and environmental monitoring of the same area may be overseen by several federal agencies. Yet water, people, fish, marine mammals, and ships flow continually across these invisible institutional borders.

Ecosystem-based management can provide many benefits over the current structure. The coordination of efforts within a specific geographic area allows agencies to reduce duplication and maximize limited resources. It also provides an opportunity for addressing conflicts among management entities with different mandates. Less obvious, but equally important, ecosystem-based management may engender a greater sense of stewardship among government agencies, private interests, and the public by promoting identification and connection with a specific area.

Finally, ecosystem-based management makes it easier to assess and manage the cumulative impacts of many different activities. For example, the U.S. Army Corps of Engineers' wetlands permitting program has been criticized for not evaluating cumulative impacts in its review of individual dredge-and-fill permits. A true ecosystem-based management approach would ameliorate this fragmented approach.

While ecosystem-based management is being attempted in some places on a limited basis, applying it broadly and successfully will take time and effort. In particular, the transition to such management will require explicit recognition of the uncertainty of current information and understanding. This uncertainty creates risks. One widely accepted guideline for managing in the face of uncertainty and risk is to adopt a precautionary and adaptive approach.

#### *Precautionary and Adaptive Management*

Scientific uncertainty has always been, and will probably always be, a reality of the management process. Because scientists cannot predict the behavior of humans or the environment with 100 percent accuracy, managers cannot be expected to manage with complete certainty. Nevertheless, scientists *can* provide managers with an estimate of the level of uncertainty associated with the information they are providing. Managers must incorporate this level of uncertainty into the decision-making process, support the research and data collection needed to reduce the uncertainties, and be prepared to adapt their decisions as the information improves.

The *precautionary principle* has been proposed by some parties as a touchstone for managers faced with uncertain scientific information. In its strictest formulation, the precautionary principle states that when the potentially adverse effects of a proposed activity are not fully understood, the activity should not be allowed to proceed. While this may appear sensible at first glance, its application could lead to extreme and often undesirable results. Because scientific information can never fully explain and predict all impacts, strict adoption of the precautionary principle would prevent most, if not all, activities from proceeding.



In contrast to the precautionary principle, the Commission recommends adoption of a more balanced *precautionary approach* that weighs the level of scientific uncertainty and the potential risk of damage as part of every management decision. Such an approach can be explained as follows:

**Precautionary Approach:** To ensure the sustainability of ecosystems for the benefit of future as well as current generations, decision makers should follow a balanced precautionary approach, applying judicious and responsible management practices based on the best available science and on proactive, rather than reactive, policies. Where threats of serious or irreversible damage exist, lack of full scientific certainty shall not be used as a justification for postponing action to prevent environmental degradation. Management plans and actions based on this precautionary approach should include scientific assessments, monitoring, mitigation measures to reduce environmental risk where needed, and periodic reviews of any restrictions and their scientific bases.

According to this approach, scientific uncertainty—by itself—should neither prevent protective measures from being implemented nor prevent uses of the ocean. Managers should review the best available science and weigh decisions in light of both the level of scientific uncertainty and the potential for damage. When the level of uncertainty is low and the likelihood of damage is also low, the decision to proceed is clearly supported. At the other extreme, when the level of uncertainty is high and the potential for irreversible damage is also high, managers should clearly not allow a proposed action to proceed. In the real world, managers will most likely face decisions between these two extremes, where the correct outcome will require balancing competing interests, using the best available information despite considerable uncertainty, and imposing some limits or mitigation measures to prevent environmental damage. After a decision is made, managers must continue to gather the information needed to reduce uncertainty, periodically assess the situation, and modify activities as appropriate.

#### *Goals and Objectives for Ecosystem-based Management Plans*

As with any major, complex undertaking, ecosystem-based management should be guided by clear, measurable goals and objectives. These goals should cover multiple uses and should be based on a combination of policy judgments, community values, and science. Although good science is essential for solving problems and scientists should advise managers about the consequences of various courses of action, science cannot determine the “best” outcome in the absence of clearly identified management goals. The setting of goals and objectives will depend on a blending of values and information.

Where multiple desirable but competing objectives exist, it is not possible to maximize each. For example, both recreational boating and marine aquaculture are potential uses of nearshore marine waters. Both provide benefits and costs to society, and both have impacts on the environment that can be lessened with proper planning. However, these activities can also conflict with each other: a large-scale aquaculture operation would prevent access by recreational boaters to certain waters. Science can inform managers of the potential positive or negative impacts of each activity but cannot ultimately determine whether to favor aquaculture or boating. Instead, a community judgment must be made, weighing the value of each activity against its potential impacts.

Ecosystem-based management will lead to better decisions that protect the environment while balancing multiple uses of ocean areas. Managers will need to work with the scientific community to develop the information and understanding needed to support such complex decisions. But the critical process of setting goals to guide management will require active participation by many different stakeholders with divergent views. This will be difficult to achieve without changes to the existing governance system.





## What is the *Precautionary Principle*?

The *Precautionary Principle* is a relatively new regulatory approach increasingly being touted by many environmental, public health, and community-based organizations as a means to “fix” our current regulatory system to prevent harm to the environment or human health from new and existing products or activities. Although there is no widely accepted or widely used definition of the *Precautionary Principle*, the basic premise is that decision-makers should implement regulatory measures to prevent or restrict actions that may harm humans or the environment, even though there is incomplete scientific evidence to assess the significance of the potential harm.

The *Precautionary Principle* is sometimes represented as “erring on the side of safety” or “better safe than sorry.” The various definitions have significant differences in meanings and implications. The strong versions of the *Precautionary Principle* encourage decision-makers to take no action unless they are certain that it will do no harm. These strong versions do not allow for any risks and require proof that a product or activity is absolutely safe. The weaker versions of the *Precautionary Principle* usually state that a decision-maker does not have to have full certainty to justify prevention of something that may be harmful. These weaker versions may use risk assessment and scientific evaluation initially, but require the decision-maker to err on the side of caution if the information is incomplete. Below are some more commonly used definitions of the *Precautionary Principle*:

“When information about potential risks is incomplete, basing decisions about the best ways to manage or reduce risks on a preference for avoiding unnecessary health risks instead of on unnecessary economic expenditures.” (US EPA)<sup>1</sup>

“Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.” (Principle 15 of the Rio Declaration on Environment and Development, 1992.)<sup>2</sup>

When “potential adverse effects are not fully understood, the activities should not proceed.” (The United Nations World Charter for Nature.)<sup>3</sup>

“When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not established scientifically. In this context the proponent of the activity, rather than the public, should bear the burden of proof.” (Wingspread Declaration.)<sup>4</sup>

---

<sup>1</sup> <http://www.epa.gov/OCEPAterms/pterm.html>

<sup>2</sup> <http://www.unep.org/Documents/Default.asp?DocumentID=78&ArticleID=1163>

<sup>3</sup> <http://www.un.org/documents/ga/res/37/a37r007.htm>

<sup>4</sup> <http://www.gdrc.org/u-gov/precaution-3.html>

**How does use of the *Precautionary Principle* differ from our current regulatory approach?**

Most regulatory decisions in the United States are based on scientific evidence and risk assessment. This system allows for the maximum benefits (improvements in the quality of products and/or life) while identifying and minimizing any potential hazard, both near and long term. It encourages innovation, economic growth and consumer power while minimizing consumer and environmental risk.

The *Precautionary Principle* represents a radical shift in how public policy is to be developed. It focuses on the *possibility* that technologies or actions could pose unique, extreme, or unmanageable risks, even after considerable testing has already been conducted. The *Precautionary Principle* fails to acknowledge that even when technologies introduce new risks, most confer net benefits — that is, their use reduces many other, often far more serious, hazards. Examples include blood transfusions, MRI scans, and automobile air bags, all of which offer immense benefits and only minimal risk.<sup>5</sup>

Although the United States has - - and should - - not formally adopted the *Precautionary Principle* as a regulatory system, it incorporates precautionary approaches in statute and guidelines. Regulatory evaluations commonly use extremely conservative assumptions and factors of safety to determine if or how a product can be used. These assumptions can include basing decisions on the impacts to high risks groups or the most sensitive species, adding factors of safety for unknown information and for future possible impacts, and similar types of conservative assumptions.

In addition, laws in this country put the burden of a safe product on the proponent of the activity in many instances. For example, within the United States food safety system, food processors are allowed to offer consumers only food that is safe. They may be held "strictly liable" if they fail to carry out their duty. "Strict liability" means that a processor who sells a food that causes injury to a consumer may be legally responsible even in the absence of actual knowledge of the product's hazard. The legal responsibility includes both the possibility of a private lawsuit by any injured consumers and the possibility of regulatory actions. Also, processors must have a reasonable basis for believing their products to be safe; they cannot simply assume this is so.<sup>6</sup>

**What are some concerns about the *Precautionary Principle*?**

The *Precautionary Principle* calls upon governments to impose regulatory measures based upon the barest potential of environmental or human harm. In other words, if a chemical substance *might* cause harm, it should be controlled or eliminated. If a new technological innovation *could* have unknown environmental effects, it should be prohibited. If a given action *could* harm a species that *might* be endangered, it should not be allowed. The *Precautionary Principle* may appeal viscerally to common-sense notions of safety, but its application will not produce a safer, cleaner world. Quite the opposite — the incorporation of the *Precautionary Principle* in environmental, health, and safety regulation is itself a threat to environmental protection and optimal safeguards for public health.<sup>7</sup>

<sup>5</sup> Conko, Gregory and Henry I. Miller, "The Perils of Precaution," Policy Review On-Line, Hoover Institution, June 2001. <http://www.policyreview.org/jun01/miller.html>

<sup>6</sup> Food and Drug Administration, U.S. Department of Agriculture. "United States Food Safety System, Precaution In U.S. Food Safety Decisionmaking: Annex II to the United States' National Food Safety System Paper," March 3, 2000. [www.foodsafety.gov/~fsg/fssvst4.html#a-intro](http://www.foodsafety.gov/~fsg/fssvst4.html#a-intro)

<sup>7</sup> Adler, Jonathan, "Dangerous Precaution: The precautionary principle's challenge to progress," National Review Online September 13, 2002. <http://www.nationalreview.com/adler/adler091302.asp>

The strongest definitions of the *Precautionary Principle* would require proof that no harm would be done by an action or product before it could be approved. Proving that an action would not harm anyone or anything now or in the future is impossible. Science cannot prove an absence of risk.

Implementing the weaker definitions of the *Precautionary Principle* would focus more effort on possible hazards, thus adding to regulation. Significant resources would be diverted to solve a possible hazard and “prove” no harm where science has not yet shown a hazard to exist. Regulators would be required to review a host of “possible” hazards rather than focusing on real and serious hazards. Regulatory schemes that divert attention, ingenuity, and money from real threats to minor risks, in the end, make us less safe.

The *Precautionary Principle* can also be used as a rhetorical weapon. Application of the *Precautionary Principle* has already elicited unscientific, discriminatory policies that inflate the costs of research, inhibit the development of new products, divert and waste resources, restrict consumer choice, and introduce new barriers to trade.<sup>8</sup>

The variations in the definitions and terms used within these definitions also lead to confusion and subjective application. For example, what are the limits, in terms of scientific uncertainty, of severity and irreversibility of consequences, over which the *Precautionary Principle* should apply? Without a clear understanding of the Principle, it will never be able to be implemented in a fair and consistent manner.

#### **Where has the *Precautionary Principle* been implemented and what are the outcomes?**

The *Precautionary Principle* is set forth in the European Union (EU) treaty and some other international treaties. The European Union is the most active in employing the *Precautionary Principle*, with Sweden and Germany taking the lead. In the United States, Hawaii, Massachusetts, Minnesota, and New Jersey are exploring the incorporation of the *Precautionary Principle* into policies and laws.

In California, the City and County of San Francisco has officially embraced the *Precautionary Principle* by resolution,<sup>9</sup> and the Los Angeles Unified School District has adopted it as part of its pest management program for schools.<sup>10</sup> Further, the California Environmental Protection Agency’s “Environmental Justice Advisory Committee” has considered (and rejected) a report that recommended incorporation of the *Precautionary Principle* in all policy and regulatory actions.<sup>11</sup>

The United States and Canada have seen the *Precautionary Principle* used in EU to restrict trade. The European Commission banned genetically modified (GM) food and hormone treated beef cattle produced in the United States and England citing the *Precautionary Principle*. Scientific evidence does not support that either of these technologies pose greater risks. Dozens of scientific bodies, including the

<sup>8</sup> Conko and Miller, *supra* note 5.

<sup>9</sup> San Francisco’s *Precautionary Principle* ordinance can be found at [http://sfgov.org/sfenvironment/aboutus/policy/legislation/precaution\\_principle.htm](http://sfgov.org/sfenvironment/aboutus/policy/legislation/precaution_principle.htm)

<sup>10</sup> Los Angeles Unified School District’s Integrated Pest Management Policy can be found at <http://www.calisafe.org/policy.htm>

<sup>11</sup> On October 14, 2003, California Environmental Protection Agency’s Interagency Working Group on Environmental Justice adopted by resolution “The Recommendations of the California Environmental Protection Agency (Cal/EPA) Advisory Committee on Environmental Justice to the Cal/EPA Working Group on Environmental Justice, Final Report,” September 30, 2003.

Resolution: <http://www.calepa.ca.gov/EnvJustice/Documents/2003/ResolutionIWG.pdf>.

Final Report: <http://www.calepa.ca.gov/EnvJustice/Documents/2003/FinalReport.pdf>

UK's Royal Society, the U.S. National Academy of Sciences, the World Health Organization and the American Medical Association, have performed analyses of the oversight that is appropriate for GM organisms (GMOs), with remarkable congruence in their conclusions:

- The newer molecular techniques for genetic improvement are an extension, or refinement, of earlier, far less precise ones;<sup>12</sup>
- Adding genes to plants does not make them less safe either to the environment or to eat;<sup>13, 14</sup>
- The risks associated with GMOs are the same in kind as those associated with unmodified and conventionally-modified organisms;<sup>15</sup> and
- Regulation should be based upon the risk-related characteristics of individual products, regardless of the techniques used in their development.<sup>16, 17</sup>

A scientific committee assembled by the World Trade Organization found that the European Commission's argument that the *Precautionary Principle* permits the restriction on imports of U.S. and Canadian beef treated with certain growth hormones was invalid for a number of reasons, including:

- The scientific studies cited by the Commission in its own defense do not indicate a safety problem when the hormones in question are used in accordance with good animal husbandry practices.
- EU health officials have expressed no concern about endogenous hormones that occur at higher levels in the un-castrated steers more common in Europe; and
- The European Union did not, at the time, ban growth hormones in the pork industry, where many European livestock operations are internationally competitive.<sup>18</sup>

In August 2002, the Zambian government refused to accept foreign food aid from the United States because it might have contained genetically modified (GM) food, despite a crippling food shortage that threatened to leave some two million people hungry in that country. Just one month before, the government of Zimbabwe announced a similar decision, but later allowed some GM food for famine relief. Contrary to scientific evidence and widespread use of GM foods in the United States, these southern African governments claimed the food was not safe enough to feed their people. Zambia's Information Minister claimed the decision reflected the "*Precautionary Principle*," because of alleged "uncertainties surrounding the likely consequences of consuming genetically modified food." Due to a hypothetical risk of foreign food, millions of Africans face a certain threat of starvation.<sup>19</sup>

---

<sup>12</sup> The Royal Society, "Genetically Modified Plants for Food Use," September 1998, p. 5. <http://www.royalsoc.ac.uk/policy/>

<sup>13</sup> *Id.*

<sup>14</sup> American Medical Association "Genetically Modified Crops and Food: Report 10 of the council on Scientific Affairs" pp. 11-16.

<sup>15</sup> National Academy of Sciences "Genetically Modified Pest-Protected Plants," *Science and Regulation* at p. 5. (2000)

<http://www.nap.edu/books/0309069300/html/>

<sup>16</sup> *Id.*

<sup>17</sup> World Health Organization "20 Questions on Genetically Modified (GM) Foods."

<http://www.who.int/foodsafety/publications/biotech/20questions/en>

<sup>18</sup> Conko, Gregory and Henry I. Miller, "Food Safety: The Precautionary Principle is the Wrong Approach," *European Affairs*, Spring 2001.

[http://www.europeanaffairs.org/archive/2001\\_spring/2001\\_spring\\_122.php4](http://www.europeanaffairs.org/archive/2001_spring/2001_spring_122.php4)

<sup>19</sup> Adler, *supra* note 7.

In the late 1980s, environmental activists were lobbying water authorities around the world, trying to convince them that carcinogenic byproducts of chlorination made drinking water a potential cancer risk. The Peruvian government saw this as a great way to save money, and it stopped chlorinating much of that country's drinking water. As a result, more than 1.3 million people contracted cholera and at least 11,000 died in one of Latin America's biggest cholera epidemics – all to save a handful of purely speculative cancer cases.<sup>20</sup>

It is, and will continue to be, difficult to assess the impacts of *Precautionary Principle* in world society. If something is never tried, both the benefits and risks will never be known, unless it is tried elsewhere and allowed to proceed. The cost of delay in the by The United States has some of the most rigorous approval processes for pharmaceutical drugs. While the FDA is supposed to guarantee the safety of new drugs brought to market, the costs of delay are often overlooked. In 1986, Dale H. Gieringer of the Decisions and Ethics Center at Stanford University reported, "The cost of a mere one-year delay in new-drug approval can be estimated at as much as 37,000-76,000 lives per decade -- several times the worldwide toll of all new-drug accidents."<sup>21</sup> For example, propranolol, the first Beta-blocker to be used extensively to treat angina and hypertension took three years longer to approve in the United States than in England. Approximately 10,000 Americans died every year for the three years it was against the law for their doctors to treat them with propranolol. Propranolol was finally approved in the US for minor uses in 1968, but was only approved in 1973 and 1976 for angina and hyper-tension respectively. The regulatory delay of this single drug may have been responsible for the death of more Americans than all other deaths from drugs in this century. Even so, the FDA came under severe criticism by Congress for "premature" approval of this valuable drug.<sup>22</sup> Although FDA has sped up its approval review from several years to six months in the last few years, this provides examples as to real costs of excess precaution.

### Recent Developments

The *Precautionary Principle* was one of the key issues addressed at the 2002 follow-up to the Rio summit, the World Summit on Sustainable Development (WSSD) in Johannesburg, South Africa. There, delegates debated amending the Rio Declaration Principle 15 definition by incorporating language stating the importance of governments adopting a precautionary approach in making regulatory decisions.

The world governments rejected this approach. Developing nations in particular were concerned that references to extreme interpretations of the *Precautionary Principle* would have an adverse effect on trade. The participating governments, including the United States, strongly supported the importance of a science-based approach to decision-making and the need to establish relationships between the science community and governments.

Paragraph 109 of the final WSSD text clearly and definitively addresses the desires of the world's nations to be cautious in decision-making but base decisions on science and not be bound by extreme interpretations of the *Precautionary Principle*. Paragraph 109 also establishes "science-based decision-making" as the preferred approach for making regulatory decisions. The final WSSD text reflects the thinking of those countries supporting a science-based approach to decision-making:

---

<sup>20</sup> Conko, Gregory, "The Precautionary Principle: Protectionism and Environmental Extremism by Other Means," International Society of Regulatory Toxicology and Pharmacology Workshop on The Precautionary Principle, June 20, 2002, Arlington, Virginia. [http://www.cei.org/gencon/027\\_03079.cfm](http://www.cei.org/gencon/027_03079.cfm)

<sup>21</sup> Tuccille, Jerome D., "FDA Reform." <http://www.frce-market.net/forums/main0210/messages/935960756.html>

<sup>22</sup> Ruwart, Dr. Mary J., "Protecting Ourselves to Death." <http://www.ruwart.com/Healing/chap6.html>

109 (f) Promote and improve science-based decision-making and reaffirm the precautionary approach as set out in Principle 15 of the Rio Declaration on the Environment and Development, which states: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

Recently, the Office of Management and Budget (OMB) recently released a report "Informing Regulatory Decisions" which includes a chapter on the current role of precaution in regulatory decision making, while explaining why precaution needs to be exercised wisely on a case-by-case basis.<sup>23</sup> There are some good conclusions to draw upon - for example the report states, "When applied appropriately, precautionary approaches can promote the protection of public health, safety and the environment by reducing potential threats. However, if precaution is taken to an extreme and rigidly applied, adverse impacts can occur."<sup>24</sup>

The report also concludes that the existing US regulatory approach already embeds a great deal of precaution, noting that, "Since the U.S. regulatory framework relies on an open and transparent system of *delegated rulemaking with revisable regulations*, the system is able to incorporate the best scientific advice at many steps in the process and respond to changes in information accordingly. This allows for an iterative process of information collection, risk assessment, and risk management when regulating emerging risks. In this iterative process, different levels of precaution are applied early on (when the scientific information is limited) and an appropriate reduction of precautionary consideration is applied as scientific knowledge and experience regarding risks, benefits, and costs increases."<sup>25</sup>

More recently, the U.S. Commission on Ocean Policy considered *and rejected* using the *Precautionary Principle* as the basis upon which all ecosystem management decisions should be made.<sup>26</sup> In issuing its Ocean Policy Report in April of 2004, the Commission noted that "the precautionary principle has been proposed by some parties as a touchstone for managers faced with uncertain scientific information."<sup>27</sup> Yet, in rejecting the *Precautionary Principle*, the Commission also noted that, "[w]hile this may appear sensible at first glance, *its application could lead to extreme and often undesirable results*."<sup>28</sup> Instead, the Commission recommended "a more balanced *precautionary approach* that weighs the level of scientific uncertainty and the potential risk of damage as part of every management decision" which "can be explained as follows:

**Precautionary Approach:** To ensure the sustainability of ecosystems for the benefit of future as well as current generations, decision makers should follow a balanced precautionary approach, applying judicious and responsible management practices based on the best available science and on proactive,

<sup>23</sup> U.S. Office of Management and Budget, "Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities," Chapter 3, pp. 51-63. [http://www.whitehouse.gov/omb/inforeg/2003\\_cost-ben\\_final\\_rpt.pdf](http://www.whitehouse.gov/omb/inforeg/2003_cost-ben_final_rpt.pdf)

<sup>24</sup> *Id.* at p. 62.

<sup>25</sup> *Id.* at p. 62-63.

<sup>26</sup> See, "Preliminary Report of the U.S. Commission on Ocean Policy, Governors' Draft, Washington, D.C., April 2004" at pp. 35-36 (hereafter, "Ocean Policy Report"). <http://www.oceancommission.gov>

<sup>27</sup> *Id.* at p. 35.

<sup>28</sup> *Id.* (emphasis added)



rather than reactive, policies. Where threats of serious or irreversible damage exist, lack of full scientific certainty shall not be used as a justification for postponing action to prevent environmental degradation. Management plans and actions based on this precautionary approach should include scientific assessments, monitoring, mitigation measures to reduce environmental risk where needed, and periodic reviews of any restrictions and their scientific bases."<sup>29</sup>

---

<sup>29</sup> *Id.* at p. 36.





## What is the *Precautionary Principle*?

The *Precautionary Principle* is a relatively new regulatory approach increasingly being touted by many environmental, public health, and community-based organizations as a means to “fix” our current regulatory system to prevent harm to the environment or human health from new and existing products or activities. Although there is no widely accepted or widely used definition of the *Precautionary Principle*, the basic premise is that decision-makers should implement regulatory measures to prevent or restrict actions that may harm humans or the environment, even though there is incomplete scientific evidence to assess the significance of the potential harm.

The *Precautionary Principle* is sometimes represented as “erring on the side of safety” or “better safe than sorry.” The various definitions have significant differences in meanings and implications. The strong versions of the *Precautionary Principle* encourage decision-makers to take no action unless they are certain that it will do no harm. These strong versions do not allow for any risks and require proof that a product or activity is absolutely safe. The weaker versions of the *Precautionary Principle* usually state that a decision-maker does not have to have full certainty to justify prevention of something that may be harmful. These weaker versions may use risk assessment and scientific evaluation initially, but require the decision-maker to err on the side of caution if the information is incomplete. Below are some more commonly used definitions of the *Precautionary Principle*:

“When information about potential risks is incomplete, basing decisions about the best ways to manage or reduce risks on a preference for avoiding unnecessary health risks instead of on unnecessary economic expenditures.” (US EPA)<sup>1</sup>

“Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.” (Principle 15 of the Rio Declaration on Environment and Development, 1992.)<sup>2</sup>

When “potential adverse effects are not fully understood, the activities should not proceed.” (The United Nations World Charter for Nature.)<sup>3</sup>

“When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not established scientifically. In this context the proponent of the activity, rather than the public, should bear the burden of proof.” (Wingspread Declaration.)<sup>4</sup>

---

<sup>1</sup> <http://www.epa.gov/OCEPAterms/pterms.html>

<sup>2</sup> <http://www.unep.org/Documents/Default.asp?DocumentID=78&ArticleID=1163>

<sup>3</sup> <http://www.un.org/documents/ga/res/37/a37r007.htm>

<sup>4</sup> <http://www.gdrc.org/u-gov/precaution-3.html>

**How does use of the *Precautionary Principle* differ from our current regulatory approach?**

Most regulatory decisions in the United States are based on scientific evidence and risk assessment. This system allows for the maximum benefits (improvements in the quality of products and/or life) while identifying and minimizing any potential hazard, both near and long term. It encourages innovation, economic growth and consumer power while minimizing consumer and environmental risk.

The *Precautionary Principle* represents a radical shift in how public policy is to be developed. It focuses on the *possibility* that technologies or actions could pose unique, extreme, or unmanageable risks, even after considerable testing has already been conducted. The *Precautionary Principle* fails to acknowledge that even when technologies introduce new risks, most confer net benefits — that is, their use reduces many other, often far more serious, hazards. Examples include blood transfusions, MRI scans, and automobile air bags, all of which offer immense benefits and only minimal risk.<sup>5</sup>

Although the United States has - - and should - - not formally adopted the *Precautionary Principle* as a regulatory system, it incorporates precautionary approaches in statute and guidelines. Regulatory evaluations commonly use extremely conservative assumptions and factors of safety to determine if or how a product can be used. These assumptions can include basing decisions on the impacts to high risks groups or the most sensitive species, adding factors of safety for unknown information and for future possible impacts, and similar types of conservative assumptions.

In addition, laws in this country put the burden of a safe product on the proponent of the activity in many instances. For example, within the United States food safety system, food processors are allowed to offer consumers only food that is safe. They may be held "strictly liable" if they fail to carry out their duty. "Strict liability" means that a processor who sells a food that causes injury to a consumer may be legally responsible even in the absence of actual knowledge of the product's hazard. The legal responsibility includes both the possibility of a private lawsuit by any injured consumers and the possibility of regulatory actions. Also, processors must have a reasonable basis for believing their products to be safe; they cannot simply assume this is so.<sup>6</sup>

**What are some concerns about the *Precautionary Principle*?**

The *Precautionary Principle* calls upon governments to impose regulatory measures based upon the barest potential of environmental or human harm. In other words, if a chemical substance *might* cause harm, it should be controlled or eliminated. If a new technological innovation *could* have unknown environmental effects, it should be prohibited. If a given action *could* harm a species that *might* be endangered, it should not be allowed. The *Precautionary Principle* may appeal viscerally to common-sense notions of safety, but its application will not produce a safer, cleaner world. Quite the opposite — the incorporation of the *Precautionary Principle* in environmental, health, and safety regulation is itself a threat to environmental protection and optimal safeguards for public health.<sup>7</sup>

<sup>5</sup> Conko, Gregory and Henry I. Miller, "The Perils of Precaution," Policy Review On-Line, Hoover Institution, June 2001. <http://www.policyreview.org/jun01/miller.html>

<sup>6</sup> Food and Drug Administration, U.S. Department of Agriculture. "United States Food Safety System, Precaution In U.S. Food Safety Decisionmaking: Annex II to the United States' National Food Safety System Paper," March 3, 2000. [www.foodsafety.gov/~fsg/fssyst4.html#a-intro](http://www.foodsafety.gov/~fsg/fssyst4.html#a-intro)

<sup>7</sup> Adler, Jonathan, "Dangerous Precaution: The precautionary principle's challenge to progress," National Review Online September 13, 2002. <http://www.nationalreview.com/adler/adler091302.asp>

The strongest definitions of the *Precautionary Principle* would require proof that no harm would be done by an action or product before it could be approved. Proving that an action would not harm anyone or anything now or in the future is impossible. Science cannot prove an absence of risk.

Implementing the weaker definitions of the *Precautionary Principle* would focus more effort on possible hazards, thus adding to regulation. Significant resources would be diverted to solve a possible hazard and “prove” no harm where science has not yet shown a hazard to exist. Regulators would be required to review a host of “possible” hazards rather than focusing on real and serious hazards. Regulatory schemes that divert attention, ingenuity, and money from real threats to minor risks, in the end, make us less safe.

The *Precautionary Principle* can also be used as a rhetorical weapon. Application of the *Precautionary Principle* has already elicited unscientific, discriminatory policies that inflate the costs of research, inhibit the development of new products, divert and waste resources, restrict consumer choice, and introduce new barriers to trade.<sup>8</sup>

The variations in the definitions and terms used within these definitions also lead to confusion and subjective application. For example, what are the limits, in terms of scientific uncertainty, of severity and irreversibility of consequences, over which the *Precautionary Principle* should apply? Without a clear understanding of the Principle, it will never be able to be implemented in a fair and consistent manner.

#### **Where has the *Precautionary Principle* been implemented and what are the outcomes?**

The *Precautionary Principle* is set forth in the European Union (EU) treaty and some other international treaties. The European Union is the most active in employing the *Precautionary Principle*, with Sweden and Germany taking the lead. In the United States, Hawaii, Massachusetts, Minnesota, and New Jersey are exploring the incorporation of the *Precautionary Principle* into policies and laws.

In California, the City and County of San Francisco has officially embraced the *Precautionary Principle* by resolution,<sup>9</sup> and the Los Angeles Unified School District has adopted it as part of its pest management program for schools.<sup>10</sup> Further, the California Environmental Protection Agency’s “Environmental Justice Advisory Committee” has considered (and rejected) a report that recommended incorporation of the *Precautionary Principle* in all policy and regulatory actions.<sup>11</sup>

The United States and Canada have seen the *Precautionary Principle* used in EU to restrict trade. The European Commission banned genetically modified (GM) food and hormone treated beef cattle produced in the United States and England citing the *Precautionary Principle*. Scientific evidence does not support that either of these technologies pose greater risks. Dozens of scientific bodies, including the

<sup>8</sup> Conko and Miller, *supra* note 5.

<sup>9</sup> San Francisco’s Precautionary Principle ordinance can be found at [http://sf.gov.org/sfenvironment/aboutus/policy/legislation/precaution\\_principle.htm](http://sf.gov.org/sfenvironment/aboutus/policy/legislation/precaution_principle.htm)

<sup>10</sup> Los Angeles Unified School District’s Integrated Pest Management Policy can be found at <http://www.calisafe.org/policy.htm>

<sup>11</sup> On October 14, 2003, California Environmental Protection Agency’s Interagency Working Group on Environmental Justice adopted by resolution “The Recommendations of the California Environmental Protection Agency (Cal/EPA) Advisory Committee on Environmental Justice to the Cal/EPA Working Group on Environmental Justice, *Final Report*,” September 30, 2003.

Resolution: <http://www.calepa.ca.gov/EnvJustice/Documents/2003/ResolutionWG.pdf>.

Final Report: <http://www.calepa.ca.gov/EnvJustice/Documents/2003/FinalReport.pdf>

UK's Royal Society, the U.S. National Academy of Sciences, the World Health Organization and the American Medical Association, have performed analyses of the oversight that is appropriate for GM organisms (GMOs), with remarkable congruence in their conclusions:

- The newer molecular techniques for genetic improvement are an extension, or refinement, of earlier, far less precise ones;<sup>12</sup>
- Adding genes to plants does not make them less safe either to the environment or to eat;<sup>13, 14</sup>
- The risks associated with GMOs are the same in kind as those associated with unmodified and conventionally-modified organisms;<sup>15</sup> and
- Regulation should be based upon the risk-related characteristics of individual products, regardless of the techniques used in their development.<sup>16, 17</sup>

A scientific committee assembled by the World Trade Organization found that the European Commission's argument that the *Precautionary Principle* permits the restriction on imports of U.S. and Canadian beef treated with certain growth hormones was invalid for a number of reasons, including:

- The scientific studies cited by the Commission in its own defense do not indicate a safety problem when the hormones in question are used in accordance with good animal husbandry practices.
- EU health officials have expressed no concern about endogenous hormones that occur at higher levels in the un-castrated steers more common in Europe; and
- The European Union did not, at the time, ban growth hormones in the pork industry, where many European livestock operations are internationally competitive.<sup>18</sup>

In August 2002, the Zambian government refused to accept foreign food aid from the United States because it might have contained genetically modified (GM) food, despite a crippling food shortage that threatened to leave some two million people hungry in that country. Just one month before, the government of Zimbabwe announced a similar decision, but later allowed some GM food for famine relief. Contrary to scientific evidence and widespread use of GM foods in the United States, these southern African governments claimed the food was not safe enough to feed their people. Zambia's Information Minister claimed the decision reflected the "*Precautionary Principle*," because of alleged "uncertainties surrounding the likely consequences of consuming genetically modified food." Due to a hypothetical risk of foreign food, millions of Africans face a certain threat of starvation.<sup>19</sup>

---

<sup>12</sup> The Royal Society, "Genetically Modified Plants for Food Use," September 1998, p. 5. <http://www.royalsoc.ac.uk/policy/>

<sup>13</sup> *Id.*

<sup>14</sup> American Medical Association "Genetically Modified Crops and Food: Report 10 of the council on Scientific Affairs" pp. 11-16.

<sup>15</sup> National Academy of Sciences "Genetically Modified Pest-Protected Plants," *Science and Regulation* at p. 5. (2000)

<http://www.nap.edu/books/0309069300/html/>

<sup>16</sup> *Id.*

<sup>17</sup> World Health Organization "20 Questions on Genetically Modified (GM) Foods."

<http://www.who.int/foodsafety/publications/biotech/20questions/en>

<sup>18</sup> Conko, Gregory and Henry I. Miller, "Food Safety: The Precautionary Principle is the Wrong Approach," *European Affairs*, Spring 2001.

[http://www.europeanaffairs.org/archive/2001\\_spring/2001\\_spring\\_122.php4](http://www.europeanaffairs.org/archive/2001_spring/2001_spring_122.php4)

<sup>19</sup> Adler, *supra* note 7.

In the late 1980s, environmental activists were lobbying water authorities around the world, trying to convince them that carcinogenic byproducts of chlorination made drinking water a potential cancer risk. The Peruvian government saw this as a great way to save money, and it stopped chlorinating much of that country's drinking water. As a result, more than 1.3 million people contracted cholera and at least 11,000 died in one of Latin America's biggest cholera epidemics -- all to save a handful of purely speculative cancer cases.<sup>20</sup>

It is, and will continue to be, difficult to assess the impacts of *Precautionary Principle* in world society. If something is never tried, both the benefits and risks will never be known, unless it is tried elsewhere and allowed to proceed. The cost of delay in the by The United States has some of the most rigorous approval processes for pharmaceutical drugs. While the FDA is supposed to guarantee the safety of new drugs brought to market, the costs of delay are often overlooked. In 1986, Dale H. Gieringer of the Decisions and Ethics Center at Stanford University reported, "The cost of a mere one-year delay in new-drug approval can be estimated at as much as 37,000-76,000 lives per decade -- several times the worldwide toll of all new-drug accidents."<sup>21</sup> For example, propranolol, the first Beta-blocker to be used extensively to treat angina and hypertension took three years longer to approve in the United States than in England. Approximately 10,000 Americans died every year for the three years it was against the law for their doctors to treat them with propranolol. Propranolol was finally approved in the US for minor uses in 1968, but was only approved in 1973 and 1976 for angina and hyper-tension respectively. The regulatory delay of this single drug may have been responsible for the death of more Americans than all other deaths from drugs in this century. Even so, the FDA came under severe criticism by Congress for "premature" approval of this valuable drug.<sup>22</sup> Although FDA has sped up its approval review from several years to six months in the last few years, this provides examples as to real costs of excess precaution.

### Recent Developments

The *Precautionary Principle* was one of the key issues addressed at the 2002 follow-up to the Rio summit, the World Summit on Sustainable Development (WSSD) in Johannesburg, South Africa. There, delegates debated amending the Rio Declaration Principle 15 definition by incorporating language stating the importance of governments adopting a precautionary approach in making regulatory decisions.

The world governments rejected this approach. Developing nations in particular were concerned that references to extreme interpretations of the *Precautionary Principle* would have an adverse effect on trade. The participating governments, including the United States, strongly supported the importance of a science-based approach to decision-making and the need to establish relationships between the science community and governments.

Paragraph 109 of the final WSSD text clearly and definitively addresses the desires of the world's nations to be cautious in decision-making but base decisions on science and not be bound by extreme interpretations of the *Precautionary Principle*. Paragraph 109 also establishes "science-based decision-making" as the preferred approach for making regulatory decisions. The final WSSD text reflects the thinking of those countries supporting a science-based approach to decision-making:

---

<sup>20</sup> Conko, Gregory, "The Precautionary Principle: Protectionism and Environmental Extremism by Other Means," International Society of Regulatory Toxicology and Pharmacology Workshop on The Precautionary Principle, June 20, 2002, Arlington, Virginia. [http://www.cei.org/gencon/027\\_03079.cfm](http://www.cei.org/gencon/027_03079.cfm)

<sup>21</sup> Tuccille, Jerome D., "FDA Reform.." <http://www.free-market.net/forums/main0210/messages/935960756.html>

<sup>22</sup> Ruwart, Dr. Mary J., "Protecting Ourselves to Death." <http://www.ruwart.com/Healing/chap6.html>

109 (f) Promote and improve science-based decision-making and reaffirm the precautionary approach as set out in Principle 15 of the Rio Declaration on the Environment and Development, which states: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

Recently, the Office of Management and Budget (OMB) recently released a report "Informing Regulatory Decisions" which includes a chapter on the current role of precaution in regulatory decision making, while explaining why precaution needs to be exercised wisely on a case-by-case basis.<sup>23</sup> There are some good conclusions to draw upon - for example the report states, "When applied appropriately, precautionary approaches can promote the protection of public health, safety and the environment by reducing potential threats. However, if precaution is taken to an extreme and rigidly applied, adverse impacts can occur."<sup>24</sup>

The report also concludes that the existing US regulatory approach already embeds a great deal of precaution, noting that, "Since the U.S. regulatory framework relies on an open and transparent system of delegated rulemaking with revisable regulations, the system is able to incorporate the best scientific advice at many steps in the process and respond to changes in information accordingly. This allows for an iterative process of information collection, risk assessment, and risk management when regulating emerging risks. In this iterative process, different levels of precaution are applied early on (when the scientific information is limited) and an appropriate reduction of precautionary consideration is applied as scientific knowledge and experience regarding risks, benefits, and costs increases."<sup>25</sup>

More recently, the U.S. Commission on Ocean Policy considered *and rejected* using the *Precautionary Principle* as the basis upon which all ecosystem management decisions should be made.<sup>26</sup> In issuing its Ocean Policy Report in April of 2004, the Commission noted that "the precautionary principle has been proposed by some parties as a touchstone for managers faced with uncertain scientific information."<sup>27</sup> Yet, in rejecting the *Precautionary Principle*, the Commission also noted that, "[w]hile this may appear sensible at first glance, *its application could lead to extreme and often undesirable results.*"<sup>28</sup> Instead, the Commission recommended "a more balanced *precautionary approach* that weighs the level of scientific uncertainty and the potential risk of damage as part of every management decision" which "can be explained as follows:

**Precautionary Approach:** To ensure the sustainability of ecosystems for the benefit of future as well as current generations, decision makers should follow a balanced precautionary approach, applying judicious and responsible management practices based on the best available science and on proactive,

<sup>23</sup> U.S. Office of Management and Budget, "Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities," Chapter 3, pp. 51-63. [http://www.whitehouse.gov/omb/inforeg/2003\\_cost-ben\\_final\\_rpt.pdf](http://www.whitehouse.gov/omb/inforeg/2003_cost-ben_final_rpt.pdf)

<sup>24</sup> *Id.* at p. 62.

<sup>25</sup> *Id.* at p. 62-63.

<sup>26</sup> See, "Preliminary Report of the U.S. Commission on Ocean Policy, Governors' Draft, Washington, D.C., April 2004" at pp. 35-36 (hereafter, "Ocean Policy Report"). <http://www.oceancommission.gov>

<sup>27</sup> *Id.* at p. 35.

<sup>28</sup> *Id.* (emphasis added)



rather than reactive, policies. Where threats of serious or irreversible damage exist, lack of full scientific certainty shall not be used as a justification for postponing action to prevent environmental degradation. Management plans and actions based on this precautionary approach should include scientific assessments, monitoring, mitigation measures to reduce environmental risk where needed, and periodic reviews of any restrictions and their scientific bases."<sup>29</sup>

---

<sup>29</sup> *Id.* at p. 36.



>> "Craig Johns" <[cjohns@calrestrats.com](mailto:cjohns@calrestrats.com)> Tuesday, August 24, 2004 >>>  
Craig:

As promised, I'm sending along comments from the Partnership for Sound Science in Environmental Policy on the State Board's July 2004 "Final Draft" Listing and Delisting Policy. Also attached are background documents on the "precautionary principle" and why it is the regulated community (POTWs, industry, trade groups, etc.) is very concerned about having the FED for the Listing Policy even suggest that the Listing Policy "embodies the spirit of the [Precautionary Principle]."

You might take close look at the excerpt from the US Commission on Ocean Policy (pp. 35-36) and why that Commission considered and rejected the precautionary principle for purposes of ecosystem management. (Att 1)

Please feel free to call if you have any questions.

Craig S.J. Johns  
PSSEP  
980 - 9th Street, Suite 2200  
Sacramento, CA 95814  
Tel: 916/498-3326  
Fax: 916/441-5449  
[www.calrestrats.com](http://www.calrestrats.com)

"Page intentionally left blank"