

## **Precautionary Principle:**

### **Reasonable, Rational, and Responsible**

(An Evolutionary, Not Revolutionary Approach to Decision-making)

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## **Introduction**

The precautionary principle is a reasonable, rational, and responsible approach to decision-making (Table 1). It provides a framework for policy making that promotes human health, a sustainable environment, and ensures that future generations of all species have an opportunity to thrive.

But first, when you got in your car this morning did you think about the relative benefits of driving your car to work, the store, or errands as compared to the cost to the environment or risks to your health should you get in an accident? Did you take the precautionary action of wearing a seat belt to reduce the risk to your health and safety? Did you think about walking or taking the bus, instead of driving, to reduce air pollution?

Some of you may take prescription drugs and are confident that the benefits outweigh the risks of harm because you trust that the Food and Drug Administration (FDA) has carefully reviewed the research and approved the sale of those medications. The FDA takes a precautionary approach when it approves drugs. It requires pharmaceutical companies to demonstrate the efficacy and safety of their products before they are put on the market. We expect that the companies that benefit from the sale of their drugs should take on the responsibility for demonstrating that the product meets certain standards of safety. From tragic experience, we have learned that when this precautionary process breaks down consumers suffer.

In contrast, we often do not take a precautionary approach to chemical exposures to children. For example, while a nursing baby receives the tremendous benefits of breast milk, they are often exposed to a number of industrial chemicals that are present in the breast milk. Often there is little information about potential for harmful development effects of the industrial chemicals found in breast milk. This raises a question: What is the equivalent seat belt for our children's health – is there a way to take precautionary measures to protect our children's health and intellectual potential from the adverse effects of industrial chemicals?

We often take a precautionary approach in our daily lives and we legislated a mandatory precautionary approach for the sale of prescription and over the counter drugs. The next evolution in the use of a precautionary approach is in the management of the use of industrial chemicals. One of the most critical questions is - What policy approach should we use as a guideline in protecting future generations – our children's children? I believe it is reasonable, rational, and responsible to use the precautionary principle, to learn from our past experience and years of scientific developments, and initiate a comprehensive and sustainable decision-making process.

## **Flavors of Precaution**

The precautionary principle was defined at the Wingspread Conference<sup>i</sup> in 1998 as:

“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 fully established scientifically.”

While the definitions of the precautionary principle come in a number of flavors, all flavors have the same common elements. It is the same with cars, some arrive at their destination more quickly, some are more environmentally friendly, some might need more repair, but all cars have basic identifiable elements, including seatbelts. There are five elements that form the foundation of all versions of the precautionary principle (Table 2).

The first common element is to have established goals and objectives. Often objectives are broad, such as ensuring the health and wellbeing of future generations. More specific goals also might be established, such as a list of health indicators or targets for health in local growth plans. For example: 'by 2015 reduce the incidence of childhood asthma by 50%' or 'by 2015 reduce the number children with learning disabilities by 10%' or 'by 2015 reduce the rate of adult-onset diabetes by 10% through weight loss programs.

The second common element is to take preventive action even in the face of uncertainty. In the 1920's the European League of Nations banned the use of lead paint based upon data indicating exposure to lead based paint could cause harmful health effects. The United States government was slow to acknowledge the harmful effects to children who were exposed to lead paint and delayed action until 1971. Had the US government taken a more precautionary approach and banned lead paint earlier, countless children could have been spared the challenges of learning disability.

A third element includes shifting the burden of responsibility for proving safety and efficacy to the proponents of an activity. This suggests that those who benefit from the action have a obligation of conducting the appropriate tests to ensure safety. For example, pharmaceutical companies benefit from the development of new drugs by making a profit when they sell a drug or medical device. Using a precautionary approach the FDA requires that a company submit data, paid for by the company, to demonstrate efficacy and safety of the proposed product prior to marketing approval. The needs and benefits of this precautionary approach is illustrated by the drug thalidomide. In the 1950's thalidomide was marketed, primarily in Europe and Australia, as a sedative and anti-nausea drug for pregnant women. Tragically, thalidomide caused a rare birth defect when consumed by women during a specific period in pregnancy. Fortunately thalidomide was not marketed in the United States because a woman in the FDA questioned the safety data. The thalidomide experience promoted Congress to increase the regulatory authority of the FDA and require more testing of drugs prior to marketing approval. The pharmaceutical companies assume the burden of responsibility to demonstrate safety of their product in contrast to the limited requirements placed on industrial chemical producers to demonstrate the safety of their products.

A fourth element encourages the exploration of a wide range of alternative actions when harmful outcomes are suspected. An initial question might be: Is it activity/chemical/ procedure really necessary? Or is a substitute as effective? A good example of exploring alternative actions is the use of integrated pest management instead of using pesticides. A number of schools systems are implementing integrated pest management policies to reduce or illuminate the use of pesticides around schools.

A final and fifth element common to definitions of the precautionary principle encourages public participation in decision making. It is essential that all stake holders have not only an opportunity to but the means to participate in discussions and the decision making process. The proponents of a product, process, or activity must provide complete and accurate information and work with all parties to ensure adequate understanding of its implications. While this may seem costly and time consuming the beginning it almost inevitably saves time and money and always produces the best results.

## **A reasonable approach**

The precautionary principle is reasonable; it provides a comprehensive and inclusive approach to decision-making that incorporates a vision of human and environmental health and quality of life. This vision of human and environmental health strives to “ensure that all living things have the best opportunity to reach and maintain their full genetic potential.”<sup>ii</sup> One might also consider this vision of human and environmental health as supporting the achievement of our “God-given potential” for “genetic potential” depending on ones perspective. Part of being reasonable is encouraging a discussion and consideration of our values. This definition of human health is particularly relevant to our children, who need an environment free from exposure to compounds that rob them of their intellectual potential such as lead, mercury and PCBs. Furthermore, the salmon of the world need clean and open streams in which to express their future generations.

The precautionary principle is reasonable because; it encourages participation of a broad range of stakeholders including business, government, non-profit organizations, health-affected groups, and most importantly the general public. Providing a healthy environment for humans and other species is best accomplished by a broad community of stakeholders working together to seek solutions. This starts by sharing information and respecting each other’s values. All stakeholders need access to technical information, and all need to be helped to understand the issues.

The precautionary principle emphasizes prevention and consideration of future generations. It is just common sense to prevent disease and promote healthy conditions. Waiting to treat disease or cleaning up toxic spills is more expensive, time consuming, and is often disabling, and often does not even work.

## **A rational approach**

The precautionary principle is rational and logical approach to decision-making. We have considerable scientific knowledge and experience that allow us to make good judgments even with uncertain or incomplete information. We have enough information, in many cases, to rationally consider alternatives, even when there may be some uncertainty or incomplete information. As many CEOs know, there is never enough information, but business doesn’t stop. CEOs must and do make good and rational decisions even with incomplete information. There needs to a shift in emphasis from increasing revenue and profits to consideration of human and environmental health.

In the fields of biological and toxicological sciences we have seen rapid advances that provide much of the knowledge we need to prevent harm. A rational person or community takes action based on an assessment of the facts combined with knowledge and experience to support the greatest good for that community. True, we must constantly review new information and update our decisions, but we should not wait for the perfect information. What we do know from toxicological sciences is that the developing organism is very sensitive to the effects of environmental contaminants and adverse effects are discovered at lower and lower levels of exposure. Here are a few examples documenting the lessons learned where the rational application of the precautionary principle would have benefited human health.

Fetal alcohol syndrome is characterized by facial deformities and severe learning disabilities that result from alcohol consumption during pregnancy. This condition and the sensitivity of the developing organism were well described by researchers in the early 1970s. It took almost 10 years after this scientific information was available for the U.S. Surgeon General to advise women to avoid consuming alcohol during pregnancy. Several more years passed before warning labels were required on alcohol beverages. Scientists continue to learn about the fetal affects of maternal alcohol consumptions and recognize that even small amount during pregnancy can result in milder forms of learning disabilities, or Fetal Alcohol Effect. But despite the new evidence, it was rational to act before this latest information was available. Prevention is a reasoned approach.

Two thousand years ago it was known that “Lead makes the mind give way”. Despite this knowledge lead was added to paint and, in the 1920s, to gasoline. As early as the 1920s the European League of Nations, despite some uncertainty about the health effects of lead exposure, chose to ban lead-based paint. Unfortunately the United States did not ban lead-based paint until 1971, resulting in the contamination of countless homes. Millions of children were exposed to harmful levels of lead because of this delay in action. In addition, the cost of demonstrating that low levels of lead exposure result in reduced IQ and learning deficits was borne by the taxpayers not by the industries that benefited from the sale of lead-based paint. Continued research on the health effects of lead has demonstrated that there are no safe levels of lead exposure for the developing infant. We have enough scientific information to make a rational and reasoned decision that lead exposure is harmful and must be eliminated. The U.S. Center for Disease Control and Prevention (CDC) has failed to act on this information and lower the acceptable blood lead level from 10 mcg/dL to 2 mcg/dL.

A more recent example of a failure to have a rational approach to prevent unnecessary exposure of children to potentially harmful chemicals involves brominated flame retardants (PBDEs). These chemicals are widely used in consumer products to prevent or retard fire, clearly a desirable action. PBDEs are used in foam rubber cushions and mattress, so you are probably sleeping on several pounds of PBDEs. The problem is that these compounds do not stay in the product, but show up in household dust and ultimately the food supply. PBDEs have been found in women’s breast milk and result in un-intended exposures to their babies. The PBDE manufacturers and distributors have not demonstrated that these chemicals will not harm the environment or cause adverse health effects. In contrast to the precautionary measure taken when introducing new medicines, we take few precautionary measures when introducing and using industrial chemicals.

These brief examples illustrate that knowledge is available to make rational decisions with regard to exposure to harmful chemicals. The challenge is to act on that information. Even when there is some uncertainty about the potential effects, we know from experience that even small amounts of chemicals can be harmful and that a precautionary approach is a rational approach.

## **A responsible approach**

Our ethical responsibility to our children, the offspring of other species, and to future generations requires a precautionary approach. It is the strategy that will be most like to help ensure an environment that will help them reach and maintain their full potential<sup>ii</sup>. Part of being responsible is encouraging a consideration of our personal and national values.

America's first bioethicist Aldo Leopold<sup>iii</sup> wrote in 1949: "A thing is right when it tends to preserve the integrity, stability, and beauty of the biotic community. It is wrong when it tends otherwise." Exposing our children to the harmful effects of industrial chemicals reduces their integrity, stability, and beauty as well as their potential to succeed and live healthy, fruitful lives. Leopold went on to say: "An ethic, ecologically, is a limitation on freedom of action in the struggle for existence". Leopold recognized that certain constraints on our freedom may be necessary to achieve a healthy outcome for the society. Laws requiring the use of seatbelts or limits on fishing restrict our freedoms but were enacted to promote a greater community good.

Garrett Hardin<sup>iv</sup> in his 1968 paper, *The Tragedy of the Commons*, recognized that many problems of society have no technical solutions, but must be managed to achieve the desired outcome. There is no technical solution to fetal alcohol syndrome once the child is affected. The only solution is the elimination of alcohol during pregnancy – or prevention. Technological advances have led to over fishing the oceans; the most responsible way to control over fishing is to restrict unlimited freedom to fish – or prevention. The idea that there are "no technical" solutions does not mean that technology is not necessary but rather that we often know what to do but for a variety of reasons do not take action. For example, we know what to do about lead based paint but do not employ the resources.

An important element of the precautionary principle is that the proponents of an activity must take responsibility to demonstrate that their chemical or product is safe and effective. Those who benefit from the activity must assume responsibility for the harm their product might cause. We have applied this concept successfully in drug development and we could easily apply this experience to industrial chemicals.

## **Conclusion**

The precautionary principle is a reasonable, rational, and responsible approach to protecting the health and potential of our children. The most critical question is - What policy approach do we adapt to protect the future generations – our children's children? The current system of

evaluating the safety of industrial chemicals is clearly not working. The precautionary principle offers a more comprehensive approach to ensuring quality human and environmental health by employing a series of elements that engage all stakeholders. The precautionary principle is an evolution not a revolutionary approach to our decision-making processes.

**Table 1. Precautionary Principle: Reasonable, Rational, and Responsible**

<p><b>Reasonable</b> (Able to discourse or discuss matters; ready of tongue or speech; sensible; common sense; sound judgment)<sup>v</sup></p>	<ul style="list-style-type: none"> <li>• Comprehensive and inclusive decision making approach</li> <li>• Brings stakeholders together</li> <li>• Emphasizes prevention rather than treatment</li> <li>• Encourages sharing of information</li> <li>• Considers future generations of humans and other species</li> </ul>
<p><b>Rational</b> (Having the faculty of reasoning; endowed with reason; coherent; rational)<sup>v</sup></p>	<ul style="list-style-type: none"> <li>• Decisions based on scientific knowledge and experience</li> <li>• We have the knowledge and experience to prevent harm to future generations</li> <li>• Uncertainty is not a reason to delay action to ensure human and environmental health</li> </ul>
<p><b>Responsible</b> (Morally accountable for one's actions; capable of rational conduct; answerable)<sup>v</sup></p>	<ul style="list-style-type: none"> <li>• Ethical responsibility and duty to prevent harm</li> <li>• Responsibility to promote human and environmental health</li> <li>• The proponents of an action are responsible for demonstrating safety</li> </ul>

**Table 2. Common Elements of the Precautionary Principle**

Element	
1	Establish goals and objectives.
2	Take preventive action even in the face of uncertainty.
3	Shift the burden of responsibility for establishing safety and efficacy to the proponents of an activity
4	Explore a wide range of alternative actions when harmful outcomes are suspected.
5	Encourage public participation in decision making.

Notes:

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<sup>i</sup> Raffensperger, C., & Tickner, J. (Eds.). (1999). *Protecting Public Health & the Environment - Implementing the Precautionary Principle*. Washington, DC: Island Press.

<sup>ii</sup> Steven G. Gilbert, Ethical, legal, and social issues: our children's future. *Neurotoxicology*, Vol 26/4 pp 521-530, 2005. (doi 10.1016/j.neuro.2004.12.006).

<sup>iii</sup> Aldo Leopold, 1949, *A Sand County Almanac*.

<sup>iv</sup> Hardin, G. (1968). The tragedy of the commons. The population problem has no technical solution; it requires a fundamental extension in morality. *Science*, 162(859), 1243-1248.

<sup>v</sup> Oxford English Dictionary