

## **THE PRECAUTIONARY PRINCIPLE – AN IMPOSSIBLE BURDEN OF PROOF FOR NEW PRODUCTS**

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The precautionary principle originated in environmental risk management to provide regulatory authority to stop specific environmental contaminations without waiting for conclusive evidence of harm to the environment (i.e., while there was still “uncertainty” about the evidence). Attempts to apply this concept to “proof of safety” for new food ingredients or products has led to the impossible demand of establishing the “absence of harm,” with a level of evidence that avoids uncertainty. Any requirement to establish safety with no uncertainty will increase costs unnecessarily, and will prove futile. Such actions would allow arbitrary regulatory decisions to stop new products, ultimately causing actual harm rather than protecting consumers, by denying beneficial products or by substituting a significant harm in place of a small theoretical one.

*Key words:* precautionary principle; precaution; uncertainty; food safety; Rio Declaration; SPS Agreement.

**T**he problem with the precautionary principle is two-fold, one logical and the other perceptual. First, the logical fault—the precautionary principle was originally developed to provide risk managers with a tool for decision-making on environmental threats from processes or substances that had not undergone safety evaluation or regulatory approval. The precautionary principle was not defined or developed for application to the intentional components of foods that require or depend on a conclusion of safety. Application of this principle could create an impossible burden of proof for new food products or ingredients. Second, the perceptual fault—the term “precautionary principle” is seductively attractive because it sounds like something that everyone should want and no one could oppose.

Upon initial consideration, it might seem that the only alternative to precaution is recklessness but, in fact, excessive precaution leads to paralysis of actions resulting from unjustified fear. In many cases, the slight but non-zero risk associated with a product or process is far safer than the alternative of doing nothing. Excellent examples include the outbreak of cholera resulting from fear of chlorinated water (Anderson, 1991) and the reluctance to permit food fortification with folic acid to reduce the incidence of specific birth defects for fear of masking vitamin B-12 deficiency (United States Food and Drug Administration [US FDA], 1996).

The precautionary principle was introduced in Europe in the early 1970s to provide environmental risk managers with a tool for decision-making on environmental threats (Freestone & Hey, 1996). It

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has since spread to a wide base of environmental concerns, and is included in the environmental regulations of the European Union (EU), Canada, and several international environmental agreements.

An early environmental application of the precautionary principle involved the prohibition of the purging of ship bilge contents and other wastes into the oceans (Freestone & Hey, 1996). This requirement was justified by the paucity of data on the effects of the purged substances. Hence, a scientific risk assessment on this practice was not possible. As a consequence, a precautionary approach was adopted to give risk managers (i.e., regulatory officials) the authority to prohibit such actions without waiting for evidence that demonstrated harm.

The specific term “precautionary principle” seems to have originated from Principle 15 of the Rio Declaration on Development and the Environment (United Nations Environment Programme [UNEP], 1992). Principle 15 sanctioned a “precautionary approach” when there are threats of “serious or irreversible damage” to the environment. Specifically, Principle 15 states that a “lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.” (UNEP, 1992, Principle 15).

### **International Consideration Of The Precautionary Principle For Food Policy**

After intense promotion by the EU, the precautionary principle was incorporated into the Biosafety Protocol that was approved in Montreal in January 2000 (Secretariat of the Convention on Biological Diversity [SCBD], 2000). The European Commission (EC) (2000) communication on the precautionary principle, released a few days later, cited the Biosafety Protocol as evidence of the consolidation of the precautionary principle into international law. The EC communication makes a major expansion of the scope of application of the precautionary principle—into food safety policy.

Discussion of the precautionary principle in the Codex Committee on General Principles has been held for three years at step 3 of the eight-step procedure. In the United States, multiple forms of precaution are built into both risk assessment and risk management, and a separate and additional precautionary principle is not applied in food safety policy (US FDA & United States Department of Agriculture [USDA], 2000). Thus, the precautionary principle would be, at best, redundant for the United States or any other nation with similar precaution built into its national laws and regulations.

### **Mutation Of The Precautionary Principle**

The original description of the precautionary principle in the Rio Declaration mutated into an assertion for food policy that should be invoked “when the scientific bases are insufficient or when there is *some uncertainty* [emphasis added]” (EC, 2000, p. 23). This language at first may seem innocuous, yet with this subtle but serious change the reasonable original description is completely transformed, so that no action may be taken and no product approved when there is any uncertainty about safety. Such a process would effectively demand conclusive proof of zero risk before any food could be considered safe. In effect, application of the precautionary principle would negate the input of science and allow food safety decisions to be made by risk managers on an arbitrary basis that would overrule risk assessment, regardless of the data supporting a conclusion of safety.

The zero-risk impetus of the precautionary principle fails to recognize that although science can provide a high level of confidence, it can never provide certainty. Absolute proof of safety is not achievable because it would require the proof of a negative, a proof that something (risk) does not exist. The precautionary principle always tells us not to proceed because there is some threat of harm

that cannot be conclusively ruled out. Thus, “the precautionary principle will block the development of any technology if there is the slightest theoretical possibility of harm.” (Holm & Harris, 1999, p. 398). With a separate precautionary principle as a component of risk management, such an assertion by regulatory decision-makers could completely negate the role of science in food safety decisions.

### **Reversed Burden Of Proof Between Rio Declaration And SPS Agreement**

It is sometimes asserted that the precautionary principle in Principle 15 of the Rio Declaration (UNEP, 1992) and the article on precaution (Article 5.7) of the World Trade Organization’s (WTO) Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) (World Trade Organization [WTO], 1994) are equivalent (EC, 2000). Actually, these descriptions of precaution are profoundly different because,

- *Principle 15* allows regulatory measures even though there is a “lack of full scientific certainty” (UNEP, 1992, Principle 15) of environmental harm. Moreover, measures taken under Principle 15 are not necessarily provisional, and there is no imposed obligation to generate evidence to justify their use.
- *SPS Article 5.7* allows regulatory measures “where relevant scientific evidence is insufficient” to demonstrate the safety of a product or commodity. The measures taken under Article 5.7 (WTO, 1994, p.72) are provisional (temporary) and there is an obligation to take steps to obtain sufficient evidence.

The false equivalency of Principle 15 and SPS Article 5.7 generates two fundamental errors that would create an impossible burden of proof for the safety of new food products and ingredients. First, “full scientific certainty” can be easily misconstrued to demand absolute proof (i.e., with no uncertainty), whereas “insufficient evidence” cannot. Second, the “full scientific certainty” in Principle 15 addresses proof of harm, whereas the “insufficient evidence” in Article 5.7 addresses proof of safety.

Together, these errors add up to a foregone conclusion—the precautionary principle can be used to stop the use of any food product or ingredient, because safety cannot be proven with certainty. Thus, the precautionary principle presents the risk of misuse to create an impossible burden of proof for the safety of food products and ingredients.

### **Adverse Effects Of The Precautionary Principle**

The death of several thousand people in Peru in 1991 resulted from discontinuation of municipal water chlorination after a risk assessment by the US Environmental Protection Agency emphasized the calculated small risk from chlorination products but failed to address the greater risk of untreated water (Anderson, 1991). Although the precautionary principle had little cachet at that time and was not used in the decision, this episode is a clear illustration of its unrestrained application.

Economic risk, with the associated decrease in resources needed to purchase food and healthcare products and services, is also associated with over zealous application of precaution (Otsuki, Wilson, & Sewadeh, 2000). Application of the new European aflatoxin standard to African export products will save a theoretical 1.4 deaths per billion population per year at the cost of decreasing African food exports by 64 percent, or by \$670 million per year. The health costs of the decreased economic resources to African countries have not yet been estimated.

## Conclusions

The precautionary principle was developed to prevent harm from hazardous environmental practices, not to serve as a food safety standard. Its application could create an impossible burden of proof for food products and ingredients. Over zealous application of precaution, which is urged by the precautionary principle, can do more harm than good, through substituting an alternative with a greater risk or through the economic costs associated with rejection of adequately safe foods.

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