

## Plastics and the Precautionary Principle

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Without a doubt, we produce, use, and discard massive amounts of plastics each year, but the body of scientific evidence reveals limited understanding of the human health impacts and ecotoxicology of plastics, especially in land-based ecosystems.<sup>1</sup> Although microplastics are present in aquatic environments and may influence the feeding, growth, reproduction, and survival of freshwater and marine biota, the extent and magnitude of potential effects are also still poorly understood. Taken together, this suggests that more definitive scientific examination is needed.

So where does this leave us from a policy standpoint on how to manage the global plastic pollution problem? Do we wait patiently until more conclusive data on the health and ecological impacts emerge before taking measures to avoid or mitigate the unknown, perceived, or potential problems? Or do we impose a precautionary principle approach that allows discretionary decisions, such as regulatory controls, bans, or phase-outs, in circumstances where there is possible harm to human health and the environment?

### WHAT IS THE PRECAUTIONARY PRINCIPLE?

A full spectrum of “precautionary principles” exist from conservative to aggressive, generating confusion and incongruity in how they are interpreted and applied. Although there are over a dozen formulations, the precautionary principle can be condensed into four basic versions enumerated from weak to strong:<sup>2</sup>

1. **Non-Preclusion:** Scientific uncertainty should not automatically preclude regulation of activities that pose a potential risk of significant harm.
2. **Margin of Safety:** Regulatory controls should incorporate a margin of safety; activities should be limited to those with no observed or predicted adverse effects.
3. **Best Available Technology:** Activities that present an uncertain potential for significant harm should require the best technology available in order to minimize the risk of harm.
4. **Prohibitory:** Activities that present an uncertain potential for significant harm should be prohibited until the proponent of the activity demonstrates there is no significant risk of harm.

In a weak or conservative precautionary scenario where “uncertainty does not justify inaction,” significant precautionary action may be invoked where regulation is permitted (but not mandated) in the absence of full scientific certainty.<sup>3</sup> Banning is rare in a conservative configuration. For plastics, policymakers can realign incentives, facilitate secondary markets, define standards through regulations, and stimulate innovation through levies, taxes, or other mechanisms. In a moderate scenario where “uncertainty justifies action,” regulatory standards with margins of safety proportional to the level of risk are instituted after cause and effect are established. Although banning is possible, measures are provisional or subject to review when new scientific evidence emerges. Since



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plastic toxicity to human health and the environment is still undetermined, when the scientific community converges around new information, regulations or bans are then reconsidered. Under an aggressive scenario where “uncertainty justifies shifting the burden and standard of proof” onto the proponent, even in the absence of a causative relationship, uncertainty necessitates forbidding the activity until it can be proven “safe.” There exists a strong presumption of risk avoidance, and therefore banning is likely. In the case of plastics, this translates to banning all plastic bag manufacturing, production, use, sale, and distribution.

Zero-risk standards are an extreme example of the precautionary principle, such as the Food Additives Amendment of 1958 (an amendment to the U.S. Food, Drugs, and Cosmetic Act that was repealed in 1996), which prohibited federal approval of food additives that posed any risk of cancer in humans or animals. Strong applications of the precautionary principle often prevent rational scientific debate, as the opportunity to present a full risk or cost-benefit analysis is eliminated until the proponent demonstrates that the activity is safe or involves acceptable risk. Consequently, the precautionary principle has the potential to mutate into a highly risk-averse philosophical premise.

Strong interpretations of the precautionary principle also contradict the fundamental principles of toxicology, in which dose-response modeling aims to determine what dose or concentration is safe. Dose-response establishes the relationship between the magnitude of exposure and the probability of health effects occurring. For all chemicals, there is a range of doses over which no apparent toxicity can be identified in exposed individuals, as well as a higher range of doses over which toxic properties appear. Evaluating the dose-response relationship for a chemical is at the heart of understanding its health risks and is how scientists determine the levels of chemical exposure that are harmful. Incorporating this fundamental toxicological principle into plastics sustainability and management decisions would help shepherd informed policies that consider data-driven

solutions as opposed to outright bans, allowing the value of plastics to remain within the economy.

A challenge with the precautionary principle is the absence of a minimum threshold for triggering the principle. It also lacks an upper bound at which the body of evidence is sufficient to decrease uncertainty to the level where, for example, a ban is lifted and a risk assessment is appropriate. Since the precautionary principle can be invoked due to scientific uncertainty for something that may pose a potential risk of harm, at what point is there sound reason to believe that harmful effects *might* occur and that they are “significant?” The degree of uncertainty that justifies precaution is unclear. Applied literally in its most robust form, a ban on plastics or stringent regulatory controls could be enacted even when the costs of compliance are high and the environmental and health risks are so low that they are outweighed by the potential benefits.

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## THE PRECAUTIONARY PRINCIPLE AND U.S. LAW

In the U.S., there is no explicit mention of the precautionary principle in any laws or policies, nor is it accepted as the official basis for risk regulation or decision-making. However, the foundations of various environmental, public health, and occupational safety laws have a precautionary disposition. For example, the U.S. National Environmental Policy Act requires federal agencies to evaluate the environmental impacts of proposed activities and mandates consideration of alternatives assessments prior to taking any action.<sup>4</sup> This was instituted to consider some level of precaution and to ensure an environmentally informed decision-making process.

Courts have upheld the U.S. Environmental Protection Agency’s (EPA) legal authority and its need to consider uncertainty in its decision-making process. Citing the Clean Air Act’s “precautionary and preventative orientation” and stating that “some uncertainty about

the health effects . . . is inevitable,” the DC Circuit Court of Appeals concurred with the EPA that Congress directed the agency’s administrator to “err on the side of caution” in making the necessary decisions.<sup>5</sup> This is a strong endorsement of the precautionary principle.

A case that influenced the extent to which federal agencies regulate was *The Society of Plastics Industry, Inc v Occupational Safety and Health Administration (1975)*, in which industry challenged the U.S. Occupational Safety and Health Administration’s (OSHA) worker exposure standard for vinyl chloride.<sup>6</sup> The court gave the agency deference, stating that it is OSHA’s duty to protect workers, even when existing methodology or research is deficient. This case profoundly impacted the degree to which the EPA regulated hazardous air pollutants under the 1970 Clean Air Act (amended in 1977 and 1990).<sup>7</sup> It also shaped how the EPA attempted to regulate new and existing commercial chemicals under the 1976 Toxic Substances Control Act (TSCA). The reformed TSCA, amended in 2016, obligates the EPA to undertake risk evaluations for existing chemicals, to eliminate identified risks, and to review all new chemicals and the different uses of new substances. Importantly, under the reformed TSCA, the EPA may not consider non-risk factors, such as cost, in determining whether a risk is unreasonable.

Although the policy statement in Section 2 of the TSCA is a variant of the precautionary principle, the operational standards require a presumption of safety in the absence of risk data. This is a deviation of a strict precautionary principle. Implementing a strong precautionary construct of the TSCA would lead to banning both new and existing chemicals until they are proven safe. The manner in which the revised TSCA aims to prioritize<sup>8</sup> and evaluate existing chemicals means that it may be a long time before testing would lead to a precautionary action. Prioritization, risk evaluation, and risk management of health and environmental impacts are lengthy and costly processes<sup>9</sup> given there are currently 40,000 active chemicals in the

TSCA inventory.<sup>10</sup> The TSCA mandates the minimum number of chemical substances that must be undergoing risk evaluation at a given time. On March 20, 2019, the EPA issued a list of 40 chemicals—20 high priority and 20 low priority—to begin the prioritization process. Once the EPA announces its final designation of a chemical as high or low priority for risk evaluation, chemicals designated as high priority will trigger a three-year risk evaluation process to determine if the chemical, under the conditions of use, presents an unreasonable risk to human health and the environment.

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## THE E.U. AND INTERNATIONAL LAW

The precautionary principle is a core tenet of European Union (E.U.) environmental law, as well as an autonomous principle encouraged by the constitutional traditions in E.U. member states. The Maastricht Treaty<sup>11</sup> formally adopted the precautionary principle in 1992, and it endures as one of the main tenets of E.U. environmental policy.<sup>12</sup> The principle underpins the E.U.’s version of the TSCA, the 2007 Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), which is an ambitious regulatory program on the production and use of chemical substances. REACH gives greater responsibility to industry to manage the risks from chemicals and to provide safety information on substances circulating in the market. It is based on the notion that industry is best suited to ensure that the chemicals it manufactures and introduces to the market in the E.U. “do not adversely affect human health or the environment,” which requires that industry understands the properties of its substances and manages their potential risks.<sup>13</sup> Before the E.U. signed REACH into law, the burden of proof was on governments to demonstrate that a product was unsafe prior to removing it from the market.

Although the status of the precautionary principle in international law is still fervently debated, it is widely cited in international agreements; however, there is no consensus on whether or not it is considered a component of customary law.<sup>14</sup> Despite the

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lack of a universally recognized definition of the precautionary principle, it has gained support in the international community as a higher-order legal principle that guides public policy, legal decisions, and the formulation of laws. The current debate in Europe centers on what specific formulation of the precautionary principle should be applied and whether it takes precedence over international law, particularly in terms of which risk assessment is relevant to trade law involving the World Trade Organization.<sup>15</sup>

While there are dozens of derivatives, articulations, and interpretations of the principle that vary considerably in scope and degree of application, the most widely recognized statement in international environmental policy is taken from the Rio Declaration on Environment and Development.<sup>16</sup> This definition aligns with the common prescription that absolute scientific certainty is not required prior to implementing “*cost-effective measures to prevent environmental degradation*” (emphasis added).<sup>17</sup> Even if the evidence is inconclusive, or the cause and effect relationships are not fully established scientifically, plausibility is sufficient to invoke regulatory intervention.

Because of the disparate guidelines, constructions, and legal rulings since the Rio Declaration, the strength and application of the precautionary principle diverge considerably. A review of the cases undertaken by the European courts suggests that while judicial decisions more consistently parallel the European Commission’s guidance on the precautionary principle by requiring plausible evidence of potential hazards in order to invoke precaution,<sup>18</sup> the principle is not consistently applied when devising legislation.<sup>19</sup>

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## THE PRECAUTIONARY PRINCIPLE AND SUSTAINABILITY

Ethics, social equity, and future risks to society have become a staple in the plastics discourse as environmental issues continue to influence the plastics pollution debate. Application of the precautionary principle is also closely intertwined with

social equity issues.<sup>20</sup> Assessing and protecting vulnerable, socioeconomically disadvantaged, or minority segments of the community who may be at greater risk from environmental hazards is an increasing component of risk management. Features of the precautionary principle have also trickled into U.S. statutory law, which is an indication that the legal and regulatory structures are now accounting for the reality of a risk society where future populations are being considered in present decisions.<sup>21</sup> This shift embodies an ethical vision for sustainability and a concern for public goods and the rights of future persons.

Consideration of economic, environmental, and social sustainability is also becoming prevalent as governments, corporations, and multinational enterprises focus on the United Nations Sustainable Development Goals (SDG)<sup>22</sup> and environmental, social, and corporate governance (ESG) in tracking their overall risk and future financial performance. From an ethical standpoint, there is an inextricable link between the precautionary principle and the principles of sustainable development. The latter acknowledges the environment’s significant impact on the health, happiness, and well-being of present and future generations. Both the precautionary principle and sustainable development were created primarily in response to issues of environmental and social quality and degradation.

Given the complex and interwoven dynamics of ecological systems, assessing uncertainty and long-term consequences are germane to environmental management and sustainability decisions. Such decisions frequently maneuver in areas obfuscated by high levels of scientific uncertainty when assessing likely costs and benefits. With waste management, sustainability, environmental justice, and public health and safety issues becoming increasingly multifaceted and international in scope, scientific documentation alone rarely justifies a path forward—legislative support and a regulatory framework are also required. The reality is that much of the discussion often becomes entangled in legalistic and regulatory disputes that

obstruct potential preventive measures, or that are complicated by cultural, social, or political disparities. The precautionary principle is thought to be a hedge or countermeasure against this impasse.

### IS THE PRECAUTIONARY PRINCIPLE A SOUND BASIS FOR PUBLIC POLICY?

Precaution is certainly a guiding principle that can mediate environmental degradation, and we do have a responsibility to protect public health and the environment, but acute applications of the precautionary principle are not a sound basis for public policy. Aggressive approaches such as launching plastic bans without safe, equitable, and economically proven alternatives are a departure from the historical system of measuring risk and exposure, assessing the reasonableness of that risk, and considering the costs and benefits. Perhaps supporting a less antithetical and more mainstream, middle-of-the-road version of the precautionary principle is realistic. This would include establishing a threshold of uncertainty, evaluating all feasible alternatives, assessing certain and uncertain outcomes, setting goals, and developing democratic and systematic decision-making criteria into a framework. But this process would no doubt take many years to complete.

In the meantime, agreeing on an internationally reasonable method to the precautionary principle that offers clarity and consistency is feasible. This approach includes measures already endorsed, but oftentimes disregarded, by the E.U.. The European Commission makes it clear that decisions on when to invoke the precautionary principle should not be based solely on an assessment of potential hazards. That is, measures should be based on an examination of the potential costs and benefits of an action or lack of action.<sup>23</sup> A cost-benefit analysis ensures that actions or regulations enhance, rather than detract from, overall social welfare, which is consistent with ESG and the global UN SDGs. There are constructs of the precautionary principle that call for considering the economic and practical feasibility of

risk management measures, along with deliberations of the costs of compliance or replacement products.

In order for the precautionary principle to work with public policy, actions taken that favor a precautionary approach should not be final or irreversible. Policies should explicitly require a periodic review in light of new scientific data and should further assign responsibility for producing evidence necessary for a comprehensive risk assessment. The European Commission recognizes that the precautionary principle is contingent on future data and that it is necessary to progress toward a full evidence-based risk assessment (which could either emphasize or negate the need for protection).<sup>24</sup> This also allows for an assessment of whether the precautionary action has produced the intended consequences, and it helps determine if the actions taken require modification. A graduated approach that includes periodic review makes actions more politically and socially palatable and less rigid.

Furthermore, in comparison with the European Commission's *Communication on the Precautionary Principle* in the E.U.'s community law, the U.S. and E.U. are not that procedurally incongruent in how they approach decision-making from a high-level, although how the precautionary principle may be interpreted varies in practice. In theory, both entities begin with a scientific evaluation that identifies the degree of scientific uncertainty; conduct a risk evaluation to identify risk management options, including the option of no precautionary measures; utilize a cost-benefit analysis; consider a reevaluation when new scientific information becomes available; and solicit interested parties. Further, a review of E.U. and U.S. regulations of 100 risks found that both jurisdictions were selective in the use of the precautionary principle, with neither consistently more precautionary than the other.<sup>25</sup> However, accepting literal and radical constructs of the precautionary principle as a legal requirement creates unfettered opportunity for arbitrary and unpredictable decisions by regulators,

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governments, and the court system. This makes it challenging for courts to consistently execute their responsibility to ensure the reasonableness of agency decisions, and it creates uncertainty for the regulated community.

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### PLASTICS POLICY AND A PRECAUTIONARY FRAMEWORK: WHERE DO WE GO FROM HERE?

The predominant challenge with plastics is that there is an enormous amount of uncertainty and limited understanding of its human health and ecotoxicological impacts. This lack of understanding could lend support to radical interpretations of the precautionary principle that ultimately result in bans or trade restrictions. Funding allocated to long-term and scientifically rigorous research is necessary, especially on human populations and freshwater, land-based, and ocean ecosystems. More research is also needed on the population-level consequences of marine debris from ingestion, entanglement, and contamination. In January 2019, a European scientific advisory body concluded that microplastics do not pose a widespread risk to the environment and human health.<sup>26</sup> Still, a lack of evidence for risk does not imply there is no risk. Work should also be committed to developing internationally consistent sampling, testing, and measurement methods to determine the fate, effects, and risks of microplastics and nanoplastics. This could help close the gaps in our limited understanding of the magnitude of potential effects on the ecosystem. Despite growing evidence that additional research is warranted, one single study alone cannot force change.

Plastic waste is at the forefront of every local, national, and international agenda and has gained political and regulatory traction with instruments such as bans, trade restrictions, and taxes. With the increasing notoriety of single-use plastics and plastic polymers, a precautionary mindset would suggest such products be a part of the chemical prioritization process of the TSCA or the chemical strategy of REACH. With regard

to microplastics, the TSCA and E.U.'s REACH already cover some plastic monomers and additives; plastic polymers are considered to be of low concern due to their high molecular weight. From a regulatory standpoint in the U.S., where would plastic polymers rank with the 40,000 other chemicals in commerce needing prioritization? Should plastic polymers take precedence over other chemicals even though there is currently no known immediate risk or toxicity? If plastics are to be regulated at this point in their lifecycle, it is important to understand these answers.

Even though plastics fall outside of any existing global definition of “hazardous waste,” plastic waste is set to be managed in 2021 under the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal. However, plastics are not even classified or defined as a hazardous material by the EPA, OSHA, U.S. Department of Transportation, the U.S. Nuclear Regulatory Commission, or the globally accepted United Nations model regulations for transportation and classification, which are the basis for most international, regional, national, and modal regulations. With the lack of any existing classification of plastics as a hazardous material or hazardous substance in the global economy, prioritization and harmonized management using any formulation of the precautionary principle will be complicated.

Some ecofriendly plastic alternatives, such as biopolymers, were prematurely introduced to the market and have greater environmental impacts and energy use and expenditure throughout their lifecycles—from resource extraction through manufacturing, transportation, and end-of-life management—than do the plastics they were to replace. Thus, applying a strict version of the precautionary principle would lead to banning all existing and future alternatives to plastics. Understanding the environmental, social, and economic impacts across the entire supply chain is necessary. The goal is to replace or supplement single-use plastics with options that are better for the environment, people, and economy, and do not further contribute to the global waste issue.

**Applying a strict version of the precautionary principle would lead to banning all existing and future alternatives to plastics.**

An action, policy, or solution that is economically, environmentally, or technologically feasible in one part of the world may not be transposable to all economies, especially when social or political factors are considered. For instance, inorganic carbon in plastics does not decompose through the anaerobic digestion processes, and it therefore lacks emissions when disposed in a permitted and secure landfill. From a policy perspective, in regions or countries that lack recycling infrastructure or advanced technologies and resources, such as Southeast Asia (which happens to have the highest share of mismanaged plastic waste in the world), the lowest carbon choice and perhaps most economical choice may be to manage plastics in a regulated and secure landfill, at least in the short term. While this may not be the most socially or politically palatable choice, it could at the very least prevent the migration of plastics into waterways. As emerging-market countries boost their waste-management capabilities, the next step will be to segregate plastic waste from other wastes. Eventually, pyrolysis<sup>27</sup> of mixed plastics waste is likely to provide the most efficient way to process the overflow of plastic waste until capabilities are in place to separate different plastic polymers.

While recycling seems preferable to incineration or using landfills since it displaces virgin plastic production, the reality is that most of today's plastic can only be recycled once or twice before the quality degrades. This means that most recycled plastic eventually ends up in landfills, is incinerated, or is downcycled into a lower quality material where that molecule is lost forever as a resource from reentering and remaining viable in a circular economy framework. Therefore, traditional mechanical recycling simply delays, rather than avoids, final disposal.<sup>28</sup> In cases where recycling is costlier, uses more energy, and has higher emissions than land disposal or incineration, what is truly being gained? Not all recycling is created equal when assessing it from an economic lens and in economically depressed regions. Even if the best available recycling technologies were fully deployed, it is highly unlikely that mechanical recycling alone

could feasibly absorb the millions of tons of excess plastic waste that is generated annually, let alone the projected by the 40% increase in plastic production over the next 10 years. The only way to reduce the amount of material deposited in landfills or incinerated is to decrease the amount we produce in the first place.

We can also make advances by regarding plastic waste as an untapped resource. Plastic loses value when designed for a single use. An economically viable approach to plastics redesign and chemical recycling is needed, as well as investments to support transformational technologies, education to increase awareness, and collaboration between industries, technology providers, and governments at all levels. If the data illustrate that most plastics in the oceans result from improper disposal, then perhaps we should consider recapturing the economic value of plastics so that there is incentive to properly manage it as a resource and not a waste. Managing plastics as a waste through the Basel Convention will deter circular economy objectives. Governments at all levels can incentivize and encourage reuse and proper disposal while investing in infrastructure; supporting the development of novel chemical recycling technologies to recycle and recover more plastic chemistries, including low-quality, low-density, and mixed polymers; and introducing policies to shepherd these efforts.

Despite deficiencies in our current approach and framework, taking a precautionary approach does not necessarily mean we should introduce immediate bans, nor does it suggest we should refrain from taking any actions to address what is undeniably a global pollution problem. We should recognize the multidimensional nature of the plastic issue and accept that it affects the entire global economy. Transforming the global plastic packaging market requires a suite of solutions, from public policy interventions and corporate commitments to sustainability and financial incentives, as well as changes in human behavior. There is not one all-encompassing policy that reaches every sector and resolves the issue of plastic waste in the environment. There will have

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to be cooperative mechanisms throughout the supply chain, reflecting the expertise, knowledge, and values of a wide range of stakeholders. And without the regulatory systems, infrastructure, and technology to collect, sort, process, recycle, recover, and redesign the wide array of plastic polymers on the market, and absent responsible and informed citizens to diligently dispose of their wastes, it doesn't matter how much we reduce our consumption—plastics will remain a global issue.

## CONCLUSION

Like many principles, there is no one definition or standard for implementing the precautionary principle, and its various formulations have led to diverging regulatory and policy actions. Thus, calls to adhere to “the” precautionary principle provide little detailed guidance for policymakers especially in the realm of plastics pollution. A shift to more precautionary policies creates both opportunities and challenges for scientists and policymakers to think differently about the manner in which studies are conducted and the results communicated. The precautionary principle has not been explicitly included in U.S. regulatory mechanisms. However, in many ways, nuanced facets of the precautionary principle are already integrated into our regulatory and corporate systems that recognize multifaceted and globally complex problems.

Local and state governments and the international community are increasingly focusing their policies and resources on plastics management. If applied in a modulated, consistent, and practical manner, elements of the precautionary principle, as derived from the E.U. Commission Communication, do not necessarily have to be a policy of absolute risk avoidance. Conversely, in the face of scientific uncertainty, there can still be a science-based approach to risk management that considers a range of scenarios, doses, impacts, costs, benefits, and ways to reduce the impact of plastics and their possible alternatives.

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9. The estimated annual costs of implementing the TSCA, without including the costs associated with manufacturer-requested chemical risk evaluations, are approximately \$80.2 million.

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