THE PRECAUTIONARY PRINCIPLE: MANAGING TECHNOLOGICAL RISKS TO PROTECT HUMANITY AND OUR PLANET

[The text in bold type in the following resolution is policy to guide the social witness of the church, in particular the public statements and advocacy of the Office of Public Witness, the Presbyterian Ministry at the United Nations, and ecumenical bodies with Presbyterian representation. It is advisory to church members, intended for adult study and group or individual response if desired: acswp@pcusa.org]

In fulfillment of the 221st General Assembly's assignment regarding sustainable development (Item 15-02), the Advisory Committee on Social Witness Policy recommends that the 223rd General Assembly (2018) of the Presbyterian Church (U.S.A.) adopt the affirmation and recommendations below, and receive the supporting rationale and research summary:

I. Affirmation and Description of Precautionary Responsibilities

To manage the risks to health and safety from new and existing technologies, we need the Precautionary Principle or precautionary approach, based on the principles of sustainability, participation, sufficiency, and solidarity as developed in Christian environmental ethics. The precautionary approach gains urgency as accelerating climate change increases the uncertainty of weather trends affecting the entire biosphere and as major advances in genetics and artificial intelligence re-open questions of human nature and purpose.

The current concept of precautionary principle dates to a 1991 international conference of 35 scientists, lawyers, policy makers and environmentalists from the United States, Canada and Europe— the Wingspread Consensus:

> **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 [yet] fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof. The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action [i.e. no commercial introduction of the new technology].**

In other words, regulators should not designate a product or process as Generally Recognized As Safe (GRAS) until there is enough research to reach a scientific consensus that it is safe. Too often governments have done the reverse, allowing a product to be on the market unless and until there is scientific consensus that it is unsafe—usually after tragedies make the headlines and result in product liability lawsuits. As Christians in the Reformed tradition, we believe governments are instituted to protect the common good and that regulation is an essential protective tool.

The precautionary principle does not entail halting technological progress, but affirms the priority of the integrity of creation and the protection of the human and other lives within it. It shifts the burden of proof toward those whose actions could harm people or de-stabilize or irreversibly disrupt natural patterns and processes. It does not tell us when reasonable people would agree that the burden of proof has been met, although as a principle it warns against depending upon the climate of opinion in a given society.

Precautionary approaches, sound science, and risk-benefit analysis are all related aspects of a rational approach to determining public policy on issues like toxic chemicals, nanotechnology, geo-engineering, genetically engineered crops and genetically modified organisms in food. Indeed,

application of the precautionary principle should include using sound science and forms of risk-benefit analysis, insofar as appropriate data are available, as part of determining whether to restrain or prohibit a given product or activity. Reason and science can never be enemies of the God whom we worship in Spirit and in truth. Respect for the truth embodied in creation urges us to support and restore the regenerative processes of nature whenever possible, and to support the scientific vocation as it explores the infinite scope of God's cosmic work. There are also a myriad of technological vocations to serve the common good in the application of scientific discovery.

Market forces can help motivate technological progress from which we may all benefit, but they cannot reliably determine long-term rewards and risks of potential harm, given the uneven distribution of burdens and benefits and the partial availability and uneven distribution of knowledge. In retrospect, the climate change crisis reflects the widespread failure of market systems to assess and reduce the impacts of fossil fuel use. Programs such as Superfund pay for cleaning up some of the most egregiously polluted areas, and require their own studies of how toxins interact in groundwater, earth, and atmosphere over time. Geo-engineering proposals to remediate or protect the atmosphere or oceans from overall climate change effects, through such things as increasing cloud cover or adding iron filings to ocean water, pose enormous and potentially irreversible risks of their own.

If one person or one company bears all the costs and risks, as well as the benefits, from some activity or product, then there is little case for public policy intervention. That person can evaluate and make her own decision. Problems arise when the beneficiaries do not bear the costs or risks. Economists call these effects on others or nature, "externalities," and the market may not factor these costs and risks into the price of a given product. To protect society, government regulation or taxation is usually needed to get those benefitting from the activity to take sufficient account of the costs and risks to others. For example: with GMO (genetically modified organism) grain, the company selling it has clear financial benefits, as may the farmer growing it. If, however, the GMO pollen blows to neighboring farms and contaminates their crops, it harms the neighbors, and then some regulation is appropriate.

GMO products or those containing potentially dangerous chemicals and nano-particles, like some food, cosmetics, and household chemicals, may pose risks to consumer health and to the environment. Research has yielded partial but not complete understanding of those risks, so people and communities need to decide how to balance the known benefits against the uncertain risks. Requiring full disclosure of product contents, including whether some chemical is in nano form, empowers democratic participation in decision-making but does not fully address the problem.

Information is costly and unevenly distributed, and the mal-distribution of information often correlates with the uneven distribution of benefits and risks, especially for new products. Thus, if "risk-benefit" analysis alone is used to determine the regulatory response to a new product or process, the analysis is intrinsically biased to underestimate the risks posed by the product and allow those immediately or directly benefitting to proceed with marketing the product. Further, the nature of public exposure or consumption of products and the complexity of processes of preparation or manufacture require different kinds of testing by different regulatory agencies.

Hence, implementing the precautionary principle means that the government regulator has to insist on adequate investigation (by government or private sector) and attention to the full costs and risks to society and the biosphere that the product may pose. Uncertainty about potential

harm to people or the environment should not stop all progress, for that would deny too many of the benefits of new technology, but neither should that uncertainty allow possible risks and unequal benefits to be downplayed or ignored. This concept of precautionary responsibility also means that, when a decision is made to proceed, monitoring of both risks and benefits should continue in a meaningful and publicly accountable way.

Although much legal regulation in the U.S. is based on forms of the precautionary principle, in practice manufacturers seeking monetary benefit can often overwhelm and weaken the precautionary regulatory processes that might pre-emptively prevent harm. The history of industrial and technological development is marked by the corresponding growth of health and safety regulation. Christians have been active with US civil society in raising public safety standards, notably following the Social Creed of the Churches in 1908, and as part of the environmental movement that spread across all nations experiencing pollution and other consequences of industrialization. Presbyterians have played a particularly significant role in conservation and wilderness preservation that is relevant to today's new challenges.[1]

As documented in this policy statement's survey of a wide range of studies, regulation in the US has become too weak regarding threats to the environment and the glorious diversity of God's world. Scientific research itself has been politicized and distorted by inappropriate ideological, commercial, and narrow religious interests. Precautionary concern has precedent in General Assembly environmental reports dating to 1971; such concern now merits more explicit and focused attention.

The Psalmist intuited the interconnectedness of life in relation to God: "How wonderful are Thy works!" is sung in many ways. A resolution at the 2016 GA applauded Pope Francis's encyclical, *Laudate Si*, a significant and powerful appeal to be aware of the incalculable impact of the loss of biodiversity. Our concern is not only the loss of resources but the diminution of life's meaning. "Because of us, thousands of species will no longer give glory to God by their very existence, nor convey their message to us."[2]

II. Recommendations for the protection of human beings and the earth:

The General Assembly policies provide recommendations for public policy, personal discipleship, and congregational and other communal action, noting that any directives are binding on agencies of the church and are advisory to its members and other church councils. Insofar as most environmental risks are borne by large numbers of people, public policy is particularly important in this area.

A. Public Policies

The following policy directions are to be advocated by the Office of Public Witness (in Washington, DC), the Presbyterian Ministry at the United Nations, and other programs and agencies of the Presbyterian Church (U.S.A.), with support encouraged from members, congregations, councils, and ecumenical bodies:

1. Federal and state budgets should provide adequate funding for research by the Environmental Protection Agency, the Food and Drug Administration, the Department of Agriculture, the Consumer Product Safety Commission, the National Science Foundation, the Centers for Disease Control, and other regulatory and scientific monitoring bodies on

the possibility of harmful effects on consumers, workers and the environment from new technologies, such as nanoparticles, geo-engineering, toxic chemicals (in food additives and packaging, pesticides, herbicides, cleaners, etc.), and GE (genetically engineered) crops and GMOs in foods;

2. The mission of regulatory agencies should be respected by:
(a) requiring corporations to track the effects of their products in cases where uncertain but potentially significant risks are identified;
(b) maintaining open access to licensing and decision-making processes (consistent with patent protections) so that there is informed and democratic involvement of all potentially affected parties;
(c) strengthening conflict of interest laws to ensure fairness in determining risks and benefits. In principle, no beneficiary should directly determine or make a decision leading to that individual, family, or commercial organization's benefit. In practice, no recent employee or significant investor in an industry or industry trade association should be allowed to serve on the staff or board of the regulatory agency or bodies over-seeing that industry or business[3];
(d) ensuring the capacity of regulatory bodies to enforce regulations, to prosecute businesses and individuals responsible for endangering or damaging public health, and to ban or suspend the sale and use of products or processes without political interference if there is significant scientific basis for questioning their safety. The cases of neocontinid pesticides and endocrine-disruptor chemicals and pharmaceuticals, for example, may merit such suspension;

3. Increased legislative and regulatory attention should be given to:

(a) Review the GRAS (Generally Recognized as Safe) classification of products now being manufactured and marketed in nano forms, using the latest research, including the behavior of such particles in the waste stream;
(b) Develop specific oversight mechanisms to account for the unique characteristics of nano materials;
(c) *Require labeling* of all chemicals in foods, pesticides, herbicides, cleaners, medical products, packaging, etc., including a notation if the material is in nano form—nano-titanium dioxide, nano-silver, etc.
(d) Expand research and monitoring of the effects of climate change on toxins already released into the environment, and of their interaction with newer toxic products, such as some used in hydraulic fracturing (fracking) and fire suppression.
(e) Continue research on the issue of the substantial equivalence of GMO and non-GMO crops and foods.
(f) Reduce the hazards from cosmetics and hair care products by passage and enforcement of the Personal Care Products Safety Act with a stronger mandate to test chemical currently in use and without preempting or preventing stronger standards by state legislation.
(g) Raise the threshold of acceptable risks for products whose "benefits" to users are not substantial, as with food additives that only affect food coloring;
(h) Require at least US labeling standards for export products and marketing, except when other countries' standards exceed ours;
(i) Require all publicity/infomercials/investor reports concerning products to note whether reported or advertised results include all evidence gathered;

4. Revive a National Commission on Bio-ethics, representing a range of perspectives and disciplines, with a mandate to evaluate all human genetic technologies involving manipulation of the genome, by CRISPR and other technologies, because these raise scientific, economic, ethical, and religious concerns;

5. Support international scientific and regulatory cooperation through such means as the United Nations Framework Convention on Climate Change, which includes the voluntary Paris Accords, and other global sustainability efforts (treated in prior energy and environmental policy of the church);

6. Increase civil and criminal penalties for accelerating climate change and develop laws regarding "crimes against the biosphere" or "crimes against future generations." Require Environmental Impact Statements to take into account 100-year climate phenomena, which are becoming more frequent, and build in remediation in an explicit way.

B. Investment Responsibility

Instruct the Committee on Mission Responsibility Through Investment (MRTI) and the Office of Faith-Based Investing and Corporate Engagement to do the following:

1. Determine which companies held by the Presbyterian Foundation and the Board of Pensions are producing or selling GMO foods or GE seeds, toxic chemicals, or nano particles.

2. Pursue appropriate forms of corporate engagement to encourage these companies to take more fully into account the risks that these products pose to workers, consumers, and the environment, and to comply with the research, development, labeling and marketing standards recommended above. (MRTI pursues similar goals in its dialogues with energy sector companies.)

3. Inform presbyteries and congregations about the findings of MRTI's research and engagement and encourage Presbyterian bodies and members, as consumers and shareholders, to advocate for responsible implementation of the precautionary principle.

4. Educate Presbyterians on the impact the churches have had in the growth of corporate responsibility practices, and on how our investments are instruments of mission through corporate dialogue on concerns about products made, sold and used by the companies in which PC(USA) holds shares, wherever the location of production or sale. By holding up the good performers as examples and pressing the others to improve—using shareholder resolutions and other measures (including possible divestment from unrepentant bad performers)—the church and its members use their assets and talents to make a difference.

C. Consumer Responsibility

Instruct the Hunger Program's office for Sustainable Living and Earth Care Concerns, and urge Earth Care congregations and others, to encourage renewable energy use and such specific lifestyle practices as:

1. Choice when possible of organic products, given still unknown cumulative and interactive effects of chemicals in pesticides, fertilizers, and growth hormones on wildlife and humans;

2. Phase out the use of plastic bottles, packaging (including phthalates added for durability), and other plastic goods not easily recyclable, thus reducing waste and preserving petroleum resources for higher value uses;

3. Limit and reduce exposure to CRT (cathode ray tube) and other screens, as these may affect the emotions and sleep capacity of users; moderation is recommended, but social impacts are generally beyond the scope of this report.[4]

D. Theology and Science Scholarship

1. Commend those Presbyterians and other Christians working on the intersections of scientific exploration and understandings of the Reformed and other religious traditions;

2. Create forums in seminaries and Presbyterian Church related colleges and universities to promote understanding of the nature of risks and rewards in the adoption of new technologies.[5]

3. Affirm the work of the Presbyterian Association on Science, Technology, and the Christian Faith.

E. Future Engagement

This report was necessarily limited in its treatment of certain emerging technologies that carry high potential environmental and public health risks, and of certain advances in robotics and artificial intelligence that have major social and other change dimensions. It was beyond our scope to address primarily biological problems, such as the spread of invasive species, or specifics of remediation, such as de-contamination of radioactive groundwater. Thus Christians and other persons of good will are encouraged:

1. to address large-scale risk factors pro-actively, drawing on both social and natural sciences and the humanities, and joining with advocacy groups and organizations as necessary;

2. to share their experiences in making public moral arguments about public health risks with the larger church;

3. to recognize shared struggles with Native or First Peoples over specific sites or public preserves, and with others opposing the "environmental racism" that disproportionately exposes people of color (and other generally less wealthy citizens) to bio-hazards;

4. to join in ecumenical solidarity and witness through such partner bodies as Creation Justice Ministries.

Rationale

[This study paper documents the bases for the policy recommendations above, moving from the Advisory Committee's assignment, to environmental theology and ethics, assessing the scope of precaution and needed

improvements in regulation, and then summarizing examples of precautionary application to GE/GMO food plants, pesticides, nano substances, and new technologies such as artificial intelligence, human enhancement (transhumanism), bio-engineering that need more public understanding and Christian ethical analysis.]

Presbyterians understand how religion, science and technology come together and share a moral commitment and a sense of reverence for God's presence in our world. Since the 1960's, PC(USA) has played a strong role in ecumenical councils developing criteria for just, sustainable, and participatory decision-making by governments and corporations, particularly in the energy and environmental field. This was the background for the overture from the Presbytery of Southern New England that called on:

"**221st General Assembly (2014) to affirm the vital importance of sustainable development through faithful stewardship of natural resources and the Precautionary Principle. Such methods of preventing irreversible ecological impacts are part of the basis for responsible, moral, and scientifically-informed human flourishing, affirming the sacred in societal and creation care, and protecting the earth for future generations. Additionally, the General Assembly direct[ed] the Advisory Committee on Social Witness Policy to:**

1) **commission a study group of three to five persons to review the precautionary or prevention principle in relation to emerging biotechnical developments and existing Presbyterian social witness policy on environmental ethics, and**
2) **prepare a study paper and resources for social media, with appropriate recommendations to the 222nd General Assembly (2016), for use by congregations throughout the denomination, enabling congregations to advocate for reform."**

This report is submitted in fulfillment of that assignment which, even while focusing on the three technologies cited (see below), was extremely broad and would ideally require on on-going advisory committee devoted to the task. The 222nd General Assembly extended our mandate. A list of scientists, ethicists, legal scholars, and business experts consulted is in addendum B; their generosity and depth of expertise is not fully represented in this text, which has tried to make complicated material as accessible as possible. There is real urgency to debates about specific products, such as the pesticide, chlorpyrifos[6], and about health trends with complex causation, such as changes in fertility capacities or birth rates of children with various neurological conditions. Beyond urging more research on endocrine-disrupter chemicals and reduced exposure to plastics, this report could not address research on matters that are still inconclusive, if already alarming.

In clearest terms, to be part of a community is to share in its risks and rewards. The expectation is that any family or enterprise shares society's benefits and does not bear a disproportionate burden of its risks and costs. This report is about how the agent of our community—our government— should seek to prevent undue risk from being inflicted on persons and creatures without their knowledge or consent, and to identify and limit risks of new technologies, even while allowing us to benefit from new technologies that are safe.

The social technology of democratic and accountable governance includes ways to evaluate risks for whole societies, based on ideas of the common good that originate in our faith. This study aims to help us think together about our role—as individual Presbyterians as well as our church as a part of the world church—in a time when the earth enters a more dangerous stage of climate change. There will be efforts to take advantage of fears, real and imagined.[7] The precautionary principle is no magic bullet to take account of the risk while enjoying reasonable amount of benefit from technology, but it is one approach that may help us, and one that reflects our reverence and stewardship of the blue-green planet entrusted to our care.

Definitions

The Precautionary Principle is, at its simplest, a modern restatement of the classical Hippocratic Oath, "I will keep them from harm and injustice," which is often summarized as "First, do no harm." The Precautionary Principle is more than a dictum for individual actions; it should also guide the behavior of institutions and nations. And, going beyond the Hippocratic Oath and its modern equivalents, it would avoid harm to the environment as well as to humans.

Although various definitions of the precautionary principle float about today in the public discourse and literature, this report sees it as the need to be extra cautious in allowing the introduction of new products and processes, and their continued sale, if their safety is not well established by scientific research and, as far as possible, practical experience. This does not preclude the use of all technological advances, but when the possibly negative effects of a product are not well understood, then it is better to delay implementation and marketing, and to insist on ongoing tracking of uncertain risks, even after products are introduced. This is especially true when the people and other creatures at risk from negative effects are not the same as those deciding to buy and use the product.[8]

Theology

The glorious diversity of God's world.

The Psalmist intuited the interconnectedness of life in relation to God: "How wonderful are Thy works!" is sung in many ways. A resolution at the 2016 GA applauded Pope Francis's encyclical, *Laudate Si*, a significant and powerful appeal to be aware of the incalculable impact of the loss of biodiversity: it is not only the loss of resources but the diminution of life's meaning. "Because of us, thousands of species will no longer give glory to God by their very existence, nor convey their message to us."[9] A human tendency to an 'instrumentalist' view of nature as purely serving our needs must give way to a theocentric view of all creation as have value and integrity before God.

Christianity has been accused of being the root cause of the earth's ecological crisis. Lynn White famously declared, in 1967, that the fault lay in "an implicit faith in perpetual progress… indefensible apart from Judeo-Christian teleology" – our sense of God's guiding human history in ways "that made it possible to exploit nature in a mood of indifference to the feelings of natural objects."[10] For White, as we look at humanity's negative impact on our environment, "Christianity bears a huge burden of guilt."[11] It is true that some Christians have made indefensible use of Genesis 1:28 (NRSV): "… fill the earth and subdue it; and have dominion over… every living thing that moves upon the earth.'" James Watt, U.S. Secretary of the Interior under Ronald Reagan, wrote that he viewed the earth as "merely a temporary way station on the road to eternal life...The earth was put here by the Lord for His people to subdue and to use for profitable purposes on their way to the hereafter."[12] From such attitudes have arisen sins of colonialism and exploitation – of countries, resources, and human beings. Sin leads people to ignore the impacts of our behavior (and corresponding risks) on other people and on nature.

Yet, Christianity offers many resources for a much more ecologically positive theology.[13] We know, for instance, that while we should seek for the common good of all humanity, we should also be respectful of all God's creation, for God declared it good (Gen 1). We remember that, "The earth is the Lord's and all that is in it, the world, and those who live in it" (Ps 24:1). The Presbyterian Church (USA) in 1990 adopted the report "Restoring Creation for Ecology and Justice", which remains a foundational policy for the denomination's work in environmental ministry. [14] The underlying theological principles were further developed in the report "The Power to Change: U.S. Energy Policy and Global Warming" adopted in 2008.[15]

Eco-Justice Norms:

The eco-justice norms developed there may be summarized as follows:

- SUSTAINABILITY: "God's call to earth-keeping." "Sustainability is the capacity of the natural order and the socioeconomic order to thrive together."
- PARTICIPATION: "Because the Creator's intention is that nature's gifts of sustenance be available to all members of the human family, all have a right and a responsibility to participate."
- SUFFICIENCY: "A reasonably secure and fulfilling life for all."
- SOLIDARITY: "Fundamental interdependence and unity with the Creator's creatures," human and non-human.

We see here a valuing of the biosphere for its own sake – God's call to earth-keeping— but balanced by an acknowledgement that Christ "came that they [humans] may have life, and have it abundantly" (John 10:10). A foundation of our Christian faith is that God created all that is, and the "The Earth is the Lord's and all that is in it, the world, and all those who live in it" (Ps. 24:1). We may conclude, as did the PC(USA) in 1996, that "no part of creation – whether other humans, other species, even the elements of soil and water is our property to use as we wish. They are to be treated with the values and ground rules of God, the ultimate owner. These values and ground rules are rooted in the fact that… God is love." [16]

Expanding Stewardship toward Membership:

In short, we are stewards of creation. The doctrine of stewardship is central to our Reformed tradition. While we often understand stewardship as a matter of dollars and cents, the doctrine is broader than that. It is an affirmation that creation belongs to God and that humankind is both gifted with and commanded to the responsibility of caring for and nurturing creation. In his Commentary on Genesis, John Calvin wrote:

> "The custody of the garden was given in charge to Adam, to show that we possess the things which God has committed to our hands, on the condition that, being content with a frugal and moderate use of them, we should take care of what shall remain. Let [the one] who possesses a field so partake of its yearly fruits [so as to] not suffer the ground to be injured by negligence; but [rather] endeavor to hand it down to posterity as [it was received], or even better cultivated. Let [the possessor] so feed on its fruits [as to] neither dissipate it by luxury, nor permit it to be marred or ruined by neglect… Let everyone regard [themselves] as the steward of God in all things which [each one] possesses.[17]"

Modern science has made us more aware than Calvin was of how much we are not just stewards, but integral parts, of nature. We now live in an "anthropocene" era, where our species dominates nature to the point of re-setting, or de-setting, the climate.[18] Nevertheless, the key message remains. As faithful stewards, we must be mindful of how we use our gifts, integrating our technological skill with our imperative for earth care. As steward-members of a single "earth community," we share one future.

Seeking a balance between the well-being of humanity and the rest of nature is not easy, given just how much of the biosphere we have taken over for human use. A much-shared proverb tells us that ""We do not inherit the Earth from our Ancestors, we borrow it from our Children."[19] We need to remember that we borrow it – or indeed take it – from the rest of the biosphere, as well.

Each of us, whether Christian or not, has a responsibility for the common good of humanity and of all God's creation, and there are many ways in which we can live out that responsibility. But individual responsibility is not enough. One significant corruption of sin is that it causes our care and attention to curve inwardly on the self, a phenomenon that St. Augustine called *incurvatus in se*. When this

happens, even if we imagine that we are acting responsibly, we lose sight of the others whom our actions impact. When it comes to the risks and harms associated with new chemicals and industrial processes, it is not enough to counsel people to act with precaution. The powerful chronically, almost inevitably, ignore the weak and poor. This is why we have delegated to each of our governments the task of keeping its citizens safe and helping them to live together in community. We have, then, the responsibility to ensure that our governments are carrying out this duty with justice for all humanity and for all creation.

In Reformed theology, the second use of the law is to restrain evil. According to Calvin, this purpose is "by means of its fearful denunciations and the consequent dread of punishment, to curb those who, unless forced, have no regard for rectitude and justice."[20] One of the ways in which government carries out its duty to protect is through law and regulation. The Precautionary Principle can help guide our governments in carrying out that duty.

Precautionary Principle and/or Risk-Benefit Analysis.

The precautionary principle is a way of thinking about risks and, especially, what to do about them. We know we should be cautious. But how cautious?

Risk-benefit analysis, done properly, can provide useful input to our thinking. Obviously for a product to be approved for sale by the government as well as the producer, the benefits should exceed the risks. The hard part, however, is that the full risks are typically less well known than the benefits, and they potentially occur to a wider range of people (not just the producer and customer) and over a longer time horizon, perhaps beyond the useful life of the product.

Therefore, we cannot leave the decisions about product safety completely up to risk-benefit analysis done by the producers. A company develops a new product to meet certain purposes—offering specific and relatively well-known benefits to consumers—and they do market research to figure how much profit they will make from selling the product. So the benefits are relatively well known to the producer, and the promise of profits brings funding to publicize those benefits.

Without regulatory requirements, however, a company developing a new product would tend to give inadequate attention to estimating the risk of potential harm to consumers, workers and especially third parties. Compared to the company and its marketers, these folks do not know in advance what is coming, are much more dispersed, and usually lack the expertise and funding to find out about the possible risks to them, especially if these would take years to emerge.

Economists since at least Adam Smith have recognized this problem—negative externalities—and have seen in these cases the need for government regulation or offsetting taxes.

For some potential costs, regulators could estimate the monetary value—potential property damage, health care bills, workdays lost, etc. In the absence of regulations, the producing company would tend to underinvest in finding out about and monetizing such risks. Also they have a conflict of interest with regard to discovering and publicizing those risks.

A bigger issue concerns the non-monetary risks. These include, but are not limited to potential damage to the ecosystem, possible mortality and morbidity that the medical system could not remedy, damage to the health of future generations, and possible disruption to the way of life for farms and businesses adjacent to companies using the technologies in question. Even if the monetized value of these costs is not zero, the benefits of a product, if great enough, can justify its usage, with proper restrictions and

disclosure of those risks. Some social costs could be justified if the new technology would certainly increase the availability of nutritious food and decrease its financial cost, especially for low-income families. Market math cannot resolve these issues. They require political decisions informed by moral guidance, to which the church should contribute.

Except when there are environmental and other third-party concerns, consumers can decide for themselves IF they are given accurate information. Although some products have clearance as Generally Recognized As Safe (GRAS), we are still finding new information, and people can decide for themselves how much precaution to take with their own health. But they need to know what they are dealing with. People are paying increased attention to the food labels that current regulations require.[21] Disclosure of harmful potential does not automatically doom a product commercially, as we see from medication ads that [as required] go on at great length to disclose the potential harmful side effects for consumers to balance against the advertised and intended benefits.

Those most vulnerable to the downside risks are typically those least able to acquire information about the risks, least able economically to accommodate the risks, and least able politically to fight for protection or ex-post compensation. Jesus and the prophets tell us to care for these most vulnerable (Matthew 25 and elsewhere), so as Christians we must give their concerns particular attention in considering the precautionary principle.

Example applications:

Introduction

Each topic has its own particular issues, so rather than setting out general rules with many exceptions, we look at three areas of technology to illustrate how we can usefully apply the precautionary principle: toxic chemicals in food and commercial products, GE crops and GMO in food, and nano particles.

An area we do not consider is medicines, but the precautionary principle, perhaps by other names, has long been a central feature in FDA regulation of pharmaceutical products. Although the primary risk is to individual taking the medicine, burdens from bad choices lead also to socially costly long-term effects (e.g. thalidomide babies, defective silicone implants, opioid addiction).

Of course, the precautionary principle could also be discussed in relation to energy sources and climate change, but ACSWP and the church have already studied this (for instance, *The Power to Change,* 2008) and we continue advocating for appropriate reforms through MRTI and other avenues.[22] The precautionary principle was applied to this issue a generation ago. Today, however, the scientific consensus has progressed beyond the precautionary phase, to where we should apply the common-sense principle—we are in hole with the excess production of greenhouse gases and we need to stop digging. The questions now are what to do? And how fast? Burning less hydrocarbon to heat our buildings, generate electricity, and power transportation are obvious parts of the solution. The precautionary principle is relevant to evaluating some of the radical proposals for technological fixes, like spreading iron filings in major parts of the ocean to encourage algae growth, putting giant sunshades in earth orbit, or creating more cloud cover. Each of these poses substantial risks to life on earth, but this report cannot give geo-engineering methods, or contexts for their use, adequate treatment.

GRAS, FDA, and the dangers of limited regulation

In these discussions, the expression “generally recognized as safe” –GRAS—plays a key role. When manufacturers are allowed officially or in practice to say whether their product is GRAS, without

requiring explicit action by a regulatory agency, it creates an obvious bias to allow products that are not acceptably safe. Even when government regulators decide what is GRAS, whether they do it right depends on whether the producers and marketers have excessive influence in the decision, whether the agency has adequate funding to conduct research and assess risks, and whether the discussions are sufficiently open to allow public debate.

FDA's implementing regulations in 1996 for the Food Additives Amendment say: "General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information."
In the last half century, many concerns have risen about food additives that might cause cancer or adverse reproductive effects, and thus such additives face a higher bar for approval.[23]

The primary distinction between the requirements necessary for GRAS status and those necessary for food additive status is the element of "common scientific knowledge" that must characterize conclusions about GRAS status.[24] The manufacturer must be prepared to "show that there is a consensus of expert opinion regarding the safety of the use of the substance."[25] Although unanimity is not required, "the existence of a severe conflict among experts regarding the safety of the use of a substance precludes a finding of general recognition."[26] A 1997 proposed clarification to the GRAS regulations, which remains the most current statement of agency policy, observed that "[t]he usual mechanism to establish that scientific information is generally available is to show that the information is published in a peer-reviewed scientific journal."[27] The agency proposed new regulations defining GRAS in 1997, but then failed to finalize the regulations until it was sued by the Center for Food Safety in 2014 and finally agreed to settle the lawsuit by issuing the regulations in 2016.[28]

Ultimately, the agency left it up to the manufacturer to determine whether an added substance is GRAS or a "food additive" that must be approved. The manufacturer does not even need to tell the agency that it has added a substance to food and has concluded that it is GRAS.[29] If the manufacturer declines to consult with FDA and if the agency finds out about the modification, the agency may exercise its powers to seize foods containing the additive as adulterated.[30] Although FDA takes the position that a manufacturer claiming GRAS status for a substance has the burden of proving that it meets the GRAS criteria in an enforcement action,[31] the agency as a practical matter has the burden of demonstrating to a court in an enforcement action that the substance is not GRAS.[32]

Independent watchdogs have criticized the GRAS system for being rife with industry conflicts of interest because the vast majority of GRAS determinations are made by either the manufacturers themselves or their hired consultants. Moreover, the current system that allows secret GRAS determinations makes it nearly impossible for FDA or manufacturers to assess the cumulative effect of all similar chemicals on consumers—as the law requires. It is unclear whether FDA will consider new kinds of GMO foods as GRAS, like they have done in the past. Moreover, a draft guidance by FDA, issued for comment in 2017, raised the question of whether new kinds of genetic engineering never used before, especially those used in genetically engineered animals, could be considered GRAS.[33] In short, the GRAS system often does not protect the consumer from potential harm and does not even make public the information she would need to protect herself.

Toxic Chemicals: FDA and EPA roles and rules, climate change, notable pesticides

Many chemicals with positive uses in the household, agriculture and industry have toxic effects when people and the environment are exposed to them. Some exposure is "accidental", as with waste spills or pesticides and herbicides migrating to neighboring farms, although it is often no accident when the routine and allowable procedures fail to prevent serious problems.[34] Other exposure is deliberate, as when chemicals are added to foods, packaging, or clothes to make them keep longer, retard flames, look better, or be cheaper to produce.

The Food and Drug Administration (FDA) regulates chemicals in food, cosmetics and pharmaceutical products.

"Any substance that is reasonably expected to become a component of food is a food additive that is subject to premarket approval by FDA, unless the substance is generally recognized as safe (GRAS) among experts qualified by scientific training and experience to evaluate its safety under the conditions of its intended use, or meets one of the other exclusions from the food additive definition in section 201(s) of the Federal Food, Drug, and Cosmetic Act (FFDCA)."[35]

The Food Additives Amendment of 1958 is the foundation for the U.S. food additive regulatory program, which oversees most substances added to food. Federal agencies made approximately 40% of the 6000 safety decisions allowing about two-thirds of the substances currently used in food. Manufacturers and a trade association made the remaining decisions without FDA review by concluding that the substances were generally recognized as safe (GRAS). Robust premarket safety decisions are critical since FDA has limited resources to monitor potentially significant scientific developments and changing uses of a substance after it enters commerce, and FDA only has access to published data or data submitted to it. Since the late 1990s, FDA no longer promulgates rules for its decisions for food contact and GRAS substances. Rather it reviews manufacturers' safety decisions and posts the results of the review on the agency's website. This shift appears to have encouraged manufacturers to submit their decisions to FDA for review but has limited the public opportunity to provide input.[36]

In summary, for food additives the regulatory policy does not follow the precautionary principle in that there is considerable uncertainty about the safety of what chemicals are allowed. (A subsequent section discusses the issue of the nano versions of chemicals.) Strong requirements for detailed labeling of contents, however, do allow consumers to inform themselves and choose their degree of precaution. With food there is relatively little risk of injury to third parties. Manufacturers' concerns about lawsuits and scandals also motivate them to be precautious.

In theory the FDA can regulate chemicals in cosmetics[37], but it only steps in if it has "reliable information" suggesting that a cosmetic creates a problem. That has usually meant that nothing is done before a public outcry, and beauty enhancement products today still contain lead, mercury, formaldehyde, and lesser-known "chemicals of concern". Years can pass while the FDA investigates and deliberates. In practice, the safety of cosmetics and personal care products is left in the hands of the companies that make them. The law requires no specific tests before a company brings a new product with a new chemical composition to market, and it does not require companies to release whatever safety data they may collect.[38]

A bipartisan bill in the US Senate, the Personal Care Products Safety Act, would require, among other things, that cosmetics makers pay annual fees to help finance new safety studies and enforcement. It would also give the FDA the authority to pull products off the shelves immediately when customers have reported bad reactions, without waiting for a review, which often takes many years. While this bill would take some steps in the right direction, it may reduce the chance for more pro-active measures. It would require FDA to test each year for only five chemicals, while over a thousand chemicals are in production and need testing. It would prevent states from passing more restrictive standards, which

California now has. Any endorsement of the bill should come with caveats recommending measures to strengthen it.

The Environmental Protection Agency (EPA) is charged with regulating most non-food, non-pharmaceutical toxic substances. The old Toxic Substances Control Act, passed in 1976, allowed thousands of untested chemicals to remain in non-food consumer goods without evidence of safety. The law was so weak that it kept the EPA from banning even asbestos, a known carcinogen, and other known hazardous materials. The law also forced the EPA to navigate a costly, cumbersome process if it wanted safety tests of a potentially dangerous chemical. In June 2016, Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which updated the 1976 Toxic Substances Control Act.

The new law, which received bipartisan support in both the U.S. House of Representatives and the Senate, includes many needed improvements, even if not all of those desired by critics of the old law:

- For the first time, requiring EPA to evaluate the safety of existing chemicals in commerce, starting with those most likely to cause risks. By November 2017 EPA had completed 1148 new chemical reviews under the new law.
- Requiring EPA to evaluate new and existing chemicals against a new risk-based safety standard that includes explicit considerations for vulnerable populations;
- Empowering EPA to require the development of chemical information necessary to support these evaluations;
- Establishing clear and enforceable deadlines that ensure both timely review of prioritized chemicals and timely action on identified risks;
- Increasing the public transparency of chemical information by limiting unwarranted claims of confidentiality and allowing for the appropriate sharing of confidential information with States and health and environmental professionals; and
- Providing a source of funding for EPA to carry out these significant new responsibilities.

We cannot yet judge the effectiveness of the new law, which will depend critically on how the EPA and other agencies implement the law. Many of its implementing regulations came into effect only in 2017. Many if not most EPA employees share a strong commitment to protecting the environment and human health. On the other hand, the current head of EPA and some senior officials there have in the past strongly opposed environmental and product regulation.[39] To help get the intended benefits of the law, PCUSA should use its influence in Washington and elsewhere to encourage the full implementation of the law, along with adequate funding and recognition of scientific evidence.

While this report does not focus on climate change, as noted above, scientific research is revealing an increasing number of ways in which climate change increases the stress that toxic chemicals put on species and ecosystems, such as pollinators (bees, bats, butterflies, etc.) and the flowering plants they pollinate. The scientific consensus on the primary cause of the greater morbidity of honeybees and the collapse of many hives is a pesticide family called neonicotionoids, some of which are now banned in various countries. There are fewer monarch butterflies along our roadsides, many fewer than two decades ago. Deforestation of their winter habitat in Mexico is part of the cause, but a much larger cause is the elimination of milkweed plants by a widely-used herbicide, glyphosate (brand name: Roundup) introduced in 1997 alongside varieties of soybean and corn genetically engineered to resist the herbicide's effects on weeds of all varieties. Because it kills nearby milkweeds, the monarch has been the victim of collateral damage, as the fate of one part of the biosphere affects many others.

Genetically engineered (GE) crops and GMOs in food; CRISPR, HGT, and Biodiversity

Genetically engineered (GE) crops have rapidly become dominant in US agriculture. The Economic Research Service of the US Department of Agriculture (USDA) reports that in 2017, 92% of all corn planted in the US was genetically engineered (GE), up from 25% in 2000. The equivalent figures for soybean were 94% (up from 54%), and for cotton 96% (up from 61%).[40] The benefits promised from adoption of GE crops include increased yields and reduced need for chemicals, as well as increased tolerance of drought or torrential-rain conditions, which may become more prevalent due to climate change.

On the other hand, the use of GE crops in the food chain (both directly for human foodstuffs and for animal feed) has caused concerns about possible negative dietary and environmental effects, as well as deleterious effects on the livelihoods and health of farmers and farm-workers in both the US and other countries (especially developing countries) to which US GE crops are exported. Before we consider how the Precautionary Principle (PP) might usefully be applied, we should consider the technologies involved, the expected benefits and risks, and the current US regulatory environment.

Although we do not analyze the issue here, we note that genetically engineered and modified animal species also present risks, perhaps even greater than GMO crops, and call for application of the precautionary principle. These aspects of what is sometimes called, industrial agriculture, have been addressed by prior Assemblies.

Definitions. We use the term GMO (genetically modified organism) to refer to foodstuffs containing GE crops or animals. The USDA defines a genetically modified organism (GMO) as "an organism produced through genetic modification," a definition which could cover all biotechnology, including traditional breeding techniques. Commonly and officially in some countries, however, GMO refers to GE organisms (plants, animals, microbes…) that have had genes "modified by introducing, eliminating or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques."[41]

Traditional breeding techniques involved selecting seeds from plants with desired traits. Traits are expressions of genes. So this artificial selection did, in fact, end up selecting genes, but it selected both those associated with desired traits, and those 'along for the ride.' We might be shocked by some of the methods used in the 20th century – exposure to X-rays or toxic chemicals – to encourage a range of gene-mutations from which to select. Given this background, many crop scientists question why genetic engineering should cause any more concern. The key difference, however, is that conventional breeding works with genes available within living specimens of the plant species being manipulated. Genetic engineering can, and often does, introduce genes from radically different species, using bacteria and viruses to introduce them into the target. The most common goals have been to make plants tolerant of herbicides or resistant to insects or other plant pests, and also to increase yield, either directly or as a side-benefit of such resistance. With herbicides—Round-Up is the most popular—farmers who do not buy the expensive patented seeds (and the herbicide) then face a double penalty of lost market share and potential crop damage if their neighbor does use Round-Up.[42]

Even as regulation and public opinion struggle to deal appropriately with the current technology of genetic engineering, the technology itself is developing rapidly, with the advent of CRISPR - Clustered Regularly Interspaced Short Palindromic Repeats. CRISPR directly edits the DNA of the target organism, and generally does not introduce DNA from another organism. Practitioners have great optimism over the potential benefits of CRISPR-edited crops.[43] Several CRISPR gene-edited crops are

expected to enter the market over the next few years.[44] The new species created by CRISPR pose some of the same risks as conventional GMOs, but so far have gotten even less regulatory scrutiny.

To evaluate the potential benefits and risks of GE-crops, we can use the PC(USA)'s eco-justice norms of Sustainability, Participation, Sufficiency, and Solidarity, listed above. GE crops are clearly intended to contribute to both sufficiency (via crop yields) and sustainability (via reduction in chemicals). Both goals are vital in our age of rapidly growing population and environmental degradation. Do GE crops yield the promised benefits, and do so safely? Are current regulatory structures adequate to evaluate not only new products but new processes of production?

The most immediate concern for many consumers is whether GMO foods cause allergies, as in the 1996 introduction of a brazil-nut gene into soy beans, whose market introduction was canceled when there were allergic reactions.[45] The existence of dietary impacts other than allergies is less substantiated and remains controversial.[46] This paper does not resolve that issue, but notes that such concerns reinforce requirements, deriving from the precautionary principle, for appropriate product labeling to enable consumers to be informed, and for ongoing monitoring of the dietary effects of GMO foods.

The next question, then, is whether GE crops have yielded the promised improvement in crop yields and reduction in chemical use. Once again, the findings are contested. A 2014 *PLOS One* review of published studies concluded that "GM technology adoption has reduced chemical pesticide use by 37%, increased crop yields by 22%, and increased farmer profits by 68%."[47] By contrast, a 2017 study by *The New York Times* used United Nations data to compare crop yields – food per acre – and pesticide use in the US and Canada versus Western Europe, which "largely rejected genetic modification at the same time the United States and Canada were embracing it." According to this study, yield trends have either been parallel or in Europe's favor. Meanwhile, herbicide use in the US has increased by 21% over the last two decades, while by contrast it has fallen 36% in France. [48] This result suggests that other approaches than GE can yield an equivalent benefit.

In developing countries, we also need to look more for alternatives to GMOs, even though their gains in crop yields and profits are higher in than in developed countries. When the Gates Foundation recently announced a major initiative to develop technologies to help farmers in Africa and Asia adapt to environment change, Divine Ntiokam, founder of the Cameroon-based Climate Smart Agriculture Youth Network, responded that "Many young people (in Africa) say they can't do farming because they don't have access to funding [to buy even basic seeds and complementary inputs]… If all these donors can actually go straight to the smallholder farmers, it's going to be much more impactful."[49] We are reminded of the Precautionary Principle's injunction to examine "the full range of alternatives." While the need for more food for more people might call for a combination of approaches – perhaps including GE crops - we need to resist the temptation to jump to the newest (and often for corporations more profitable) technological fixes, without adequate consideration of more traditional, less costly and less risky options.

What about broader environmental impacts of GE crops? One widely discussed concern is that of horizontal gene transfer (HGT) – that genes introduced into GE crops might spread into neighboring crops (adversely affecting, for instance, organic farmers) and into wild plants (perhaps introducing insecticide resistance there). This, too, is a very controversial area. Some claim that GE-induced HGT will be lower than natural background levels of HGT,[50] a point which ignores the concern that the potential impact of even rare HGT from GE plants may be greater than that from natural HGT. Others note examples such as the rapid contamination of supposedly non-GMO papaya after ringspot-resistant

GE papaya was introduced in Hawaii in 1998.[51] Again, the Precautionary Principle would suggest the need for more caution, more testing, and more ongoing tracking.

Another environmental question is the impact of GE crops on biodiversity. One argument is that GE crops, by increasing crop yields, will reduce the amount of land needed for agriculture and thus protect undisturbed lands for 'in situ' biodiversity.[52] Clearly, for that to be true, the yield-benefits of GE would have to be significant, the evidence for which is not clear, as noted above. Further, biodiversity is not just about saving wild-land from agriculture. It is also about saving today's wide variety of crop germlines, adapted to their local environments by years of breeding by local farmers.[53] This genetic-heritage is being damaged by the increasing use of mono-cropping of GE variants, and yet is vital to future adaptation to environmental change.[54]

Connecting to Prior PCUSA ecological thought and policy

Such a concern reminds us that, when new technology is introduced, the precautionary approach should be applied to not just the technology itself, but also to the economic and political environment in which it operates.[55] This can and should extend to not just the impacts in the US, but also to, in particular, the developing world, as US GE- crops are either provided as food aid, or sold within the terms of Free Trade Agreements which may adversely affect both local diets[56] and the use (and even survival) of local seed. The 2006 PCUSA Report, *Just Globalization,* noted that "subsidies for domestic agriculture… make similar products from abroad noncompetitive" and that both subsidies and developed-country technologies [which would now include GE crops] create "risks as these countries lose their ability to be self-sufficient in… feeding their own citizens."[57] The 1996 PCUSA report, *Hope for a Global Future,* concludes that "Trade rules that enable affluent nations to profit at the expense of poor nations or that do not contribute substantially to the reduction of poverty in all nations cannot be accepted ethically."[58]

How well does US regulation apply the Precautionary Principle to the concerns outlined above? According to the USDA, "The Federal government has a coordinated, risk-based system to ensure that new biotechnology products are safe for the environment and human and animal health" based on the 1986 *Coordinated Framework for Regulation of Biotechnology*. "The Coordinated Framework is based upon existing laws designed to protect public health and the environment. The U.S. government has written new regulations, policies, and guidance to apply these laws to biotechnology-derived products."[59]

Needed Improvements in US regulatory approach, beyond 'substantial equivalence'

On the other hand, some see US regulation of GE crop and GMO foods as fragmentary, inadequate, and struggling to keep up with technological change. The USDA is still citing a 1986 framework in the face of rapidly-evolving technology, although there were small updates in 1992.[60] Further updates, requested by the White House in 2015[61], are not yet approved much less implemented. A proposal in early 2017 was considered some to be 'underwhelming'.[62]

When GE crops first emerged, the government's Office of Science and Technology Policy decided to fit such products into existing law, allocating regulatory responsibility to Environmental Protection Agency (EPA), the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA). The EPA has authority to regulate GE organisms that produce pesticides or toxic chemicals under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The USDA has powers relating to plant health and has used these powers to regulate GE crops developed using agrobacteria that introduce 'foreign' DNA. The FDA has responsibility to keep food safe; companies may submit their products to a

voluntary safety review. State laws play little role in regulating GMOs, but some municipal governments have banned GMO crops.[63]

The gaps in this approach—trying to use old regulations to address novel issues—are well illustrated by the 2016 development of a white mushroom, gene-edited to prevent browning, that completely 'escaped' regulatory review, because the recently-developed CRISPR-cas9 technique was used, which directly edited the mushroom DNA rather than introducing any 'foreign' DNA.[64] All CRISPR-edited crops similarly escape regulation now.[65] Concerns with the adequacy of GMO regulation were evident, however, long before CRISPR complicated the picture.

One key issue was the use of the concept of 'substantial equivalence.' In using regulations designed to follow health, safety and environmental legislation covering conventional products, the assumption is that the focus should be on the nature of the products produced, and not on the process which produced them. The Office of Science and Technology Policy's 1992 Statement of Scope adopted a risk-based approach under which agencies were supposed to exercise regulatory authority only when the "risk posed by the introduction [was] unreasonable"—the opposite of the precautionary principle— and regulatory oversight was supposed to focus on the characteristics and risks of the biotechnology product – not the process by which it was created.[66]

The government's approach followed the principle of 'substantial equivalence' to long-established existing foods. The application of this idea to GM foods was developed by a Working Group established by the Organization of Economic Cooperation and Development (OECD), which recommended that only when there was no basis whatsoever for comparison with natural foods should the GM food be evaluated on the basis of 'its own composition and properties.'[67] The OECD working group applied 'substantial equivalence' only to food safety, but it has since been applied also to environmental impacts of GE crops. There are no standardized tests to establish substantial equivalence, and critics regard substantial equivalence as a method of encouraging GM foods, while providing an excuse for regulatory agencies to avoid their responsibility to protect the public health and safety. Thus, current US regulation of GE crops and of GM foods in general are not based on the Precautionary Principle, but by contrast on a rather loose assessment of risk. Furthermore, lack of adequate funding often hinders the research and enforcement needed to implement the laws and regulations.

These weaknesses in the regulatory environment show the need for fuller application of the Precautionary Principle. In line with our eco-justice norms of Sustainability, Participation, Sufficiency and Solidarity, we believe that GE crops can be beneficial **as long as** they serve to:

- "Produce abundant, safe, and nutritious food.
- Reduce harmful environmental inputs
- Provide healthful conditions for farm workers
- Protect the genetic make-up of native species
- Enhance crop genetic diversity
- Foster soil fertility
- Improve the lives of the poor and malnourished
- Maintain the economic viability of farmers and rural communities"[68]

In line with the Wingspread definition the Precautionary Principle and the PCUSA's ethical norm of participation, regulators' decision-making should include consultation of all those affected by GMO technology. Everyone must have access to adequate information. As the 2002 PCUSA report *We Are*

What We Eat noted in its brief consideration of GMOs, "people of faith are called to be informed about the issues through reliable sources of information, to raise questions, and to make responsible choices. Be cautious about media hype or fear campaigns. Rather, choose credible sources of information."[69] As Christians, we need to be well informed, to help all those affected be similarly informed, and to use this information in advocacy to ensure appropriate regulation of GE crops and GMO foods.

Nanotechnology—Non-biological applications

Nano particles are a special type of chemical whose potential toxicity and beneficial uses, as well as risks, differ substantially from those of the non-nano forms of the same chemical. A material with familiar properties in solid form acts surprisingly differently when in the form of nano dust, with particle diameters of under 100 nanometers (billionths of a meter). Generally, the nano forms are more reactive because of the much higher ratio of surface area to volume and mass. Nano particles oxidize and make other chemical bonds much more quickly, even to the extent sometimes of becoming like an explosive. Nano particles also often absorb or reflect light very differently from the conventional particles of the same material.[70]

[Due to the limitations on this study, we do not consider nano-biological products or entities like oil-eating bacteria which may, in fact, be genetically engineered. There are also ultra-small machines which may called nanobots but which may be larger than nano implies, similarly beyond our scope.]

Nano silver has potent anti-bacterial properties, making it useful in medical applications, but it could possibly penetrate through skin and other membranes, enter the blood stream, and collect in various organs, where the long-term effects are not fully understood. Bandages for victims of burns and for post-surgical sites often contain nano silver now, which substantially reduces the likelihood of infections. Even though the long-term risks are not fully known, the short-term positive effects seem clear enough to justify continue use of nano silver in bandages.

Titanium dioxide is in many white consumer products, including sunscreen, toothpaste, powdered sugar and various sweets—reflecting sunlight and making whites appear brighter. In some products at least some of the molecules are at nano scale, but this information is not usually included in the labels. Although titanium dioxide is not very reactive chemically, even at nano scale, and there has been no clear evidence of harm in the long-term, some consumer-safety advocates have campaigned against it. In response, Dunkin' Donuts stopped including it in powdered sugar on their donuts in 2015. In terms of the precautionary principle, the non-substantive benefits of whiter looking sweets and toothpaste (in contrast to the benefit of infection-free wounds) would not justify the allowance for nano titanium dioxide in food, toothpaste, etc., especially without nano-specific labeling to inform consumers and let them decide.

Many industrial manufacturing uses of nano-particles involve fusing them back together, as in printed electronic circuits and ultra-thin films on glass or plastic, which then have unique and useful properties. Firms need to take adequate precautions for worker safety, but consumers and other third parties are not at risk, since the material in the final product is no longer in nano form.

A new frontier in nano engineering involves manipulating and aggregating nano particles into tiny structures. Regulatory agencies—it is not clear which ones—need to keep an eye on this technology as it develops and to do independent research on the risks that some nano structures could pose to human health and the environment.

Although EPA and FDA have started investigating the potential risks posed by nanoparticles, neither engineered nanoparticles nor the products and materials that contain them are subject to any special regulation regarding production, handling or labeling. EPA's "A to Z Index of Environmental Topics" does not have a line for Nano particles or Nano technologies. A part of FDA, the Center for Drug Evaluation and Research (CDER) has been doing research on the properties of nano materials as they are used in drug products, but it has not yet developed a regulatory framework to assess their safety and efficacy.[71]

Given the potential for long delays in the evidence of harmful negative effects surfacing, for instance as nanoparticles of one sort or another accumulate in the liver or other organs, the precautionary principle would guide us in uncertain cases to restrain rather than allow the sale and use of nano materials in foods and skin products while researchers collect further evidence. This precautionary attitude is especially important where the reputed benefit of the products is only to enhance appearance, not to improve health or nutrition.

New Technologies to Watch

Some new technologies have not presented specific dangers and have no regulatory framework or agency. Yet some experts see potentials for grave danger. Two examples are artificial intelligence and human enhancement—possibly leading to the synthetic development of a species of post Homo sapiens.

Artificial Intelligence

Artificial intelligence (AI) is here already, but in benign forms so far—doing things that humans already do, but doing them faster, cheaper, and perhaps more carefully and thoroughly. Headline events are IBM computers beating humans at chess and Go, an even more complex game. Here, although the computers learn in ways and use strategies that even the best players find mystifying, the rules of the game are set by humans, and a board confines the scope and risks—gains or losses. AI there endangers only the egos of the Grand Masters.

AI is also getting real-world application in tasks such as reading the results of MRIs and other scans. Here the speed and thoroughness of AI pays off in finding tumors or other abnormalities that the human radiologist might miss. Then the human can look again at the spot found by AI and say, "ah, yes, we're glad to find that". Search engines and computerized personal assistant applications use algorithyms that appear learn based on pattern recognition and prediction.

Dangers may arise, however, when the AI would find something too complex for the human to understand and then, more quickly than a human could double check, would take real world action. Financial markets are an immanent example. AI models so far have not consistently outperformed the market, as far as reported, but firms are working on it. Once one or more firms has an AI model that they believe is a winner, it is hard to see how regulations could prevent its use, not only for making forecasts but also for directing trading in real time.[72]

If one or two firms with small market-share portfolios did this, it would probably not cause a problem. Success would expand their market shares, however, and one can envision a time when a few firms wielding AI trading strategies dominated whole markets—stock, bonds, or derivatives. Then the interaction of competing AI strategies could drive wild gyrations in the markets. Regulation would have difficulty preventing this, since many firms already use computer automated trading to execute non-AI trading strategies. Perhaps the best remedy would be one proposed to discourage ultra-high frequency

trading—a very low percentage tax on each trade (known as the Tobin tax), which would be too small to discourage buying or selling on the basis of fundamental values.

One military application is also often mentioned, that of programming autonomous (not simply remotely piloted) drones to fire on targets identified by their software. This might further integrate contemporary warfare into the world of videogames.

Human Enhancement

Another area of concern is *human enhancement*, meaning "any attempt to temporarily or permanently overcome the current limitations of the human body through natural or artificial means… whether or not the alteration results in characteristics and capacities that lie beyond the existing human range."[73] Therapeutic enhancements - such as contact lenses, or hearing aids, or insulin for diabetics, or an artificial hip or prosthetic limb – are widely accepted, but the borderline between therapeutic and 'beyond normal' uses is unclear. Human growth hormone, for instance, can be used to treat a child's pituitary disorder, or can be used to help a perfectly normal child grow taller than they would otherwise have done. Are both uses ethical?

New technologies are making ethical decisions harder. "Existing human enhancement technologies include reproductive technology, embryo selection by pre-implantation, genetic diagnosis, physically enhancing drugs, cognitive enhancers, and plastic surgery. Emerging technologies include human genetic engineering [now including CRISPR's carefully-directed editing] and neural implants, as well as speculative technologies such as mind Uploading."[74] Here we could face a dangerous extension of AI, if people link their brains up to programs whose machinations neither they nor anyone else fully understands. Interactions among a societal subset of AI-driven humanoids—competing or coordinating together—could create serious problems for all people.

New technologies might soon cross over into *transhumanism,* the idea of humans engineering a posthuman / superhuman future. Even without going this far, human enhancement clearly raises questions of economic justice (who will be able to afford enhancements?), of technological risk (do we really understand the long-term effects of enhancements? Steroids on steroids?) and of just what it means to be made 'in the image of God.' While we may celebrate enhancements that improve human thriving, we need to apply the precautionary principle to their application when it endangers the meaning or even the survival of our species.[75] Sociologists, AI scientists, and ethicists (Christians and others) need to think together about how to address these challenges.

Conclusions

God has charged us to take care of each other and of all creation. Through geological forces and evolution, God created our world and we should not casually put it at risk in order to meet some corporation's quarterly earnings target or to do the bidding of a political donor. The precautionary principle should guide our nation's regulatory decisions.

Although laws may set out with the precautionary principle, in practice the manufacturers seeking monetary benefit have often been able to overwhelm and weaken the precautionary regulatory processes that might pre-emptively prevent harm. Most exceptions to this pattern have been when introduction of a product causes demonstrable harm, often only brought to public attention with lawsuits. Manufacturers and government regulators should regularly update—tightening or relaxing—product safety ratings and restrictions as more research and experience become available. To enable democratic

participation by all those affected, manufacturers and regulators need to make publicly available (and in readily accessible and readable form) information about the risks as well as benefits of any product or process.

Beyond strengthening public health and environmental protections, the precautionary principle is intended to deal with *un*intended consequences. Although our focus has been on improvements to the US regulatory framework, by using the four major ethical categories developed within the ecumenical movement, the principles of sustainability, participation, sufficiency, and solidarity, we acknowledge the broad ways that technological developments—say, the "digital divide"—affect cultures, and how technologies can be used for social control rather than liberation. Democratic participation is conditioned by cultural capacity, and the most advanced corporations leave much conventional oversight and regulation (and taxation) by conflicted political processes far behind. This is to leave open, then, the question of how much transformation our own and other developed societies will need to undergo if we are to avert truly unmeasurable risks of climate changes interacting with dysfunctional or inadequate government. [END]

[Two annexes and the endnotes follow]

Annex A: **Historical origins of the precautionary principle and its application in the United States and Europe**

Many commentators argue that the precautionary principle originally emerged from Germany in the mid-1970's. A few argue that its development started at the 1972 Stockholm Conference on the Human Environment. In any case, the first international treaty using the term precautionary principle came about after international conferences discussing the protection of the North Sea. At those meetings, Germany championed the concept. Initially, the parties did not even use the term "precaution," but agreed that action should be taken to prevent "damage to the environment can be irreversible or remediable only at considerable expense and over long periods and that, therefore, coastal states and the EEC must not wait for proof of harmful effects before taking action." Finally, in November 1987, at the second conference where the London Declaration was adopted, a "precautionary approach" was adopted. (Ministerial Declaration for the Second International Conference on the Protection of the North Sea, Nov. 25, 1987).

The Precautionary Principle, although not always called exactly by that name, is now integrated into many international conventions[76] and US and European domestic laws and is embedded in many US occupational safety and environmental laws. It is well described in the Wingspread Consensus Statement on the Precautionary Principle[77]:

> *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. In this context the proponent of an activity, rather than the public, should bear the burden of proof. The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action.*

United States

In the United States, the principle, though not always using the term "precautionary principle" began to be stated in strong terms in worker health and safety law, then in environmental law, and finally rather weakly in food safety law. In fact, interpretations of what constitutes sufficient scientific evidence and how precautionary agencies should be are given their strongest expression in occupational health and safety law, The Occupational Safety and Health Act of 1970, in particular, the General Duty Clause of the law stipulates that the employer must maintain a place of employment free from recognized hazards that are causing or likely to cause death or serious physical harm.[78]

The Clean Air Act of 1970 and its subsequent amendments require the Environmental Protection Agency (EPA) to adopt measures to control air pollutants when the pollutants "may reasonably be anticipated to endanger public health or welfare"[79] (USC §7521(a)(1)). Absolute proof of endangerment is not required, but a reasonable belief may require action. The Act moreover requires the EPA to set air quality standards to protect the most vulnerable populations, with "an adequate margin of safety."[80] (USC §7409(b)(1)).

In 2007, in *Massachusetts v. EPA*,[81] the US Supreme Court underscored that the EPA cannot arbitrarily decide not to take precautionary action, in this case on whether or not to regulate carbon dioxide as an air pollutant that causes global warming. The Court wrote:

> Under the Act's clear terms, EPA can avoid promulgating regulations only if it determines that greenhouse gases do not contribute to climate change or if it provides some reasonable explanation as to why it cannot or will not exercise its discretion to determine whether they do. It has refused to do so, offering instead a laundry list of reasons not to regulate, including the existence of voluntary Executive Branch programs providing a response to global warming and impairment of the President's ability to negotiate with developing nations to reduce emissions. These policy judgments have nothing to do with whether greenhouse gas emissions contribute to climate change and do not amount to a reasoned justification for declining to form a scientific judgment. Nor can EPA avoid its statutory obligation by noting the uncertainty surrounding various features of climate change and concluding that it would therefore be better not to regulate at this time.

In short, the Court ruled that the precautionary approach of the Clean Air Act requires the EPA to take action even if the politics of the time argues against such precautionary action. It is worth noting that this Court was rather conservative, and one might have expected that it would not have endorsed such a precautionary approach after three decades of anti-regulatory rhetoric and practice in US politics.

Nonetheless, in US policy making, cost-benefit analysis of regulations has often trumped the precautionary language in the laws of the US. An expansive definition of cost benefit analysis has been forced on the agencies by the Office of Management and Budget (OMB) in both Republican and Democratic administrations. The OMB is supposed to review, not stop, regulations using cost benefit analysis, but has often held up environmental and health regulations for years, well beyond the 120-day limit the OMB regulations stipulate. Even relatively minor regulations, such as the June 2011 proposal by the EPA to regulate nano pesticides languish and are effectively killed.[82]

Even major rules have languished in the White House offices of the OMB. Cass Sunstein, the first Obama Administration appointee to head the OMB, is one of the most vociferous critics of the Precautionary Principle and an ardent champion of cost-benefit analysis as the primary tool for assessing and making regulatory decisions. Only after he left the OMB, was the silica dust rule to protect workers from a potent carcinogen finally released after 12 years.

Europe

In Europe, the Precautionary Principle found its way into both law and practice between 1980 and the present. The 1992 treaty[83] that created the European Union (EU) made the Precautionary Principle the bedrock of EU environmental policy:

> *Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay. Environmental protection requirements must be integrated into the definition and implementation of other Community policies. (Article 130R[2])*

Article 130R(3) calls for agencies to use "available scientific and technical data" and to assess "the potential benefits and costs of action or lack of action."

The European Commission (EC) formed a Commission on the Precautionary Principle, which declared that it would be the policy of the European Union to use the Precautionary Principle "where preliminary objective scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal, or plant health may be inconsistent with the high level of protection chosen for the community"[84]

The resulting policies have created what some characterize as a "guilty until proven innocent" approach to approving new products. The Precautionary Principle has been invoked by EU nations as part of the reason for opposing the importation of US beef raised using hormones prohibited in Europe and for the slow, careful adoption of genetically modified (GM) crops in Europe. [85]

Europe's chemical safety law, REACH, was designed to incorporate the Precautionary Principle and has been staunchly criticized by some US chemical industries and their supporters in the US Congress. Nonetheless, it is unclear how actively the agency implementing the law is promoting the search of alternative chemicals that should be a part of the precautionary process.[86]

Europe's agricultural rules, relating to pesticides, food additives, hormones in beef, genetically modified food and antimicrobials, incorporate the Precautionary Principle and thus are criticized by US politicians as "non- tariff" barriers to free trade. Former Senator Max Baucus from Montana, while on a trip to Europe to promote a US–EU free trade agreement wrote in the *Financial Times* that he would work at "ensuring that regulatory process are streamlined and based on sound science … eliminating unfair barriers that keep our agricultural products out of the European market without any scientific justification—for example, blocking genetically engineered crops and beef and pork containing feed additives that have been deemed to be safe [in the United States][87] Calls for "sound science" are often code for anti-regulatory arguments, and often the same politicians arguing for "sound science" have cut the science budgets of agencies like the EPA when they have attempted to research alternatives to chemicals or other technologies currently being used in industry or agriculture.

This account of the precautionary principle's formal uses does not include a survey of its adoption and application within the Christian churches, although such a survey is available from the Advisory Committee on Social Witness Policy, along with a brief policy summary of prior Presbyterian uses of the concept. The United Methodist Church and the Evangelical Lutheran Church in America, for examples, use the precautionary principle in their social teaching and policy work. More broadly, the World Council of Churches in the 1970's developed an ethical framework for debating the safety and sustainability of nuclear power (as well as the impacts of nuclear weapons), other energy technologies, and human genetic experimentation. Its ethical criteria were used and elaborated internationally though

national councils of churches, assisting many developing nations in their dealings with developed nations, transnational institutions, and corporations.

We conclude with a brief quotation from the ecumenical report, *Human Values and Advancing Technology*:

"Using science (by research) and technology (by application) we have solved many problems through concentrating effort on clearly defined sequences of tasks. Yet…a too narrow concentration of attention has frequently contributed to our failure to anticipate unintended consequences. Because these consequences are now arising on so large a scale, ways must be found to cope with major deficiencies in our policy-making process. (…)

Increased carbon dioxide appears to trigger a chain of events: warming of world climates, increased melting of polar ice caps, rising sea levels, and the consequent flooding of the world's major seaports and fertile coastal plains. Scientists have estimated that the point of no return may be reached by the end of the century. … Public and private agencies must proceed immediately to develop and evaluate alternatives so that ultimate decisions can be made wisely and in time."

That quotation from Cameron P. Hall, a Presbyterian minister then working for the National Council of Churches of Christ in the U.S.A., was written in 1967.

Annex B. **Contributors to the Report**

This report was developed by a task group of the Advisory Committee on Social Witness Policy that included Dr. Steven Webb, an economist and primary final writer, Dr. Linda Eastwood, a physicist and theologian, and Dr. Christian Iosso, an ethicist and staff to the Committee. Rev. Ray Roberts, PhD, hosted two meetings of a reference group at the Westfield (NJ) Presbyterian Church. The task group was enabled to focus on the regulatory nexus by Thomas McGarity, Esq., Professor of Law at the University of Texas and past director of the Center for Progressive Regulation, who met with the reference group at its second meeting. Dr. Jaydee Hanson, a consultant from the Center for Food Safety, provided extensive research on ecumenical background and practical advocacy concerns. Dr. Roger Willer, an ethicist with the Evangelical Lutheran Church in America, and Dr. Donna Riley, Professor of Engineering Ethics Education at Purdue University, gave valuable comment.

The reference group that gathered in Westfield included Dr. Douglas Miller, a biochemist and pharmacologist with extensive corporate research and development experience, Dr. Eric Schaff, Esq., Northern NJ Regional Director of the Environmental Protection Agency, Dr. William Menke, Professor of Earth and Environmental Sciences at Lamont-Doherty Earth Observatory and The Earth Institute at Columbia University, and Dr. Andrew Sackman, Arizona State University. Ms. Martha Smith, formerly of the Yale University Groundwater Project, Rev. Dr. Susan DeGeorge, Esq., Stated Clerk of Hudson River Presbytery and Adjunct Professor of Law at Pace University, and Dr. Fred Hitzhusen, Professor, Agricultural, Environmental and Development Economics at The Ohio State University, joined the group by phone.

ENDNOTES:

[1] Stoll, Mark R. *Inherit the Holy Mountain: Religion and the Rise of American Environmentalism*. (Oxford/New York: Oxford University Press, 2015) Stoll underlines the disproportionate role of Presbyterians and other Reformed Christians in the conservation and wilderness preservation movements, and in the government bodies developed to further those goals.
[2] Rowan Williams, https://www.commonwealmagazine.org/embracing-our-limits
[3] Public interest groups have proposed that legislators voting on regulations affecting their donors or sources of campaign donations should be required to disclose those financial ties, which can be quite significant.
[4] Some studies report potentially isolating, depressive, sleep-reducing, and addictive aspects of "small screen" exposure through excessive use of personal electronic devices. The larger cultural and economic impacts are argued in Franklin Foer. *World Without Mind: The Existential Threat of Big Tech*. (NY/London: Cape/Penguin, 2017).
[5] A still helpful example can be found in Dieter Hessel, ed. *The Agricultural Mission of Churches and Land Grant Universities* (Ames: Iowa State University Press, 1980). Then-General Assembly Moderator John Conner convened professors and campus ministers from 12, primarily Midwestern universities, to look at the land grant system's contributions to research, appropriate technology, food sufficiency and sustainablilty.
[6] See Nicholas Kristof, "Trump's Legacy: Damaged Brains," *The New York Times*, Oct. 29, 2017, p. 9. This op ed is deliberately strident in pointing to a scheduled ban that was suspended, and to impacts of chemicals targeted at some species but affecting others, including humans.
[7] Two books by Naomi Klein address the dangers of societies acting too rapidly and the limits economic practices may put on properly accountable rapid action: *The Shock Doctrine: The rise of Disaster Capitalism* (2007) and *This Changes Everything: Capitalism vs. the Climate* (2014). In the first book she describes ways private or partisan interests can take advantage of weakened political decision-making in disasters and their aftermath. In the second, her particular opponents are the kind of highly anti-regulatory or "neo-liberal" capitalism which supports continuously increased consumption and the false solutions that still depend on the largest private interests.
[8] See, for instance, the 2016 report from the U.S. National Academies of Science, Engineering, and Medicine (NASEM) on gene driven research.
[9] Rowan Williams, https://www.commonwealmagazine.org/embracing-our-limits
[10] Lynn White, "The Historical Roots of Our Ecologic Crisis," *Science* (1967) 55, p.1205. (White's thesis has been much debated by Christian ethicists, historians, and others. One example clarifying Reformed approaches in contrast to White can be found in Gordon and Jane Douglass, "Creation, Reformed Faith, and Sustainable Food Systems," in Robert L. Stivers, ed. *Reformed Faith and Economics* (Lanham, MD: University Press of America, 1989), pp. 127ff.
[11] Ibid., 1206.
[12] Ron Wolf, "God, James Watt, and the Public Land," *Audubon* 83, (1981), 65.
[13] e.g. Case-Winters, Anna. *Reconstructing a Christian Theology of Nature: Down to Earth*. Aldershot, Hants, England: Ashgate Pub. Ltd, 2007
[14] Presbyterian Church (U.S.A.). *Restoring Creation for Ecology and Justice*: A Report Adopted by the 202nd General Assembly (1990), Presbyterian Church (U.S.A.). Louisville, KY: Office of the General Assembly, the Presbyterian Church (U.S.A.), 1990. p.22-32.
[15] Presbyterian Church (U.S.A.) *The Power to Change: U.S. Energy Policy and Global Warming – A Report Adopted by the 218th General Assembly (2008), Presbyterian Church (U.S.A.)*. Louisville, KY: Office of the General Assembly, the Presbyterian Church (U.S.A.), 2008. p.13
[16] Presbyterian Church (U.S.A.). *Hope for a Global Future: Toward Just and Sustainable Human Development*: and Study Guide. Louisville, Ky. (100 Witherspoon St., Louisville, KY, 40202-1396): Office of the General Assembly, 1996. p.59.
[17] *Commentaries on the First Book of Moses Called Genesis*, by John Calvin, Trans. John King (2 vols. Edinburgh, 1847) 1:125. (Modified to make the language less gendered and more inclusive.)
[18] Most who use the term, "Anthropocene," are not optimistic about human capacity to limit technology or distribute its benefits equitably. A more positive view can be found in Diane Ackerman, *The Human Age: The World Shaped by Us*. (NY: Norton, 2014).
[19] The origin of this proverb is not known. Often said to be native-American, it may in fact have started with Wendell Berry. See http://quoteinvestigator.com/2013/01/22/borrow-earth/
[20] Calvin, *Institutes*, bk. II, 1:307.
[21] https://www.webmd.com/news/breaking-news/food-additives/20150723/foods-clean-labels
[22] MRTI, The Committee on Mission Responsibility Through Investment, pursues engagement with companies that may lead to divestment, as noted in Recommendation Section II. B. of this report. Others urge a strategy of immediate divestment of companies in the fossil fuel sector.
[23] FDA's implementing regulations in 1996 for the Food Additives Amendment say: "General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information."
Lars Noah, "Legal Aspects of the Food Additive Approval Process", a background paper commissioned by the Institute of Medicine of the National Academy of Sciences for a 1997 Food Forum workshop.
[24] 21 C.F.R. § 170.30(a).
[25] Food and Drug Administration. Substances Generally Recognized as Safe, Notice of Proposed Rulemaking, 62 Fed. Reg. 18938, 18939 (1997) [hereinafter 1997 GRAS NPRM].
[26] FDA, 1997 GRAS NPRM, at 18939.
[27] FDA, 1997 GRAS NPRM, at 18,940. The agency recognized, however, that common knowledge in the scientific community could also be based upon "(1) publication of data and information in the secondary scientific literature, such as scientific review articles, textbooks,

and compendia; (2) documentation of the opinion of an "expert panel" that is specifically convened for this purpose; or (3) the opinion or recommendation of an authoritative body." Id., at 18,941.

[28] https://www.centerforfoodsafety.org/press-releases/3550/victory-cfs-wins-first-step-in-major-legal-battle-to-protect-food-safety

[29] FDA, 1997 GRAS NPRM, at 18941. See Lars Noah, & Richard A. Merrill, Starting From Scratch?: Reinventing The Food Additive Approval Process, 78 B.U.L. Rev. 329, 330 (1998).

[30] FDA, 1997 GRAS NPRM, at 18939; 1992 FDA Policy Statement, at 22,989. See also Noah & Merrill, Starting from Scratch, at 363, 377.

[31] FDA, 1997 GRAS NPRM, at 18939).

[32] Peter B. Hutt & Richard Merrill, Food and Drug Law, at 333.

[33]https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf

[34] https://www.nytimes.com/2017/11/01/business/soybeans-pesticide.html?nytmobile=0

[35] FDA website, Dec. 2017.

[36] Thomas G. Neltner, Neesha R. Kulkarni, Heather M. Alger, Maricel V. Maffini, Erin D. Bongard, Neal D. Fortin, and Erik D. Olson, "Navigating the U.S. Food Additive Regulatory Program," *Comprehensive Reviews in Food Science and Food Safety*. 10 (2011): 342-68.

[37] Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act

[38] "Get Toxic Chemicals Out of Cosmetics," *Scientific American.* Nov. 2017, p. 10

[39] https://weather.com/science/environment/news/2017-12-19-epa-scott-pruitt-lean-superfund-sites; https://www.nytimes.com/2017/12/22/climate/epa-buyouts-pruitt.html;

[40] https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx

[41] https://www.usda.gov/topics/biotechnology/biotechnology-glossary

[42] The challenge in evaluating the glyphosate in Round-up can be seen in internal company documents that also show efforts to shape or push back in public debate: Danny Hakim, "Monsanto's Research Sway is Seen in Disclosed Emails," *The New York Times*, August 2, 2017.

[43] For example: https://futurism.com/geneticists-have-used-crispr-gene-editing-to-create-crops-that-grow-more-food/

[44] Melody M. Bomgardner, "CRISPR: A new toolbox for better crops," Chemical and Engineering News, 95 (24), June 12, 2017. https://cen.acs.org/articles/95/i24/CRISPR-new-toolbox-better-crops.html

[45] J A Nordlee, S L Taylor, J A Townsend et al. 1996. "Identification of a Brazil-Nut Allergen in Transgenic Soybeans". *The New England Journal of Medicine*. 334 (11): 688 http://www.nejm.org/doi/full/10.1056/NEJM199603143341103#t=article

[46] Hilbeck A., et al. 2015. "No Scientific Consensus on GMO Safety". *Environmental Sciences Europe*. 27, no. 1. https://enveurope.springeropen.com/track/pdf/10.1186/s12302-014-0034-1?site=enveurope.springeropen.com

[47] Wilhelm Klümper and Matin Qaim, 2014, "A Meta-Analysis of the Impacts of Genetically Modified Crops." *PLoS ONE*. 9, no. 11: e111629.

[48] Donna Hakim, "Doubts About the Promised Bounty of Genetically Modified Crops," *New York Times*, Oct. 29, 2016. https://www.nytimes.com/2016/10/30/business/gmo-promise-falls-short.html

[49] Thin Lei Win, "New crops, technology needed to help farmers adapt to rising heat - Gates Foundation," Thomson Reuters Foundation, 12 December 2017. http://news.trust.org/item/20171212142555-bd381/

[50] Keese, Paul. 2008. "Risks from GMOs due to Horizontal Gene Transfer". *Environmental Biosafety Research*. 7, no. 3: 151. https://www.ebr-journal.org/articles/ebr/pdf/2008/03/ebr0742.pdf

[51] Claire Hope Cummings, *Uncertain Peril Genetic Engineering and the Future of Seeds*. Boston, Mass: Beacon Press, 2008, 25-26

[52] Indur Goklany, *The Precautionary Principle: A Critical Appraisal of Environmental Risk Assessment*. Washington, D.C.: CATO Institute, 2002. Chapter 3.

[53] This concern for biodiversity was embodied for a period in a seed repository at Ghost Ranch, the Presbyterian Church's conference center in Abiquiu, New Mexico. While many innovative practices remain, this program of the high altitude desert farm depended on specific volunteers.

[54] Claire Hope Cummings, *Uncertain Peril Genetic Engineering and the Future of Seeds*. Boston, Mass: Beacon Press, 2008.

[55] Jack Ralph Kloppenburg, *First the Seed: The Political Economy of Plant Biotechnology*. Madison: University of Wisconsin Press, 2005.

[56] Andrew Jacobs and Matt Richtel, "A Nasty, Nafta-Related Surprise: Mexico's Soaring Obesity," *The New York Times*, December 11, 2017. https://www.nytimes.com/2017/12/11/health/obesity-mexico-nafta.html

[57] Presbyterian Church (U.S.A.). *Resolution on Just Globalization: Justice, Ownership, and Accountability*. Louisville, KY: Office of the General Assembly, 2006, p.18.

[58] Presbyterian Church (U.S.A.). *Hope for a Global Future: Toward Just and Sustainable Human Development: and Study Guide*. Louisville, Ky: Office of the General Assembly, 1996, p.26.

[59] https://www.usda.gov/topics/biotechnology/how-federal-government-regulates-biotech-plants

[60] https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/57_fed_reg_6753__1992.pdf

[61] https://obamawhitehouse.archives.gov/blog/2015/07/02/improving-transparency-and-ensuring-continued-safety-biotechnology

[62] http://www.slate.com/articles/technology/future_tense/2017/04/u_s_biotechnology_regulations_are_woefully_out_of_date.html

[63] A 2014 summary of this regulatory environment may be found at https://www.loc.gov/law/help/restrictions-on-gmos/usa.php

[64] https://www.nature.com/news/gene-edited-crispr-mushroom-escapes-us-regulation-1.19754

[65] https://www.nytimes.com/2017/01/09/science/genetically-edited-foods-crispr.html

[66] https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/57_fed_reg_6753__1992.pdf p.6753

[67] OECD, Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles (1992), https://www.oecd.org/science/biotrack/41036698.pdf

[68] These criteria were proposed by agricultural scientists at University of California Davis: Ronald, Pamela C., and Raoul W. Adamchak. *Tomorrow's Table: Organic Farming, Genetics, and the Future of Food*. New York: Oxford University Press, 2008, p.xi-xii.

[69] Presbyterian Church (U.S.A.). *We Are What We Eat: A Report Approved by the 214th General Assembly (2002)*, Presbyterian Church (U.S.A.). Louisville, KY: Advisory Committee on Social Witness Policy and the Rural Ministry Office, 2002, p.21.
[70] https://www.sciencedirect.com/science/article/pii/S1878535217300990
[71] https://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm309677.htm
[72] A regulator would not be able to tell by observing transactions whether the firm was using AI programs or simply a trading algorithm designed by humans.
[73] Institute for Ethics and Emerging Technologies, "Human Enhancement," https://ieet.org/index.php/tpwiki/human_enhancement accessed 1/23/18.
[74] Ibid.
[75] Daniel McFee, "The Risks of Transhumanism: Religious Engagements with the Precautionary and Proactionary Principles," in *Religion and Transhumanism: The Unknown Future of Human Enhancement*, ed. Calvin Mercer and Tracy J. Trothen (Santa Barbara, CA: Praeger) 2015, pp.217-228; "Thought experiments: Brain-computer interfaces," *The Economist* 6-12/Jan./2018: Technology Quarterly.
[76] See, e.g., RIO DECLARATION ON ENVIRONMENT AND DEVELOPMENT, June14,1992, 31 I.L.M. 874, 879 ("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."); CARTAGENA PROTOCOL ON BIOSAFETY, Jan. 29, 2000, 39 I.L.M. 1027 Art. 10(6) ("Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse/effects of a living modified organism on the conservation and sustainable use of biological diversity in the Part of import, taking also into account risks to human health, shall not prevent that party from taking a decision, as appropriate, with regard to the import of the living modified organism in question . . . in order to avoid or minimize such potential adverse effects.");
U.N. FRAMEWORK CONVENTION ON CLIMATE CHANGE, May 9, 1992, 21 I.L.M. 849, ("The Parties should take precautionary measures to anticipate, prevent or minimize the cause of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures.");
THE WORLD CHARTER ON NATURE, G.A. Res. 37/7,¶ 11, U.N. Doc. A/RES/37/7 (Oct. 28, 1982) ("Activities which might have an impact on nature shall be controlled, and the best available technologies that minimize significant risks to nature or other adverse effects shall be used.");
THE LONDON CONVENTION ON THE PREVENTION OF MARINE POLLUTION BY DUMPING WASTES AND OTHER MATTER, 1996 Protocol to the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, Mar. 24, 2006, art. 3, para. 1 ("Appropriate preventative measures are[to be] taken when there is reason to believe that wastes or other matter introduced into the marine environment are likely to cause harm even when there is no conclusive evidence to provide a causal relation between inputs and their effects.") ;
AGREEMENT FOR THE IMPLEMENTATION OF THE PROVISIONS OF THE UNITED NATIONS CONVENTION ON THE LAW OF THE SEA OF 10 DECEMBER 1982 RELATING TO THE CONSERVATION AND MANAGEMENT OF STRADDLING FISH STOCKS AND HIGHLY MIGRATORY FISH STOCKS, G. A. 164/37, art. 6, U.N. Doc. A/CONF164/37 ("States shall apply the precautionary approach widely to conservation....").
[77] Wingspread Consensus. 1998. "The Wingspread Consensus Statement on the Precautionary Principle." Science & Environmental Health Network 26 January.. http://www.sehn.org/wing.html
[78] Occupational Safety and Health Act. 1970. United States Code Title 29. USC §651–683
[79] See The Clean Air Act, 42 U.S.C. §7521(a)(1), "The Administrator shall by regulation prescribe (and from time to time revise) in accordance with the provisions of this section, standards applicable to the emission of any air pollutant from any class or classes of new motor vehicles or new motor vehicle engines, which in his judgment cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health or welfare." Other provisions in the Clean Air Act contain similar requirements, including the requirement that pollutants be controlled using the best available technology.
[80] See The Clean Air Act 42 U.S.C. §7409(b)(1), "National primary ambient air quality standards, prescribed under subsection (a) of this section shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. Such primary standards may be revised in the same manner as promulgated."
[81] Massachusetts v. EPA, 127 S.Ct. 1438 (2007) p.6 The Supreme Court remanded the case to the U.S. Court of Appeals for the District of Columbia Circuit, which in turn ordered that "EPA's denial of the International Center for Technology Assessment's 1999 rulemaking petition be vacated and Nos. 03-1361,03-1362, 03-1363, and 03-1364 be remanded for further proceedings consistent with the Supreme Court's opinion.".
[82] *Federal Register* 76: pages 35383-35395, June 17, 2011.
[83] Treaty on European Union, February 7, 1992, 1992 O.J. (C 191) 1, art. 130R(2).
[84] "Commission adopts Communication on Precautionary Principle," available at: http://europa.eu/rapid/press-release_IP-00-96_en.htm.
[85]https://www.researchgate.net/publication/223941148_Chemicals_regulation_and_precaution_Does_REACH_really_incorporate_the_precautionary_principle
[86] http://www.bbc.com/news/world-europe-33055665
[87] Baucus, Max. 2013. "Transatlantic Trade Deal Is a US Priority." *Financial Times*, March 3.