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National Science and Technology Council
Emerging Technologies Interagency Policy Coordination Committee
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Ave.
Washington, DC 20504

**RE: Docket No. FDA–2015–N–3403**

Center for Food Safety (CFS) is a nonprofit, public interest organization with a mission to empower people, support farmers, and protect the earth from the harmful impacts of industrial agriculture. At the same time, CFS works to promote and protect regenerative, sustainable agriculture. CFS represents over 700,000 farmer and consumer members who reside in every state across the country. For over two decades, CFS has been the leading U.S. public interest organization working on the issue of genetically engineered (GE) organisms. CFS has a major program area specific to GE foods and labeling, and numerous staff members—scientific, policy, campaign, and legal—whose work encompasses the topic. CFS staff are recognized experts in the field and intimately familiar with the issue of GE organisms, the inadequacy of their oversight, their risks, and their adverse impacts. CFS submits these comments on the Office of Science and Technology Policy's notice and request for information on *Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology*.

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**TABLE OF CONTENTS**

## INTRODUCTION

When the U.S. established the current Coordinated Framework for the Regulation of Biotechnology in 1986, there were significant concerns that this radical new technology could cause a host of novel harms to public health, the environment, and U.S. agriculture. These concerns have been borne out by time. In short, to date, regulation of GE organisms in the U.S. has been an unmitigated disaster. Current GE crops are having significant agronomic and environmental adverse impacts, impacts that are going unaddressed and unassessed. Despite nearly thirty years of research and development and billions of dollars, genetic engineering has shown itself to be mainly the marriage of chemical pesticide corporations and the control of seeds, with these chemical companies profiting from GE crop systems engineered to be resistant to the pesticides that they sell, to the detriment of farmers, consumers, and the environment. Future planned GE organisms—including fish, plants, insects, and animals—portend even worse impacts. Some GE organisms created with newer forms of genetic engineering are going completely unregulated, a category of organisms growing with alarming speed. GE ingredients have rapidly expanded into our food supply, without any premarket approval or independent safety testing, and without product labeling, leaving consumers in the dark. Other risks to health and the environment remain unknown, because of industry patent and contract control over research.

Yet the U.S., unlike most of the rest of the world, has failed to enact new legislation to address GE organisms and their novel risks, or to even require their labeling in food products. Instead, under the current Framework, the U.S. has attempted to regulate by fitting "square pegs in round holes," by regulating GE products using statutes that were written before GE technology was even possible. This has created huge regulatory gaps, mismatches in expertise and authority, and oversight methods and mechanisms from the agencies that are haphazard, and in many ways negligent. The Framework has been anything but "coordinated."

Worse still, federal agencies have constrained themselves: existing laws—the Plant Protection Act; the Federal Food, Drug, and Cosmetic Act; and the Federal Insecticide, Fungicide, and Rodenticide Act, among them—actually grant broad powers to agencies, allowing for robust regulation. Yet for political and economic reasons, agencies have simply refused to apply these authorities to create responsible, fulsome oversight. This too has resulted in massive regulatory gaps, incoherent regulation among agencies, regulation by agencies that lack critical expertise, and the failure to keep pace with new technological developments, such as new methods and products of genetic engineering. At all agencies, regulators place commercialization ahead of safety, and refuse to face up to GE crops' significant agronomic and environmental impacts. Consequently the current U.S. oversight system fails to adequately assess, address, or prevent the known harms associated with GE crop cultivation, or to respond to them when they occur.

The concerns presented by GE technology at the time the Framework was created have been borne out, and new concerns have come to light, yet so far, the government has treated the Coordinated Framework as a means to *avoid* responsible regulation of biotechnology. This façade must be torn down. Accordingly, CFS urges the Office of Science and Technology Policy, and through it, the Food and Drug Administration (FDA), U.S. Department of

Agriculture (USDA), and Environmental Protection Agency (EPA), in the strongest possible terms, to use this opportunity to jettison the old framework and start again, establishing a responsible framework for the oversight of biotechnology. Rather than double down on the current framework, which has been a dismal failure, the agencies responsible for regulating biotechnology should correct the fundamental errors that underlie the current system, and implement binding regulations that address GE organisms in a responsible manner based on core governance principles.

## THE CURRENT SITUATION

Genetic engineering presents a host of well-documented adverse impacts and risks to consumers, farmers, and the environment.

### GE: A Pesticide-Promoting Technology

Despite two decades of promises about reducing world hunger, ameliorating global malnutrition, or combating global warming,[1] biotechnology firms have instead only delivered a handful of GE commodity crops that produce insecticides and/or withstand direct application of herbicides.[2] Over 5 of every 6 acres of transgenic crops worldwide (84%),[3] and 94% of soybeans, 89% of cotton, and 89% of corn grown in the U.S. in 2015 were GE, herbicide-resistant (HR) varieties.

Nearly all HR crops are Monsanto's "Roundup Ready" varieties, engineered to be resistant to glyphosate, the active ingredient in Roundup pesticide.[4] *Ctr. for Food Safety v. Vilsack*, 718 F.3d 829, 836 (9th Cir. 2013) (describing Monsanto's Roundup Ready "crop system" of the GE crop and associated pesticide). The Roundup Ready GE crop system has made glyphosate the most used pesticide in history, with over 280 million pounds applied in U.S. agriculture in 2012 alone.[5] Overall, in the 16 years from 1996 to 2011, an extra 527 million pounds of herbicides were sprayed in U.S. agriculture because of GE crops.[6]

These Roundup Ready crops are also responsible for an epidemic of "superweeds" that have evolved resistance to glyphosate on 70 million acres in the U.S. On the same principle by which bacteria evolve resistance to overused antibiotics,[7] the current resistant weed epidemic has cost U.S. farmers approximately $1 billion in damages to crops.[8] Almost unknown prior to Roundup Ready crops, glyphosate-resistant weeds now infest millions of acres of U.S. cropland.[9] In order to kill them, farmers apply herbicide cocktails, resort to soil-eroding tillage, and/or hire weeding crews to hoe the weeds by hand.[10] Thus, GE crop production systems lead to increased erosion of valuable topsoil and up to six-fold increases in the cost of weed control for farmers,[11] as well as environmental impacts.

The pesticide firms' "solution" to this resistant weed epidemic is a "next-generation" of GE crops "stacked" with resistance to multiple other toxic herbicides, such as Agent Orange component 2,4-D and the closely related dicamba.[12] Yet far from providing any panacea, these new GE crops will instead lead to vastly increased herbicide use, such as a three- to seven-fold rise in agricultural use of 2,4-D,[13] and increasingly intractable weeds resistant to multiple

herbicides.[14] GE crops resistant to multiple herbicides are the industry's major research and development focus, the future of agricultural biotechnology.[15]

The extraordinary use of pesticides associated with GE crops has had profound consequences. For example, the massive use of glyphosate with Roundup Ready crops has contributed to an alarming decline in the monarch butterfly.[16] Monarch caterpillars feed only on milkweed plants, once common in corn and soybeans fields. Glyphosate has nearly eradicated milkweed from Midwest cropland, the monarchs' major breeding range, depriving monarch caterpillars of their chief food source.[17] As a result, the Fish and Wildlife Service (FWS) recently concluded that Endangered Species Act protection may be warranted for monarchs.[18]

Glyphosate is also a leading culprit in herbicidal drift injury to sensitive crops,[19] and injures wild plants that many other organisms depend upon for food and/or habitat. Glyphosate is frequently detected in the air, rain, and water bodies of the Midwest and South.[20] Glyphosate-containing Roundup formulations are extremely toxic to tadpoles and frogs, and likely have contributed to the worldwide decline in frog populations.[21]

The public health and environmental risks from these HR GE crop systems are intimately intertwined. Earlier this year the World Health Organization's International Agency for Research on Cancer concluded that glyphosate is "probably carcinogenic to humans,"[22] and that 2,4-D is possibly carcinogenic.[23] 2,4-D is linked to higher risk of cancer, Parkinson's disease, and developmental disorders, and is also an environmental toxin.[24] Increased spraying of 2,4-D--resistant crops will exacerbate these impacts. Because glyphosate is "probably carcinogenic to humans,"[25] and it is widely found in the atmosphere, rainfall, surface waters and human urine,[26] the vast amounts now used in GE crop production systems may pose a risk to public health as well. Both public health and environmental impacts will be exacerbated by greater use of other herbicides to which newer GE crops are immune.

**Transgenic Contamination**

Another major adverse impact of GE crops is transgenic contamination—the unintended, undesired presence of transgenic material in organic or traditional crops, as well as wild plants. Transgenic contamination occurs from gene flow from GE crops, cross-pollinating their conventional or organic counterparts in the field and/or wild relatives, or when GE seeds become mixed with non-GE seeds at various stages of the crop production process: during harvesting operations, processing, or transport.[27] *Geertson Seed Farms v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624, at *4 (N.D. Cal. Feb. 13, 2007) ("Biological contamination can occur through pollination of non-genetically engineered plants by genetically engineered plants or by the mixing of genetically engineered seed with natural, or non-genetically engineered seed.").[28]

Harm from transgenic contamination manifests in several ways. As the U.S. Supreme Court has explained, this "injury has an environmental as well as an economic component." *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 155 (2010). The agronomic injury causes significant economic damage to farmers. Hundreds of unique GE contamination episodes have been documented involving corn, rice, wheat, alfalfa, flax, canola, and other crops.[29] These contaminations have resulted in the rejection by foreign markets of GE-contaminated supplies,

farmers' loss of GE-contaminated seed stocks for planting purposes, removal of potentially hazardous GE-contaminated food items from supermarket shelves, and loss of valuable grain export markets to other nations capable of providing the GE-free supplies demanded by foreign markets.[30] Domestic GE-sensitive markets are harmed by contamination as well: organic growers are at particularly great risk of losing their customers and markets, and potentially their organic certification, since USDA organic standards prohibit use of GE seed, and require that all inputs in organic production be 100% organic. More crucially, organic consumers buy organic specifically to avoid GE crops, and reject GE-contaminated products, costing organic growers their reputation and customers.

Collectively, transgenic contamination has cost U.S. farmers billions of dollars in rejected sales, lost exports, and closed agricultural markets,[31] with new episodes cropping up regularly.[32] To take just one example, widespread contamination of U.S. rice supplies with an unapproved variety of GE rice grown in field trials resulted in one billion dollars in losses due to lost rice exports and depressed rice prices, a dramatic reduction in planting stock as GE-contaminated seed lines were taken off the market,[33] and numerous lawsuits by rice farmers seeking compensation.[34]

Additionally, contamination can be irreparable, because it becomes difficult or impossible to contain once it occurs, resulting in a fundamental loss of choice for farmers and consumers. *See, e.g., Geertson Seed Farms*, 2007 WL 518624, at *9 ("For those farmers who choose to grow non-genetically engineered alfalfa, the possibility that their crops will be infected with the engineered gene is tantamount to the elimination of all alfalfa; they cannot grow their chosen crop."); *Ctr. for Food Safety v. Vilsack*, No. C 08-00484 JSW, 2009 WL 3047227, at *8 (N.D. Cal. Sept. 21, 2009). Unlike chemical pollution, transgenic contamination can propagate itself over space and time via gene flow. *Geertson Seed Farms*, 2007 WL 518624, at *5 ("Once the gene transmission occurs and a farmer's seed crop is contaminated with the Roundup Ready gene, there is no way for the farmer to remove the gene from the crop or control its further spread.").[35] And the risk of contamination itself creates costly burdens for organic and conventional farmers and businesses, such as the need for DNA testing or crop buffer zones. *Monsanto*, 561 U.S. at 154.

Additionally, escape of transgenes into related wild plant populations is, in most cases, irreparable. Oregon, for example, continues the Sisyphean task of trying to find and destroy feral populations of Monsanto's Roundup Ready GE bentgrass that escaped field trials there over a decade ago. *Int'l Ctr. for Tech. Assessment v. Johanns*, 473 F. Supp. 2d 9, 13, 29 (D.D.C. 2007).[36] Crops like GE alfalfa and GE canola that can spread outside of agricultural fields and persist there for years as weeds in feral (wild) form become more difficult, costly, and environmentally damaging to control when they harbor herbicide-resistance traits. In this way, weedy GE herbicide-resistant canola has become a progressively more prevalent and serious weed in Canada and California.[37] These impacts become even more serious when the GE crop has the ability to spread great distances, and/or has wild relatives that it can cross-pollinate, thus transferring the property of herbicide resistance. For instance, GE glyphosate-resistant bentgrass grown only in supposedly "contained" field trials has been detected miles from sites where it was grown,[38] poses a threat to native plants that it outcompetes, and is immune to glyphosate—the herbicide that in many situations is the only acceptable means of control.

Transgenic contamination incidents have not been limited to a single crop; corn, rice, canola, alfalfa, grasses, and other crops have all been contaminated. In 2008, the U.S. Government Accountability Office (GAO) analyzed several major contaminations, found that they had caused over a billion dollars in damages,[39] and concluded that "the ease with which genetic material from crops can be spread makes future releases likely."[40]

**Industry Claims of GE's Alleged "Benefits" Are Baseless**

Juxtaposed against these significant adverse impacts, independent studies have concluded that GE crops have not resulted in yield increases, whereas traditional breeding has increased yields.[41] A 2014 USDA report summarizing GE crop production stated: "over the first 15 years of commercial use, GMO seeds have not been shown to definitively increase yield potentials, and in fact, the yields of herbicide-tolerant or insect-resistant seeds may be occasionally lower than the yields of conventional varieties."[42]

Nor have GE crops benefited farmers financially: USDA's report goes on to say that several researchers have found "no significant differences" between the net financial returns to farmers who use GE crops and those who use traditional.[43] GE crop adoption by farmers is attributable to several factors, including that pesticide/chemical companies have acquired a substantial portion of the world's seed firms and leave farmers with little choice in the marketplace, and the high risk of being contaminated, even if they were to choose traditional.[44]

**Wholly Inadequate Federal Oversight**

<u>Food and Drug Administration (FDA)</u>

Like other agencies, FDA applies its authority under the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA) to GE foods, but it has no specific regulations applying the FFDCA to GE foods. Instead, FDA issued only a "statement of policy" on the topic, in 1992.[45] Pursuant to that guidance, the manufacturer, not FDA, determines whether a GE substance is "generally recognized as safe" (GRAS), and any consultation with FDA on that decision is voluntary. Generally, FDA presumes that GE substances are GRAS.

FDA neither makes any health and safety approval finding for GE foods, nor undertakes any independent analysis of their health risks.[46] The sum of FDA's role is a confidential consultation with industry where FDA reviews selected summaries of the industry's data, and even that is voluntary. Tellingly, the consultation culminates in FDA sending a "no questions" letter conveying the GE food developer's—*not FDA's*— safety assurances.[47] A typical FDA response, from a 2011 letter to Dow Chemical on a corn engineered to be resistant to the pesticide 2,4-D:

> Based on the safety and nutritional assessment *Dow has conducted*, it is our understanding that *Dow has concluded* that DAS-40278-9 corn is not materially different in any respect relevant to food or feed safety from corn varieties currently on the market and that the genetically engineered corn does not raise issues that would require premarket review or approval by FDA. . . . *Based on the*

> *information Dow has provided* to FDA, we have no further questions concerning the new corn variety, DAS-40278-9 corn, at this time. However, as you are aware, it is *Dow's continuing responsibility* to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.[48]

FDA has also claimed that it has oversight of GE animals under the FFDCA, pursuant to its "new animal drug" authority. It has no regulations so applying that authority; rather, FDA 2009 issued a guidance document in 2009 explaining how the agency intended to apply that authority to GE animals. FFDCA defines the term "drug" as including, among other things, "articles (other than food) intended to affect the structure or any function of the body of man or other animals . . . ."[49] "New animal drug" in turn means any drug that has not been used to a material extent or for a material time and is not recognized by "experts qualified by scientific training and experience" as safe and effective for use under the conditions prescribed, but which is intended for use in animals.[50] Rather than treat the genetic construct in a GE food animal as a new animal drug, FDA could have chosen to treat the genetic construct as a new food additive, thus requiring the submission of the data required for any new food additive. Nonetheless, FDA has interpreted the "new animal drug" definitions to encompass the rDNA construct in a GE animal, which by design affects the structure or function of the body of the GE animal in order to bring those animals within the agency's regulatory purview.

This oversight mechanism for GE animals is hugely problematic for a number of reasons. First, FDA's application of animal drug provisions to transgenic food animals is an unprecedented interpretation of the agency's authority under the FFDCA. Transgenic animals are very different from veterinary animal drugs, presenting new difficulties in assessment and oversight. The genetic constructs being reviewed are not similar new drugs for the animals, but constructs intended to change the nature of the animal; they do not eliminate health problems in the animal. In at least the case of the AquAdvantage salmon, the GE construct seems to make the salmon less healthy, causing increased focal inflammation and skeletal and gill defects, among others. Forcing transgenic square pegs into pre-existing statutory round holes is an endemic problem of U.S. oversight under the Framework. Further, a GE animal applicant must submit evidence establishing only that its "new animal drug" is both safe and effective for the intended use, with "safe" referring only to "the health of man or animal." Hence, environmental risks resulting from the production, transport, and use of GE food animals like the proposed AquAdvantage salmon are nowhere contemplated under FDA's statutory process. Other countries, such as Canada, require both an environmental agency approval and a food agency approval for GE animals. FDA's review of GE animals is also inadequate to comprehensively address issues of food and environmental safety because the agency's primary objective and scope is only to assess whether an applicant has a legitimate "claim" for safe and effective use. Hence the scope of FDA's authority as applied to GE animals is unclear; indirect and cumulative impacts on the environment from the animal (as opposed to the impacts on the animal from the construct) might escape regulatory review. Another fundamental problem is the lack of transparency in these "drug" approvals: the public does not know what proposals are pending, and there are no mechanisms for public participation. Moreover, FDA recently changed its guidance so that it no longer requires a public comment session prior to the approval of a GE animal or insect.

FDA should not be the primary agency regulating GE animals and insects, given its lack of expertise in critical areas, such as broader impacts on the environment.

U.S. Department of Agriculture (USDA)

USDA oversight is also exceedingly weak. While USDA does formally "deregulate," or approve, some GE crops before commercialization (unlike FDA), GE crop developers increasingly evade USDA regulation entirely by genetically engineering plants without inserting transgenes from a listed "plant pest" such as *Agrobacterium*.[51] USDA has declared these GE crops beyond its regulatory authority, and thus they receive no federal oversight.[52]

For those GE crops USDA does regulate, it has adopted an extremely narrow interpretation of its authority. Based on this self-cabined view, the agency has simultaneously acknowledged the significant harms of GE crops—in the form of transgenic contamination and increased pesticide use—but refused to regulate them to ameliorate those harms. *Ctr. for Food Safety*, 718 F.3d at 841 (recognizing the impacts of transgenic contamination and increased herbicide use from the USDA approval of Roundup Ready alfalfa, but affirming USDA's refusal to regulate the crop based on those harms because they were not "plant pest" harms).

Remarkably, in approving dozens of transgenic crops planted on millions of acres, USDA never analyzed their impacts under the National Environmental Policy Act's requirements for an Environmental Impact Statement until required to do so by court orders. *Geertson Seed Farms,* 2007 WL 518624; *Center for Food Safety*, 2009 WL 3047227. Courts have repeatedly found USDA management of GE crops inadequate and unlawful. *See, e.g., Center for Food Safety*, 451 F. Supp. 2d 1165, 1182-85 (D. Haw. 2006) (USDA's approval of GE crop experimental field tests violated environmental laws, describing USDA's arguments as "utterly without merit," its actions as evincing "utter disregard," and constituting an "unequivocal violation of a clear congressional mandate," and "abdication" of its responsibilities); *ICTA*, 473 F. Supp.2d at 29 (vacating USDA approval of another GE crop experimental field trial, finding the record "devoid of any evidence" that USDA had analyzed environmental risks); *Geertson Seed Farms*, 2007 WL 518624, at *7 & 10 (N.D. Cal. Feb. 17, 2007) (finding USDA's attitude toward risk assessment in a GE crop approval as "cavalier," and concluding that USDA "simply ignore[d]" the risks in question or "refused" to analyze them); *Ctr. for Food Safety v. Vilsack*, 734 F. Supp. 2d 948, 953 (N.D. Cal. 2010) (vacating another GE crop approval as unlawful, finding USDA's position showed an "apparent perception that conducting the requisite comprehensive review is a mere formality, caus[ing] some concern that Defendants are not taking this process seriously").

With respect to GE animals and insects, despite having agreed with a 2011 USDA inspector general's recommendation[53] that USDA's Animal and Plant Health Inspection Service (APHIS) develop new regulations for GE animals and insects, APHIS has not developed new regulations. This is disturbing given that according to the inspector general's report, up to 2009, USDA had already funded 62 projects to develop GE animals and insects. Despite not having developed the regulations for oversight of GE insects, APHIS has approved field trials of two GE insects, a GE bollworm and a GE diamond back moth. The APHIS rules need to be more precautionary; we should not have to prod a sponsor of the research to place more stringent

controls than APHIS. Further, both USDA and FDA's Center for Veterinary Medicine regulate GE insects, currently in an ad-hoc, uncoordinated manner.

Environmental Protection Agency (EPA)

EPA oversight also has proved exceedingly weak. EPA reviews only a small subset of GE crops that produce their own pesticides, provides no oversight of pesticide-resistant superweeds, and fails to analyze GE crop-specific changes to pesticide use. Further problems with EPA oversight are discussed *infra* in the specific recommendation section.

## FUNDAMENTAL PROBLEMS WITH THE COORDINATED FRAMEWORK

Many, if not all, of the current problems with U.S. oversight are connected to fundamental problems in the original Framework. This is not an accident. The Framework was developed by a task force of the White House Office of Science and Technology Policy (OSTP) in 1986, spurred by concerns of protecting and furthering U.S. economic interests in the developing field of biotechnology. Yet at the same time that revolutionary change in patenting law was making this technology profitable, public interest organizations were raising significant concerns about human health and environmental safety. In fact, it was at this time that the first approval of experimental field testing (of a GE bacterium) was successfully challenged in court after the approving agency failed to analyze the potentially significant environmental impacts.[54] Demands by this growing industry, seeking future commercialization and market stability, coupled with the growing uproar over its potential risks, culminated in the development of the Framework.[55] In setting the policy, the government's dual aims were to assuage consumers' concerns that emerging novel products would undergo government review, while simultaneously protecting U.S. economic markets from international competition and speeding commercialization.[56] Notably, the biotech industry's influence and interests weighed heavily in the formulation of the Framework policy.[57] Indeed, in describing the Framework's creation and implementation, the official who oversaw biotech policy at FDA from 1979–1994 was quoted by the New York Times in 2001: "In this area, the U.S. government agencies have done exactly what big agribusiness has asked them to do and told them to do." [58]

A significant body of academic literature has analyzed the Framework's failings.[59] In summary, numerous scholars have pointed out that the Framework's patchwork of shared responsibility leaves many holes in the oversight of GE organisms, resulting in "piecemeal and all together ineffective regulation,"[60] and "sizable gaps in coverage, with the concomitant risk of significant harms slipping through the cracks and into the environment."[61] Scholars have further noted that, under the Framework, "environmental risks posed by genetically engineered organisms are not addressed in a coherent manner," in part because there is no single law that governs the products of biotechnology.[62] In lieu of new legislation, the laws agencies use were written "before scientists even knew that rDNA modifications were possible" and, as a consequence, agencies have difficulty "keeping pace with new technological developments."[63] In applying existing authorities under the Framework, scholars charge that U.S. agencies have made a mere "pastiche" of the laws, and as a result "diluted these statutory powers" as applied to GE crops.[64] These failings are due in part to the Framework's focus on the "products" rather than the "process" of genetic engineering.[65]

As a result of the Framework's flawed paradigm, there have been "multiple failures on the part of regulatory agencies to recognize that genetically modified products sometimes do create

new and different issues than those raised by the conventional products they routinely regulate."[66] And federal agencies have not "adequately address[ed] the unique degree of exposure potential and the unique evolutionary impacts [genetically modified organisms] may have."[67] Instead, the "limited nature of regulatory review" fails to result in a fulsome analysis of the risks of GE organisms.[68] In those ways, the U.S. system stands in stark contrast to the more precautionary approach that the majority of the rest of the world takes.[69]

These fundamental problems are summarized below.

**Failure to Enact New Law(s) Addressing GE Organisms**

The failure of the U.S., unlike most of the rest of the world, to enact new legislation to specially address GE organisms instead resulted in the application of laws that were written for different purposes, before GE technology was possible, creating oversight mismatches. That failing resulted in gaps, incoherence, agencies lacking relevant expertise, and the failure to keep pace with new technological developments, such as new methods of and products of genetic engineering.

**Failure to Address the Different and Novel Risks Posed by GE Organisms**

Under the Framework, agencies were charged with using existing authorities to regulate GE organisms. The policy rested on the assumption that existing statutory authority was in fact and in law broad enough to address GE products' risks and impacts. While new authorities specifically geared to the regulation of GE organisms would have been most desirable, agencies' existing robust authority, if applied prospectively, could have been sufficient. Yet the agencies instead have compounded problems by failing to utilize the existing statutory authorities they have, cabining them as applied to GE products, refusing to prospectively apply them, refusing to account for GE organisms' differences and novel risks, and leaving those risks unassessed.

For example, and as discussed further *infra*, the broad "noxious weed" harm authority of the Plant Protection Act would allow many types of known environmental harms of GE crops to be regulated by USDA. Also, FDA could regulate GE foods under the food additive provisions of the FFDCA, which would mandate more extensive tests and generate a safety approval by the agency, rather than the current abbreviated testing by industry and cursory agency review. FDA similarly has authority to require labeling of GE foods under the FFDCA. Instead the self-cabined approach of regulatory review has hobbled the U.S. government's ability to address the novel impacts of GE organisms.

**Failure to Use the Process of Genetic Engineering as the Trigger for Regulation**

The Framework was based on the misguided "substantial equivalence" assumption—the assumption that GE products are the equivalent of natural organisms. As a consequence, agencies do not use the process of genetic engineering as the trigger for regulatory oversight, as explicitly recommended by the National Academy of Sciences. This has two serious consequences. First, an increasing number of GE organisms (e.g., GE plants developed without listed plant pests) go completely unregulated. Second, even when GE organisms are regulated, the serious problems they cause (e.g., transgenic contamination, resistant pests) often go

unaddressed, since there is a proxy trigger for regulation. A new Coordinated Framework must ensure that all organisms developed by genetic engineering be regulated, and that each agency promulgate binding regulations that explicitly address the known and potential risks of GE organisms.

**Failure to Embody the Precautionary Principle**

After two plus decades of research and commercialization, there are many established adverse impacts from GE organisms. But there is still much more that we do not know about their risks, since assessment and oversight is limited. But, unlike much of the rest of the world, the U.S. has eschewed the precautionary principle as way of making decisions in the face of scientific uncertainty about genetic engineering. Instead it has favored rapid, reckless commercialization. Reasonable precaution, based on established scientific theory or high quality research showing strong evidence of harm—but short of the near certainty that science often fails to deliver—is a scientifically and socially justifiable principle. The public should not have to accept substantial harm while waiting for final pieces of risk assessment research. Reasonable precaution favors public safety, while risk assessment without precaution favors premature advancement of industry products. The use of precaution is especially justified in agriculture because more sustainable farming systems that are less reliant on pesticides and GE crops have been shown to have multiple benefits, including high productivity and profitability, and less environmental harm compared to the current industrial agriculture that GE crops are designed to support. The U.S. takes a precautionary approach in many other oversight areas.

**Failure to Implement Statutory Authority Through Binding Regulations**

The Framework is often thought to be a legal framework, but it is merely a "statement of policy" or guidance document that tasks individual agencies with promulgating their own policies to address the products of biotechnology. It provides the agencies with a voluntary—not mandatory—standard for regulation, and it is up to the agencies to implement it. It has no "hard law" requirement for rigorous and adequate regulation. While the guidance is itself weak in principle, it also fails to require any binding commitment on the part of the agencies or the GE industry. And worse, while the Framework is intended to combine existing statutory authorities into a network of comprehensive regulation, the agencies have thus far used other agencies as excuses to avoid having to regulate. For example, pursuant to the framework, FDA has at least twice enacted its own "statements of policy" or guidances with regard to its duties, rather than binding regulations: first in 1992, with regards to its oversight of GE food and food safety, and then again in 2009, with regards to its oversight of GE animals.

**Failure to Provide Transparency**

Under the Framework, GE foods are not labeled, as they are in 64 countries around the world, leaving U.S. consumers in the dark. Without labeling there is no traceability or accountability for adverse effects on health. Neither does FDA publicly disclose the data provided to it by GE crop developers for its "voluntary consultation" process. USDA does not disclose locations of GE crop field trials to enable neighboring farmers to guard against transgenic contamination, nor does it monitor such GE crops to assess whether contamination

has occurred, leaving the extent of contamination unknown. Independent academic study of GE crops and risks they may pose is impeded by biotech patents and contract control of GE seeds.

**Failure to Regulate the Significant Adverse Impacts of GE Organisms**

Over the life of the Framework, regulators have intentionally turned a blind eye to the significant adverse harms that we know GE crops cause, like transgenic contamination, the generation of resistant weeds, and massive increases in pesticide use. Agencies charged with preventing transgenic contamination have repeatedly failed to require adequate gene containment measures, leading to numerous GE contamination episodes that have cost U.S. farmers and the food industry billions in rejected export shipments, reduced prices, food recalls, and testing costs. At the experimental stage, agencies have allowed GE crop developers to essentially regulate themselves, or follow confinement recommendations not designed to reliably prevent contamination. At the commercial stage, the burden to prevent or respond to contamination has been entirely on the harmed community: traditional farmers. This defies basic principles of fairness, as well as venerable tenants of property law, and disadvantages one farming sector in favor of another. The companies that own the patented GE seed should be held legally responsible for addressing this problem through prevention and compensation of those harmed. Traditional farmers should not have to shoulder the burden of lost income due to GE contamination. There is also no monitoring of GE crops by the federal government after commercialization, despite agency post-market monitoring and adaptive response being a major recommendation of the 2002 National Research Council report on the regulation of GE crops.

Further, though HR GE crops make up the vast majority of all commercialized GE crops in the U.S., and their use has led to dramatic increases in pesticide use, EPA does not evaluate or regulate the environmental risks of these crop systems under the pesticide laws. As a result, introduction of GE crops has fostered an epidemic of HR weeds and increasing herbicide use, which harms both farmers and the environment.

## SOLUTIONS: A FRAMEWORK FOR RESPONSIBLE OVERSIGHT OF GE ORGANISMS

The U.S. government must fix the failings of the biotechnology Framework, not double down on them. To do this, it must begin by rejecting the misguided decisions upon which the 1986 Framework is based, and instead adopt and implement oversight principles that address GE organisms in a responsible manner, in line with that of the regulatory frameworks in other developed countries.

Now is the moment to correct the core errors described above and instead adopt governance principles that, when implemented through binding law, could begin to remedy previous errors. Accordingly, we call on the Administration to adopt a new *Framework for the Responsible Oversight of Genetically Engineered Organisms*, based on the following principles:

**A Precautionary Foundation**

A precautionary approach requires GE-specific oversight mechanisms that account for the unique characteristics of the GE organisms. Within those mechanisms, the protection of public health, farmers, and the environment should be the primary focus. The programs should encourage ongoing risk research and immediate action to mitigate impacts of potential risks.

**Mandatory, GE-specific Regulation**

Ideally, new legislation should be enacted that is GE-specific. Absent that, agencies should use the robust existing statutory authority they have to protect the food system, agriculture, and the environment. Regulation should be framed and implemented with the understanding that GE organisms present a greater potential for harms known in other contexts (e.g., HR weeds), but may also pose unfamiliar risks requiring different regulatory analysis, data, and mechanisms. Voluntary mechanisms, such as "statements of policy" or guidance, should not be relied upon. Rather, mandatory regulations at all agencies should be promulgated that fully address known risks and require more thorough testing to better detect and assess unfamiliar ones. Agencies should develop mandatory regulation for organisms developed using genetic engineering processes that independently evaluate engineered foods and organisms for risks, including food safety risks and direct and indirect environmental harm. Until proven safe, GE crops and animals should not be released into the environment or commercialized.

**Health, Safety, and Environmental Protection Must Come First**

Regulation should prioritize health, safety and environmental protection over commercialization and development interests. This includes both regulation as well as risk research and funding.

**Transparency**

Assessment and oversight requires mechanisms ensuring transparency throughout the food system and regulatory process, including labeling of GE products; developing public databases of health and safety information; requiring that the developers publically release all health, safety and environmental risk research; and allowing independent research to be undertaken. Developers must not be allowed to claim that health, safety, and environmental risk information be kept confidential. This includes both regulation as well as risk research and funding.

**Manufacturer Liability and Fundamental Fairness**

Biotech companies that make and sell GE organisms should be held liable for the significant losses their products impose on organic and traditional farmers. Traditional farmers' rights and seed, fish, and livestock choice should be protected and contamination of non-GE crops or animals prevented. The burden of contamination prevention should be shouldered by those companies profiting from the sales of GE organisms, not by those harmed by contamination.

**Public Participation and Inclusion of Broader Socioeconomic Concerns**

Consideration of GE's significant effects, including social impacts, should occur at each stage of the regulatory process. Public participation in the regulatory process must be meaningful, timely, and full. When evaluating any alleged future benefits of GE crops, standards of comparison must meaningfully include the kinds of successful sustainable agricultural systems that are emerging and necessary for the future viability of our food production and rural communities, such as organic and agroecological-based farming. Unsustainable and harmful industrial agriculture must not be the accepted standard of comparison against which GE crops, or the pesticides used on them, are judged to be needed and useful.

## SPECIFIC RECOMMENDATIONS FOR RESPONSIBLE OVERSIGHT OF GE ORGANISMS

Absent new statutory authority, as explained above, USDA, FDA, and EPA, can still utilize their existing authorities under the Plant Protection Act (PPA); Federal Food, Drug, and Cosmetic Act (FFDCA); Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), respectively, to effectively regulate the products of biotechnology. Below are some examples of ways that agencies can significantly improve oversight, and begin to apply responsible principles of oversight.

**U.S. Department of Agriculture (USDA)**

In order to responsibly regulate GE organisms, USDA does not necessarily need new statutory authority; it only needs the political willpower to regulate responsibly under the authority it already has. A law already exists that could much better address many of the above issues, should it only be fully, prospectively applied by USDA to GE crops. It provides USDA broad authority to protect the environment, agriculture, and health from direct and indirect harms. That law is the Plant Protection Act (PPA) of 2000.[70]

USDA has primary authority over all transgenic plants.[71] Until the passage of the PPA in 2000, USDA derived its authority over transgenic plants[72] from the former Federal Plant Pest Act (FPPA) of 1957[73] and former Federal Plant Quarantine Act (PQA) of 1912.[74] These laws were passed to prevent the introduction of damaging pests and plant disease agents from abroad, and to mitigate the adverse effects of such pests and pathogens. USDA's regulations on transgenic plants, 7 C.F.R. Part 340,[75] were promulgated in 1987 pursuant to those authorities and amended in 1993.[76] When the PPA was enacted in 2000, APHIS simply continued to use its existing regulations and has never updated them to reflect its newer authority, the PPA.[77]

Apply the PPA to GE Crops

On June 20, 2000, Congress repealed the former Plant Quarantine Act, the Federal Plant Pest Act, and the Federal Noxious Weed Act and replaced them with the PPA, 7 U.S.C. § 7701–7772, as part of the Agricultural Risk Protection Act. In passing the PPA, Congress consolidated and broadened the scope of these previous statutes and enhanced USDA's authority to regulate

plants and related plant items in order to prevent the introduction or dissemination of both "plant pest" harms and "noxious weed" harms.

The PPA defines these types of harms extremely broadly. A "noxious weed" harm is defined as "any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment."[78] "Plant pest" means: "any living stage [of a list of organisms] that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product."[79] Hence individually and combined, these broad definitions of types of harms over which USDA has authority under the PPA cover both direct and indirect harm to plants, the environment, plant products, the environment, public health, and the interests of agriculture.

The PPA also provided USDA multiple new, powerful tools with which it can carry out its mandate. For instance, the agency may

- hold, seize, quarantine, or apply other remedial measures to destroy or dispose of any plant, plant pest, noxious weed, plant product, article, or means of conveyance if necessary to prevent spread of new plant pests or noxious weeds[80];
- issue subpoenas[81] and conduct warrantless inspections[82];
- provide cost recovery measures[83];
- establish quality assurance programs[84];
- develop a classification of status and action levels for risks[85]; and
- develop integrated management plans.[86]

The PPA also substantially increased USDA's enforcement authority[87] by increasing the amount of penalties that USDA could impose.[88]

This is the statutory authority that USDA must apply to GE crops, current and future, in GE-crop-specific regulations. Current impacts like transgenic contamination of traditional and organic crops, the epidemic of HR weeds, and massive pesticide increases from GE crop systems could plainly be addressed, pursuant to the PPA and new GE crop specific regulations, based on USDA's broad PPA authority over "noxious weed" harms and "plant pest" harms. So could future types of harms, from newer forms of genetic engineering, if regulations were appropriately broadly drawn to cover all types of genetic engineering as the baseline.

It is important to clarify that GE crops do not need to present the same types of harms as traditional plant pests or traditional noxious weeds in order for USDA to responsibly regulate them under the PPA. They are not the same thing. As discussed above, GE crops create novel risks and impacts that demand GE-specific types of regulation. Indeed, from the very start, regulation of GE organisms has been based upon creative application of pre-existing statutes that were never intended for them. GE plants are not microscopic plant pests; GE insect-resistant plants are not spray-on pesticides; transgenic animals are not veterinary animal drugs; and GE microorganisms are not toxic chemicals. GE organisms could never have been regulated in the first place without considerable regulatory adaptation of existing laws by USDA, EPA, and FDA. What matters here is that the PPA draws the bounds of the harms over which USDA has

authority quite broadly, and definitions that clearly can encompass regulation of GE crops based on their existing environmental and agronomic harms. Under the PPA, USDA has broad authority to address the full range of adverse agricultural, public health, and environmental impacts associated with GE crops,[89] in order to fulfill the PPA's purpose to "protect[] the agriculture, environment, and economy of the United States."[90]

Enact New Robust GE Crop Regulations Fully Implementing the PPA

Yet, USDA has, thus far, completely failed to implement its additional authority under the PPA to address twenty-first century challenges. Instead USDA has continued to regulate under its outdated Part 340 regulations, promulgated in 1986 pursuant to older, narrower authority, despite the fact that Congress passed the PPA fifteen years ago. Since 2004, USDA has recognized this failing, and has proposed, in stops and starts, new updated regulations implementing the PPA. In 2008 it proposed regulations, only to withdraw them and begin all over again earlier this year.[91]

This must end, with the promulgation of new GE crop regulations with all due haste. The new regulations must integrate both the PPA's noxious weed harm authority and its plant pest harm authority in a holistic manner as to GE crops. The combination of the authorities, as explained above, provide USDA the best means of reviewing and regulating GE crops for their current and future adverse impacts.

Unlike the current biotechnology rules that limit USDA to a plant pest harm analysis, applying and integrating its noxious weed harm authority into new GE crop regulations and analyses will allow USDA to conduct a more comprehensive analysis, and apply the proper statutory scope of its authority. In so doing, USDA will be able to better address a broader range of impacts from GE crop production systems, such as transgenic contamination and the development of HR weeds and other kinds of indirect harm, some of which were not anticipated when GE crop regulations were first formulated under the more limited scope of the Plant Pest Act. So doing would also clarify any perceived authority limitations under USDA's plant pest harm authority being applied alone. USDA also can and should assess the safety of GE crops for human and animal consumption. Addressing and preventing these harms should be explicit protection goals in regulations.

Regulate All GE Crops

One major problem with the current regulations is USDA's narrow interpretation of its plant pest authority alone, which it alleges limits its authority over GE crops. While this overly narrow interpretation is erroneous, it has allowed the agency to refuse to address the impacts of existing GE crops, like transgenic contamination. It has also allowed the agency to permit some GE crops to circumvent any USDA review at all, if those GE crops, while still genetically engineered, are not engineered with specific listed plant pest transgenic constructs. However, genetic engineering can be accomplished without use of listed plant pest organisms, an alarming gap in USDA's jurisdiction that is currently allowing transgenic plants to circumvent any review at all. The integration of the full PPA beyond merely the plant pest authority provides USDA the opportunity—and duty—to go beyond the taxonomic trigger, and include all engineered crops

with potential harms pursuant to USDA's broader noxious weed authority. The sound science-based alternative that would close this gap, recommended by the National Academy of Sciences, is for USDA to replace the current taxonomic trigger and instead use the genetic engineering process itself as USDA's "trigger" for initial regulation.[92]

USDA must instead regulate *all* GE crops, and the agency should so clarify in its new regulations. The cultivation of GE crops has demonstrably led to serious harms, such as effects stemming from increased herbicide use and HR weeds that could have been prevented or ameliorated with proper regulation and management. There is no sound scientific distinction between including some forms of GE crops under USDA authority on the one hand, and, on the other hand, excluding other GE crops that may raise the same agronomic and environmental impacts, simply because of the form of genetic engineering used. Further, genetic engineering—including, for example, new genomic editing techniques—has higher rates of unintended and potentially harmful effects than traditional breeding.[93] Newer genome editing processes use *in vitro* recombinant nucleic acid technologies, and should therefore be included under the USDA regulatory umbrella.

Hence, it makes sound scientific sense for USDA in new regulations to begin from the regulatory platform that all products of modern biotechnology are regulated, using genetic engineering as the trigger for regulatory review. The National Research Council of the National Academy of Sciences explicitly advocated this process-based trigger.[94] This would give regulatory authority to USDA over all GE organisms and would provide clarity, consistency, and transparency to the regulatory process. Importantly, it would also close the current gap that allows GE organisms to be field tested and/or commercialized without any oversight at all, if they are not engineered with particular plant pest nucleic acids or vectors.[95]

Address and Ameliorate Their Adverse Impacts

Starting from the regulatory perspective that all GE crops are regulated, USDA should then of course have the ability to address specific differences (e.g., herbicide resistant) between different types of GE crops, and regulate them accordingly. However, USDA alone should have authority to determine whether and how its regulations apply to a particular GE organism. USDA should in no way give field trial permit applicants the authority to decide whether a GE organism is subject to regulation. Giving industry such discretion would create uncertainty, rely on the industry interpretation of risk, and undermine the integrity of federal oversight.

USDA should include known adverse impacts of GE crop production systems—such as increased herbicide use, rapid evolution of HR weeds, and transgenic contamination—in its risk assessments. USDA should also revise regulations broadly enough to be adaptive, so as to be able to detect and assess currently unanticipated GE crop threats, in addition to making genetic engineering, broadly defined, the trigger for regulation. Any additional risk characterization should be in addition to and after the default trigger requiring analysis and approval of all GE organisms prior to any attempted use or commercialization.

As explained above, the broad statutory definition of a noxious weed harm can encompass direct and indirect injury to crops and other interests of agriculture, public health, or

the environment from any plant. USDA should clarify that, based on the plain language of its statutory definition, this PPA authority can be used to regulate harms from GE crop production systems such as transgenic contamination, HR weeds, loss of biodiversity or ecosystem services, impacts to public health, and harm to the livelihoods of GE, non-GE, and organic farmers. For both noxious weed and plant pest harms, USDA should rely on the plain language of the statute to discern the scope of its authority, and not unscientifically constrain itself by comparing the harms of GE crop production systems to solely those of traditional noxious weeds or plant pests. GE crops can logically cause different harms than traditional agricultural pests. Rather, USDA should acknowledge and address the significant harms that GE crop production systems cause, using the authority it has, in order to protect agriculture and the environment, as the PPA mandates.

Establish a Commercial Permit System and Lifecycle Regulation

In place of the current deregulation process, USDA should implement a two-tiered permitting process: one tier for experimental permits for field trials and a second tier for commercial permits, allowing some GE crops to be sold in commerce with restrictions as needed. This would simplify the system and clarify that USDA always has continuing jurisdiction over all GE crops grown in the United States. Under commercial permits, USDA should retain jurisdiction to monitor, collect data to confirm risk assessments and detect unanticipated harms, and impose protective measures when necessary to manage GE crop production systems and emerging risks. As discussed *supra* the PPA provided USDA broad post commercialization remedial enforcement authority, [96] to hold, seize, quarantine, or apply other measures to destroy or dispose,[97] issue subpoenas[98] and conduct inspections;[99] and issue monetary penalties.[100]

USDA should oversee and regulate all GE crop production systems throughout the crop life cycle, rather than unconditionally removing GE crops and their progeny from oversight. For instance, USDA should monitor HR crop systems for gene flow, seed contamination, HR weed populations, or loss of ecosystem services, and impose appropriate control measures if monitoring reveals a problem. Monitoring should include measurement of changes in pesticide use and toxicity that are associated with harm to ecosystems beyond the local farm scale, such as degradation of water quality, air pollution, climate impacts, or loss of biological resources. This would provide a basis for ascertaining the health and environmental effects of increasing GE crop production across the U.S. USDA should also actively monitor, assess, mitigate, and prevent harmful impacts of GE crop production systems on farmers' livelihoods, the health of rural communities, and the environment, including non-target organisms.

Finally, USDA should adopt regulatory provisions requiring GE crop manufacturers to gather post-commercialization data and submit such data on an ongoing basis to USDA, and requiring USDA to independently conduct post-commercialization monitoring to verify such data and to address the most critical ongoing environmental concerns. Further, USDA should establish a set of regulatory restrictions in order to prevent transgenic contamination by all farmers who use GE technologies, and require GE farmers to institute specific, concrete contamination prevention measures on their farms.[101] USDA should also create a transgenic contamination registry so that it can track and eliminate known sources of transgenic

contamination across the supply chain. This will ensure that non-contaminated foundation seeds not only remain a source of our national heritage but also can also be used for public plant breeding in perpetuity.

Enact a Moratorium on Approval, Planting, and Deregulation of Any New GE Crops Until USDA Updates Its Biotechnology Regulations

USDA's biotechnology program should establish a fundamental management goal of preventing transgenic contamination from GE crops to conventional and organically grown crops and wild plants. Despite the agency's statutory mandate to further and protect the interests of all farmers, not just the biotechnology industry, USDA is sorely failing in this regard. Although transgenic contamination is well-established to cause agronomic, environmental, and economic harms to traditional farmers, as well as negate their fundamental right to grow the crop of their choice, USDA has failed to require any transgenic contamination prevention measures on the part of growers of commercial GE crops. Those few measures in place for regulated GE crops have evidently failed to prevent field trial contaminations on numerous occasions. Instead, the burden of protecting traditional crops falls entirely on growers of conventional and organic crops. Establishing strict GE contamination prevention measures, such as mandated isolation distances and GE-free geographic zones, is essential to preserving the future success of all types of U.S. agriculture.

Accordingly, USDA should institute a moratorium on the approval, planting, and deregulation of all GE crops until the agency establishes regulatory means by which transgenic contamination can be responsibly addressed. For crops already in unrestricted commercial production, USDA must determine and mandate best management practices to mitigate transgenic contamination and the associated harms to farmers, consumers, and the environment.

**Food and Drug Administration (FDA)**

FDA and GE Foods

FDA is responsible for food safety under the FFDCA.[102] The FFDCA grants FDA the authority and imposes a statutory duty to regulate food labeling, food additives, and adulterated foods. Regarding "adulterated" foods, the FFDCA mandates that FDA protect the food system from foods that contain any "poisonous or deleterious substance which may render it injurious to health."[103] Food additives (substances used in food or components of food or that might affect the characteristics of food) require premarket approval and labeling.[104]

As explained above, FDA has no specific regulations for applying its FFDCA authority to transgenic foods. By definition, transgenic ingredients would be defined as food additives, and would have to undergo extensive premarket safety testing, including long-term animal studies.[105] However, in 1992 FDA issued a policy statement on transgenic foods,[106] determining that they would be presumed to be "generally recognized as safe" (GRAS), an exemption from the food additive requirements. Based on the GRAS presumption, FDA determined that no labeling was required.

So while the FFDCA provides FDA with several means of regulating the safety of GE foods, FDA decided to use the least protective provision of the FFDCA. Unlike the Act's food additive sections, the GRAS section provides for only voluntary safety assessment and no safety approval by the agency. Instead, the GRAS sections of FFDCA recognize the responsibility of the owner of the food to determine food safety. FDA's rationale for doing this was a determination that GE foods were not meaningfully different than foods that are not engineered. Since those traditionally-produced substances were GRAS, FDA would consider the GE versions to be GRAS, unless data determined otherwise. FDA made this decision not through binding regulations, but through a policy guidance document, despite its force-of-law impacts.

One problematic limitation of the GRAS provisions of the Act is the voluntary nature of submission of data on the food for review by FDA. This leaves the determination of whether to even submit to FDA review up to food producers whose self-interest is to market their products. But the GRAS provisions also leaves it to the same self-interested parties to determine the types of tests used to determine the safety of the GE food. This is because the GRAS provisions do not mandate particular tests or testing methods, as have traditionally been done in the so-called "red book" for food additives, which contains nearly 300 pages of testing guidance.[107] Similarly, there is also testing guidance for determining the safety of food genetically engineered to protect plants from pests, which are approved for safety by EPA. The instructions provided to GE food developers in the 1992 FDA guidance provide only very broad advice for determining the safety of GE foods, such as whether those foods might be allergenic or toxic. But the 1992 policy does not provide any specific details on which safety tests should be used, or how they should be conducted, choices that have a big impact on the likelihood that possible harm will be detected.

Another important limitation of the current evaluation of GE food safety by FDA is that the safety data reviewed by the agency is not the actual test data, but rather a summary of that data produced by the submitter.[108] This allows the self-interested food developer or marketer to apply its own interpretation of the meaning of the data, which may not correspond to the interpretation of an independent scientist or regulator, and may obscure the observation of troubling data from the FDA reviewer. Independent analysis of data summaries submitted to FDA, obtained through Freedom of Information Act (FOIA) requests, showed errors made by the agency or submitter in its evaluation or interpretation of the data, inconsistencies in tests performed between similar GE foods and in the analysis of those tests, lack of basic statistical analysis of data in several cases, and several instances where submitters refused to comply with FDA requests for additional data in order to complete its review.[109]

That analysis and others also show that only a handful of tests are typically performed by the companies submitting data, such as limited analysis of possible changes in the composition of the food compared to non-engineered counterparts, non-standardized allergenicity tests relying heavily on indirect tests of simulated digestive stability that do not have an established history of success, sequence matching with known allergens that cannot reliably predict the allergenicity of engineered proteins new to the food supply, limited and inconsistent testing for toxic compounds produced by the engineered plant, limited tests for changes in the GE plant compared to genetically similar (isogenic) counterparts, improper use of non-isogenic standards to determine substantial equivalence, no long-term animal toxicity tests, and other limitations.[110]

Despite this, FDA has robust authority to require any specific GE food to undergo the food additive process. But because FDA has chosen the GRAS process for GE foods, in most cases the agency would require some indication that food may be unsafe before it would require application of the food additive process. That could come from the testing done during the GRAS process. However, because the GRAS testing process is so limited, it may be unlikely to detect even preliminary indications of harm that would prompt FDA to apply the food additive process to a GE food.

That some GE foods could be harmful to eat is not generally in dispute. The possibility of producing harmful GE foods was demonstrated in the 1990s when soybeans engineered for improved protein content by inserting a gene coding for a protein from Brazil nuts later was shown to be the major allergen from this nut.[111] Although the resultant allergenicity of the transgenic soybeans was detected using immunoassays based on serum from people allergic to Brazil nuts, it is important to note that those tests are not available for proteins new to the food supply, as may occur through GE. Matching of the protein sequence of known allergens with new GE proteins is also not reliable for transgenic proteins new to the food supply. The digestive stability test that is available is newer and less proven, not entirely predictive, and sometimes difficult to interpret.

Other sources also recognized that unintended and largely unpredictable changes resulting from the added gene(s), the influence of the engineered gene on the genes of the plant, or disruption of the chromosomal insertion site, could sometimes lead to harmful changes in the food. The 2000 National Research Council (NRC) report on the regulation of pest-protected GE crops recognized that food from some of these crops could be very harmful.[112] That report also noted that tests for allergencity needed to be improved, but there has been no change in the tests used to detect GE allergens since that time. While that report addressed pest-protected GE in particular, the risk principles that apply to those crops also apply to engineered crops, generally. A 2004 NRC report noted that most common types of genetic engineering were more likely to produce unintended changes in GE crops than most common types of breeding.[113] This report noted that our understanding and identification of the thousands of compounds that food crops produce, some of which are toxic but not usually found in the food portion of the plant in significant amounts, is far from complete. The report recommended that better methods need to be developed to identify and test for these compounds, to determine whether they are produced in the food portion of engineered crops. The reviews cited previously show that only a few possible toxic compounds have been assessed under GRAS reviews, and even those inconsistently.[114]

Several peer-reviewed studies have identified possible harm from foods developed using GE, while some others have not. Reviews of the published literature on tests of GE foods have come to differing conclusions about the safety or possible harm of GE foods, demonstrating that the general level of safety or risk of GE foods remains unresolved.[115]

No long term testing is performed for GE food safety. Short-term tests cannot reliably detect chronic harm or harm that requires longer periods to develop.[116] A widely cited[117] review of 24 long-term and multi-generational tests of GE foods incorrectly concluded that sub-chronic (90 day) tests in rats were sufficient to determine long-term risks.[118] This study has been widely

relied upon to argue that GE crops have been shown to be safe in long-term tests and that such tests are not needed. Instead, there are several serious shortcomings in the review that refute both claims about the adequacy of sub-chronic studies for predicting long-term harm and the general safety of GE foods. First, of the 24 research studies reviewed, 21 were for crops engineered with either herbicide resistance (mostly glyphosate) or Bt genes. While very important, these genes represent only a tiny fraction of possible and likely engineered genes in the future, and are therefore of little predictive value concerning GE generally.

Second, of the 24 studies, only 6 followed Organisation for Economic Cooperation and Development (OECD) guidelines for the required number of test animals, which is critically important to provide reasonable levels of statistical power to detect harm. Of those six, only two used the widely accepted standard of comparison of isogenic crop varieties (genetically nearly identical except for the engineered gene). This is needed to determine whether any observed possible harm was really associated with the engineered gene. These two remaining studies involved animal species not typically used to determine human health risks (cows and fish), and in the case of the salmon study, higher levels of triglycerides (a circulatory risk factor) were found in the blood of the GE fish. Other studies cited by Snell et al. did find changes in the test animals fed GE foods that may suggest harm, but these were dismissed by the authors as flawed.

Finally, the Snell et al. review is not an adequate measure of the ability of 90 day (sub-chronic) tests to determine long-term harm, contrary to the authors' assertion. To determine this, 90-day tests would have to actually predict harm detected in long-term studies of the same gene/crop combination. Nothing like this was shown in the studies reviewed. Therefore this was an inadequate test. Instead, as referred to above, previous reviews comparing 90-day and long-term tests have shown that shorter studies often could not predict long-term harm.

In summary, perhaps the most widely cited review that concludes that 90-day safety studies currently used for safety assessment of GE foods in the European Union (but not the U.S.), does not demonstrate either that GE crops are generally safe based on available long-term and multigenerational tests, or that 90-day tests are sufficient to reliably predict long-term harm.

While some scientists have claimed that GE foods are safe, most of the studies mentioned above and many others make no such general claims. In particular, regardless of the safety of the few current widely commercialized GE foods, all major science bodies that have examined this question have determined that the safety of each engineered food is determined by the characteristics and properties of the particular gene and the crop it is added to. The environmental conditions under which a crop is grown are also understood to affect the expression of genes, and may influence the safety of the added gene via its interactions with genes in the plant. This means that each gene/crop combination has its own risk profile, which must be determined separately. This in turn means that even if a particular GE food is determined to be safe, that has no bearing on the safety of foods made with other genes. In other words, no broad generalization about the safety of a GE food can be made, and as a class GE foods cannot be assumed to be GRAS.

Only adequate, independent assessment of each engineered food may determine its safety. The only way to ensure that adequate testing for the safety of GE foods occurs is for

FDA to evaluate them as food additives under the FFDCA. In order to ensure that all GE foods are regulated they must be regulated by process, i.e. because they have been engineered. This recommendation does not rely on an expectation that any particular percentage of engineered foods may be harmful to health, but rather due to the widely accepted recognition that some of them may be. Determination of food safety deserves special consideration, care, and caution because of our intimate and constant exposure to food and potentially harmful substances that it may contain. If fifty engineered genes are eventually added to a common food, and only one of them is harmful, the resulting food would nonetheless be harmful and the harmful engineered gene should be excluded from the food supply. Therefore, regulation of GE foods should not be based on whether some or even most of those foods are or will be safe, but rather that any harmful GE food must be detected and excluded from our food. The current regulation of GE foods in the U.S. falls woefully short of this standard, as shown by CFS's analysis.

Secondly, FDA should develop detailed testing standards appropriate for engineered foods, as for chemical food additives under the red book. Where there are gaps in our current testing methods that may be filled by development of new methods, such as "omics" testing processes, long-term animal testing, improved allergen testing, and more complete knowledge of possible toxic and anti-nutrient substances produced in food crops, FDA should work to improve and develop protocols to make them more reliable and cost-effective. These must include adequate long-term testing methods and protocols.

Finally, testing of the safety of whole foods is a new field, and presents legitimate challenges. While testing of GE foods must be improved, current understanding suggests that there will remain some uncertainty about the safety of GE foods. And in fact, all risk assessments are imperfect and result in uncertainties about their conclusions about risk. One way to provide an additional measure of safety for concerned citizens is to require mandatory labeling of GE foods, so consumers can decide for themselves whether they want to accept any possible risk from GE foods.

FDA and GE Labeling

FDA similarly has sufficient authority under the FFDCA to require labeling of GE foods, yet has failed to use it. In fact, since 1992, the agency has explicitly disavowed responsibility for labeling GE foods under its Statement of Policy. CFS has previously provided FDA with a legal blueprint and impetus for requiring labeling under the FFDCA by issuing a new statement of policy and binding regulations requiring labeling.[119]

Specifically, as CFS's 2011 legal petition explains, FDA should rescind FDA's 1992 Statement of Policy: Foods Derived from New Plant Varieties, and issue a new policy declaring that a production process is "material" under FFDCA section 201(n) if it results in a change to a food at the molecular or genetic level because a significant share of consumers would find it relevant to their purchasing decisions. FDA should then issue new regulations under 21 C.F.R. § 101 requiring the labeling of all foods produced using genetic engineering.

In addition to genetic engineering, other novel and unnatural food production technologies are either on the horizon or are currently in use, many completely unbeknownst to

consumers. The use of these novel food technologies on a commercial scale has so far slipped underneath FDA's current threshold for "materiality" because they make silent, genetic, and molecular changes to food that are not capable of being detected by human senses. As the use of these and future food production technologies proliferates, consumers know less and less about the food they put in their bodies.

The power and duty to modernize the oversight of food lies with FDA. Under the FFDCA, FDA's authority to require labeling based on production processes goes well beyond the agency's antiquated definition of "material" facts. FDA's current policy on what is or is not material for labeling purposes a self-created limitation, outdated, and does not stem from the statute. Among other reasons, the FFDCA authorizes FDA to require labeling for GE foods in order to prevent consumer deception, such as deception of consumers through the omission of information like whether a food is genetically engineered or not.

FDA and GE Animals

Finally, as discussed above, FDA currently regulates transgenic animals as "new animal drugs" under the FFDCA, pursuant to a guidance document. Yet this attempt to shoehorn insects and animals into the definition of animal drugs ignores that transgenic animals are very different from veterinary animal drugs, presenting new difficulties in assessment and oversight. It also prevents FDA from adequately considering environmental risks resulting from the production, transport, and use of GE food animals. FDA's current review is inadequate to comprehensively address issues of food and environmental safety because the agency's primary objective and scope is only to assess whether an applicant has a legitimate claim for safe and effective use. FDA needs to establish binding regulations as a starting point for any adoption of the FFDCA to any aspect of GE animals. Given FDA's lack of expertise in this area, other agencies, including EPA and the expert wildlife agencies, FWS and National Oceanic and Atmospheric Administration's National Marine Fisheries Service (NMFS), should be given primary authority under a new framework, with their own binding regulations in place, in order to allow for proper consideration of and protection against the significant environmental effects of GE animals.

**Environmental Protection Agency (EPA)**

EPA oversees all pesticides marketed and used in the U.S. under FIFRA.[120] Accordingly, EPA's main role in the Framework is to regulate pesticides created through biotechnology.[121] Most such pesticides are generated in the tissues of GE plants, and are referred to as plant pesticides or "plant-incorporated protectants" (PIPs). GE pesticide-producing plants are the second-largest application of agricultural biotechnology. At present, these pesticidal plants are limited to GE varieties of corn and cotton that express various crystalline proteins derived from the soil bacterium *Bacillus thuringiensis (Bt)*, and hence they are often called Bt corn and Bt cotton.

These novel crystalline (Cry) proteins are present in Bt corn grain, and found in food products made from corn. The first Bt corn variety was approved two decades ago, and yet the EPA has still not established adequate safety testing requirements for PIPs or the GE plants that express them.

Pursuant to FIFRA, EPA has the legal authority to require premarket testing before approval and to impose restrictions to ensure safety and prevent unreasonable adverse effects. Every pesticide chemical to be sold in the U.S. must be registered with EPA before it can be distributed or sold.[122] If a substance is found to have "unreasonably adverse effects on the environment," it cannot be registered and brought to market.[123] The agency conducts a cost-benefit analysis, balancing the benefit of allowing a pesticide to be registered and sold in the market with any potentially harmful effects.[124] Accordingly, EPA's FIFRA mandate requires that all pesticides, including PIPs, are not used in a manner that would unreasonably harm health and the environment.[125]

EPA Lacks Adequate Testing and Protocols

To fulfill this mandate, EPA should require long-term animal feeding studies with GE plant pesticidal material (e.g. grain) as the best approach to assess any health impacts they may pose.[126] Such feeding trials would have the potential to capture potential adverse impacts of the plant pesticide itself as well as any adverse food safety effects of the mutagenic genetic engineering process.

EPA's current testing system is entirely inadequate.[127] It is limited primarily to simple tests conducted with a microbial surrogate of the plant pesticide that may well differ from the pesticide produced by the GE plant. Tests that are conducted to purportedly establish the equivalence of the two ("test substance equivalence" tests) to justify use of the surrogate in safety testing are inadequate to the task, failing to meet standards recommended by an EPA Scientific Advisory Panel. The tests conducted with this microbial surrogate pesticide are limited to acute oral toxicity ($LD_{50}$) in rodents, and two simple tests designed to assess potential allergenicity: digestive stability and amino acid homology to known allergens. The $LD_{50}$ tests provide essentially no information on potential long-term health effects from long-term exposure to low levels of plant pesticides in foods. The allergenicity tests are also inadequate for a number of reasons, including the fact that test conditions are not standardized.

EPA should require independent testing of GE pesticidal plants that contain more than one plant pesticide because of the possibility of harmful synergistic interactions, as recommended by the agency's scientific advisers:

> In general, the Panel believed that studies showed that synergism is not easily predicted, and therefore testing for synergistic effects when two or more PIPs are combined is warranted.[128]

Despite the potential for harmful synergism, EPA assumes that a GE plant that contains several or many different plant pesticides is safe based on tests conducted on each one separately. Already, one widely planted GE corn type—SmartStax—contains six Bt insecticidal toxins – three targeting above-ground and three targeting below-ground insect pests. Independent testing is required for GE plants representing each unique combination of plant pesticides.

Insect Pest and Weed Resistance Issues

The GE crops grown today and for the foreseeable future incorporate pest management technologies. Both pesticidal plants (e.g. Bt corn and cotton) and HR crop systems are highly prone to foster rapid evolution of resistance in pests and weeds. Therefore, if these GE crops are to be grown at all, mandatory resistance prevention and management programs are necessary to prevent the substantial human health, environmental, and agronomic costs entailed by resistance. EPA has thus far largely failed to account for these costs of resistance, as required under FIFRA, in its evaluation of either pesticidal GE crops or herbicides for their intended uses on GE HR crops.

*Insect Pest Resistance*[129]

EPA required insect resistance management (IRM) plans for the first GE pesticidal corn and cotton plants with toxins that killed above-ground pests like the European corn borer and bollworm caterpillars. The IRM plans involved GE plants that expressed high enough levels of Bt toxins to kill over 99.99% of target pests (high-dose strategy); and refugia of non-Bt plants comprising 20% to 50% of a field to provide a reservoir of unexposed, susceptible insects to mate with any that evolved resistance from continual exposure to Bt toxins. Together, these measures have been largely successful in forestalling above-ground insect pest resistance to Bt toxins.

In contrast, EPA has failed to prevent resistance from evolving to the second class of GE pesticidal corn plants with toxins that target the corn rootworm. In designing IRM plans for these corn varieties, EPA rejected the recommendations of its scientific advisors on several occasions, and acquiesced to the profit-driven motivations of the pertinent GE corn developers. Refugia requirements were set too low to forestall resistance, and reduced still more. As a result, corn rootworm resistance to Bt toxins is developing rapidly throughout the Midwest, leading to environmental costs in terms of increasing use of toxic chemical insecticides and rising economic costs in expenditures to purchase and apply them.

EPA has recently proposed a plan that combines integrated pest management (IPM) with IRM to forestall further emergence of Bt-resistant corn rootworm (CRW) and manage resistant CRW where they occur. The plan is premised on the fact that nearly all Bt-resistant CRW have been found in fields where corn is grown year after year, and would require that a portion of Bt corn growers in certain regions establish crop rotations (e.g. corn/soybeans) to lessen selection pressure for further evolution of resistant CRW. The principle underlying this proposal is sound; crop rotation offers real potential to forestall CRW resistance to Bt corn. CFS urges EPA to strengthen this plan by requiring longer more complex rotations and also substantially larger refugia of non-Bt corn.[130]

*Weed Resistance*

EPA initially intended to regulate the use of herbicides for direct application to GE HR crops to forestall or slow the evolution of HR weeds.[131] However, EPA never followed through on this plan. As a result of EPA (and USDA) inaction, massive and often exclusive use of glyphosate for weed control on glyphosate-resistant crops has spawned an epidemic of glyphosate-resistant weeds.

The control measures elicited by these resistant weeds have entailed substantial human health, environmental, and agronomic costs. Glyphosate tolerance and resistance in weeds has led to higher rates and more frequent applications of glyphosate, additional use of other toxic herbicides, and an increase in soil-erosion from additional tillage operations.[132] Weed control costs in southern cotton and Illinois soybeans have skyrocketed six-fold thanks to glyphosate-resistant weeds.[133] The introduction of GE multiple-HR crops for the purpose of facilitating control of glyphosate-resistant weeds will rapidly lead to a toxic spiral of still more herbicide use and yet more intractable weeds resistant to multiple herbicides.[134] The human health and environmental costs of these control measures are accompanied by increased weed control costs for farmers.

EPA has recently proposed weed resistance management plans for herbicides used with HR crops. The initial plan was formulated for Enlist Duo herbicide (a combination of 2,4-D and glyphosate), to be used on Dow AgroSciences Enlist (2,4-D/glyphosate-resistant) corn and soybeans. However, these resistance management plans are weak and doomed to fail.[135] Their most significant flaw is the lack of any herbicide resistance prevention component. That is, they impose absolutely no restrictions on the amount or the frequency of herbicide use, which largely determine the selection pressure on weeds for evolution of resistance. Instead, they are purely reactive monitoring programs that seek to respond to, rather than prevent emergence of, weed resistance. Their second major flaw is that they delegate virtually all responsibility for implementation and enforcement to the company that sells both the GE crop and the companion herbicide. Since prevention or management of weed resistance must involve strict limits on the use of the HR crop system (GE crop and/or companion herbicide), the company has a direct financial conflict of interest in carrying out weed resistance management.

HR Crop Systems and Herbicide Drift Damage

Herbicides applied to GE HR crops also present much higher risks of damage to neighboring and sometimes distant plants (both crops and wild plants) via herbicide drift and volatilization than do the same herbicides in the conventional crop context.[136] The increased threat arises from a combination of several factors. First, HR crops lead to sharply increased use of the herbicides they are designed to withstand, because the herbicide resistance trait eliminates the risk of crop injury at much higher rates than are possible in a conventional crop setting. Second, herbicides are generally applied much later in the season (late spring to summer) on HR crops than is the case with conventional crops, where most herbicide applications are in the early- to mid-spring. This later application period coincides with a time when crops and wild plants have emerged and often reached reproductive stages of growth, and are thus more

susceptible to herbicide drift damage, and when temperatures are higher, which increases the risk of long-distance vapor drift.

Here too, EPA has not developed effective regulation to eliminate or even mitigate this threat. EPA relies on a plethora of label restrictions that are unrealistic and unworkable and, practically speaking, unenforceable. Because such label restrictions will quite often not be followed, they have the effect of justifying uses of an herbicide that will cause considerable damage.

Instead, EPA must conduct "real-world" assessments of drift damage from use of herbicides on HR crops—and on this basis deny HR crop uses of herbicides if the real-world assessment shows they will cause harm. In this context, EPA must also consider the human health impacts of herbicide spray and vapor drift on farmworkers and others, including children, in the vicinity of sprayed farmland.

Novel Forms of GE-based Pest Management: RNA interference

A novel form of GE pest management involves RNA interference (RNAi). RNAi is a process by which organisms shut or dial down the activity of their own genes or those of invading organisms (e.g. bacteria). Biotechnology companies have commandeered this process to develop GE plants (e.g. corn) for pest control purposes. The GE plant is engineered to contain RNA sequences that, when consumed by the insect pest, shuts down certain critical genes and thereby kills the pest. USDA recently approved, for unregulated commercial use, a corn variety engineered with RNAi to kill corn rootworm. This GE corn cannot be grown commercially unless or until EPA approves the RNAi mechanism it incorporates.

RNA was long thought to function almost exclusively as a passive translation mechanism for genes to express proteins. It is only since the 1990s that we have begun to learn of a whole new range of functions of so-called "active RNA," such as RNAi. We know far too little about RNAi and its range of potential adverse impacts to approve for commercial use any GE crop that utilizes it, particularly for pesticidal purposes. RNAi is fraught with poorly understood side effects and uncertainties, including potential effects on non-target organisms (including humans).[137] EPA recently convened a Scientific Advisory Panel (SAP) on RNAi, and the SAP raised numerous serious concerns about potential human health and environmental impacts of this untested and poorly understood technology.[138]

EPA should reject any proposed RNAi application for pesticidal purposes unless or until scientific understanding of RNAi is sufficient to fully assess its risks.

**All Agencies Must Comply with the National Environmental Policy Act (NEPA) and Administrative Procedure Act (APA)**

Finally, all federal agencies are required to comply with NEPA for "every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment."[139] A proposal for a new Coordinated Framework, whether implemented through federal regulations or otherwise, and by one or more agency, is a major federal action that may significantly affect the quality of the

human environment, and hence the agencies must comply with NEPA when enacting and/or acting upon this process. Further, agency decisions, including implementing this new process, have the force of law and require formal notice and comment under the APA.[140]

Submitted by

Center for Food Safety

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[56] *See, e.g.*, Kurt Eichenwald et al., *Biotechnology Food: From the Labe to a Debacle*, N.Y. TIMES, Jan. 25, 2001, *available at* http://www.nytimes.com/2001/01/25/business/25FOOD.html. As quoted in the article, according to Henry Miller, who oversaw biotech policy at FDA from 1979-1994: "In this area, the U.S. government agencies have done exactly what big agribusiness has asked them to do and told them to

do." *See id.* ("Even longtime Washington hands said that the control this nascent industry exerted over its own regulatory destiny — through the Environmental Protection Agency, the Agriculture Department and ultimately the Food and Drug Administration — was astonishing.").

[57] *See id.* (quoting a senior research fellow responsible for biotechnology issues at the FDA, who stated "In this area, the U.S. government agencies have done exactly what big agribusiness has asked them to do and told them to do.").

[58] *See, e.g.*, Kurt Eichenwald et al., *Biotechnology Food: From the Lab to a Debacle*, N.Y. TIMES (Jan. 25, 2001), http://www.nytimes.com/2001/01/25/business/25FOOD.html. According to Henry Miller, who oversaw biotech policy at FDA from 1979–1994: "In this area, the U.S. government agencies have done exactly what big agribusiness has asked them to do and told them to do." *Id.* Moreover, "[e]ven longtime Washington hands said that the control this nascent industry exerted over its own regulatory destiny—through the Environmental Protection Agency, the Agriculture Department and ultimately the Food and Drug Administration—was astonishing." *Id.*

[59] *See, e.g.*, Rebecca Bratspies, *Is Anyone Regulating? The Curious State of GMO Governance in the United States*, 37 VT. L. REV. 923, 928–31 (2013) (examining the framework's history, purpose, and consequences); Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2230–37 (2004) (exploring the framework's regulatory gaps, inconsistencies and overlap between the various agencies and their regulation of genetically engineered organisms); Keith Aoki, *Food Forethought: Intergenerational Equity and Global Food Supply—Past, Present, and Future*, 2011 WIS. L. REV. 399, 463–64 (2011) (concluding that inter-agency cooperation sounds good in theory, but the result has been ineffective regulation); Margaret R. Grossman, *Biotechnology, Property Rights and the Environment*, 50 AM. J. COMP. L. 215, 223–26 (2002) ("Congress has not enacted regulatory measures specifically designed to address the risks and concerns connected with biotechnology"); Rebecca Bratspies, *Some Thoughts on the American Approach to Regulating Genetically Modified Organisms*, 16 KAN. J.L. & PUB. POL'Y 393, 406–07 (2007) (criticizing the "substantial equivalence," doctrine for permitting agencies to act simultaneously as regulators and promoters for GE technology); John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L. REV. 807, 823–24 (2001) (criticizing the framework's conclusion that techniques of genetic engineering are not inherently risky and that genetic engineering is not regulated as a process, but rather that the products are regulated in the same way as products of any other technology); Douglas A. Kysar, *Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 HARV. L. REV. 525, 558–59 (2004) (concluding that the framework embraced the "substantial equivalence" doctrine resulting in policymakers determining that no new laws were required to regulate GE organisms, and exploring criticisms that responsible agencies have diluted their powers in regulating GE crop varieties); Mary Jane Angelo, *Regulating Evolution for Sale: An Evolutionary Biology Model for Regulating the Unnatural Selection of Genetically Modified Organisms*, 42 WAKE FOREST L. REV. 93, 112–41 (2007) (providing a detailed history of the framework and the specific of regulatory powers each agency has to regulate biotechnology); D. L. Uchtmann, *Starlink—A Case Study of Agricultural Biotechnology Regulation*, 7 DRAKE J. AGRIC. L. 159, 169–70 (2002) (exploring the framework and noting the fact that there was no alternative, all-encompassing biotechnology statute when the framework was developed); Doug Farquhar & Liz Meyer, *State Authority to Regulate Biotechnology Under the Federal Coordinated Framework*, 12 DRAKE J. AGRIC. L. 439, 457 (2007) ("Congress wrote many of the laws used to govern biotechnology before scientists even knew that rDNA modifications were possible, and the laws are not keeping pace with new technological developments"); Gregory N. Mandel, *Toward Rational Regulation of Genetically Modified Food*, 4 SANTA CLARA J. INT'L L. 21, 22, 38–39, 59 (2006) (exposing

inefficiencies and overlap problems of regulatory power between the three agencies, and encouraging more communication between agencies).

[60] Keith Aoki, *Food Forethought: Intergenerational Equity and Global Food Supply-Past, Present, and Future*, 2011 Wis. L. Rev. 399, 464 (2011); Mary Jane Angelo, *Regulating Evolution for Sale: An Evolutionary Biology Model for Regulating the Unnatural Selection of Genetically Modified Organisms*, 42 Wake Forest L. Rev. 93, 142 (2007) (noting that the "agencies regulate in a piecemeal fashion with no clear standards to guide their decisions on whether a GMO should be permitted to be released into the environment"); John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. Cal. L. Rev. 807, 823 (2001) ("[M]ultiple agencies are charged with monitoring disparate portions of [GE regulations] with no effective means for ensuring comprehensive and consistent coverage."); Cinnamon Carlarne, *From the USA with Love: Sharing Home-Grown Hormones, GMOs, and Clones with A Reluctant Europe*, 37 ENVTL. L. 301, 318 (2007) ("[W]hile these three agencies participate in regulating GM products, regulatory authority is fragmented and no single agency has clear or decisive control. Due to its complexity, the U.S. regulatory regime lacks the type of clarity and coordination necessary to effectively handle such a weighty issue.").

[61] Margaret R. Grossman, *Biotechnology, Property Rights and the Environment*, 50 Am. J. Comp. L. 215, 226 (2002).

[62] John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. Cal. L. Rev. 807, 823 (2001) (outlining the current state of the law regarding the regulation of GE plants).

[63] Doug Farquhar & Liz Meyer, *State Authority to Regulate Biotechnology Under the Federal Coordinated Framework*, 12 Drake J. Agric. L. 439, 457 (2007).

[64] Douglas A. Kysar, *Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 Harv. L. Rev. 525, 559 (2004).

[65] *See* L. Uchtmann, *Starlink--A Case Study of Agricultural Biotechnology Regulation*, 7 Drake J. Agric. L. 159, 208 (2002) ("On its surface, the regulatory system focuses on the 'products' of biotechnology, not the process. Nevertheless, the 'process' of biotechnology is often important as the trigger for special regulatory oversight."); Douglas A. Kysar, *Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 Harv. L. Rev. 525, 641 (2004) (arguing that the process/product distinction is responsible for many of the problems in regulating GE products); Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 Wm. & Mary L. Rev. 2216, 2242 (2004) ("The cause of many of the deficiencies [of the framework] . . . can be traced to two problematic presumptions that formed the Coordinated Framework's foundation: (1) that the techniques of biotechnology are not inherently risky, and (2) that biotechnology should not be regulated as a process—that is, the products of biotechnology should be regulated in the same manner as conventionally created products."); Rebecca Bratspies has added that:

> A major problem with "substantial equivalence" is that it permits agencies to act simultaneously as regulators and promoters for this new technology . . . . The Coordinated Framework assumes that 'by the time a genetically engineered product is ready for commercialization, it will have undergone substantial review and testing during the research phase, and thus, information regarding its safety should be available.' However, the limited nature of regulatory review shapes the development of safety information in a fashion that does not promote a full consideration of all risks associated

> with these novel organisms. Because of the assumption of substantial equivalence, the onus and burden of proof is on the authorities to prove that a GMO is unsafe before they may impose use restrictions. This is directly contrary to the European approach and has led to jockeying in the international trade context.

Bratspies, *Some Thoughts on the American Approach to Regulating Genetically Modified Organisms*, at 406–07 (quoting Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23302, 23304 (June 26, 1986)).

[66] Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 Wm. & Mary L. Rev. 2216, 2243 (2004).

[67] Mary Jane Angelo, *Regulating Evolution for Sale: An Evolutionary Biology Model for Regulating the Unnatural Selection of Genetically Modified Organisms*, 42 Wake Forest L. Rev. 93, 142 (2007).

[68] Bratspies, *Some Thoughts on the American Approach to Regulating Genetically Modified Organisms*, at 406–07.

[69] Debra M. Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply*, 61 FOOD & DRUG L.J. 167, 186 (2006) ("[T]he U.S. approach differs greatly from the international approach embodied by the Codex principles and Cartagena Protocol, most significantly by not adopting the precautionary principle that would require premarket approval conditioned upon a case-by-case risk assessment to consider the intended and unintended effects of the GM product *before* its release. In promulgating its regulatory scheme, FDA appears to have given little weight to the scientific uncertainty and risks recognized by its EU counterparts as inherent in GMOs.").

[70] 7 U.S.C. §§ 7701 *et seq*.

[71] BD. ON AGRIC. AND NATURAL RES., DIV. ON EARTH AND LIFE STUDIES, NAT'L RESEARCH COUNCIL, ENVIRONMENTAL IMPACTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION 101 (2002) [hereinafter *NRC 2002 Report*].

[72] *See* Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23302, 23342-43 (June 26, 1986).

[73] 7 U.S.C. § 150aa-jj.

[74] *Id*. §§ 151-164, 166-167.

[75] 7 C.F.R. §§ 340 – 340.9 (2011); Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe are Plant Pests, 52 Fed. Reg. 22,908 (June 16, 1987).

[76] Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status, 58 Fed. Reg. 17,044 (Mar. 31, 1993); Genetically Engineered Organisms and Products; Simplification of Requirements and Procedures for Genetically Engineered Organisms, 62 Fed. Reg. 23,945 (May 2, 1997).

[77] *See* Plant Protection Act, Revisions to Authority Citations, 66 Fed. Reg. 21,049 (Apr. 27, 2001) (revising the genetically modified plant regulations to change authority citations to the PPA without revising the regulations); *see also* Plant Pest Regulations; Update of Current Provisions, 66 Fed. Reg.

51,340 (Oct. 1, 2001) (noting that "the provisions of this proposed rule do not differ significantly from what we would have proposed under the authority of those applicable provisions of law that were repealed by the Plant Protection Act").

[78] 7 U.S.C. § 7702(10) (emphases added).

[79] *Id.* § 7702(14).

[80] *Id.* § 7714 (a)(1)(A) (General Remedial Measures for New Plant Pests and Noxious Weeds).

[81] *Id.* § 7733 (Subpoena Authority).

[82] *Id.* § 7731(b) (Inspections, Seizures, and Warrants).

[83] *Id.* § 7735(2), (3) (Enforcement Actions of Attorney General).

[84] *Id.* § 7721 (Plant Pest and Disease Management and Disaster Prevention).

[85] *Id.* § 7714(c)(1) ("To facilitate control of noxious weeds, the Secretary may develop a classification system to describe the status and action levels for noxious weeds. The classification system may include the current geographic distribution, relative threat, and actions initiated to prevent introduction or distribution.").

[86] *Id.* § 7714(c)(2) ("In conjunction with the classification system, the Secretary may develop integrated management plans for noxious weeds for the geographic region or ecological range where the noxious weed is found in the United States.").

[87] *Id.* § 7732 ("The Secretary may gather and compile information and conduct any investigations the Secretary considers necessary for the administration and enforcement of this title.").

[88] *Id.* § 7734 (Penalties for Violation).

[89] *Id.* § 7702(10).

[90] *Id.* § 7701(1).

[91] Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms, 80 Fed. Reg. 11,598 (Mar. 4, 2015).

[92] NRC 2002 Report, *supra* note 71, at 79, 83 ("The committee finds that the APHIS process should be made significantly more transparent and rigorous…."). The National Research Council (NRC) of the National Academy of Sciences (NAS) stated that such a trigger is the scientifically correct approach: "… transformation [e.g. genetic engineering] is both a useful and logically justifiable regulatory trigger," and "all transgenic crops should be reviewed through regulatory oversight." *Id.* The NAS committee also emphasized that use of genetic engineering as the trigger for regulation did not conflict with a commitment to a case-by-case, risk -based approach to regulation and was consistent with the Framework. *Id.* at 81 ("a full process-based trigger is consistent with the 1992 OSTP scope document.").

[93] National Academy of Sciences, National Research Council, SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS (2004), at 64.

[94] National Academy of Sciences, National Research Council, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION (2002) ("2002 NAS Report"), at 79, 83.

[95] Genetic engineering is not limited to organisms that are "genetically modified using a recombinant DNA process." It can also be produced from an organism or organisms in which the genetic material has been changed through the application of (a) *In vitro* nucleic acid techniques which include, but are not limited to, recombinant deoxyribonucleic acid (DNA) or ribonucleic acid (RNA), direct injection of nucleic acid into cells or organelles, encapsulation, gene deletion, and doubling; or (b) Methods of fusing cells beyond the taxonomic family that overcome natural physiological, reproductive, or recombination barriers, and that are not techniques used in traditional breeding and selection such as conjugation, transduction, and hybridization. *In vitro* nucleic acid techniques can include recombinant DNA or RNA techniques that use vector systems, and techniques involving the direct introduction into the organisms of hereditary materials prepared outside the organisms such as biolistics, microinjection, macro-injection, chemoporation, electroporation, microencapsulation, and liposome fusion.

[96] 7 U.S.C. § 7732 ("The Secretary may gather and compile information and conduct any investigations the Secretary considers necessary for the administration and enforcement of this chapter.").

[97] *Id.* § 7714 (a)(1)(A).

[98] *Id*. § 7733 (Subpoena authority).

[99] *Id*. § 7731(b) (Inspections, seizures and warrants).

[100] *Id*. § 7734 (Penalties for violation).

[101] In establishing contamination prevention measures, CFS urges USDA to explicitly acknowledge that liability for transgenic contamination elimination, economic damages from lost markets, and restitution for adverse livelihood impacts must rest with the GE seed patent holder.

[102] 21 U.S.C. §§ 301 *et seq.* (2011).

[103] *Id.* § 342(a)(1) (2011).

[104] *Id.* § 348 (2011).

[105] *Id.*

[106] Statement of Policy: Foods Derived from New Plant Varieties, *supra* note 45.

[107] Guidance for Industry and Other Stakeholders
Toxicological Principles for the Safety Assessment of Food Ingredients
*Redbook 2000.*
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm2006826.htm.

[108] Gurian-Sherman, D. 2003. Holes in the biotech safety net: FDA policy does not assure the safety of genetically engineered foods. https://www.cspinet.org/new/pdf/fda_report__final.pdf.

[109] Ibid.

[110] Freese, W. and D. Schubert. 2004. Safety testing and regulation of genetically engineered foods. *Biotechnology and Genetic Engineering Reviews* 21: 299—324. And Gurian-Sherman, D, ibid

[111] Nordlee, JA et al. 1996. Identification of a Brazil-nut allergen in transgenic soybeans. New England Journal of Medicine 34(11): 688—692.

[112] National Research Council. 2000. Genetically modified pest-protected plants: Science and regulation. National Academy Press, Washington, DC.

[113] National Research Council. 2004. Safety of genetically engineered foods: Approaches to assessing unintended health effects. National Academy Press, Washington, DC.

[114] Freese and Schubert, ibid; Gurian-Sherman, ibid.

[115] Krimsky, S. An illusory consensus behind GMO health assessment. Science, Technology and Human Values DOI: 10.1177/0162243915598381 p.1—32.

[116] Betton, G. et al. 1994. A critical review of the optimum duration of chronic rodent testing for the determination of non-tumourigenic toxic potential: a report by the BTS Working Party on Duration of Toxicity Testing. Human Experimental Toxicology 13(4):221-32.

[117] American Association for the Advancement of Science. 2012. Statement by the AAAS board of directors on labeling of genetically modified foods. http://www.aaas.org/sites/default/files/AAAS_GM_statement.pdf.

[118] Snell, C. et al. 2012. Assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials: A literature review. Food and Chemical Toxicology 50: 1134–1148.

[119] *See* Citizen Petition from Ctr. For Food Safety to FDA (Sept. 29, 2011), Dkt. No. FDA-2011-P-0723, *available at* http://www.centerforfoodsafety.org/files/ge-labeling-petition-10-11-2011-final.pdf.

[120] 7 U.S.C. §§ 136-136y.

[121] The term "pesticide" includes "any substance … intended for preventing, destroying, repelling or mitigating any pest." *Id*. § 136(u).

[122] *Id*. § 136a(a).

[123] *See, e.g.*, *No Spray Coalition, Inc. v. City of New York*, 351 F.3d 602, 604-05 (2d Cir. 2003) (citing 7 U.S.C. § 136a(c)(5)(D)).

[124] *See, e.g.*, Peter J. Martinez, Damon L. Worden, Luke M. Jones, and Jason S. Juceam, *Environmental Crimes*, 43 AM. CRIM. L. REV. 381, 452 n.540 (2006).

[125] EPA, Plant Incorporated Protectants (Current as of Apr. 18, 2007), http://www.epa.gov/opp00001/biopesticides/pips/index.htm.

[126] William Freese and David Schubert, 2004. Safety testing and regulation of genetically engineered foods. *Biotechnology and Genetic Engineering Reviews* 21: 299—324.

[127] See generally Bill Freese, 2001. A critique of the EPA's decision to re-register Bt crops and an examination of the potential allergenicity of Bt proteins. Friends of the Earth, December 9, 2001, and references cited therein.

[128] FIFRA Scientific Advisory Panel Meeting, February 25-26, 2009. A set of scientific issues being considered by the Environmental Protection Agency regarding: The data required to register plant-incorporated protectants. SAP Minutes No. 2009-04.

[129] For documented discussion, see Center for Food Safety, Comments to FIFRA Scientific Advisory Panel Considering Scientific Uncertainties Associated with Corn Rootworm Resistance Monitoring for Bt Corn Plant Incorporated Protectants (PIPs), Docket EPA-HQ-OPP-2013-0490, December 3, 2013.

[130] For documented discussion, see Center for Food Safety, Comments to the Environmental Protection Agency regarding EPA's proposal to improve corn rootworm management. Docket EPA-HQ-OPP-2014-0805, April 15, 2015.

[131] Diana M. Horne. 1992. EPA's response to resistance management and herbicide-tolerant crop issues. Weed Technology 6(3): 657-661.

[132] National Academy of Sciences, National Research Council, *Impact of Genetically Engineered Crops on Farm Sustainability in the United States* (2010).

[133] R.F. Service. *What happens when weed killers stop killing?* Science 341: 1329 (2013).

[134] D.A. Mortensen et al. *Navigating a critical juncture for sustainable weed management.* BioScience 62: 75-84 (2012).

[135] For documented discussion, see: Center for Food Safety. *Comments to EPA on EPA's proposed registration of Enlist Duo herbicide containing 2,4-D and glyphosate for new uses on herbicide-tolerant corn and soybean*, Appendix A, Part 1, Docket EPA-HQ-OPP-2014-0195, June 30, 2014.

[136] For following, see Ibid.

[137] J.G. Lundgren, J.J. Duan. RNAi-based insecticidal crops: potential effects on nontarget species. BioScience 63: 657-665 (2013).

[138] FIFRA Scientific Advisory Panel Meeting, January 28, 2014. A set of scientific issues being considered by the Environmental Protection Agency Regarding RNAi Technology: Program Formulation for Human Health and Ecological Risk Assessment. SAP Minutes No. 2014-02.

[139] *See* 42 U.S.C. § 4332(2)(C).

[140] *See* 5 U.S.C. § 553.