May 2021

2021 GMO Regulatory and Legislative Outlook REPORT

IRT
Institute for Responsible Technology

Protect Nature Now

Contents

Introduction by Our Founder Jeffrey Smith

Federal regulations on genetically modified organisms (GMOs) have, from the start, been inadequate to protect human health and the environment. Thirty years ago, an enthusiastic Executive Branch sought rapid commercialization of GMOs. They created a regulatory framework, which distributed decision-making among the FDA, EPA, and USDA. The administration sought to avoid any new laws created by Congress. So, it asked the agencies to regulate GMOs based on laws and policies already in place.

Unfortunately, these laws were crafted before the advent of genetic engineering technology and have never been adequate to address its unique, unprecedented risks and the possible adverse outcomes for human health and the environment. Genetic engineering technologies have continued to evolve, becoming more accessible and powerful than ever. Therefore, the glaring loopholes in the outdated US regulations pose more danger than ever.

The FDA's GMO policy and the process of its creation exemplify the shortcomings of the regulatory framework in general. Introduced on May 29, 1992 and still in force today, the FDA policy assumes that GMOs are substantially equivalent to non-GMOs. It allows the developers to determine if their products are considered Generally Recognized As Safe. The agency does not require any safety evaluations. They don't require any labels for consumers. Any consultation with the FDA by the developer is strictly voluntary. A company can choose to introduce GM food to the market without even informing the agency (as an extension of this policy, GMOs produced in other countries can quietly enter the US food supply without testing, labeling, or notification).

The rationale for FDA's hands-off approach is conveyed in a sentence of the policy: "The agency is not aware of any information showing that foods derived by these new methods differ from other foods in uniform or meaningful way."

The FDA's GMO policy is one of the weakest in the world and is subject to regular criticism by prominent scientists and organizations.

Twenty years ago, the editor of *Lancet* said, "It is astounding that the FDA has not changed their stance on genetically modified food adopted in 1992. The policy is that genetically modified crops will receive the same consideration for potential health risks as any other new crop plant. This stance is taken despite good reasons to believe that specific risks may exist. Governments should never have allowed these products into the food chain without insisting on rigorous testing for effects on health" (Ewen, 1999). The Royal Society of Canada also described substantial equivalence as "scientifically unjustifiable and inconsistent with precautionary regulation of the technology" (Andrée, 2004).

[The FDA policy] allows the developers to determine if their products are considered Generally Recognized As Safe. The agency does not require any safety evaluations.

The USDA and EPA policies on GMOs have similarly been criticized. They lack state-of-the-art science; they ignore numerous ways that GMOs can damage health and the environment. The limited scope of the laws they reference pushes more and more GMOs into loopholes, evading meaningful oversight. Furthermore, the rest of the US government has adopted the false premise that no significant differences exist between GMOs and non-GMOs. This stands as the basis for the government's GMO trade policy, labeling policy, and all things GMO.

An in-depth analysis of the archaic US regulatory policies reveals an urgent need for a revamped regulatory framework that focuses on data-based risk assessment, realistic assessment of the latest gene-editing technology, and minimization of the potential risk to the environment and people's health.

Legislative Overview

Federal Safety Regulation

One of the common criticisms about regulations that oversee GMOs is that they regulate the *product* and not the *technology*. It is blind to the technology used to create the *product* and therefore blind to the set of potential side effects that are unique to or typical of the process used to create the product. Thus, regulations treat GM/GE products the same as the *product* of the same type produced using any other *technology*.

Federal regulation does not regulate GMOs specifically – it applies the same regulatory framework to GMOs as the corresponding non-GMOs. Regulatory authority for GMOs in the US is split between three government agencies and departments: the US Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the US Department of Agriculture (USDA), and the Animal and Plant Health Inspection Services (APHIS).

Coordinated Framework for the Regulation of Biotechnology was first proposed in 1984 by the White House Office of Science and Technology to outline the basic policy framework for regulating biotechnology products. It was adopted in 1986, outlining three basic principles to guide legislative and regulatory approach to biotechnology products (Office of Science and Technology Policy, 1986):

1. The US policy would focus on the product of genetic modification techniques, not the process itself.
2. Only regulation grounded in verifiable scientific risks would be tolerated.
3. GM products are on a continuum with existing products and, therefore, existing statutes are sufficient to review the products.

These principles have since guided the US legislative and regulatory approach. In 2017, the Trump administration updated the Coordinated Framework for the Regulation of Biotechnology in light of 30 years of technological and scientific development. This update outlined additional principles for the regulation of biotechnology products (EPA, 2020).

From the 2017 update to the Coordinated Framework for the Regulation of Biotechnology:

"Principles for the Regulation of Biotechnology Products

- Federal statutes and implementing laws regulate products based on specific uses. This approach means that products with the same use are subject to the same oversight types by the relevant regulatory agencies.
- The intended introduction of biotechnology products into the environment can be subject to Federal oversight under Federal statute(s) related to such products and their intended application.
- It is the characteristic of a biotechnology product that the environment in which it will be introduced, and its application will determine its risk (or lack thereof).
- Exercise of agency oversight within the scope afforded by statutes should commensurate with the risk posed by introducing the biotechnology product and should not focus on the fact that it was created or has been altered by a particular process or technique.
- Under the relevant statutory provisions, the regulatory system should distinguish between

those biotechnology products that require a certain level of Federal oversight and those that do not, following a risk-based approach to regulation.

- Future scientific developments will lead to further refinements of the Coordinated Framework. Experience with earlier basic scientific research has shown that regulatory regimens can be modified to reflect a more complete understanding of the potential risks involved as science progresses. Refinements to the Coordinated Framework should consider any such updates to regulatory processes."

There are two important points that this update makes:

- Future regulation must keep pace with scientific and technological development. The regulatory framework needs to be continuously updated, considering the latest scientific developments and the understanding of underlying risks; this has not been the case with the current regulatory framework.
- Risk assessment is based on introducing and evaluating a particular product, regardless of the technology used to create it.

This update has been, in general, a continuation of the regulatory approach of the 1986 Coordinated Framework for the Regulation of Biotechnology. It does emphasize the need for the regulatory oversight to keep pace with the scientific and technological development. It obligates regulators and legislators to act on new scientific evidence, if the currently applied risk assessment methods or principles fail to consider the risks exposed by the new evidence. However, it makes no provisions for overcoming the existing regulatory challenges or how to handle the new challenges posed by the rapidly developing gene-editing technology.

Table 1. Overview of the US regulatory framework within the Coordinated Framework for the Regulation of Biotechnology (EPA, 2020)

Agency	Statute	Protection Goal
EPA	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	Prevent and eliminate unreasonable adverse effects on the environment. For environmental and occupational risks, this involves comparing economic, social, and environmental risks to human health and the environment and benefits associated with pesticide use. For dietary or residential human health effects, the sole standard is the "safety" of all the combined exposures to the pesticide and related compounds.
EPA	Federal Food, Drug, and Cosmetic (FD&C) Act	Ensure that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.
EPA	**Toxic Substance Control Act (TSCA)**	**Prevent the manufacture, processing, distribution in commerce, use, or disposal of chemical substances, or any combination of such activities with such substances, from presenting an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible population, without consideration of costs or other non-risk factors.**
FDA	Federal Food, Drug, and Cosmetic (FD&C) Act	Ensure human and animal food is safe, sanitary, and properly labeled. Ensure human and animal drugs are safe and effective. Ensure the reasonable assurance of the safety and effectiveness of devices intended for human use. Ensure cosmetics are safe and properly labeled.
FDA	Public Health Service (PHS.) Act	Ensure the safety, purity, and potency of biological products.
USDA	Animal Health Protection Act (AHPA)	Protect livestock from animal pest and disease risks.
USDA	Plant Protection Act (PPA.)	Protect agricultural plants and agriculturally important natural resources from damage caused by organisms that pose plant pest or noxious weed risks.
USDA	Federal Meat Inspection Act (FMIA)	Ensure that the United States' commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled.
USDA	Poultry Products Inspection Act (PPIA)	Ensure that the United States' commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled.
USDA	Egg Products Inspection Act (EPIA)	Ensure that the United States' commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled.
USDA	Virus-Serum-Toxin Act (VSTA)	Ensure that veterinary biologics are pure, safe, potent and effective.

Regulation of Genetically Modified Microbes

Microbes (microorganisms) represent several different categories of organisms: bacteria, archaea, fungi, protozoa, algae, and viruses. They are widespread in nature and play a vital role in ecological and environmental balance and human health, among other things. They form complex microbial systems called microbiomes, which perform vital roles like providing plant nutrition in the soil by capturing and converting nitrogen from the air, regulatory role in human and animal metabolism, etc.

Microbiomes represent complex systems of thousands of different microbes' species that form a symbiotic, interdependent system that can be easily disrupted by altering one of its components. Genetic modification of microbes poses unique regulatory challenges due to their complex role in the environment, human and animal health. However, the current regulation and legislation have not been developed for GM microbes leaving significant regulatory gaps.

Toxic Controlled Substances Act (TSCA)

The central piece of regulation of GM microbes is currently the Toxic Controlled Substances Act (TSCA). It allows EPA to regulate GM microbes that are not regulated by other agencies. Most GM microbes fall under the TSCA. The original TSCA was passed in 1976, before the advent of genetically modified organisms, to regulate the introduction of new or already existing chemicals. It was amended in 2016 by Frank R. Lautenberg as Chemical Safety for the 21st Century Act (The Lautenberg Act or 2016 TSCA law), which changed some existing TSCA provisions and standards.

The risk analysis's most significant change is switching from a *risk-benefit balancing* standard to a *risk-based safety* standard, separating risk assessment from risk management. This requires eliminating any identified unreasonable risk, providing the EPA with an expanded mandate to act on any such risk.

However, the changes are still driven by needs related to the regulation of chemicals. This update did not address the significantly more complex and long-lasting impact of living GE microbes or significantly change the risk assessment standards. The shortcomings are apparent in the following review of the approval process.

EPA requires manufacturers of intergeneric GM microbes (that contain foreign genetic material) to submit a Microbial Commercial Activity Notice (MCAN) for review at least 90 days before the commercialization of the product. For non-intergeneric GM microbes, a premanufacturing notice (PMN) is required. They are treated the same as a new chemical substance or significant new use of the existing chemical substance, which has a lower level of scrutiny than MCAN.

Field trials of GM microbes require a TSCA Experimental Release Application (TERA) submitted at least 60 days before the field test. This evaluation period is relatively short and leaves very little room for a detailed analysis of the available data and potential collection of additional data.

GM microbes' regulatory treatment as toxic chemicals is based on a broad legal interpretation of EPA's regulatory mandate, which has never been seriously challenged in court. This ambiguous regulatory authority is based on the inclusion of microorganisms, especially living microorganisms, like bacteria and algae, in the legal definition of "chemical substances," leaving the EPA's regulatory mandate open to a legal challenge. Since the existing legislation has not clearly established the EPA's regulatory authority, it can be argued that new legislation is needed that would establish this authority. This also raises the question of regulatory scrutiny: whether the EPA, in the absence of clear regulatory authority, has not been enforcing the regulation as strictly as it would have if it had this clear regulatory authority.

Another significant regulatory gap exists in the Toxic Controlled Substances Act (TSCA), which regulates most GM microbes. TSCA only regulates substances manufactured "for commercial purposes," defined broadly by the EPA as "the purpose of obtaining an immediate or eventual commercial advantage." (Mandel, 2014) This means that GM microorganisms not developed for commercial purposes can easily escape regulatory scrutiny.

The new chemical review process under TSCA

has mostly relied on being legislatively expedited to reach decisions without necessarily generating relevant information of risk assessment to public health and the environment. The EPA is unable to access or require meaningful data for new chemicals within the deadline for decisions on PMNs (Silbergeld, 2015). For instance, EPA exempted whole categories of new chemicals from review just to reduce its workload and regulatory burden, with the rationale that reveals deep structural problems within the regulatory framework:

"It is the intention of the exemption to encourage the manufacture of safer polymers by reducing the industry's reporting burden for this category of chemical substances and concentrating the Agency's review resources on substances expected to pose a higher risk" (EPA, 2013)

This practice of exempting whole categories deemed to be of lower risk can have considerable consequences if applied to microorganisms.

For those new chemicals not exempted, assessment methods have been developed to fit the limitations on data submitted by most PMNs. These methods are less and less reliant on biologically based information (actual toxicity testing) and increasingly dependent on inferences based mostly on the chemical structure to infer both hazard (quality of toxicity) and risk (likelihood or severity of toxicity) (Silbergeld, 2015).

TSCA section 8 provides reporting and record-keeping requirements for post-market surveillance and risk management of regulated products. This can be applied to GM microorganisms. The EPA regulations limit such record-keeping to "known" human health effects and a variety of environmental effects, including (Mandel, 2014):

(1) Gradual or sudden changes in the composition of animal life or plant life, including fungal or microbial organisms, in an area.

(2) Abnormal number of deaths of organisms (e.g., fish).

(3) Reduction of the reproductive success or the vigor of a species.

(4) Reduction in agricultural productivity, whether crops or livestock.

(5) Alterations in the behavior or distribution of a species.

(6) Long-lasting or irreversible contamination of components of the physical environment, especially in the case of groundwater and surface water and soil resources that have limited self-cleansing capability.

The effectiveness of this provision is severely impaired by the following:

- A company is only required to maintain records of allegations of such effects and not to itself identify or mitigate such effects.
- A company is only required to retain the information and is not required to report the allegations to the EPA.

Section 8(e) of TSCA requires the company to report to the EPA any information that "reasonably supports the conclusion that [the chemical] substance or mixture presents a substantial risk of injury to health or the environment." However, the agency has not yet issued specific implementation regulations, making the enforcement of this provision unclear.

Section 6 of TSCA gives the EPA potential risk management options, including the prohibition of a product, restrictions on the quantity or use of a product, requirements for labeling or communicating the risks of a product, restrictions on product disposal, testing requirements, and reporting requirements.

However, the EPA must make a finding based on a quantified cost-benefit calculation that the product poses an "unreasonable risk" and that the proposed regulatory action is the least burdensome for protecting against the unreasonable risk. As enforced by the courts, these requirements are challenging for the agency to satisfy.

One of only six EPA rulings under Section 6 of TSCA, a proposed ban on certain asbestos products was based on ten years of study and a 45,000-page record. Even then, it was struck down by a federal appeals court in 1991 for lacking sufficient cost-benefit analysis and not imposing the least burdensome regulation (Mandel, 2014). That was the last time the EPA tried to exercise its regulatory authority under Section 6 of TSCA.

It leads to the conclusion that TSCA imposes unrealistic data and certainty requirements. Based on the available knowledge and level of existing

Table 2. Overview of Regulatory Limitations of GM Microbes under TSCA

Stage of the Regulatory Process	Limitations
Regulatory Scope	Only covers development "for commercial purposes."
Pre-market assessment	No provisions for the creation of new data Assessment methods limited by the submitted data
Risk-management options	Limited by the "least burdensome regulation" standard
Post-market assessment and monitoring	No reporting requirement for adverse effects or events No identification and mitigation requirement for adverse effects or events

data on GM microbes, it would be impossible for the EPA to enforce its regulatory authority under the TSCA after an environmental release.

The 2016 TSCA law mandates that the EPA makes decisions about chemical risks based on the "best available science" and the "weight of the scientific evidence" (Singla, 2019). The EPA defined "weight of the scientific evidence" in its 2017 regulations as follows: "a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based on strengths, limitations, and relevance."

Individual State's Rights Under TSCA

The 2016 TSCA law also includes two significant new pre-emption provisions (K&L Gates, 2016): "TSCA now precludes state action on a chemical if the EPA determines through a risk evaluation that such chemical does not present an unreasonable risk or if the EPA promulgates a rule to address the identified risks posed by the chemical.

The scope of federal pre-emption matches the scope of the hazards, exposures, risks, and uses or conditions of using a given chemical included in the EPA's final action on such a chemical. For example, if EPA were to conduct a risk assessment limited to the particular use of a chemical and did not evaluate or take final action related to other uses of the chemical, then pre-emption would not apply to such other uses.

Pre-emption based on the final action by the EPA (whether by a determination of no unreasonable risk or a final rule addressing chemical risks) is effective when such final action occurs. Additionally, the amended law also ***precludes states from requiring the development of information regarding a chemical that would be "reasonably likely" to duplicate information that will otherwise be required to be developed under TSCA***, such as in the course of an EPA risk evaluation.

The law also creates the new concept of "pause pre-emption." Under this concept, a state is temporarily pre-empted from imposing any new restrictions on a given chemical from the time that the EPA defines the scope of a risk evaluation for a high-priority chemical. This is until the EPA publishes its final risk evaluation or when the deadline for completing the evaluation expires, whichever is earlier. The pre-emption scope matches the scope of the EPA's risk evaluation. If certain risks or chemical uses are not included in EPA's risk evaluation scope, the "pause pre-emption" does not apply. A state could take new action on such chemical related to risks or uses outside that scope.

Since the EPA must provide at least one year between identifying a chemical for prioritization and publishing the scope of the associated risk

evaluation, states would have an opportunity to place restrictions on a chemical by statute or administrative action before the pause pre-emption taking effect."

States also have been left with some additional regulatory authority, as long as it does not supersede any EPA decisions (K&L Gates, 2016):

"For example, states can act on any chemical or particular use of a chemical that the EPA has not yet addressed and can implement reporting, monitoring, or disclosure requirements not imposed under federal law. States also can adopt and enforce chemical regulations that are identical to the federal regulations. As a practical matter, this empowers states to adopt parallel regulations and then to interpret and enforce them independently of the EPA.

Similarly, states can adopt regulations related to water quality, air quality, and waste treatment or disposal, notwithstanding EPA action. However, such regulations cannot:

i. restrict the manufacture, processing, distribution, or use of a chemical substance.

ii. address the same hazards and exposures, concerning the same conditions of use included in EPA's risk evaluation. Additionally, the amended TSCA does not pre-empt the State's "right to know" or other laws requiring disclosure of the presence of, or exposure to, a chemical.

States may seek a mandatory waiver from pause pre-emption or a discretionary waiver from general pre-emption where certain criteria are established. Under the waiver provisions, the EPA must grant a State a waiver from pause pre-emption if the State enacted a statute or proposed or finalized an administrative action intended to prohibit the use of a chemical no later than 18 months after EPA initiates the prioritization process for a chemical or when the EPA publishes the scope of its risk evaluation, whichever is sooner.

The EPA must also grant a waiver regarding pause pre-emption if a State applies for it and demonstrates that a proposed state restriction would not unduly burden interstate commerce. In addition, it would not cause a violation of federal law, and the State's concern about the chemical in question is based on peer-reviewed science.

States may also apply to the EPA for discretionary waivers from the general pre-emption provisions. However, such waivers require rulemaking by the EPA based on a determination that:

i. compelling conditions warrant granting the waiver to protect the health or the environment.

ii. compliance with the proposed state requirement would place no undue burden on interstate commerce.

iii. the proposed state requirement is designed to address a risk that was identified using the best available science.

Given the requirement for rulemaking and the required substantive determination, it appears unlikely that discretionary pre-emption would be feasible in any but extraordinary circumstances."

The Endangered Species Act (ESA)

Any intentional environmental release of GM microorganisms that could endanger a listed species would have to be reviewed under the Endangered Species Act (ESA). This statute prohibits Federal Agencies from taking any action that would jeopardize a listed species (Section 7). It also prohibits private entities from taking any action that might kill or harm a listed species without an acceptable mitigation plan (Section 9). Section 7 includes any action by a federal agency, including a decision to grant permits and federal funding to private activities. These decisions are made based on "best scientific and commercial data available," and there is no mandate for developing new data (Mandel, 2014).

This outlines the significant drawbacks of the current legislative and regulatory framework. The federal agencies are tasked under the ESA to prevent any environmental release that could endanger a listed species. However, this assessment is based on available data. The company applying for release is not obligated to provide unambiguous evidence that the environmental release will not impact the listed species. It can rely on the lack of evidence that shows that the environmental release would have a negative impact with full knowledge that the federal agencies do not have the mandate

to require the development of relevant data.

Even if the federal agency ordered the data development, this would be limited by existing information, and there is no requirement for the data to be conclusive.

Limitations of The Current Regulatory Framework

All of this shows that the current concept of applying the existing regulatory framework developed for toxic chemicals, plants and animals to GM microbes is not a sound approach to regulating such a sensitive subject matter. The technological developments have made the gene-editing technology widely available, while the regulatory agency oversight is limited to the "commercial" development, leaving a massive regulatory vacuum. Risk assessment procedures are limited to the "best available science," and evaluation periods are typically too short for providing a meaningful, in-depth scientific assessment (60 to 90 days).

In addition, there are also significant institutional challenges that further exacerbate this situation:

"EPA may be constrained by inadequate funding and by the authority given to it under TSCA to address the anticipated influx of genetically engineered microbes for industrial use, which could lead to regulatory delays, inadequate review, and/or legal challenges." (Carter, 2014)

Overall, it is clear that the current regulatory framework creates significant gaps in both the scope of its authority and the scrutiny applied to the GM microbes. It is relatively easy to circumvent the regulatory authority. When regulatory scrutiny is applied, the risk assessment tends to be superficial and conducted on extremely short timelines, usually ignoring potential long-term effects.

GMO Legislative Outlook

Risk-Based Approach and Use of Financial Instruments Within Its Framework

A risk-based approach is the most likely form of risk management of GMOs proposed by the biotech industry and the scientific community. It is a 2-dimensional algorithm considering the likelihood of an adverse event and the level of harm inflicted by such an event (environmental or public health). Below is an example of such an algorithm from the Stanford Model. Environmental risk categories are: Negligible, Low, Moderate, and High.

There is a two-pronged approach that can utilize the risk-based framework above to maintain or improve safety and security standards:

- Automatic classification of GM microbes as high risk due to unpredictable nature of the technology used to produce them, and automatic classification of any technology that releases GM microbes into the environment as high risk.

Table 3: Tabular Algorithm of GMO Classification In The Stanford Model Environmental Risk Categories.

RISK				
Very High	Low	Moderate	High	High
High	Low	Low	Moderate	High
Low	Negligible	Low	Moderate	Moderate
Very Low	Negligible	Negligible	Low	Moderate
	Marginal	**Minor**	**Great**	**Major**
HARM				

- Introduction of financial instruments to discourage or limit GM Events with Moderate or High risk

The first is self-explanatory: any risk categorization carries a degree of subjectivity, and the introduction of a risk-based approach would be subject to this. In the risk-based approach, the high-risk GM event category could then be banned by legislation, creating a legal ban on GM microbes based on risk assessment.

GM Event = adverse event caused by GM research, trial and testing or release

GM Entity = company or organization conducting GM research, trial, and testing or release

Financial Instruments Can Be Used To Further Manage Risk

Any GM Event with High or Very High likelihood would probably require efforts to mitigate or reverse environmental damage or prevention measures to preserve public health. Also, any GM Event with the potential for Great or Major harm could inevitably inflict a burden on the taxpayers because of extensive environmental damage that, even if reversible, would take some time to repair.

Therefore, it would not be unreasonable to protect the taxpayers and minimize the burden inflicted on the local population by a GM Event. This can be done by requiring the GM Entity to make available the financial resources required for mitigation or repair of environmental damage in advance of their activities that could potentially cause GM Event; when the likelihood of such event is High or Very High, or when the potential damage by such an event is Great or Major. This way, in the case of the GM Event, the state and local authorities can act immediately to mitigate the situation without additional burden on the taxpayers.

The predicted effect for this is two-fold:

1. It would reserve GM research with increased risk for entities with significant financial resources and proper infrastructure, which could most effectively mitigate and reduce the risk of GM Event. It would promote the research and development of GM microbes that can only inflict Marginal or Minor harm on the environment – those that can be used in a contained and isolated environment.
2. It would also instantly punish lack of safety, which would promote research with higher safety standards, additionally raising the bar.

The addition of financial instruments to regulate the risk from GM microbes as a second layer to the risk-based approach outlined above equitably changes the risk distribution. The current regulation places the financial burden of remediation and mitigation efforts on the taxpayer. Thus, relying on the federal agencies to prosecute and pursue financial compensation from responsible parties. Placing the financial risk squarely on the entities responsible for the environmental release provides additional security layers to the public interest. This type of regulation can be characterized as "promoting responsible research."

Release of GMOs

For the release of GM microbes into the environment, there are two major issues; (i) risks associated with shortcomings of the technology, and (ii) risks associated with lack of adequate knowledge about the microbes' impact on human health and the environment. (niche, swap, general structure/function unclear)

The shortcomings of the technology include:

- Errors occurring during the genetic engineering process that result in GM microbes that are different than those intended.
- Mutability: even if the resultant GM microbes are the ones that are intended, they may mutate after safety assessments or after release into the environment.

Both of these outcomes may result in unpredictable adverse human health and environmental effects. Therefore, it would be reasonable for any GM microbe regulation to address these issues and require that the following standards are included in the risk assessment process:

1. **Quality control** – the manufacturer must prove that the product released is genetically identical to the GM microbe intended for the release. The production process does not create unintended deviations in the genome, RNA transcripts, proteins, and metabolites.

2. **Stability** – the manufacturer must prove that the product is genetically stable over many generations and will not mutate into a new organism differing from the product.

Without verifying that the GM microbe is what is intended and will remain so, any risk assessment will be flawed in invalid. The actual organism's structure and function could be different than the one evaluated. This also compromises any evaluation of the intended benefits of the GM microbe, which may be reversed or compromised.

Therefore, from both the safety and efficacy standpoints, quality control and stability must be required within any assessment protocol for GM microbes being considered for release into the environment. And because microbes created or used in enclosed facilities can escape into the environment, the same assessment criteria must be considered there as well.

It is worth noting that the standards outlined above are more stringent than the ones that exist currently. Risks associated with shortcomings of knowledge, however, are more complicated and problematic.

There are more microbes in a teaspoon of soil than people on earth, yet most of the microbe types have yet to be characterized. Science has only begun to tap into the vast knowledge, interdependence, and value of the microbiome.

Microbes play an indispensable role in the health of humans, other higher organisms, and ecosystems. But even cutting-edge science today is still a long way from understanding complex relationships. It is currently impossible to predict the downstream impact of releasing a GM microbe, mainly because the microbe may persist permanently in the environment, exchange genetic material with other microbes, mutate in response to outside stimuli, and travel or spread unrestricted to new locations and ecosystems. A gene added to a soil bacterium intended to enrich the soil in the Midwestern US, for example, might end up causing damage to forests or deserts or even in our gut bacteria.

How can we justify making irreversible changes to a complex and interactive system that we don't yet understand?

Given that human and environmental health is in the balance, a responsible policy would be to delay any environmental release of GM microbes until our understanding of the potential impacts has been developed to attain a high degree of confidence.

Urgent: Genetically Engineered Microbes Pose an Unprecedented Threat

The pandemic made it abundantly clear that microbes and viruses can spread quickly across the globe and wreak havoc. Genetic engineering amplifies this risk considerably. Widespread disease, soil infertility, species extinction, even ecosystem collapse, are all possible outcomes when we tinker with the microbiome.

Our global coalition will soon launch our short film, *Don't Let the Gene Out of the Bottle*. It uses real-world *near* catastrophes to highlight the unparalleled dangers of GE microbes and viruses. It illustrates how they could wipe out agriculture, spread disease, even change weather patterns. It also underscores the insanity of the ongoing enhancement of potentially pandemic pathogens while providing a hopeful call to action and a clear path forward.

Watch the short film now and learn more about our campaign.

Please sign up for updates, share our information, and add this urgent topic to the causes you care about and support.

Conclusion

The current legislative and regulatory framework regarding GM microbes is clearly and woefully out of date. It has failed to keep up with the technological and scientific developments in the field of genetic modification. This has allowed the opening of significant regulatory gaps where risk assessment is not conducted at all or conducted without adequate procedures and tools. Therefore, a new legislative and regulatory framework is needed to address these shortcomings.

The new legislative and regulatory framework must define the object of legislation in such a way as to include all existing and any future GM technology. This would prevent the circumvention of the regulatory oversight by a future GM technology. If the legislation would focus on GM microbes, it might be legally necessary to regulate the product and not the technology formally. However, that product can be defined in such a way to allow the technology to be regulated indirectly to avoid the development of regulatory gaps with further scientific and regulatory development.

For instance, the EU legislation defines GMOs as "organisms in which the genetic material (DNA) has been altered in a way that it does not occur naturally by mating or natural recombination." This is a broad definition that covers all gene-editing technologies, present, and future. Using this definition to regulate the product would effectively also regulate any future application of the GM technology.

The most effective approach to regulate GM microbes' mandates that any new legislation must reinforce the current safety standards. It must do so by providing adequate risk assessment tools and procedures, especially concerning the provision of necessary safety data. Also, the new legislation should make provisions for adequate enforcement of regulatory oversight. As described above, factors have been found posing a severe limitation to the enforcement of individual agencies' regulatory authority, including funding and personnel. In practice, this would significantly strengthen regulatory standards and ensure their stricter enforcement more in the legislation's spirit. Lax enforcement and unreasonable data standards have been significant factors in the current regulatory framework.

However, it can be expected that any legislation originating from the biotech industry will seek to weaken the regulatory framework. This could be accomplished easily by further weakening the data requirements and reporting to allow GM organisms to be registered with little regulatory scrutiny.

In light of this analysis, a two-pronged approach provides the best chance of successfully achieving effective and meaningful regulation of GM microorganisms. At one end, proposing legislation specifically addressing GM microorganisms. Simultaneously, a reform to the Toxic Controlled Substances Act (TSCA) providing additional authority and tools to regulate the EPA.

This includes a provision to request additional data if the "best scientific and commercial" data is deemed insufficient or inconclusive. The 2016 amendment to TSCA already opened the door for this. By reforming the TSCA in parallel with proposing new legislation focused on GM microorganisms, the existing regulatory framework could be strengthened immediately without waiting for a new regulatory framework to be developed and implemented based on the GM microorganism-specific legislation. A reform to the Toxic Controlled Substances Act (TSCA) would also find support from environmentalists in Congress, further improving its chance of success through a broader coalition.

Finally, given our current lack of understanding of the complexity of microbiome interactions, the permanent and irreversible nature of outdoor releases of GM microbes, the ability of microbes to travel around the globe, our inability to adequately predict the impacts of GM release, and the foundational role of microbes in human and environmental health, we propose that outdoor releases be disallowed at this time. Regulations regarding GM microbe development and use would therefore address contained use and the safety considerations therein.

References

Andrée, P., Sharratt, L. and Network, C.B.A., 2004. *Genetically Modified Organisms and Precaution: Is the Canadian Government Implementing the Royal Society of Canada's Recommendations: a Report on the Canadian Government's Response to the Royal Society of Canada's Expert Panel Report*," Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada". Polaris Institute.

Carter, S.R., Rodemeyer, M., Garfinkel, M.S. and Friedman, R.M., 2014. *Synthetic biology and the US biotechnology regulatory system: Challenges and options* (No. DOE-JCVI-SC0004872). J. Craig Venter Institute, Rockville, MD (United States)

EPA, 2013, *Polymer exemption overview as amended by TSCA PMN Rule Amendments of 1995.* Updated Sept. 15. E.P.A., Washington, DC. http://www.epa.gov/oppt/newchems/pubs/polyexem.htm

EPA, 2020, Update to the Coordinated Framework for the Regulation of Biotechnology, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/update-coordinated-framework-regulation-biotechnology

Ewen, S.W. and Pusztai, A., 1999. *Health risks of genetically modified foods*. The Lancet, 354(9179), p.684.

K&L Gates, 2016, The Most Contentious Issue Federal Preemption in the Amended Toxic Substances Control Act, https://www.klgates.com/The-Most-Contentious-Issue--Federal-Preemption-in-the-Amended-Toxic-Substances-Control-Act-07-28-2016

Mandel, G.N. and Marchant, G.E., 2014. *The living regulatory challenges of synthetic biology*. Iowa L. Rev., 100, p.155.

Office of Science and Technology Policy, 1986, *Coordinated Framework for Regulation of Biotechnology*, Available at: https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf

Silbergeld, E.K., Mandrioli, D. and Cranor, C.F., 2015. *Regulating chemicals: law, science, and the unbearable burdens of regulation*. Annual review of public health, 36, pp.175-191

Singla, V.I., Sutton, P.M. and Woodruff, T.J., 2019. *The Environmental Protection Agency Toxic Substances Control Act systematic review method may curtail science used to inform policies, with profound implications for public health*. American journal of public health, 109(7), pp.982-984

Appendix A: The US GMO Legislation

Federal

Federal legislation covers biosafety, biosecurity, ethical standards, and labeling of genetically modified salmon.

Selected Federal Bills Addressing Genetically Modified Organisms

Bill No.	Congress Session	Summary
S 1717	**112th**	Prevention of Escapement of Genetically Altered Salmon in the United States. It shall be unlawful for a person to— (1) ship, transport, offer for sale, sell, or purchase genetically altered salmon or other marine fish, or a product containing genetically altered salmon or other marine fish, in interstate or foreign commerce; or (2) have custody, control, or possession of, with the intent to ship, transport, offer for sale, sell, or purchase genetically altered salmon or other marine fish, or a product containing genetically altered salmon or other marine fish, in interstate or foreign commerce.
S 738	**114th**	To reduce the risks associated with genetically altered salmon in the United States. (1) minimize the risk that genetically engineered salmon will be introduced into the marine environment off the coasts of Alaska, Washington, Oregon, and California; and (2) ensure that consumers in the United States can make informed decisions when purchasing salmon. LABELING REQUIREMENT REQUIREMENT FOR ENVIRONMENTAL IMPACT STATEMENT
S 485 / H.R. 1225	**111th**	To reauthorize the Select Agent Program by amending the Public Health Service Act and the Agricultural Bioterrorism Protection Act of 2002 and to improve oversight of high containment laboratories.

H.R.1103/S.282 - Genetically Engineered Salmon Labeling Act

Introduced: 2019-01-30

Sponsor: Rep. Young, Don [R-AK-At Large]; Sen. Murkowski, Lisa [R-AK]

Last Action: Referred to the House Committee on Energy and Commerce; Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Description: It is a bill that amends the market name of genetically altered salmon in the United States and other purposes.

H.R.8045 - Genome Editing Threat Assessment Act

Introduced: 2020-08-14

Sponsor: Rep. Joyce, John [R-PA-13]

Last Action: Referred to the House Committee on Energy and Commerce.

Description: To require the Department of Homeland Security to develop a threat assessment on the potential homeland security vulnerabilities associated with genome modification and editing and for other purposes.

Other Federal Legislation Mentioning GMOs & Related Technologies

S.RES.275 — A resolution calling for international ethical standards in genome editing research.

Introduced: 2019-07-15

Sponsor: Sen. Feinstein, Dianne [D-CA]

Last Action: Referred to the Committee on Foreign Relations. (Sponsor introductory remarks on measure: CR S4824-4825)

Description: A resolution calling for international ethical standards in genome editing research.

S.3548 — CARES Act

Introduced: 2020-03-19

Sponsor: Sen. McConnell, Mitch [R-KY]

Last Action: Committee on Small Business and Entrepreneurship. Hearings held.

Description: A bill to provide emergency assistance and health care response for individuals, families, and businesses affected by the 2020 coronavirus pandemic.

H.R.8309 — Keep America Secure Act

Introduced: 2020-09-17

Sponsor: Rep. Rogers, Mike D. [R-AL-3]

Last Action: Referred to the Subcommittee on Economic Development, Public Buildings, and Emergency Management.

Description: To authorize certain authorities of the Department of Homeland Security, and for other purposes.

H.R.2 — Moving Forward Act

Introduced: 2020-06-11

Sponsor: Rep. DeFazio, Peter A. [D-OR-4]

Last Action: Received in the Senate.

Description: To authorize funds for Federal-aid highways, highway safety programs, and transit programs, and for other purposes.

S.1790 — National Defense Authorization Act for Fiscal Year 2020

Introduced: 2019-06-11

Sponsor: Sen. Inhofe, James M. [R-OK]

Last Action: Became Public Law No: 116-92.

Description:

H.R.6395 — National Defense Authorization Act for Fiscal Year 2021

Introduced: 2020-03-26

Sponsor: Rep. Smith, Adam [D-WA-9]

Last Action: Presented to President.

Description: To authorize appropriations for fiscal year 2021 for military activities of the Department of Defense and for military construction, to prescribe military personnel strengths for such fiscal year, and for other purposes.

H.R.269/S.1379 — Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019

Introduced: 2019-01-08 / 2019-05-08

Sponsor: Rep. Eshoo, Anna G. [D-CA-18]; Sen. Burr, Richard [R-NC]

Last Action: Became Public Law No: 116-22.

Description: A bill to reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

H.R.5685 — Securing American Leadership in Science and Technology Act of 2020

Introduced: 2020-01-28

Sponsor: Rep. Lucas, Frank D. [R-OK-3]

Last Action: Referred to the Subcommittee on Courts, Intellectual Property, and the Internet.

Description: To invest in basic scientific research and support technology innovation for the economic and national security of the United States, and for other purposes.

State

Selected State Bills Addressing Genetically Modified Organisms

State	Bill No	Title	Summary
Hawaii	H 687	Pesticide Use	Authorizes counties to regulate genetically engineered organisms and pesticide use to the extent that the regulations are more stringent than state or federal laws.
Hawaii	H 1391	Genetic Engineering	Mandates the Department of Agriculture to take precautionary measures to anticipate, prevent, or minimize the adverse effects of biotechnology and genetic engineering.
Hawaii	S 610	Pesticide Rules and Ordinances	Expressly pre-empts counties from enacting, adopting, or enforcing ordinances or rules relating to GMOs. Expressly pre-empts counties or other political subdivisions from enacting, adopting, or enforcing ordinances or rules relating to pesticides.
Hawaii	S 2574	Genetically Modified Organism Risk Disclosure	A biotech company that sells any genetically modified animal, genetically modified plant, or genetically modified seed that the biotechnology company knows, or has reason to believe, will be used to produce an agricultural commodity shall provide written notice to the purchaser that fully and clearly discloses the possible legal and environmental risks that the use of the genetically modified animal, genetically modified plant or genetically modified seed may pose to the purchaser.
Missouri	HCR 79	Restricted Use of Modern Agricultural Technologies	Opposes legislative or regulatory actions that are not based on sound science that may restrict modern agricultural technologies.
New York	A 298	Damages for Violation of Patent	Affirmative defense for violation of patent for GMOs protecting farmers against accidental planting of GMO seeds.
New York	A 652	Genetically Modified Organism Registry	An act to amend the agriculture and markets law in relation to establishing a genetically modified organism registry
New York	A 3407	Study of Genetically Modified Organisms	Requires a study of genetically modified organisms and cross pollination, the impact on wildlife, and the effect on human consumption. Requires reporting and recommendations by department of agriculture and markets, DEC, and department of health.

Most Recent Relevant State Legislation

New York - A732/S6502

A bill to amend the environmental conservation law to prohibit the use of glyphosate on state property was recently passed in New York.

Sponsors: Linda B. Rosenthal (Assembly); Jose M. Serrano (Senate)

Co-Sponsors: Jo Anne Simon, Thomas Abinanti, David Weprin, Charles Barron, Harvey Epstein, Rebecca Seawright, Deborah Glick, Anthony D'Urso, William Colton, Karines Reyes, Felix Ortiz, Judy Griffin, Fred Thiele, Richard Gottfried, Monica P. Wallace, Robert J. Rodriguez, Phil Steck, Charles Fall, Steven Otis, Barbara Lifton, Sandy Galef (Assembly)

Alessandra Biaggi, David Carlucci, Brad Hoylman, Anna M. Kaplan, John C. Liu (Senate)

All sponsors and co-sponsors were Democrats.

Senate Votes: Environmental Conservation Committee Vote: Jul 20, 2020: 8(yes, 6D+2R) – 1(no, R) – 2(yes with reservations, 1D+1R)

Rules Committee Vote: Jul. 21, 2020: 12(yes, 12D) – 6(no, 6R) – 1(yes WR, R)

Finance Committee Vote: Jul 21, 2020: 16(yes, 16D) – 6(no, 6R) – 1(yes WR, R)

Senate Vote: Jul 22, 2020: 45 (yes, 39D+6R) – 15(no, 15R)

This bill was passed by the Democratic majority in both Senate and the Assembly. This was the third version of this bill: two previous bills failed in 2015 and 2017, when there was a Republican majority and split majority in the Senate, respectively. This suggests that Republican members of the NY state legislature are likely to oppose any regulatory framework for GMOs.

Other State Legislation Mentioning GMOs & Related Technologies

Vermont

S 160 - An act relating to agricultural development.

Introduced: 2019-03-19

Last Action: Signed by Governor on June 20, 2019

Description: An act relating to agricultural development

S 55 - An act relating to the regulation of toxic substances and hazardous materials.

Introduced: 2019-01-25

Last Action: Signed by Governor on June 19, 2019

Description: An act relating to the regulation of toxic substances and hazardous materials

H 525 - An act relating to miscellaneous agricultural subjects.

Introduced: 2019-03-19

Last Action: Governor approved bill on June 17, 2019.

Description: An act relating to miscellaneous agricultural subjects

New York

A 3878 - Requires persons who sell or distribute genetically engineered plants, planting stock or seeds to provide written instructions to purchasers or growers of such stock.

Introduced: 2019-01-31

Last Action: referred to agriculture.

Description: Requires persons who sell or distribute genetically engineered plants, planting stock or seeds to provide written instructions to purchasers or growers of such stock.

A 4595 - Relates to requiring genetically modified salmon that is sold or offered for sale be labeled.

Introduced: 2019-02-04

Last Action: referred to consumer affairs and protection.

Description: Relates to requiring genetically modified salmon that is sold or offered for sale be labeled.

A 4688 - Relates to prohibiting the sale of live genetically modified salmon.

Introduced: 2019-02-05

Last Action: referred to environmental conservation.

Description: Relates to prohibiting the sale of live genetically modified salmon.

A 5002 - Relates to requiring clear and conspicuous labeling of all consumable commodities, including infant formula.

Introduced: 2019-02-06

Last Action: enacting clause stricken.

Description: Relates to requiring clear and conspicuous labeling of all consumable commodities, including infant formula.

A 6028 - Creates a task force to monitor and report on the effects of the use of genetically modified organisms in the food supply.

Introduced: 2019-02-26

Last Action: enacting clause stricken.

Description: Creates a task force to monitor and report on the effects of the use of genetically modified organisms in the food supply.

S 2473 - Provides for the labeling of food or food products that contain a genetically engineered material or that are produced with a genetically engineered material; defines terms; imposes penalties for false labels and misbranding; sets forth exemptions.

Introduced: 2019-01-25

Last Action: Referred to Consumer Protection.

Description: Provides for the labeling of food or food products that contain a genetically engineered material or that are produced with a genetically engineered material; defines terms; imposes penalties for false labels and misbranding; sets forth exemptions.

Hawaii

H.B. 1923/ SB 2374

Introduced: 2020-01-17

Last Action: Referred to AEN/CPH, JDC.

Description: Prohibits certain food labeling practices concerning foods with non-genetically-modified-organisms, organic foods, and gluten-free foods.

Appendix B

European GMO Legislation

Directive 2001/18/E.C. (OJ L106 of 17.04.2001) on the "deliberate release of GMOs into the environment" regulates the release of GMOs into the environment, either for experimental (field trials) or for commercial purpose (placing on the market). This directive defines a standard EU procedure for allowing deliberate GMO release into the environment.

Directive 2015/412 amended Directive 2001/18/E.C. is allowing the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory once they have been authorized at the EU level.

Key provisions of directive 2001/18/E.C:

- The EU definition of a GMO (see article 2): a genetically modified organism (GMO) means an organism, except for human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.
- Common methodology and principles for environmental risk assessment (see Annex II) before any GMO release into the environment.
- Mandatory labeling and traceability of GMOs at all stages of the placing on the market
- Mandatory post-market monitoring requirements, including on long-term effects associated with the interaction with other GMOs and the environment.
- Approvals for the release of GMOs to be limited to a maximum of ten years (renewable)
- Mandatory information to the public, including public registers for recording information on the deliberate release of GMOs into the environment.

To obtain authorization for experimental release of G.M.O., the applicant (called "the notifier") must submit an application (called "the notification") containing the particulars set out in part B of Directive 2001/18/E.C. (see Article 6). These particulars must include an evaluation of the environmental risks which the notifier has carried out.

The decision to authorize (or reject) the release of the GMO is exclusively incumbent on the competent national authority which has received the notification. Hence the authorization procedure for experimental release is a purely national one. This corresponds to a feature of the authorization of release for experimental purposes. The

Table 4: GMO Authorizations Involving Non-Medical & Non-Industrial Use of Microbes In The EU. Since 2003

Notification Number	Member State	Publication (d/m/y)	Institute or Company	Project title
B/NL/07/03	Netherlands	7/6/2007	Kiwa Water Research	A field test with sensor-based on genetically modified bacteria which can detect toxic compounds in water
B/GB/04/R39/1	United Kingdom	19/03/2004	Natural Environment Research Council (UK.)	Strategies for risk assessment, evaluating the environmental impact of fungal diseases suppressing GM bacteria on non-target species
B/ES/14/07	Spain	15/12/2014	Instituto Valenciano de Investigaciones Agrarias (IVIA)	Reduction of the period for citrus flowering by the use of a viral vector based on Citrus leaf blotch virus

authorization to proceed with this release applies only in the Member State in which the notification has been submitted. In the event of authorization, the notifier may release the GMO in compliance with the conditions set out in this authorization.

The authorization procedure for placing a GMO on the market is not a national one but is the one involving all EU Member States. This is because the authorization for placing a GMO on the market implies its free movement throughout the European Union territory. It includes both the national and the EU level safety assessment – the EU is in the form of the European Food Safety Authority (EFSA).

EU Official GMO Links

Full lists of GMOs approved by the EU:

Experimental

Plants:
https://gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx

Non-Plant:
https://gmoinfo.jrc.ec.europa.eu/gmo_browse.aspx

Stats:
https://gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx

Commercial:
https://gmoinfo.jrc.ec.europa.eu/gmc_browse.aspx

National Registries:
https://gmoinfo.jrc.ec.europa.eu/links_ms.aspx

Reference: Plan, D. and Van den Eede, G., 2010. The EU legislation on GMOs. JRC Scientific and Technical Reports, EUR, 24279. Available at: https://core.ac.uk/download/pdf/38627562.pdf