REGULATORY FOCUS

Genetically Engineered Foods and their Regulation: the Way Forward after Twenty Years of Adoption

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This article reviews the US history and impact of Genetically Engineered (GE) crops over two decades, explains the federal oversight of GE crops and suggests improvements to federal oversight to ensure the safety of GE crops and greater consumer confidence in GE foods. The article also discusses public attitudes toward GE foods and the issues surrounding the labeling of those foods, including the law requiring mandatory disclosure signed by President Obama on 29 July 2016.

Twenty years ago, the first farmers planted Genetically Engineered (GE) soybeans that were tolerant to the herbicide "glyphosate." Currently, there are 10 crops with GE varieties grown on millions of acres in the US. Although a strong body of evidence documents no significant human health or environmental harms related to GE crops or food products, controversy surrounding those crops and the foods and ingredients made from those crops, has not subsided and is arguably more vocal than ever.

At the same time, the federal regulatory system overseeing GE crop safety has remained nearly unchanged during those 20 years. As the next generation of GE crops emerges, it is time to revisit and update the regulatory system to both reflect current science and provide consumers with confidence that GE crops are safe.

Background on GE Crops

To develop a GE crop variety, scientists generally remove a gene from one organism (or a specific variety of an organism) and transfer that gene to a different organism (or different variety) using recombinant DNA methods. Those methods allow scientists to cut DNA and insert foreign DNA at the cellular level. The new gene becomes integrated into every cell of the organism and is inherited by the modified organism's offspring. In most cases, the

new gene produces a new protein providing the organism with a useful trait the organism would not otherwise have.{1}

Most commercially grown GE crops in the US contain introduced genes providing either resistance to pests or tolerance to herbicides.{2} For example, GE corn and cotton contain genes from the soil bacterium *Bacillus thuringiensis* (Bt). The proteins produced by the Bt genes kill selected insect pests when ingested, eliminating the need to spray chemical pesticides. Scientists have long been aware of the pesticidal aspects of Bt because organic farmers have for decades used Bt microbial sprays as an environmentally-friendly insecticide to prevent pest damage.{3}

GE soybeans, corn, canola, sugar beets, cotton and alfalfa contain one of several genes to protect them from particular herbicides. Those genes allow certain herbicides to be applied to the crop without harming it, giving farmers more flexibility using herbicides to control weeds, such as treating a field after the crop has emerged, not just before. The most common herbicide-tolerant seeds protect crops from the herbicide glyphosate, commercially named "Roundup."® Farmers also plant herbicide-tolerant seeds tolerant to the herbicides glufosinate and 2,4 D.

Other commercially grown GE crops include varieties of squash and papaya engineered with plant virus genes that render those crops virus-resistant. Farmers also can grow GE potatoes that are non-bruising and low in the probable carcinogen acrylamide as well as GE apples that are non-browning. Additionally, farmers can plant GE corn that is drought-tolerant and also GE soybeans producing oils with a healthier fatty acid profile.{4}

According to the US Department of Agriculture, total GE crop acreage in the US in 2015 was approximately 175 million acres. Approximately 92 percent of all field corn (mostly used for cattle feed and ethanol production), 94 percent of all soybeans and 94 percent of all cotton grown in the US are GE seed varieties with one to as many as seven different genes.{5} Other engineered crops—alfalfa, sugar beets, canola, squash, papaya, apples and potatoes—are grown on smaller acreage.

Outside the US, GE crops are grown in 28 countries by more than 18 million farmers on 444 million acres. The largest adopters outside the US include Brazil, Argentina, India, Canada and China. GE crops are grown by small-scale farmers in countries such as China, India, Burkina Faso and the Sudan.{6}

The benefits from GE crops tend to be crop specific and depend both on the environment in which the crop is grown and the surrounding agricultural system. For example, the use of Bt cotton in the US has substantially reduced the use of broad-spectrum and highly-poisonous chemical insecticides.{7} Similar benefits have been documented when Bt cotton has been used in China, India and other countries. In those countries, some farmers were able to reduce their pesticide use while other farmers not using pesticides obtained higher yields. Farmers in China also have significantly fewer hospitalizations because they avoid poisonings from applying chemical pesticides.{8} In short, many small-scale developing country farmers, who typically have tiny plots, experience greater yields, lower costs, fewer illnesses and higher incomes with reduced harm to insects, birds and other species when growing GE crops.

Herbicide-tolerant crops, such as soybeans, corn, cotton, canola and sugar beets, have simplified farming by reducing the effort and time needed to battle weeds. Farmers who plant herbicide-tolerant soybeans save time on their farms, allowing them to increase overall household income through a second job; however, their farm income may not increase because they pay a premium for GE seeds. The use of herbicide-tolerant crops has contributed to farmer's adopting 'conservation tillage,' which conserves the top layer of soil by reducing the frequency of tillage. However, the total amount of herbicide use has not decreased because so many acres of farmland now are sprayed with glyphosate.{9}

The use of Bt corn in the US also has resulted in a significant reduction in the amount of chemical insecticides used by non-GE farmers.{10} Scientific studies have shown farmers growing Bt corn reduce the total insect population on their farms and also on the farms of neighbors who do not grow GE corn. Although they didn't purchase or plant the Bt corn, those farmers experience less damage to their crops, reduce their use of insecticides and obtain higher yields.{11}

Finally, GE papaya grown in Hawaii protected most, if not all, of the Hawaiian papaya trees from becoming infected by the papaya ringspot virus. Without the virus-resistance trait, the trees would no longer produce commercially-viable fruit.

Scientific evidence that current GE crops and the foods and ingredients made from those crops are safe for human consumption is substantial. For example, a recent National Academy of Science report thoroughly reviewed all available evidence on GE crop safety and concluded "no differences have been found that implicate a higher risk to human health safety, from these GE foods than from their non-GE counterparts."{12} The same conclusion has been reached by other scientific bodies, including the European Commission and the World Health Organization.{13,14} It should be noted while humans eat some GE crops whole, such as papaya, sweet corn and squash, the vast majority of GE crops enter the US food supply as highly-processed ingredients, such as oils or high-fructose corn syrup. When those ingredients are made, all of the crop's DNA (including the new foreign DNA) and all proteins (including those synthesized from the foreign DNA) are eliminated, making the ingredient biologically and chemically identical to that produced from a non-GE crop.{15}

Despite their benefits, current GE crops also have had negative impacts. Overuse and misuse of glyphosate-tolerant crops with their corresponding herbicide by farmers—such as the reliance of the same herbicide year after year in the same field—has resulted in the development of 14 unique glyphosate-tolerant weed species found on millions of acres of US farmland.{16,17} Farmers with glyphosate-tolerant weeds in their fields must spray additional herbicides, thereby reducing the benefits of the GE crop. Similarly, improper use of some Bt corn varieties killing below-ground corn rootworm pests has resulted in the development of resistant corn rootworm populations.{18} These impacts, which decrease the benefit of growing a GE crop, will continue unless GE crop developers and farmers use GE crops in a more sustainable manner. For those seeds to remain effective for future farmers, today's farmers need to use GE seeds along with integrated weed and pest management practices.

There also have been some significant negative economic impacts from GE crops. For example, when Starlink corn, which was only approved for feed purposes, was found in food products, it led to food product recalls in the US and significant trading losses.{19} More recently, an unapproved variety of GE corn was found in grains to be imported into China. The ships containing the unapproved grain were turned away, at a significant cost to the grain company.{20} Another example is the recent documentation of the inadvertent presence of the GE varieties in crops for the non-GE market, causing economic losses to farmers.{21}

Consumer Perceptions and Misconceptions of GE Crops and Foods

Whether reading newspapers or browsing the Internet, it is easy to get the false impression that most consumers know a lot about GE crops and foods. Over the past several years a number of organizations have released polling data showing consumers overwhelmingly support mandatory labeling of all foods containing an ingredient that came from a GE crop.{22,23,24} However, a more detailed review of the survey data available suggests at least half, if not most, American consumers know little about GE foods and as a result, their opinions are not consistent with scientific evidence on safety of those crops.

In a 2013 poll by Rutgers University, half of the nationally representative sample stated they had heard "very little" or "nothing at all" about GE foods. Similarly, two-thirds of them had never had a conversation about GE foods with anyone else.{25} A more recent Harris poll, conducted in May, 2016, obtained similar results when it asked the nationally representative sample, "how familiar are you with the debate around genetically modified organisms in food?" A little more than half of respondents considered themselves to be "very familiar" or "somewhat familiar," while just under half considered themselves to be "not very familiar" or "not familiar at all."{26}

In 2015, a poll conducted by the University of Florida found 84 percent of a nationally representative sample supported mandatory labeling of foods containing GE ingredients. However, they also found 80 percent of consumers supported labeling of foods containing DNA, which is found in all living organisms.{27} Similar results emerged from a poll conducted by Oklahoma State in early 2015.{28} If the same percentage of consumers want

GE foods and DNA labeled, the results may say more about what consumers know about biology than about what they understand about GE foods.

It is not surprising recent surveys also find the public's view on GE food safety is significantly different than that of scientists and the overwhelming weight of scientific evidence. The Pew Research Center and the American Association for the Advancement of Science conducted a survey in 2014 of scientists and the public on a number of science-related issues. They found that 88 percent of scientists believe it is safe to eat GE foods, while only 37 percent of the public feels that way. This 51 percent difference was greater than the views between scientists and the public on whether climate change is caused by humans (a 37 percent gap) and whether it is safe to eat foods grown with pesticides (a 40 percent gap).{29} The general belief that GE foods are not safe is confirmed by a 2016 Harris poll which found 81 percent of those sampled thought GMO labeling is "a health and safety issue."{30} A recently published study found most of the people in the US who are strongly opposed to GE food are actually "disgusted" by those foods and their opinion cannot be swayed by any scientific evidence on safety.{31}

These results reflect that despite the recent national debate over the labeling of GE foods, at least half of the public knows little about genetic engineering. In addition, those who have some knowledge about GE foods seem more likely to believe they are not safe and oppose them, despite the scientific evidence supporting the safety of GE foods.

The Federal Regulatory System for GE Crops

The federal regulatory system for GE organisms was established in 1986 in the "Coordinated Framework for the Regulation of Biotechnology."{32} That policy focused on three existing agencies—the US Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). According to policy, all three agencies would use existing laws to regulate GE organisms. Further, the policies stated oversight would be based on the final product, not the process by which the product was developed.

USDA regulates the import, interstate movement, transport and environmental release of GE crops through regulations issued under the *Plant Protection Act*. Under those regulations, regulated GE crops must submit to one of three oversight processes before release into the environment.

The first process, known as "notification," is used if the GE crop meets eligibility criteria and the field trial meets established containment standards. The applicant provides USDA with a notification detailing the release and USDA has 30 days to respond. As many as 1,000 field trials are authorized each year using this procedure.

The second process is called "permitting." It requires a more detailed application and a longer review time at USDA before the release is authorized. Permitting is not as common as the notification although hundreds of permits have been issued since USDA began regulating GE crops. The third process is a called a "petition for non-regulated status," where a developer requests that USDA determine there is no plant pest risk and the crop no longer needs regulation. The petition process is the primary path to commercialization and more than 150 crops have been deregulated.{33}

EPA regulates GE crops that have been engineered to express a pesticide, called Plant Incorporated Protectants (PIPs) under the *Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)*. All pesticides, including PIPs, must be registered under FIFRA, which requires EPA to determine the PIP will not cause "unreasonable adverse effects on the environment" and it does not have any food-safety concerns for any edible portions.{34} So far, EPA has registered at least 85 PIPs.{35}

To ensure food safety, FDA regulates food under the *Federal Food, Drug and Cosmetic Act (FFDCA)*, which requires pre-market approval only for "food additives." FDA determined in 1992 that adding DNA into crops and its resulting product are

not "food additives" and they do not require mandatory pre-market approval.{36} FDA set up a voluntary consultation process by which GE crop developers can share food safety data with FDA so the agency can identify any deficiencies. To date, approximately 150 GE crops have completed the FDA voluntary consultation process.{37}

Under the US regulatory system discussed above, the number of agencies with oversight for a particular GE product depends on the crop, the introduced trait and the purpose of the product (e.g., to act as a pesticide). A corn plant that expresses a pesticidal protein is regulated by all three agencies—by FDA because it is a food crop; by EPA because it produces a pesticide; and by USDA because it could be a potential "plant pest." An herbicide-tolerant corn would be regulated by USDA and FDA, whereas an herbicide-tolerant bentgrass would only be regulated by USDA.

Deficiencies in the Regulation of GE Crops and Proposed Solutions

With more than 20 years of experience regulating GE crops, the federal regulatory system is overdue for an overhaul. On 2 July 2015, the Office of Science and Technology Policy (OSTP) announced it was reviewing the "Coordinated Framework" policy to (1) clarify the roles and responsibilities of the different agencies; (2) adopt a mechanism to regularly review and update the Coordinated Framework going forward and (3) develop a long-term strategy to ensure the regulatory system can address the risks, if any, associated with future products.{38} USDA also announced on 5 February 2016 the department would review and revise its regulation of GE crops by adding new legal authorities and reducing the number of GE crops considered "plant pests."{39} While both processes are ongoing and should be supported, they may not address the different deficiencies in the current regulation of GE crops.

A Mandatory Pre-Market Approval Process at FDA is Necessary to Ensure Safety and Provide Consumer Confidence

In the FDA voluntary process, a GE crop developer submits a summary of data showing the GE crop is substantially equivalent to its traditionally bred counterpart and does not pose any novel food risk. FDA reviews the data and alerts the developer to any concerns regarding the developer's food safety assessment. FDA concludes the process with a letter stating it has "no further questions about the safety of the GE crop," but it does not render an opinion on whether the GE crop is safe to eat.

The FFDCA puts the burden on FDA to find a GE crop potentially unsafe before it can stop its introduction into the food supply. In contrast, every other country with a functional regulatory system for GE crops requires a government food-safety approval before a GE crop is marketed. In the US, GE crops need formal approval to be planted outdoors (see below), but no formal approval to enter the food supply. This policy was not established because GE crops are more dangerous to the environment than they are to eat; rather, it is a result of trying to fit products made using a new technology into an old regulatory scheme not designed for engineered crops.

Before any GE crop is made into a food product, FDA should have to formally determine its safety for human and animal consumption. Congress should amend the FFDCA to require a mandatory pre-market approval process open to public participation and review. Formal approval of GE crops might lengthen the approval process, but approval also would result in greater assurance of safety and provide greater public confidence in the safety of these widely-consumed crops. Improving public confidence in the safety of GE crops and ingredients made from them is essential, especially since the survey data noted in this article documents how many consumers do not think GE foods are safe to eat.

In 2004, Senator Richard Durbin (D–Illinois) introduced legislation giving FDA such authority (S. 2654), but Congress did not act on that proposed legislation.{40} More recently, Congressman Pompeo (R–Kansas) introduced legislation requiring GE seed developers to go through the consultation process, but would not impose a requirement that FDA give its opinion on the GE crop's safety.{41}

When that bill passed the House of Representatives on 23 July 2015, it was amended to require developers complete the FDA consultation process because USDA would need the FDA consultation letter before it could authorize the GE crop to be grown commercially. If that bill became law, it would have been a small step in the right direction, but the preferable option is to give FDA mandatory approval authority.

USDA Needs to Establish Science-Based Regulations Addressing the Real Potential Impacts of Growing GE Crops

USDA's regulatory system for GE plants is based on the definition of a "plant pest" in the *Plant Protection Act.* GE plants subject to USDA oversight include (1) any crop that is a listed plant pest and (2) any crop introducing DNA from a listed plant pest or an organism whose plant pest status is undetermined.{42} For example, the regulations capture any GE crop using agrobacterium DNA as part of the transformation process to insert a new gene into a plant. The regulations do not include crops engineered using a gene gun, unless the inserted DNA comes from a listed plant pest or an organism where the plant's pest status is undetermined.

Until the last few years, every GE plant tested outdoors went through the notification or permitting requirements. In addition, every GE plant that became a commercial product completed the petition process where USDA determined that the GE crop was no longer be regulated. However, beginning in 2011, USDA started receiving inquiries from GE seed developers about whether GE crops that did not have plant pest components in the introduced DNA or used agrobacterium to transform the plants were regulated. USDA has responded to those inquiries, stating that those GE crops are not regulated and can be released into the environment without oversight. As of early 2016, USDA found numerous crops—some of which contain newly introduced DNA without any plant pest components and others developed with new gene-editing techniques—were not within its statutory authority and therefore, do not need to comply with the regulations.{43}

USDA's recent decisions have resulted in some GE crops not being regulated. Those determinations have not been science- or risk-based decisions where potentially risky GE crops are regulated and GE crops without any potential risks are not regulated. Instead, USDA made those decisions based solely on whether any "plant pest" components are part of the engineering process. For example, one seed developer could introduce an herbicide-tolerance gene into corn using agrobacterium that would be regulated, yet introducing the same gene using the gene gun would not be regulated. If those regulatory decisions continue, developers may intentionally seek to avoid regulation, resulting in the introduction of potentially risky GE-crops into the environment. The public will, as a result, lose confidence in both the USDA's oversight and the environmental and agricultural safety of GE crops because the regulatory process is not science-based.

USDA needs to establish a regulatory system based on whether a GE crop has potential risk, not based on whether it falls within the narrow definition of a "plant pest." This recommendation was made in a recent General Accounting Office report looking at USDA oversight of GE crops and found it has exempted GE crops in the last few years.{44} USDA announced a proposal in early 2016 to revise its regulations by adding its authority under the "noxious weed" provisions of the *Plant Protection Act* and by narrowing their interpretation of a "plant pest." However, that proposal is not likely to capture more GE crops and could possibly exempt the vast majority of GE crops in the future.{45} Therefore, if USDA is unable to conduct science-based regulation of GE crops under its current law, Congress should pass legislation to require it.

USDA's narrowly focused oversight of GE crops as potential "plant pests" also does not adequately address some of the agricultural impacts of GE crops. Every time USDA has received a petition for non-regulated status, it has been granted because no GE crop has exhibited plant pest characteristics. USDA and GE crop developers spend significant resources proving what is obvious—that using agrobacterium to introduce a gene or using a small amount of DNA from a known plant pest does not result in the GE crop becoming a plant pest. At the same time, farmers' use of herbicide-tolerant GE crops have led to the development of resistant weeds and GE crops producing a biological pesticide have led to resistant pest populations. Both of these agricultural impacts were predicted before USDA

granted those crops non-regulated status, but USDA could not address those risks in its regulation of those crops because of its narrow authority under the *Plant Protection Act.*

A better and more efficient USDA regulatory system would spend little or no time on insignificant risks (such as becoming a plant pest) and concentrate oversight on properly managing and reducing likely impacts from using GE crops, such as weed and pest resistance. If USDA cannot manage environmental and agricultural impacts of GE crops using existing laws, it should request Congress to establish legal authority to carry out reasonable oversight to manage such potential impacts.

EPA Needs to use its Oversight of GE Crops and Conventional Pesticides to Prevent the Development of Resistant Pests and Weeds

EPA does a reasonably good job ensuring pesticide-producing plants are safe before they are grown. It conducts a thorough environmental assessment of each PIP before it is allowed to be used commercially. EPA's decisions to register pesticide-producing plants are often time-limited, so EPA can revise or revoke the registration if new information becomes available. However, EPA should improve its oversight of engineered Bt crops after they are commercialized to prevent or delay the development of resistant pests.

When EPA registers Bt corn varieties, the agency imposes obligations on farmers who plant those crops that will delay the development of resistant pests, which harm the technology's effectiveness. The seed developers are required to enter into a contract with the farmer requiring the farmer to plant a portion of their farms with non-Bt varieties; this area serves as a "refuge" for pests not resistant to the Bt pesticide. EPA instituted those requirements because it has a responsibility to preserve the Bt technology, which is a relatively benign and highly-effective biological pesticide, for future farmers.{46}

In the years after the requirement for refuges was made mandatory in 2001, the percentage of noncompliant farmers has varied from 20 percent to 35 percent or more. {47,48} As Bt corn was adopted by additional farmers, including many who planted corn in the same field over successive years, corn rootworms resistant to one or more of the Bt toxins have developed.{49} To limit the spread of resistant insect populations and to preserve other Bt toxins still effective at killing either corn rootworms or corn borers, EPA needs to impose additional requirements on Bt corn seed developers and the farmers who grow Bt corn. Additional requirements should include, but not be limited to, not allowing the use of soil insecticides with Bt corn, requiring farmers to use corn with two different Bt toxins effective on the same pest, requiring developers to establish remediation plans in advance of resistance developing, and requiring farmers to rotate between different Bt toxin varieties in their corn fields.{50,51} An EPA Office of Inspector General report also identified a number of actions that EPA should use to prevent the development of resistant pests.{52} Therefore, EPA should use its legal authority broadly to make the use of Bt corn not only safe but sustainable.

While EPA does not regulate herbicide-tolerant GE crops, it does regulate the use of the herbicides with those seeds. When EPA modified the registration of glyphosate for use with glyphosate-tolerant corn, soybeans, cotton, sugar beets and other engineered crops, it did not impose any weed-resistance management requirements. Overuse of glyphosate on glyphosate-tolerant crops has resulted in the development of 14 glyphosate-resistant weed species on millions of acres of farmland.{53} More recently, EPA began requiring weed resistance management as a requirement of its registration of other pesticides, such as 2,4, D and Dicamba, when used with GE crops. The requirements include directing farmers to alert developers of resistant weeds as well as requiring farmers and seed developers to carry out remediation to prevent their spread. Farmers also need to carry out resistant-weed management and seed developers need to develop resistant-weed management plans.{54,55} Those requirements are a good first step, but EPA needs to be vigilant and modify herbicide registrations with additional weed management conditions if resistant weeds develop.

Labeling Foods with Ingredients from GE Crops

Over the past several years, mandatory labeling of foods and ingredients from GE crops has become a very contentious issue. Four states have voted on ballot initiatives involving mandatory labeling—California in 2012, Washington in 2013, Oregon in 2014 and

Colorado in 2014. All have been defeated by small margins except in Colorado where it was defeated by a large margin. Vermont enacted a mandatory law in 2014, which became effective 1 July 2016. In response to the Vermont law, a number of food companies have announced plans to label all their food products nationwide.

Congress also has addressed the issues surrounding labeling of GE foods. Congressman Pompeo introduced legislation in 2015 to initiate federal oversight of voluntary labeling of foods that contain—or do not contain—GE foods. The legislation aimed at codifying current FDA labeling policy, which states GE foods only need to be labeled if they are "materially" different from their conventional counterpart. The legislation would preempt Vermont's (and any other states) mandatory labeling law. The legislation, HR 1599, was approved on 23 July 2015 by a vote of 275 to 150.{56}

In early 2016, Senator Pat Roberts (R–Kansas) introduced S. 2609, which established a voluntary labeling system.{57} It was approved by the Senate Agriculture Committee, but failed to pass the Senate vote on cloture, needing 60 votes to pass. At the end of June, a compromise bill (S. 764) was introduced by Senators Roberts and Debbie Stabenow (D–Michigan). That bill gives authority to the Secretary of Agriculture to promulgate regulations that establish a nationwide mandatory disclosure system for food manufacturers to provide information to consumers about whether a food or an ingredient in a processed food came from a GE crop. Those regulations, which are to be completed within two years of enactment of the law, must provide the food manufacturer with three options for the disclosure: (1) text on the food package; (2) a symbol on the food package designed by USDA or (3) a digital link from the package, such as a QR code. It also preempts the Vermont law and any other state labeling laws. That bill was passed by the Senate on 7 July by a vote of 63-30 and passed the House on 14 July by a vote of 306-117. It became law when President Obama signed it on 29 July 2016.

As USDA implements the new mandatory disclosure law, there are several issues to keep in mind about providing consumers with information about GE content as well as identifying foods without any GE content. First, any disclosure must be neutral, accurate and not misleading. Such a system will require definitions of what is genetic engineering, what is or is not a genetically engineered ingredient or food and how the disclosed information (for both GE and non-GE labeling) can be stated in a factual manner without suggesting the food is not as safe as its non-GE counterpart, nor is it superior to its counterpart. Second, a decision will be needed about whether ingredients derived from a GE crop, but have none of the introduced DNA or its molecular product, will be considered a GE food or a non-GE food. Many food ingredients made from GE crops, such as sugar, high-fructose corn syrup, corn oil, soybean oil and canola oil are biologically and chemically identical to ingredients made from non-GE crops. Labeling the thousands of foods with those ingredients as "GE" could be considered false and misleading. Third, a decision will be needed about how to disclose information about a processed food product where only a minor ingredient came from a GE crop. For example, would a frozen pizza have to be disclosed as "GE" even if the only ingredient that came from a GE crop was a tiny amount of maltodextrin (made from cornstarch), not the tomato, cheese, wheat or other major ingredient? Finally, a national definition of what constitutes a non-GE food is needed so consumers who want to purchase those foods know what that label claim means. Today, many products are labeled non-GE without explaining to the consumer what that term means.

As the labeling debate moves into a stage where the details need to be determined in regulations the parties on both sides of the debate will need to get beyond the rhetoric and dive into the nuances. Determining the details will help ensure USDA establishes an accurate, neutral and informative system of disclosing information about foods with and without GE ingredients.

Conclusion

After more than 20 years of experience growing GE crops, those crops have had significant benefits, but also some negative impacts. Food and ingredients from those crops are safe to eat, even if consumers may not be aware of the data supporting their safety or believe otherwise. However, the federal regulatory system for GE crops is less than ideal. It over-regulates some crops and under-regulates others and does not generate consumer confidence in GE crop safety.

Now is the time for the federal government to review and revise its oversight. For some agencies, Congressional action may be necessary, such as providing mandatory approval authority to FDA. In other instances, an agency needs to establish stronger risk management conditions, such as EPA's oversight of PIPs. With implementation of the proposed changes set forth in this article, the public can be reassured the federal government has the tools needed to ensure the safety of GE crops and also develop a regulatory system to support the sustainable use of GE crops now and into the future.

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