

FOR THE RECORD

Concerns about Federal GMO Food Legislation

In their article “Mandatory Food Labeling for GMOs” (Winter 2014–2015), Thomas Hemphill and Syagnik Banerjee mentioned proposed federal legislation intended to circumvent differing state mandates on the labeling of foods containing genetically modified organisms (GMOs). The bill, H.R. 4432, is better known as the CFSAF bill or the Pompeo bill after its lead sponsor, Rep. Mike Pompeo (R-Kansas).

Pompeo and his co-sponsors have good intentions for the bill, trying to expand the use of genetic engineering. But we have serious concerns about the bill, as we explained in our recent *Forbes.com* op-ed, “A Faustian Bargain on Labeling Genetically Engineered Food” (Feb. 25, 2015). Here, we briefly summarize our concerns.

The bill is the product of lobbying by the Coalition for Safe Affordable Food (CFSAF), a group that represents food companies and farm organizations. The bill has four goals:

- Eliminate confusion and uncertainty from the prospects of a 50-state patchwork of safety and labeling laws for genetically engineered food, by affirming that the U.S. Food and Drug Administration is the definitive national authority.
- Require the FDA to conduct a safety review of all new genetically engineered traits before they are introduced into commerce.
- Direct the FDA to establish federal standards for companies that want to label their product voluntarily to indicate the absence or presence of food ingredients produced with molecular genetic engineering techniques.
- Direct the FDA to define the term “natural” for use on food and beverage products so that food and beverage companies and consumers have a consistent legal framework that will guide food labels and inform consumer choice.

FDA preemption / With respect to the first goal, we agree that Congress should explicitly preempt state and local GMO safety and labeling laws. Such laws are inherently misleading because they wrongly imply that genetically engineered ingredients belong to a “category” of substances that are less safe or nutritious than “natural” substances. The use of genetic engineering does not make the resulting food any less (or more) healthy or safe—unless the GMO was engineered to be so. As federal regulators have said repeatedly, labeling to identify food derived from plants modified with the newest techniques of genetic engineering would erroneously imply a meaningful difference where none exists.

In an ideal world, Congress could pass legislation to affirm that the FDA is the sole authority to require mandatory labeling and that, as the FDA announced in a 1992 policy statement, labeling is appropriate when it conveys “material” information that bears on safety or usage. As the FDA stated at the time, risk-related factors in the context of novel foods could include the presence of a completely new substance in the food supply, an increase in the level of a natural food toxin, significant changes in the level of a macronutrient, or the presence of a potent allergen where a consumer would not expect to encounter it.

GMO review / We disagree strongly with the creation of a new requirement that the FDA conduct a safety review of all new GMOs before they are introduced into commerce. Laboratory research on plants has been robust since the invention of molecular genetic engineering techniques in the early 1970s, but the commercialization of GMO products has been slowed by unscientific, excessive government regulation that discriminates against modern, molecular genetic engineering techniques. For a quarter-century,

genetically engineered crops have been the most scrutinized products in human history, yet there is no scientific justification for such a burden. GMOs are far more precisely and predictably crafted than their “natural” predecessors, and none has caused documented harm to a person or disruption to an ecosystem.

Hundreds of risk-assessment experiments as well as innumerable observations of “real-world use” have confirmed the safety of genetic modification technology. In spite of this vast amount of evidence, there has been no reduction or rationalization of the regulatory burden placed on plants made by the newer techniques of genetic engineering. In many cases, regulatory stringency and burdens are actually increasing, sometimes in the naive hope that this will reassure skeptics.

This provision of the legislation would represent yet another escalation of regulation without any justification for it—except perhaps as a bargaining chip for the creation of explicit prohibitions against state and local regulation. That is not a sufficient justification.

At present, the FDA operates a voluntary consultation program for genetically engineered foods whereby the developer provides the agency various information about the product. Published reports indicate that developers have, without exception, submitted to this voluntary consultation and it appears to be more than adequate to protect American consumers.

There is a broad consensus that there is no scientific reason to regard food made with modern molecular techniques as different from other food. Corn modified to be pest-, disease-, or herbicide-resistant is still corn regardless of the breeding method used to introduce or enhance the trait. Therefore, even the “voluntary” consultation—which no food producer would dare to flout—is gratuitous and excessive. Virtually identical foods made with older, less precise, and less predictable techniques are not routinely subject to review, voluntary or otherwise.

Another concern is that a required FDA review and approval of new genetically engi-

neered foods would constitute a “major federal action” that would trigger FDA procedural obligations under the National Environmental Policy Act. In the past, activists acting in bad faith have frequently delayed approvals by bringing numerous nuisance lawsuits that claimed purely procedural deficiencies under the act.

Another concern we have about this goal is that it would add to the gratuitous delays in FDA review of applications. For example, under its authority to regulate “veterinary drugs,” the FDA floundered for more than 15 years in reviewing the AquAdvantage genetically engineered, fast-growing salmon. (See “The Use and Abuse of Science in Policymaking,” Summer 2012.) As the application neared the finish line, for political reasons the approval was hijacked by the Obama White House, where seemingly it has vanished into an Alice-in-Wonderland rabbit hole. This regulatory debacle has virtually eliminated an entire, once-promising sector of U.S. biotechnology.

Perhaps the most potent argument against compulsory reviews is that the FDA’s “voluntary” consultations are currently taking years, even for negligible-risk, uncomplicated products.

This provision would do absolutely nothing to enhance the safety of the food supply. In fact, by creating even more burdensome regulation and uncertainty about the path to the marketing of important new products, it would do exactly the opposite. Regulatory changes are in order, but they should be in the direction of making regulation more scientific and risk-based, not mandatory regulatory oversight focused on a bogus pseudo-category.

That leads us to perhaps the greatest concern of all about the legislation: that Congress is among the loosest of loose cannons. Once it is engaged in crafting legislation, given the reality of members’ poor scientific literacy and their penchant for political horse-trading, there’s no telling where we could end up.

Voluntary labeling standard / We are also concerned about the provision directing

the FDA to establish a GMO labeling standard, even if food companies’ use of the labeling would be voluntary. In theory, labeling should be beneficial to consumers by providing them with information they consider useful, and food companies would have economic incentive to provide information they believe consumers would value. But federal law requires that food labels be truthful and not misleading, and labels that imply any sort of warning about GMOs are, by definition, misleading.

The FDA could provide guidance about the use of specific terms such as “GMO free” or “Non-GM verified,” along with specifying the paperwork that is required to document such a claim, just as the agency did years ago for dairy products from cows not treated with the protein bovine somatotropin, better known as rBST. (It should be noted that the FDA has not enforced those rules consistently and many dairy products bear misleading labels.)

Such involvement would also be helpful because it would preempt state efforts to define those terms, again avoiding a patchwork of arbitrary and possibly inconsistent requirements. If federal regulators exercise their authority to define terms, companies using them appropriately on labels would gain a safe harbor from litigation under state and local food laws. Consumers would benefit from uniform terminology, and companies would gain certainty about which terms are allowable.

Defining “natural” / That said, we are also skeptical of the provision directing the FDA to define “natural” foods. Such a pursuit would be a red herring. In a world where the genetics of practically every commercially traded organism has been shaped to some extent by the hand of man, could the term “natural” be meaningful?

In the past decade, numerous class-action lawsuits have been brought against food companies seeking damages for false advertising when the company placed the words “all natural” or “100 percent natu-

ral” on the label of food products. In spite of many requests—some coming from federal trial judges—the FDA has consistently declined to define the term “natural,” most recently in January 2014. The agency claims that it has higher priorities for its time and resources than getting into a years-long philosophical and ideological quagmire. At best, this exercise would have nothing at all to do with the healthfulness or quality of food; in effect, it would be the regulatory equivalent of trying to determine how many angels can dance on the head of a pin.

In summary, some elements of H.R. 4432 could be useful, but it should contain only those provisions that are necessary and sufficient to benefit the public. Such provisions would include confirmation that FDA policies on genetically engineered foods preempt those of states and localities, and an endorsement of the existing U.S. Department of Agriculture’s National Organic Program policy that genetically engineered materials in organic products introduced inadvertently do not deprive those products of the “organic” label.

Pompeo and his co-sponsors intend to promote the development of foods made with modern genetic engineering techniques. But they must ensure that, in attempting to single out one technology for relief from harassment, their actions do not perpetuate the myth that genetic engineering is some sort of homogenous “category” amenable to generalizations. It is not, and legislation that treats it as such—even with the best of intentions—would be misguided and subject to a more magisterial influence: the Law of Unintended Consequences.

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