

## The biotech battle

By Michael F. Jacobson and Gregory Jaffe - 10/21/15 09:00 AM EDT

The friends and foes of agricultural biotechnology have long been blasting away at one another on the issue of labeling foods that contain ingredients from genetically engineered (GE) crops. In multi-million-dollar battles waged over referenda calling for the mandatory labeling of foods with ingredients from GE crops, voters in California, Oregon, and Washington narrowly rejected such labeling; Colorado voters rejected it by a wide margin. And in Vermont, the legislature voted to require labeling by July 1, 2016. That made Congress the next battleground, because the food industry hates dealing with a patchwork of state labeling laws.

In Congress, Round 1 went to the opponents (including biotech developers, food manufacturers, farmers, public researchers, and others) of mandatory labeling, with the House voting last July to preempt state labeling laws, such as Vermont's law. The House bill, HR. 1599, sponsored by Rep. Mike Pompeo (R–Kan.), also would require the U.S. Department of Agriculture to develop a *voluntary* system for labeling *non*-GE foods, modeled after the successful organic-labeling program.

But amidst the Sturm und Drang over labeling, a more important issue is lurking under the surface. Currently, the Food and Drug Administration does not formally approve GE crops as being safe to eat. Companies *voluntarily* send the FDA safety data, and, after studying that information, the agency doesn't actually approve crops, but says "we have no further questions at this time." The lack of an FDA approval is not very reassuring to skeptical consumers and allows critics to charge, accurately, that GE crops have never been approved by FDA. Meanwhile, Japan, the European Union, Canada, and other countries formally approve GE crops.

While participation in FDA's oversight is voluntary, seed developers have "consulted" with FDA for all currently commercialized GE crops. That might change in the future. GE seed companies are currently developing GE crops that specifically avoid USDA oversight and their next move might be to also avoid FDA's voluntary process. Similarly, there is no guarantee that developers of GE crops in a foreign country such as China will "voluntarily" submit to FDA oversight.

The House bill could easily have required formal FDA approval, which would go a long way toward assuring consumers that all foods made from GE crops will be safe when marketed. But instead it creates a regulatory scheme that would have made Rube Goldberg smile. The bill would give new authority for commercializing GE crops to USDA, but USDA would not be able to allow marketing until the FDA had completed the voluntary consultation. So, indirectly the voluntary consultation process would be required—but the FDA *still* would not give its seal of approval, just a quiet "no objection."

You'd think that critics would want GE crops to be rigorously evaluated and then formally approved by the FDA. But many critics, some of whom reluctantly acknowledge that there is no evidence that any of the current GE crops are harmful, clearly do not want any process that bolsters public confidence in the technology.

You also might think that the biotech industry, food manufacturers, and farmers would want the FDA's stamp of approval to bolster confidence in GE crops. But only a handful of those stakeholders have publicly supported giving FDA approval authority.

Round 2 in this battle starts today, Oct. 21, when the Senate Agriculture Committee holds its first hearing on the federal regulation of biotechnology. No bill has been introduced, but both sides are lobbying fiercely (almost exclusively on labeling, with little attention being paid to the arguably more important regulatory role of FDA). Unfortunately, Congress could enact a confusing and convoluted system whereby FDA not only would not formally approve GE crops but would make any FDA oversight subservient to USDA's oversight. Such a system would neither protect consumers nor increase confidence in a technology that has benefited farmers and the environment and has not yet harmed a single person.

We hope sensible minds prevail and that the Senate bill would establish a formal approval process, the crucial step to establishing oversight by an independent FDA that would assure safety and alleviate consumers' concerns. We're fortunate that the currently commercialized GE crops are safe, but labeling is no substitute for safety. And safety shouldn't be left to chance.

Jacobson is the president of the Center for Science in the Public Interest. Jaffe is the director of biotechnology.