With just a few days to go before Halloween, I present you with a tale of horror – at least for large portions of the food industry and, as our authors from Crowell & Moring argue below, also for many consumers. It's about the potential requirement of labeling for products containing genetically engineered ingredients. Because sometimes, after you get what you ask for, you're sorry. As usual, the views of column authors are not necessarily the views of our publication. – J. Huffman

Frankenfood Fight: Why Mandatory Labeling of GMO Foods is Unnecessary and Unwise

By John Fuson and Warren Lehrenbaum

In just a few short days, on Nov. 6, voters in California will decide whether to pass Proposition 37, the California Right to Know Genetically Engineered Food Act. If approved, the new law would require that food produced from genetically engineered organisms bear labels prominently displaying the words "Genetically Engineered," "Partially Produced with Genetic Engineering," or "May be Partially Produced with Genetic Engineering."

The Act defines genetic engineering to include the use of recombinant DNA (rDNA) and certain other laboratory techniques, but not cross-breeding or other "conventional" breeding methods which result in gene combinations that might not otherwise occur in nature.

The California initiative is only the latest in a steady stream of attempts at the local, state and national level to enact similar labeling requirements into law. However, with an economy that would rank 8th largest in the world, and with genetically engineered (GE) ingredients present in roughly 80% of processed food sold in the United States, the impact of passage in California could be profound.

Most likely, as proponents of Prop. 37 hope, a mandatory labeling requirement would substantially decrease the availability on supermarket shelves of GE food or food that contains ingredients derived from genetically modified organisms ("GMO foods"). Moreover, given the size of the California market, and the powerful influence that has on the marketing decisions of food processors and grocery manufacturers, it is reasonable to expect that, if Prop. 37 is passed into law and survives judicial challenge, foods containing genetically modified ingredients will start to disappear from supermarket shelves across the country, not just in California.

Proponents of mandatory labeling for GMO foods generally offer two rationales to justify requiring such labeling (these rationales are explicitly acknowledged in the "Findings and Declarations" and "Statement of Purpose" sections of the proposed California legislation).

Argument #1: Consumer Choice

Consumers, GE labeling advocates argue, should have the right to choose whether or not they consume foods containing GE ingredients, and mandatory labeling of GMO foods is necessary to allow consumers to exercise that choice.

On its face, the consumer choice argument might seem obvious and compelling; after all, we are all consumers of food and want to be able to make informed choices about the foods we eat. However, upon further analysis, it becomes evident that the "consumer choice" argument is misleading, and also wrong.

In those jurisdictions where mandatory labeling requirements for GMO foods already have been enacted into law, such as European Union countries, consumer choice has been eliminated, not enhanced. GMO foods essentially have disappeared from the supermarket. Food processors made the binary decision, in these instances, to move away from GMO ingredients because they concluded that the potential loss of market share from consumers rejecting GMO-labeled products would outweigh the lower costs of using GMO ingredients. (For a more robust discussion of this phenomenon see C. Carter and G. Gruere, *Mandatory Labeling of Genetically Modified Foods: Does it Really Provide Consumer Choice?* AgBioForum 6(1&2) 2003.)

Of course, this marketplace reality is not lost on the advocates of mandatory labeling, who, in many instances, are the same organizations that categorically oppose any production or consumption of GMO foods. For these proponents, such requirements are more of a Trojan horse designed to drive GMO foods from the market, rather than an honest attempt to provide consumers with an opportunity to choose between GMO and non-GMO foods.

These advocates also argue that without a mandatory labeling requirement, consumers will be unable to distinguish between (and therefore unable to choose between) GMO and non-GMO foods; however, this is simply untrue. Consumers who want to avoid GMO foods can do so now with confidence, by purchasing and consuming foods that are certified organic. Under the USDA's National Organic Program, genetic engineering is specifically designated as an "excluded method."

Thus, the "consumer choice" argument is largely a deception.

Argument #2: Food Safety

Because the safety of GE foods is uncertain, GE labeling advocates argue, consumers need to have labels to avoid any safety risks. This rationale is essentially a variation on the "consumer choice" argument.

However, this argument is more pernicious than just "consumer choice" because it challenges the integrity of the food regulatory system in the U.S. and utterly disregards the notion that food safety regulation should be based on sound science.

GMOs are regulated comprehensively in the U.S., pursuant to the Coordinated Framework for Regulation of Biotechnology (the "Coordinated Framework") which divides jurisdiction over biotechnology products among several different regulatory agencies. *See* 51 Fed. Reg. 23302 (June 26, 1986). Under the Coordinated Framework, the FDA has primary responsibility for assuring the safety of GMO foods and food additives. The EPA shares part of this responsibility with respect to the food safety of crops that are engineered to resist insects and other pests (referred to as "plant incorporated protectants"), which are regulated by EPA as pesticides. *See, generally*, 40 C.F.R. Part 174.

FDA applies the same scientific rigor in evaluating the safety of GE food that it applies to chemical residues and other materials that

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may be found in food. For example, before a GE crop enters the market, it is subject to safety review by FDA as part of a "consultation" process. See Consultation Procedures Under FDA's 1992 Statement of Policy—Foods Derived from New Plant Varieties, available at *1.usa.gov/OWX6Zx*.

Under the consultation process, a company seeking to market a GMO crop provides FDA with a comprehensive data set to demonstrate to FDA that the genetic modification does not present any food safety concerns and does not alter the fundamental nature of the food article. Typically these submissions include the following types of data:

(i) data regarding any known or suspected allergenicity or toxicity of expression products encoded by the introduced genetic material, including in vitro and in vivo biochemical and toxicological studies, bioinformatic analysis of the potential for toxicity, and assessment of structural similarity to known protein allergens;

(ii) data comparing the composition and nutritional characteristics of the bioengineered food to that of food derived from the parental variety or other commonly consumed varieties with special emphasis on important nutrients and toxicants that occur naturally in the food; and

(iii) data on the characteristics, influence, heritability and stability of the introduced DNA.

If, at the conclusion of a consultation, FDA determines that unresolved safety issues exist, the agency will regulate the GMO trait as a food additive.

On the other hand, successful completion of the consultation process means that, based on the scientific data, FDA has found no evidence that the GMO crop presents any risk to health, and no meaningful difference between the genetically engineered version of the crop and the conventional version. Although the consultation process is nominally a voluntary one, successful completion of consultation is typically a prerequisite for obtaining other regulatory approvals needed to commercialize a GMO crop (e.g., approval from the USDA).

In addition, a company that fails to pursue consultation runs the risk that foods derived from its GMO crop will be deemed "adulterated" by FDA under Sect. 402 of the Federal Food, Drug, and Cosmetic Act (FFDCA).

FDA has taken a slightly different approach to the regulation of GE food-producing animals. Specifically, FDA regulates the use of rDNA constructs in animals and their offspring pursuant to its authority over new animal drugs (See, U.S. Food and Drug Administration, Guidance for Industry No. 187, *Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs*, May 17, 2011). That means, in addition to demonstrating the safety and efficacy of rDNA constructs in the target animals, sponsors must also show that when used in food producing animals, the genetic alterations pose no risk to the human consumers of those animals. This is the same showing that sponsors must make for antibiotics and other drugs used to treat disease in food producing livestock animals.

Finally, the scientific rigor that FDA applies to approval decisions also underlies its decisions about appropriate labeling for food products. In general, an article of food must bear a label that accurately describes the basic nature of the food (*See* 21 C.F.R. § 102.5). Therefore in instances where FDA determines, based on its evaluation of the data, that a GMO crop differs in some material way from its non-GMO counterpart, FDA will require labeling to address any material difference. (For example, FDA has required additional labeling to distinguish genetically modified high oleic acid soybean oil from non-modified soybean oil. See, e.g., Biotechnology Consultation Note to the File BNF No. 000039, available at *www.fda.gov/food/biotechnologysubmissions/ucm161157.htm.*)

Conversely, FDA cannot require special labeling that is based solely on the use of a particular production process, such as genetic engineering, if the resulting articles of food are not materially different from their "conventional" counterparts, since to do so would result in a label that is false or misleading (by implying that there is a material difference when none exists) (*See*, *e.g., Stauber v. Shalala*, 895 F. Supp. 1178, 1193 (W.D. Wis 1995)).

Importantly, even if FDA does not require labeling for a particular GMO product because the agency concludes that there is no material difference between the GMO product and its conventional counterpart, producers of the non-GMO product are free to label their products to indicate that they are not genetically engineered (See U.S. Food and Drug Administration, Guidance for Industry, *Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering*, Draft, January 2001).

This is roughly analogous to kosher or halal foods: A segment of the population desires to avoid foods that employ certain production practices, and producers of those foods are free to label them accordingly, giving consumers the ability to choose foods that are produced using the practices they desire.

Conclusion

Mandatory labeling initiatives like Prop. 37 are, at best, misguided. They seek to impose a labeling requirement on GMO foods when voluntary labeling is just as effective at informing consumer choice, which suggests that their true aim is not to provide consumers with information to guide their purchases but rather to eliminate GMO foods from the marketplace. They are premised on the notion — unsupported by any credible scientific evidence — that all genetically modified food organisms present some as yet unidentified food safety risk that must be "warned" of. But perhaps most importantly, they undermine the existing regulatory system by suggesting that FDA cannot be relied upon to evaluate all relevant food safety data regarding a particular GMO food and determine whether that food presents any new risks or other material differences that warrant labeling.

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