Proposition 37 Advisory III: Frequently Asked Questions

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As we reported in Proposition 37 Advisory I, the November 6, 2012 election in California will include a vote on a ballot initiative known as the Genetically Engineered Foods Labeling Initiative. In Proposition 37 Advisory II, we established a framework analyzing the Initiative and each of its provisions. In this Proposition 37 Advisory III, we respond to many of the most Frequently Asked Questions that we receive about this potentially groundbreaking law.

If passed, Proposition 37 will amend California's Sherman Food, Drug and Cosmetic Law, codified at Chapter 5 of Part 5 of Division 104 of the California Health and Safety Code. The new provisions, if enacted, will require labeling on raw and processed foods offered for sale to consumers in California that are designated as "genetically engineered," and would render genetically engineered or processed foods "misbranded" if they are labeled or advertised as "natural." The new law will be enforced by civil lawsuits brought in the Superior Court by the Attorney General and district attorneys, and by private citizens who may bring suits for injunctive relief and to recover their attorneys fees and costs.

The following discussion addresses questions that we receive most frequently from clients about the Initiative. We believe this information will be of interest to the regulated community, and encourage readers to send us further questions you may have.

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1. What is the Purpose of Proposition 37?

The stated purpose of Proposition 37 is "to create and enforce the fundamental right of the people of California to be fully informed about whether the food they purchase and eat is genetically engineered and not misbranded as natural so that they can choose for themselves whether to purchase and eat such foods." Proposition 37, Sect. 2, Statement of Purpose. The prefatory text of the measure makes many claims, among them that:

- Genetic engineering of plants and animals "often causes unintended consequences" and "can lead to adverse health or environmental consequences."
- Genetic engineering "can increase the levels of known toxicants in foods and introduce new toxicants and health concerns."
- Mandatory identification of GE foods can provide a critical method for tracking the potential health effects of eating them.
- Organic farmers are prohibited from using genetically engineered seeds, yet their crops can be contaminated from neighboring lands.
- The labeling, advertising and marketing of genetically engineered foods using terms such as "natural," "naturally made," "naturally grown," or "all natural" is misleading to California consumers.

Proposition 37, Findings and Declarations.

The Analysis of the Legislative Analyst, prepared by the Office of the Attorney General, provides more information. The Legislative Analyst describes "genetic engineering" as the process of changing the genetic material of a living organism to produce a desired change in that organism's characteristics, which is used to develop new plant and animal varieties that are later used as sources of foods. Sometimes, these changes may be to make a crop resistant to disease or pesticides. Such foods are referred to as "GE foods."

According to the Legislative Analyst, 88 percent of the corn and 94 percent of the soybeans produced in the U.S. in 2011 were grown from genetically engineered seeds. Genetically engineered crops may also be included in processed foods. The Legislative Analyst presents an estimate that 40 percent to 70 percent of food products sold in grocery stores in California contain genetically engineered ingredients.

The Legislative Analyst takes the position that Federal law does not specifically require the regulation of GE foods, although it points out that the U.S. Department of Agriculture currently restricts the use of genetically engineered crops that are shown to cause harm to other plants, and that the U.S. Food and Drug Administration is responsible for ensuring that most foods and food additives are safe and properly labeled. Similarly, although California agencies are not specifically required to regulate GE foods, the Department of Public Health ("DPH") is responsible for regulating the safety and labeling of most foods in California.

2. If Proposition 37 is passed, what will the new law require?
If passed, Proposition 37 will establishing a ***Labeling Requirement*****,** which will require "disclosure" for food products that are genetically engineered, and a ***Labeling Prohibition***, which will make it unlawful for genetically engineered or processed foods to be labeled as "natural." These requirements are examined in more detail below.

Labeling Requirement
Section 110809 of the Initiative would establish a labeling requirement for certain food products that are "produced with genetic engineering," rendering such products "misbranded" if their labeling does not include required statements "disclosing" that the products are genetically engineered. Specifically, Section 110809 would require that the words "Genetically Engineered" appear on the front of the package of any "raw agricultural commodity" that is offered for retail sale in California, if it "is or may have been" produced "entirely or partially" with "genetic engineering." If the product is not packaged or labeled separately, then a label with these words would be required "on the product shelf or bin" in which it is displayed for sale.

Section 110809 also applies to processed foods, but would require the use of a different labeling phrase, and would allow the phrase to appear "on the front or the back of the package." The required phrases are "Partially Produced with Genetic Engineering" or "May be partially Produced with Genetic Engineering."

Notwithstanding these requirements, Section 110809 would not require specific ingredients to be listed or identified. Nor would it require that the term "genetically engineered" be placed on the label to precede the "common name" or "primary product descriptor" of a food for which labeling is required.

Labeling Prohibition
Section 110809.1 would prohibit the use of the terms natural," "naturally grown," "all natural," or "any words of similar import that would have any tendency to mislead any consumer" on the "label" of any food product that is genetically engineered or simply processed and is not otherwise exempt from this requirement. Section 110809.1 would also prohibit the use of these terms on any "accompanying signage in a retail establishment," and in "any advertising or promotional materials" for any product that is genetically engineered. Similar to Section 110809, summarized above, Section 110809.1 would treat any product as "misbranded" if its labeling or promotional materials include the prohibited terms.

Key Definitions
Both the labeling requirement and the labeling prohibition would apply to food products that are "genetically engineered." Section 110808(c) defines the term "genetically engineered" as a food "produced from an organism or organisms in which the genetic material has been changed through the application of" any of the following: (1) "in vitro nucleic acid techniques," (2) "fusion of cells" or "hybridization techniques that overcome natural physiological, reproductive or recombinant barriers," if the donor materials "do not fall within the same taxonomic family, in a way that does not occur by natural multiplication or natural recombination."

Several of these terms are scientific terms of art, and are defined for purposes of Section 110808(c). In particular, Section 110808(c)(2)(i) defines "organism" as "any biological entity capable of replication, reproduction or transferring genetic material." Section 110808(c)(2)(ii) defines "in vitro nucleic acid techniques" as techniques that "include but are not limited to" "DNA or RNA techniques that use vector systems and techniques involving the direct introduction into the organisms of hereditary materials prepared outside the organisms." Such techniques include "micro-injection," "macro-injection," "chemoporation," "electroporation," "micro-encapsulation" and "liposome fusion."

The labeling requirement will apply to processed food that is genetically engineered. The labeling prohibition will apply to all processed foods, including processed foods that are genetically engineered and those that are not. Thus, Section 110808(d) defines "processed food" to include food that is not a "raw agricultural commodity," and "any food processed from a raw agricultural commodity that has been subject to processing." Examples of "processing" include "canning,

smoking, pressing, cooking, freezing, dehydration, fermentation or milling."

3. What labeling requirements does the federal government impose for genetically engineered foods?
Federal law does not require the labeling of genetically engineered foods. In 2001, the Food and Drug Administration ("FDA") issued draft guidance on the subject for public comment. The Draft Guidance represents FDA's current thinking on voluntary labeling indicating whether foods have or have not been developed using bioengineering, or genetic engineering.

As the Draft Guidance points out, the Federal Food, Drug, and Cosmetic Act ("FFDCA") governs the extent to which the FDA is charged with governing the labeling of foods. Section 403(a)(1) of the FFDCA indicates that a food is "misbranded" if its labeling is false or misleading. Section 201(n) further states that labeling is misleading if it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual.

Historically, the FDA has required special labeling for information that is "material." According to the Draft Guidance, information is considered "material" where its absence may: 1) pose special health or environmental risks; 2) mislead the consumer in light of other statements made on the label; or 3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic, or functional characteristics of the food it resembles when in fact it does not.

Section 403(i) of the FFDCA requires that each food bear a common or usual name or, in the absence of such a name, an appropriately descriptive term. In addition, Section 201(n) requires that the label of the food must reveal all material facts about the food. Thus:

- If a bioengineered food is significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food, the name must be changed to describe the difference.
- If an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use, a statement must be made on the label to describe the issue.
- If a bioengineered food has a significantly different nutritional property, its label must reflect the difference.
- If a new food includes an allergen that consumers would not expect to be present based on the name of the food, the presence of that allergen must be disclosed on the label.

The Draft Guidance states that the FDA has no basis for concluding that bioengineered foods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed through biotechnology present any different or greater safety concern than foods developed by traditional plant breeding. Thus, FDA has not concluded that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed, and thus does not require special labeling of all bioengineered foods.

Although FDA recognizes that the use of bioengineering is not a material fact for purposes of the FFDCA, the agency also recognizes that many consumers may be interested in the information, and that some manufacturers may want to respond to this consumer desire voluntarily. The Draft Guidance goes on to provide further specifics on acceptable labeling.

4. Who would be subject to Proposition 37?
Proposition 37 does not expressly identify the persons who may be held liable. Thus, it may be instructive to look to other provisions of the Health & Safety Code ("HSC"), into which provisions of the Initiative will be incorporated. The Initiative will create a new class of food products that may be deemed "misbranded" under the Health & Safety Code ("HSC"). Section 110760 of the HSC makes it unlawful for "any person to manufacture, sell, deliver, hold or offer for sale" any food that is misbranded. Thus, the following could all be held liable under that provision:

- Manufacturers ("manufacture")
- Distributors ("sell," "deliver")
- Storage Facilities ("hold")
- Retailers ("sell")
- Shippers/Transporters ("deliver")
- Marketers ("offer for sale")

HSC Section 110765 also makes it unlawful to misbrand any food. Thus, it might appear that any person involved in the

labeling process could be sued. Significantly, HSC Section 11077 also makes it unlawful "to receive in commerce" any food that is misbranded.

In their totality, these provisions suggest that a very wide scope of persons might be sued under Proposition 37. The extent of their potential liability is less clear.

5. Are There Any Exemptions Under Proposition 37

Yes. Section 110809.2 establishes nine separate exemptions from the Labeling Requirement set forth at Section 110809. On the face of the Initiative, there are no exemptions from the Labeling Prohibition. Other provisions of the Health and Safety Code, however, which pre-date the Initiative, already establish exemptions from certain HSC requirements. Any person who is subject to the new law should examine those provisions as well.

Each of the nine exemptions from the Labeling Requirement is discussed below.

Foods From Animals That Are Not Genetically Engineered

Section 11089.2(a) establishes an exemption for food that consists "entirely" of, or is "entirely derived from," an "animal that has not itself been genetically engineered." This exemption is available for food from an animal "regardless of whether such animal has been fed or injected with" a genetically engineered food or drug.

Foods Grown, Raised Or Produced Without The Knowing And Intentional Use Of Genetically Engineered Seed Or Food

Section 110809.2(b) establishes an exemption for a raw agricultural commodity or a food "derived from" a raw agricultural commodity that is "grown, raised or produced" without the "knowing and intentional use" of seeds or foods that are genetically engineered. In order to qualify for this exemption, the person "otherwise responsible" for complying with the Labeling Requirement must obtain "from whoever sold the commodity or food" a "sworn statement" that the commodity or food:

1. has not been genetically engineered, either "knowingly or intentionally;" ***and***
2. has been segregated from, and has not been "knowingly or intentionally commingled with" food that "may have been" genetically engineered "at any time."

Processed Food That Includes Genetically Engineered Processing Aids or Enzymes

Section 110809.2(c) provides an exemption for "any processed food" that otherwise would be subject to the Labeling Requirement "solely" because the processed food includes "one or more genetically engineered processing aids or enzymes."

Alcoholic Beverages

Section 110809.2(d) establishes an exemption for "any" alcoholic beverage, provided it is "subject to the Alcoholic Beverage Control Act."

Temporary Exemption for Low Level Presence of Genetically Engineered Ingredients in Processed Foods

Section 11089.2(e) establishes an exemption until July 1, 2019 for processed foods that contain certain levels of genetically engineered ingredients, provided that:

1. no single genetically engineered ingredient "accounts for more than one-half of one percent of the total weight" of the processed food; ***and***
2. the processed food does not contain "more than ten" engineered ingredients.

Foods Determined By An Independent Organization Not To Be Produced From Or Commingled With Genetically Engineered Seed or Food

Section 110809.2(f) establishes an exemption where an "independent organization" has determined that a food has not been produced "knowingly and intentionally" from genetically engineered seed or food. This exemption applies only where the determination has been made using a sampling and testing procedure "approved in regulations" by the Department of Public Health. This provision goes on to establish criteria that must be satisfied before a sampling or testing procedure may be approved. Sampling must be done "according to a statistically valid sampling plan consistent with principles recommended by internationally recognized sources . . . ." Testing (a) must be "consistent with" the most recent guidelines published by the Codex Alimentarius Commission and (b) must not "rely on testing . . . in which no DNA is detectible."

Foods Certified As Organic

Section 110809.2(g) establishes an exemption for "food that has been lawfully certified to be labeled, marketed and offered for sale as 'organic' pursuant to the federal Organic Food Products Act of 1990" and regulations promulgated thereunder.

Food That Is Not For Retail Sale
Section 110809.2(h) establishes an exemption for food that is "not packaged for retail sale." In order to qualify for this exemption, the food must be (a) a "processed food prepared for and intended for immediate human consumption" or (b) must be "served, sold or otherwise provided" in a "restaurant or food facility" that is "primarily engaged in the sale of food" for "immediate human consumption."

Medical Food
Section 110809.2(i) establishes an exemption for "medical food." The term "medical food" is not defined.

Other Exemptions Under Existing Provisions of the Health & Safety Code

Foods Intended for Export
HSC Section 110790 also exempts "food intended for export," provided that such food meets all of the following requirements:

1. It accords to the specifications of the foreign purchaser.
2. It is not in conflict with the laws of the importing country.
3. It is labeled on the outside of the shipping package to show that it is intended for export.

6. Will a State Agency Enforce Proposition 37?
Primary enforcement authority over the Sherman Food, Drug and Cosmetic Law, where most of Proposition 37 would be placed, is vested in The State Department of Health Services. Presumably, Food and Drug inspectors, who are authorized agents of the Bureau of Food and Drug, would have authority to inspect or investigate for compliance with the Labeling Requirement or the Labeling Prohibition under HSC Section 109945.

Sections 111840 and 111900 of the HSC also authorize the Attorney General, District Attorneys and certain City Attorneys to commence actions in the Superior Court to enforce the Act by way of injunction or to recover civil penalties.

7. Does Proposition 37 Allow For "Citizen Suit" Litigation?
Proposition 37 provides for significant and sweeping enforcement actions that may be brought to obtain injunctive and monetary relief. In addition to actions by the Attorney General, District Attorneys and certain City Attorneys (addressed in FAQ No. 6 above) the Initiative allows private persons to bring actions to "enforce" Proposition 37. The scope of these provisions is extremely broad, engendering significant concerns throughout the food-supply chain.

Direct Enforcement Rights
As the Initiative is drafted, Section 110809.4 provides that "any person" can file a lawsuit in Superior Court for a temporary or permanent injunction to prevent or cease alleged violations of Proposition 37. It appears that these actions could be brought to address alleged violations of the Labeling Requirement and the Labeling Prohibition. This direct enforcement mechanism under Section 110809.4 will be added to a preexisting California statute known as the "California Organic Products Act of 2003."

Enhanced Private Enforcement Rights
Unlike most laws providing injunctive relief, Proposition 37 establishes a relaxed standard for private parties that bring enforcement actions. Section 111910(a) provides that private enforcers are exempt from the ordinary requirement for showing "irreparable damage or loss," and need not show any "unique or special individual injury or damages" in order to prevail. (Importantly, this relaxed legal standard may not apply to all enforcement actions brought under the Initiative, but only to actions brought under this provision.)

Lawsuits Under the Consumers Legal Remedies Act
Section 110809.4 of Proposition 37 will allow any "consumer" to bring an action under the Consumers Legal Remedies Act ("CLRA"). The incorporation of consumer enforcement provisions under the CLRA substantially enhances enforcement opportunities for private parties. For example, Proposition 37 violations are expressly deemed to be "deceptive practices" under the CLRA. This statutory designation creates significant private enforcement incentives for plaintiffs' lawyers, because it authorizes recovery of many different types of damages under the CLRA. CLRA enforcement actions are widely used by plaintiffs' attorneys, and can be difficult to defend on the merits. Consequently, parties subject to Proposition 37 may face excessive prosecution, and may risk liability far greater than any actual damages for misbranding.

8. What Monetary Remedies Would Be Available Under Proposition 37?
Many different legal and equitable remedies are available under Proposition 37, including direct monetary damages (*i.e.*, the actual cost of the mis-labeled product purchased), as well as punitive damages under the CLRA. As noted above,

remedies may include injunctive relief (e.g., an order to require a Proposition 37 defendant to perform specific actions or take certain steps to address violations. Significantly, Proposition 37 also provides broad discretion for an award of "***reasonable attorney's fees and all reasonable costs incurred in investigating and prosecuting the action*** as determined by the court." Section 111910(b) (emphasis added). Finally, restitution is traditionally available under the CLRA, and provides an alternative theory for compensation that may extend beyond a plaintiff's actual damages.

9. Can my company be liable for distributing "misbranded" food to others for resale if my company does not produce and label the products?

Potential liability under Proposition 37 is created by breach of the duties imposed by the broad labeling requirements applicable to certain food products. Because Proposition 37 is incorporated into an existing California statutory scheme for food product regulation (Section 109875), requirements and liability triggers are derived from terms that do not appear in the ballot initiative. Proposition 37's application thus appears to be extremely broad. Any foods that are "misbranded" under its requirements – or requirements already codified by other statutes – create liability risks for entities that "sell" or "deliver" or "hold" such food. Section 110760. Distributors will need to be proactive to ensure they either have sufficient documentation, or other reliable data, showing foods they distribute are properly labeled or are otherwise exempt from Proposition 37.

One particularly troubling issue for distributors, and others in the downstream chain of food sales, arises from the technical details of Proposition 37's definitions. Many entities in the food-supply chain will not have the expertise to determine whether "genetic engineering" is an issue. Nonetheless, they may be legally responsible under Proposition 37 and potentially subject to liability, ***even without knowledge or intent the food products they distribute or sell contains genetically engineered ingredients***. Proposition 37 appears to place a duty, as well as the risk of private enforcement, on all parties in the food-supply chain.

Further Information and Resources

The full text of Proposition 37 is available on the California Secretary of State's website at http://www.sos.ca.gov/elections/vig-public-display/110612-general-election/prop-37/prop-37-text.pdf. An Official Summary prepared by the Attorney General of California is available at http://vig.cdn.sos.ca.gov/2012/general/pdf/37-title-summ-analysis.pdf.