

## Proposition 37 Advisory II: A Framework for Analysis

OCTOBER 11, 2012

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](#). Proposition 37 Advisory II addresses the Initiative in more detail.

If passed, this Initiative 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 or 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 discussion below provides an analytical framework for those who may be subject to the law. We begin by summarizing the Operative Provisions of the Initiative – the labeling requirement and the labeling prohibition. Next, we examine the Key Definitional Terms and the Exemptions that determine when and to whom the Initiative applies. We conclude by reviewing the Enforcement Provisions that determine how this law will be enforced, including who may be sued and by whom and the monetary and injunctive relief that plaintiffs will be authorized to seek in suits to enforce the law.

### Operative Provisions

[Section 110809](#) of the Initiative will establish a Labeling Requirement for certain food products that are "produced with genetic engineering," rendering such products "misbranded" under the Health & Safety Code if their labeling does not include required statements "disclosing" that the products are genetically engineered. [Section 110809.1](#) will establish a Labeling Prohibition, rendering certain "genetically engineered" or processed food products "misbranded" if their labeling or advertising present them as "natural."

**Labeling Requirement:** [Section 110809](#) is cast as a "disclosure" requirement. In plainer terms, this is a labeling requirement. [Section 110809](#) requires that certain words appear on the label for food products subject to the Initiative, and renders those products "misbranded" if the words are not included.

[Section 110809](#) requires 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 must appear "on the product shelf or bin" in which it is displayed for sale.

[Section 110809](#) also applies to processed foods, but requires the use of a different labeling phrase, and allows 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 the requirements above, [Section 110809](#) does not require specific ingredients to be listed or identified. Nor does 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](#) affirmatively prohibits the use of certain terms on the labeling or promotional materials of food products subject to the Initiative. Similar to [Section 110809](#), summarized above, [Section 110809.1](#)



### Contacts

For additional information, please contact:

**San Francisco, CA**  
[Stanley W. Landfair](#)  
415.267.4170

[Ann G. Grimaldi](#)  
415.267.4104

**Washington, DC**  
[John Conner, Jr.](#)  
202.496.7649

**Los Angeles, CA**  
[Robert S. Schuda](#)  
213.243.6136

**San Diego, CA**  
[Cordon T. Baesel](#)  
619.699.2555

[Stephen L. Marsh](#)  
619.699.2418

treats any product as “misbranded” if its labeling or promotional materials include the prohibited terms.

[Section 110809.1](#) prohibits 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](#) also prohibits 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.

#### Key Definitional Terms

The critical provisions of the Initiative, which determine to whom and when the Labeling Requirement and Labeling Prohibition apply, are found in [Section 110808](#) under the heading “Definitions.” The key definitions are discussed below.

**Genetically Engineered:** Both the Labeling Requirement and the Labeling Prohibition apply to food products that are “genetically engineered.” [Section 110808\(c\)](#) defines the term “genetically engineered” to refer to a food is “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.”

Many of the quoted terms above are scientific terms of art. The Initiative thus defines several of these terms specifically for purposes of [Section 110808\(c\)](#).

**Organism:** [Section 110808\(c\)\(2\)\(i\)](#) defines “organism” as “any biological entity capable of replication, reproduction or transferring genetic material.”

**In Vitro Nucleic Acid Techniques:** [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.”

**Processed Food:** The Labeling Requirement applies to processed food that is genetically engineered. The Labeling Prohibition applies to all processed foods, including processed food that are genetically engineered and those that are not. [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.”

**Processing Aid:** [Section 110808\(e\)](#) defines a “processing aid” as a substance that is added to a food:

1. “during . . . processing” but that is “removed . . . from the food before it is packaged;”
2. “during processing,” and is “converted into constituents normally present” and “does not significantly increase the amount of the constituents naturally found in the food;” or
3. “for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect . . . .”

**Food Facility:** Neither the Labeling Requirement nor the Labeling Prohibition applies to food that is served or sold at a restaurant or other “food facility.” [Section 110808\(f\)](#) defines “food facility” to have the same meaning as in Section 113789 of the Health and Safety Code, which in turn defines the term as an operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption at the retail level . . . .” (Readers should refer to Section 113789 for a long list of examples of facilities that are embraced by this term, and a further list of facilities that are excluded.)

#### Exemptions

[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. Each of the 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.

#### Enforcement Provisions

The starting point for enforcement is not the Initiative itself but the Health and Safety Code, into which the many provisions of the Initiative are incorporated. Many provisions of the Health and Safety Code already provide for a broad range of judicial and administrative actions, which may be brought by the Attorney General, district attorneys and by the California Department of Public Health.

The Initiative also includes two provisions that address enforcement in ways that are specific to the Initiative. The first, [Section 110809.4](#), provides that violations of the Labeling Requirement and Labeling Prohibition shall be deemed to be violations of California’s Consumer Legal Remedies Act (“CLRA”), and thus brings violations of the Labeling Requirement and Labeling Prohibition into the realm of violations that may be prosecuted by the Attorney General, District Attorneys, and “any consumer” under the CLRA. The second, [Section 111910](#), amends Section 111910 of the Health and Safety Code to allow private citizens (defined as “any person”) to bring suit in Superior Court to enjoin violations of the Initiative and to recover litigation and investigation costs, in addition to legal fees which are currently permitted under Section 111910.

**Citizen Suits Under the Consumer Legal Remedies Act:** Under [Section 110809.4](#) of the Initiative, any violation of the Labeling Requirement or the Labeling Prohibition “shall be deemed” a violation of [Section 1770\(a\)\(5\)](#) of the Civil Code, and renders such violations of the Initiative “Deceptive Practices” for purposes of the CLRA. [Section 1780\(a\)](#) of the CLRA provides that violations may be prosecuted by “[a]ny consumer who suffers any damage as a result of the use or employment . . . of a method, act or practice declared to be unlawful by [Section 1770.](#)” The Initiative expressly states that failures to disclose (Section 110890) or inclusion of prohibited labeling statements (Section 110809.1) “each [shall] be deemed to cause damage” to a consumer, and CLRA [Section 1780\(a\)](#) authorizes recovery of actual damages, injunctive relief, restitution, punitive damages, and “any other relief that the court deems proper.”

**Citizen Suits Under the Health and Safety Code:** [Section 111910](#) of the Initiative amends Section 111910 of the Health and Safety Code, in two ways. Subsection (a) will be amended to allow plaintiffs, including both public prosecutors and citizen plaintiffs, to bring suits in Superior Court to enjoin violations of the Labeling Requirement and Labeling Prohibition. Subsection (b) will be amended to allow plaintiffs who obtain injunctive relief to recover “all reasonable costs incurred in investigating and prosecution the action,” in addition to the attorneys fees that already were recoverable under this provision. Importantly, subsection (c) will remain unchanged. That subsection provides that [Section 111910](#) “shall not be construed to limit or alter the powers of the department or its authorized agents to bring an action to enforce this chapter” pursuant to any other provision of law. As noted above, the Attorney General, District Attorneys and the California Department of Public Health already possess substantial authority to enforce the Health and Safety Code provisions -- irrespective of any new powers added under the Initiative.

#### 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-sum-analysis.pdf>.

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