A. Scope

Background

The Affordable Care Act (ACA) (2010), in part, amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act), requiring chain restaurants and similar retail food establishments to provide calorie and other nutrition information for standard menu items. Providing accurate, clear, and consistent nutrition information, including the calorie content of foods, in restaurants and similar retail food establishments will make such nutrition information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices¹.

Menu Labeling Legislation in California as it relates to Federal Law

In 2008, SB 1420 (Padilla) was signed into law and added Section 114094 to the California Retail Food Code (CalCode) relating to food facilities and the disclosure of nutritional information (hereinafter “menu labeling law”)².

In 2011, SB 20 (Padilla) was signed into law to harmonize state and federal requirements by repealing the calorie content disclosure requirements of the California Retail Food Code Section 114094 and replacing it with the requirements of the federal Patient Protection and Affordable Care Act. SB 20 also provided state penalties (infraction/civil penalties) for noncompliance with those federal rules and listed the department and identified the California Department of Public Health (CDPH) and local enforcement agencies as the governing bodies for this rule³.

Current CalCode Section 114094 Language

(a) A food facility subject to Section 343(q)(5)(H) of Title 21 of the United States Code or subject to this section as it read on July 1, 2011, shall comply with the requirements of that section of the United States Code and the regulations adopted pursuant thereto.
(b) Notwithstanding the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104), and to the extent permitted by federal law:
   (1) Enforcement of this section shall be made pursuant to Section 113713.
   (2) (A) A violation of this section is, notwithstanding Section 114395, an infraction, punishable by a fine of not less than fifty dollars ($50) nor more than five hundred dollars ($500). A second violation within a five-year period from a prior violation shall be punishable by a fine of not less than one hundred dollars ($100) nor more than one thousand dollars ($1,000). For a third or subsequent violation within a five-year period, the fine shall be not less than two hundred fifty dollars ($250) nor more than two thousand five hundred dollars ($2,500). A food facility shall not be found to have committed a violation under this paragraph more than once during an inspection visit.
   (B) Alternatively, the enforcement agency may assess a civil penalty of an amount that is no less than or greater than the amounts specified for fines in this paragraph.

² http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=200720080SB1420
³ http://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201120120SB20

California Menu Labeling Guidelines
These guidelines were developed by a collaboration of representatives from the California Conference of Directors of Environmental Health, the California Department of Public Health, the California Restaurant Association, the California Retailers Association, the California Hotel and Lodging Association and other representatives from the retail food industry. Much of the language was taken from the FDA web page/guidance documents.
Who is affected by the Rule

The Food and Drug Administration (FDA) has finalized two rules requiring that calorie information be listed on menus and menu boards in chain restaurants and similar retail food establishments and vending machines.

**Menu Labeling** - Applies to restaurants and similar retail food establishments if they are part of a chain of 20 or more locations, doing business under the same name, offering for sale substantially the same menu items and offering for sale restaurant-type foods.

- The total number of establishments is based on number located within the United States. Chains with less than 20 locations in California but 20 or more throughout the United States are subject to the rule and enforceable in California.

**Vending Machine Labeling** - Requires operators who own or operate 20 or more vending machines to disclose calorie information for food sold from vending machines, subject to certain exemptions. Note: this guidance document will primarily address requirements for Restaurants and Similar Retail Food Establishments. For questions regarding vending machine labeling requirements, utilize FDA guidance document and reach out to your local enforcement agency.

What is the meant by “similar retail food establishments”?

The rule defines “restaurant or similar retail food establishment” as a retail establishment that offers for sale restaurant-type food, except if it is a school as defined by 7 CFR 210.2 or 220.2. (21 CFR 101.11(a))

The rule defines “restaurant-type food” as food that is:

1. Usually eaten on the premises, while walking away, or soon after arriving at another location; and
2. Either:
   - (a) Served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments; or
   - (b) Processed and prepared primarily in a retail establishment, ready for human consumption, of the type described in subparagraph (a) of this definition, and offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment. In other words, restaurant-type food is the subset of food previously exempt from Federal nutrition labeling requirements under sections 403(q)(5)(A)(i) and (ii) of the FD&C Act that is usually eaten on the premises of the establishment, while walking away, or soon after arriving at another location. (21 CFR 101.11(a))

Examples of food that generally would be considered restaurant-type food include:

- food for immediate consumption at a sit-down or quick service restaurant;
- food purchased at a drive-through;

---

4 http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm461934.htm
5 http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm513910.htm
- take-out and delivery pizza, hot pizza at grocery and convenience stores that is ready to eat, and pizza slices from a movie theater; hot buffet food, hot soup at a soup bar, and food from a salad bar;
- foods ordered from a menu or menu board at a grocery store intended for individual consumption (e.g., soups, sandwiches, and salads); and self-service foods and foods on display that are intended for individual consumption (e.g., sandwiches, wraps, and paninis at a deli counter; and cookies from a mall cookie counter; bagels, donuts, and rolls offered for individual sale).

Examples of food that generally would not be considered restaurant-type food include foods that are grocery-type items that may be ready for immediate consumption but that consumers usually store for use at a later time or customarily further prepare would not be considered “restaurant-type food.”:
- food bought from bulk bins or cases (e.g., dried fruit, nuts) in grocery stores;
- foods to be eaten over several eating occasions or stored for later use (e.g., loaves of bread, bags or boxes of dinner rolls, whole cakes, and bags or boxes of candy or cookies);
- foods sold by weight that are not self-serve and are not intended solely for individual consumption (e.g., deli salads sold by unit of weight such as potato salad or chicken salad), either prepacked or packed upon consumer request; and foods that are usually further prepared before consuming (e.g., deli meats and cheeses).

<table>
<thead>
<tr>
<th>Table 1. Examples of restaurants or similar retail food establishments that may be subject to the menu labeling regulation in accordance with 21 CFR 101.11. (To be covered, a particular establishment must meet all of the criteria for being a covered establishment, including being part of a chain with 20 or more locations)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of restaurant or similar retail food establishments Regulated under 21 CFR 101.11</td>
</tr>
<tr>
<td>Chain Bakeries</td>
</tr>
<tr>
<td>Chain Cafeterias</td>
</tr>
<tr>
<td>Chain Coffee shops</td>
</tr>
<tr>
<td>Chain convenience stores that sell restaurant-type foods</td>
</tr>
<tr>
<td>Chain delicatessens</td>
</tr>
<tr>
<td>Chain food takeout and delivery establishments (such as pizza takeout and delivery establishments)</td>
</tr>
<tr>
<td>Chain superstores that sell restaurant-type foods</td>
</tr>
<tr>
<td>Community coffee shop with less than 20 locations</td>
</tr>
<tr>
<td>Dining facilities at colleges and universities that are part of a chain</td>
</tr>
<tr>
<td>Food service facilities and concession stands located in entertainment venues (such as amusement parks, bowling alleys, and movie theaters) and are part of a chain</td>
</tr>
<tr>
<td>Grocery stores that sell restaurant-type foods and are part of a chain</td>
</tr>
<tr>
<td>Ice cream shops and mall cookie counters that are part of a chain</td>
</tr>
<tr>
<td>In-patient only food service facilities located in hospitals</td>
</tr>
<tr>
<td>Mobile lunch wagons, food trucks, and sidewalk carts</td>
</tr>
<tr>
<td>Quick service restaurants, including those that located in other types of establishments, such as airports, shopping malls, and hospitals when they are part of a chain</td>
</tr>
<tr>
<td>Retail confectionary stores that are part of a chain</td>
</tr>
<tr>
<td>Schools serving meals under The National School Lunch or Breakfast Programs as defined in 7 CFR 210.2 or 220.2</td>
</tr>
<tr>
<td>Single or Regional Bakeries with less than 20 locations</td>
</tr>
<tr>
<td>Table service restaurants that are part of a chain</td>
</tr>
<tr>
<td>Transportation carriers (trains and airplanes)</td>
</tr>
</tbody>
</table>
B. Menu

What information needs to be included on the menu board?

The following information that must be provided on menus and menu boards includes all of the following:

- Calories
- A succinct statement to enable consumers to understand, in the context of a total daily diet, the significance of the calorie information provided on menus and menu boards;
- A statement on menus and menu boards about the availability of additional written nutrition information;
- Nutrition information that must be available in written form on the premises of the covered establishment and provided to the customer upon request; and Standard menu items that are self-service or on display.

How does the Rule define “menu or menu board”?

Menus and menu boards are the primary writing of the covered food facility from which a customer makes an order selection, including but not limited to, breakfast, lunch, and dinner menus; dessert menus; beverage menus; children’s menus; takeout menus; menus mailed or delivered from a restaurant; other specialty menus (such as, catering); electronic menus; and menus on the Internet. The primary writing of a covered food facility can include more than one form of written material; the critical factor is whether the written material is or is part of the primary writing of a covered establishment from which a customer makes an order selection.

Determining whether a writing is or is part of the primary writing of the covered food facility from which a customer makes an order selection depends on a number of factors, including whether the writing lists the name of a standard menu item (or an image depicting the standard menu item) and the price of the standard menu item, and whether the writing can be used by a customer to make an order selection at the time the customer is viewing the writing. The menus may be in different forms such as a booklets, pamphlets, or single sheets of paper. Menu boards include mounted or free standing panels inside or outside a covered establishment including those used in counter service or drive-in or drive-through service.

General Format Requirements for declaring Calories on Menus and Menu Boards

You must declare the number of calories contained in each standard menu item listed on the menu or menu board, as usually prepared and offered for sale.

Multiple Servings Menu Items: In the case of multiple-serving standard menu items, this means the calories declared must be for the whole menu item listed on the menu or menu board as usually prepared and offered for sale (e.g., “pizza pie: 1600 cal”); or per discrete serving unit as long as the discrete serving unit (e.g., pizza slice) and total number of discrete serving units contained in the menu item are declared on the menu or menu board, and the menu item is usually prepared and offered for sale divided in discrete serving units (e.g., “pizza pie: 200 cal/slice, 8 slices”).

---

6 21 CFR 101.11(b)(2)(i)(A)
7 21 CFR 101.11(b)(2)(i)(B)
8 21 CFR 101.11(b)(2)(i)(C)
9 21 CFR 101.11(b)(2)(ii)
10 21 CFR 101.11)(b)(2)(iii)
11 21 CFR 101.11(b)(2)(i)(A)
Increments: You must declare calories to the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories, except that you may express amounts less than 5 calories as zero.

Format: You must list the number of calories adjacent to the name or the price of the associated standard menu item;
- The term “Calories” or “Cal” must appear as a heading above a column listing the number of calories for each standard menu item or adjacent to the number of calories for each standard menu item.
- Font Size: In a type size no smaller than the type size of the name or the price of the associated standard menu item, whichever is smaller;
- Font Color: In the same color, or a color at least as conspicuous as that used for the name of the associated standard menu item; and with the same contrasting background or a background at least as contrasting as that used for the name of the associated standard menu item.

How does the Rule address Seasonal, Promotional or Daily Specials?

The labeling requirements apply to all standard menu items. It does NOT apply to foods that are not standard menu items, including:
- Items such as condiments that are for general use, including those placed on the table or on or behind the counter;
- Daily specials;
- Temporary menu items;
- Custom orders;
- Food that is part of a customary market test; and
- Self-service food and food on display that is offered for sale for less than a total of 60 days per calendar year or fewer than 90 consecutive days in order to test consumer acceptance.

C. FDA Guidance Documents

FDA Links to additional requirements
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm437403.htm#_II.A.1

What do I do if I can't find my specific question answered in the FDA guidance documents?

The FDA will continue to update and issue additional editions of guidance as resources permit. We will collect questions from correspondence and other inquiries that we receive and consider including them in future editions of this guidance. Submit your questions concerning the interpretation of the requirements of the food labeling regulations to the Office of Nutrition and Food Labeling (HFS-800), Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740.

FDA guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA guidance documents means that something is suggested or recommended, but not required.

The FDA guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.
D. Enforcement

When will the Rule start being enforced in California?

Facilities subject to the rule must comply by December 1, 2016 and can be subject to enforcement at that time. The FDA statement that it intends to begin enforcement one year from the date that the notice was published in the federal register (May 2017) was in reference to enforcement using federal funds. California is not utilizing federal funds for enforcement and this date is not applicable\(^{12}\).

However, in alignment with FDA’s commitment, California local enforcement agencies are also committed to working flexibly and cooperatively with food facilities covered by the menu labeling rule and providing education and technical assistance prior to strict enforcement of said regulations.

What do local enforcement agencies do if they do see a violation (i.e., find that a chain food facility that should provide nutritional information under the menu labeling law has not provided any nutritional information at all)?

Local enforcement agencies may record it as a minor violation on the Food Official Inspection Report. Under the menu labeling law, a violation is considered an infraction. Local enforcement agencies may choose to be flexible for the first six months to allow for restaurants to come into compliance. It is recognized however, that ability to comply is typically outside the scope of the Person-In-Charge (PIC) duties and that outreach, communication and notification(s) of enforcement is best done by contacting the permit holder or by obtaining corporate contact information during a routine inspection. It is recommended to local enforcement agencies that initial notification and informational bulletins regarding the new regulation be sent to permit holders and/or corporate contacts.

Will local enforcement agencies check for accuracy of the nutritional information?

Under the menu labeling law, local enforcement agencies will verify that the requisite information is provided per the menu labeling law. They will not be required to test for accuracy of the information. (i.e., they will check if a chain has the calories on the menu, but will not verify that the calories on the menu are accurate)

What if a local enforcement agency receives a complaint regarding the accuracy of the nutritional disclosure? (e.g., Customer complains that a menu says the item has 1000 calories and after the customer had the item tested, it was discovered that the item has 1500 calories)

No enforcement mechanism is provided under the menu labeling law for local enforcement agencies to check for accuracy. However, the local enforcement agency may refer the case to other appropriate government entities that have jurisdiction over the complaint under another body of law (e.g., depending, it may be referred to the local district attorney for violations under other theories of law) or if the local agency has jurisdiction under another law, they may act. Furthermore, local enforcement agencies may verify that a restaurant used a “reasonable basis” per the menu labeling law to determine the nutritional information.

Will local enforcement agencies regulate food facilities that do not fall under the menu labeling law but that voluntarily provide nutritional information?

No. If a food facility does not meet the definition of a chain food facility under the menu labeling law then they will not be regulated by the local enforcement agencies. However, federal and state agencies like the FDA and the CDPH may have jurisdiction over nutrient claims under other bodies of law.

\(^{12}\) http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm498356.htm