



WOULD YOU LIKE 500 CALORIES OF FRIES WITH THAT 540-CALORIE BURGER?

NEW FDA REGULATIONS TO REQUIRE CHAIN RESTAURANTS TO POST NUTRITION INFORMATION

As part of the health care reforms of 2010, Congress imposed a new regulatory scheme on chain restaurants. New legislation requires restaurant chains to provide extensive nutrition information about every regular menu item. Some of that information—notably calorie counts—must be set out on every menu and menu board. The U.S. Food and Drug Administration (“FDA”) is drafting implementing regulations. This process has proven surprisingly complex as the FDA tries to take into account the many ways in which food is prepared and presented, and the many kinds of establishments that serve food. Although some details are still undetermined, it is clear that restaurants will need to expend significant effort and money to comply with the eventual regulations.

This *Commentary* will summarize the new legislation, the draft regulations the FDA published earlier this year, and some of the issues shaping the rulemaking process.

The FDA currently plans on having final regulations in place by June 30, 2012,¹ and intends to make the regulations “effective” six months later.²

CURRENT LAW AND THE PUSH TO FIGHT OBESITY THROUGH MENU LABELING REGULATIONS

All packaged food sold in the United States must bear a label stating the food’s nutrition content, including calories per serving. See Food, Drug, and

Cosmetic Act (“FD&C Act”) § 403(q)(1); 21 C.F.R Part 101. Until recently, restaurants were exempt from federal nutrition labeling requirements.³

Recent years have seen increasing political support for requiring restaurants to disclose nutrition information, especially calories. Many believe, or at least hope, that better information will help consumers avoid obesity. According to the FDA, posting nutrition information “should help consumers limit excess calorie intake and understand how the foods that they purchase ... fit within their daily caloric and other nutritional needs.” 76 Fed. Reg. 19192, 19220 (April 6, 2011). More generally, the FDA asserts that “nutrition labeling requirements should help consumers to make more informed choices about the nutritional content of the food they purchase.” *Id.*

It is far from clear that menu labeling laws will improve public health. A July 2011 study published in the prestigious *BMJ* (formerly known as the *British Medical Journal*) found that a New York City menu labeling law has had, on average, no effect on calorie intake. That same study reviewed prior research on the subject and found that those studies “showed mixed results.” Some studies predicted a modest impact, while others found no measurable effects.⁴

Nevertheless, a patchwork of state and local jurisdictions have already enacted menu labeling laws. The best known of these are laws governing California and New York City.⁵ Similar legislation has also been passed in Connecticut, Maine, Massachusetts, New Jersey, Oregon, Vermont, and a variety of cities and counties. These laws will soon be joined (and largely preempted) by FDA regulations.

FEDERAL LEGISLATION

Congress first legislated menu labeling in 2010, with the passage of the Patient Protection and Affordable Care Act (“PPACA”). This lengthy bill is better known as part of President Obama’s sweeping efforts at health care reform, and is known to its detractors as “Obamacare.” Section 4205 of the PPACA mandates that chain restaurants provide nutrition information, and it calls upon the FDA to issue implementing regulations.⁶ This section falls within a portion

of the bill designed to prevent disease. See PPACA Title IV (“Prevention of Chronic Disease and Improving Public Health”) Subtitle C (“Creating Healthier Communities”).

The menu labeling law does not cover every business that sells food. Rather, Section 4205 covers only “restaurant[s] or similar retail food establishment[s]”⁷—a phrase that the FDA is struggling to define. (See *below*.) Furthermore, Section 4205 does not apply to every “restaurant or similar retail food establishment,” but only to those that are “part of a chain with 20 or more locations.” FD&C Act § 403(q)(5)(H)(i).

The scope of Section 4205 is, however, considerably broader than just “fast food” restaurants. As long as a restaurant is part of a 20-establishment chain, it is covered regardless of the prices charged, the kind of food served, or whether there is table service. FD&C Act § 403(q)(5)(H)(i).

Section 4205(b) requires chain restaurants to:

- 1) Post calorie information on menus, on menu boards, and next to self-service displays;
- 2) Make available printed information containing a broader range of nutritional information; and
- 3) Post a statement concerning suggested daily caloric intake.

The statute exempts some food items, including condiments, daily specials and other temporary menu items, and food served as part of a marketing test. FD&C Act § 403(q)(5)(H)(vii).

PREEMPTION OF STATE AND LOCAL REGULATIONS

A notable feature of this legislation is that it preempts conflicting state law. States and their subdivisions are now precluded from establishing “any requirement for nutrition labeling of food that is not identical to the [federal] requirement[.]” FD&C Act § 403A(a)(4) (as amended by PPACA § 4205(c)).

As noted above, restaurants that are not part of 20-location chains are exempt from the new federal requirements. However, these smaller businesses can choose to be regulated by the federal mandate in order to obtain the benefit of federal preemption. A business that registers with the FDA will be subject to FDA menu labeling regulations but becomes exempt from all state and local regulation. See FD&C Act § 403(q)(5)(H)(ix); § 403A(a)(4).

The preemption of local regulation is of significant benefit to restaurant chains. Chains operating across state borders need not worry whether local regulations are inconsistent, enabling them to use a single menu for all their locations. And while compliance with the FDA regulations will by no means be costless, restaurants (of any size) are shielded from potentially more onerous local regulation.

AN OVERVIEW OF THE FDA'S PROPOSED REGULATIONS

The FDA does not view Section 4205 as being immediately enforceable.⁸ Section 4205 calls upon the FDA to implement regulations to carry out the section's mandate. FD&C Act § 403(q)(5)(H)(x). Accordingly, the FDA published proposed rules, along with an extensive explanation, on April 6, 2011. See 76 Fed. Reg. 19192-19236.

The proposed regulations implement the mandates set out in Section 4205. The regulations specify where on a menu required information must be posted, the type size and color of the statements, how to provide information about self-service foods (such as buffets and salad bars), and a host of other details.

These regulations will impose significant burdens on restaurants. Restaurant owners will need to redesign menus, and many will need to purchase new menu boards in order to add a column disclosing the calories in each item. The required disclosures will tend to crowd out other information that restaurants would otherwise place on their menus, such as additional product offerings or promotional messages. For example, chain restaurants will be required to print, on every menu page: "A 2,000 calorie daily diet

is used as the basis for general nutrition advice; however, individual calorie needs may vary." 76 Fed. Reg. 19234 (proposed 21 C.F.R. 101.11(b)(2)(i)(B)).

UNRESOLVED ISSUES AFFECTING THE PROPOSED REGULATIONS

The FDA, in drafting the proposed regulations, is struggling to apply a somewhat murky legislative mandate to a large and heterogeneous industry. The questions the FDA is grappling with include the following. Each has generated significant commentary, both by the FDA as it seeks input and in the comments submitted by people and businesses in response:

- What establishments, in addition to restaurants, are covered by the new regulations?
- Must information be provided regarding alcoholic beverages?
- How accurate must the nutritional information be?
- When will the new regulations come into effect?

Who is Regulated? A wide variety of businesses sell food to consumers for immediate consumption. Such businesses include traditional restaurants, grocery stores, convenience stores, movie theaters, sports arenas, hotels, amusement parks, airlines, and many others. Determining which establishments are now regulated has proven controversial.

Until passage of PPACA, "restaurants or other establishments in which food is served for immediate human consumption" were exempt from nutritional labeling requirements. FD&C Act § 403(q)(5)(A). The scope of Section 4205 is not set out in parallel language. Section 4205 applies to each "restaurant or similar retail food establishment." FD&C Act § 403(q)(5)(H)(i). This implies that there may be many establishments that remain unregulated—establishments "in which food is served for immediate consumption" but that are not "similar" to a restaurant.

The FDA, at least, is of this view. Its proposed regulations would cover only establishments “where the sale of food is the primary business activity.” 76 Fed. Reg. 19233 (proposed 21 C.F.R. § 101.11(a)). The FDA’s intent is to exempt movie theaters, amusement parks, general merchandise stores, hotels, trains, and planes, but not grocery stores or convenience stores. 76 Fed. Reg. 19197-98.

Must Nutrition Information Be Provided for Alcoholic Beverages? Section 4205 mandates the disclosure of nutrition information regarding all “food that is a standard menu item.” FD&C Act § 403(q)(5)(H)(i). Under the FD&C Act, “food” is defined to include “articles used for food or drink.” FD&C Act, § 201(f). Citing this statutory definition, the FDA takes the position that alcoholic beverages are “food” subject to FDA jurisdiction. 76 Fed. Reg. 19202.

Nevertheless, the FDA proposes that the new “labeling requirements ... do not apply to alcoholic beverages.” 76 Fed. Reg. 19233 (proposed 21 C.F.R. § 101.11(b)(1)(ii)). The FDA’s rationale is that primary responsibility over the labeling of most alcoholic beverages resides with another agency (the Alcohol and Tobacco Tax and Trade Bureau, which is part of the Treasury Department). 76 Fed. Reg. 19202; see *also* 27 U.S.C. § 205(e) (authorizing the Treasury to issue labeling regulations). Thus, although the FDA believes labeling would result in health benefits, the FDA also believes that “it is not clear that Congress intended for the nutrition information disclosures required by section 4205 to apply to alcoholic beverages” 76 Fed. Reg. 19203.

How Accurate Must the Nutrition Information Be? Menu labeling is hardly an exact science. A July 2011 study comparing the calorie content of foods to the claims posted on restaurant menus found that virtually no menu disclosures were accurate to within 10 calories. Some menu claims understated calorie content by hundreds of calories. On the whole, calories were overstated as often as they were understated. The authors of the study viewed “poor quality control of portion size” as the likely cause of the inaccuracies.⁹

Section 4205 requires restaurants to have a “reasonable basis” for their claims. FD&C Act 403(q)(5)(H)(iv). The FDA interprets this phrase to mean (among other requirements) that dishes must have no more than 120 percent of the calories, sugars, fats, cholesterol, or sodium declared. 76 Fed. Reg. 19235 (proposed 21 C.F.R. § 101.11(c)(4)).

Many restaurants may have trouble meeting this standard of accuracy. There is considerable variation from one serving of a dish to the next, particularly in restaurants that prepare their meals individually, by hand. Thus, if the proposed rule is adopted without change, some restaurants will need to impose tighter controls on how their meals are prepared.

When Must Restaurants Comply with the New Regulations?

The regulations implementing Section 4205 are not yet final; the FDA’s internal timetable aims to publish the final rules by June 30, 2012.¹⁰ The FDA proposes “that the final rule become effective six months from the date of its publication.” 76 Fed. Reg. 19219.

This timetable puts restaurants in a bind. The new regulations will force restaurants to redesign their menus. Many restaurants will find that they need to purchase new menu boards, and all will need to have their menu items analyzed to determine nutrient content. These tasks take time, and menu redesigns in particular may not fit into the six-month window between publication of the final regulations and their implementation. But since the final regulations may be quite different from the current proposals, work done before the final rules are published may be wasted.

CONCLUSION

Congress passed Section 4205 hoping that many consumers will significantly alter their behavior upon learning how many calories they are being served. If the law proves effective, many consumers will avoid meals that they view as containing excessive calories. Some consumers might also react to the new calorie disclosures by eating out less frequently, and others might avoid entire restaurant chains that they view as serving unhealthy food.

Restaurant chains therefore will need to prepare for the upcoming regulations—both to understand how to comply and also to plan how to compete for business in the new regulatory environment. Although the final regulations are not likely to become effective before the end of next year, restaurants would be well advised to begin their preparations significantly before the deadline.

LAWYER CONTACT

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ENDNOTES

- 1 <http://www.accessdata.fda.gov/FDATrack/track-proj?program=healthcare-reform&id=ACA-4205-Implementation>.
- 2 76 Fed. Reg. 19192, 19219 (April 6, 2011).
- 3 Until March 2010, this exemption was set out in the Food Drug and Cosmetic Act at § 403(q)(5)(A)(i).
- 4 Duanovsky, *et al.*, “Changes in energy content of lunch-time purchases from fast food restaurants after introduction of calorie labeling: cross sectional customer surveys,” *BMJ* 2011; 343:d4464 (published July 26, 2011).
- 5 Cal. Health & Safety Code § 114094; Rules of the City of New York, Title 24, § 81.50.
- 6 The language of Section 4205(b) is codified as Section 403(q)(5)(H) of the Food, Drug, and Cosmetic Act (21 U.S.C. § 343(q)(5)(H)).
- 7 FD&C Act § 403(q)(5)(H)(i).
- 8 More precisely, although the FDA views portions of Section 4205 to be immediately effective, “FDA now intends to complete the notice-and-comment rulemaking process for [Section 4205] before initiating enforcement activities.” 76 Fed. Reg. 4360 (Jan. 25, 2011).
- 9 Urban, *et al.*, “Accuracy of Stated Energy Contents of Restaurant Foods,” *JAMA* (July 20, 2011); Fisher, Christopher, “Overall Calorie Counts Accurate on Restaurant Menus, But Vary Widely For Some Individual Foods,” *The Behavioral Medicine Report* (July 20, 2011).
- 10 <http://www.accessdata.fda.gov/FDATrack/track-proj?program=healthcare-reform&id=ACA-4205-Implementation>.