



Regulation Review

New Nutrition Label Guidelines

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The Food and Drug Administration (FDA) has released a pair of proposed rules that would update the form and content of nutritional fact labels. The new guidelines purport to give consumers a more complete picture of food products. The proposals represent the most major change in labeling stand-

ards since the early 1990s. Together, the unofficial, pre-publication versions of the rulemakings are 512 pages.

The first rule, “[Revision of the Nutrition and Supplement Facts Labels](#),” adjusts how labels describe a product’s nutrient composition relative to FDA’s suggested daily value. The [second rule](#) handles a number of other issues including: the overall layout of the label, the number of servings in a given product, and the “typical” serving size. It curiously singles out the serving size for breath mints, mandating that labels list mints as “1 unit.” Interested parties will have 90 days to submit comments.

BREAKDOWN

- Total Compliance Costs: \$4 Billion
- Annualized Costs: \$354 Million
- Total Paperwork Burden: 2.89 Million Hours

ANALYSIS

Although FDA is promulgating two separate rulemakings, it conducted a singular, cumulative [Regulatory Impact Analysis \(RIA\)](#). Considering these proposals as a singular action, it is clearly one of the most significant regulatory measures of the year. With potential costs exceeding \$4 billion, it is the most expensive rule so far in 2014. The nearly 3 million additional hours of paperwork represent the year’s second highest non-tax-related burden.

Given the size of these burdens, it is no surprise that both proposals exceed the thresholds for the Unfunded Mandate Reform Act and the Regulatory Flexibility Act. These cost burdens will be widespread. FDA estimates that the new standards will affect 59,872 firms and 741,134 Universal Product Codes (UPCs), or food items. Of the nearly 60 thousand firms, 65 percent are considered small businesses.

With such large and universal costs, one would assume that this rule addresses serious, immediate issues. Yet it is only a part of the administration’s overall push to combat obesity and direct consumer and producer behavior via regulatory “nudges.” The administration seeks to combat obesity by reducing consumer confusion, or as the RIA reads: “Increased ease of nutrition label use from the decreased need to do arithmetic.”

FDA argues that these changes will help consumers make more nutritious choices and could also push

producers to reformulate their ingredients to meet increased demand for healthy products. The agency further claims that these gradual shifts will decrease the long-term health risks posed by obesity. However, even they note a great degree of uncertainty on this:

Note that consumers may offset any reduction in their consumption of unhealthy items with consumption of unlabeled or unhealthy meals or snacks. Consumers substitute between nutrient sources when attempting to modify their food choices (Ref. 30). Because we lack any data or information on how consumers would substitute between foods in response to the labeling changes, the benefit estimates in this analysis may over- or understate the effects realized if we finalize the nutrition labeling proposals as proposed.

The idea of “nudging” consumers and producers toward a particular goal depends on whether the regulatory action necessarily achieves that goal. One part of these rules, that is actually mandated by the Nutrition Labeling and Education Act, is to update the serving size of certain products to a portion “typically” consumed. Under this rule, some serving sizes will actually increase. For instance, currently 20-ounce sodas list a typical serving as 8 ounces. The new version will claim that the whole 20 ounces now constitute a single serving.

One could argue that the authority of a government-mandated label could suggest to the consumer that the proper, more nutritious way to consume such a product is in 8 ounce servings. Whereas describing the “proper” serving as a full bottle, may suggest to the consumer that they finish it in one serving. If consuming increased quantities of such products leads to poor health outcomes, promoting the idea of consuming a whole container at once could be a counter-productive consequence of the rulemaking. For producers, it seems to follow that more rapid consumption would mean increased demand for certain products, and thus motivate the producers to promote such products over more healthy ones.

Although there may be issues with the reasoning and unintended consequences of the rule, there are concerns about the cost-benefit balance. The RIA describes the costs and benefits of extending the compliance deadline from the proposed two years to either three or four. Another option FDA considered was including a daily value amount of sodium intake. However, that simply maintained benefits while increasing costs. The table below compares the various figures of the timeline options.

Cost and Benefits of Options, Mid-point Estimates (in Billions)		
Option	Costs	Benefits
2-year deadline	\$2.3	\$21.1
3-year deadline	\$1.5	\$20.5
4-year deadline	\$0.6	\$20.1

As with most instances where a rule’s alternative extends the compliance deadline, there is a decrease in costs due to entities phasing in compliance more gradually, and a forgoing of benefits due to less compliance over that period. Agencies generally choose the shorter option because they want to maximize benefits. However, the

cost-benefit calculus in this case suggests that FDA may want to consider either of its proposed alternatives.

Shifting from the two-year option to the three-year one yields \$800 million in fewer costs, versus \$600 million in lost benefits. Shifting from the two-year option to the four-year one yields even more dramatic results: \$1.7 billion in decreased costs against \$1 billion in decreased benefits. As shown below, the 4-year timeline actually yields the highest net benefits.

Net Benefits of Options, Mid-point Estimates (in Billions)	
<u>Option</u>	<u>Net Benefits</u>
2-year deadline	\$18.8
3-year deadline	\$19
4-year deadline	\$19.5

President Obama’s Executive Order 13,563 directed agencies to produce regulations that: “in choosing among alternative regulatory approaches... maximize net benefits.” This seems like a clear situation where, in present form, FDA is not following the President’s order. Between this issue, the high cost estimates, and questionable reasoning on its purported benefits, there are concerns FDA will need to address before finalizing these rules.