Regulation Review

FDA Trans Fat Ban

JUNE 16, 2015

Banning “trans fats” could cost $11 billion, according to the Food and Drug Administration (FDA), which recently released a “declaratory order” regarding partially hydrogenated oils, the source of trans fats. The order finds that trans fats are no longer considered “generally recognized as safe (GRAS) for any use in human food.” Instigated by “citizen petitions,” FDA made this determination under an arcane provision in the Code of Federal Regulations (CFR), outside of the usual notice and comment rulemaking process. FDA expects full compliance by June 18, 2018.

BREAKDOWN

- Average Total Costs: $6.2 Billion ($417 Million Annualized)
- Average Total Benefits: $140 Billion ($9.4 Billion Annualized)

ANALYSIS

What little analysis FDA does provide looks at “the costs of all significant effects of the removal, including packaged food reformulation and relabeling, increased costs for substitute ingredients, and consumer, restaurant, and bakery recipe changes,” and the “expected medical expenditure savings” as its benefits. The figures above are their average estimates, though they do give a range of figures with high-end costs reaching $11 billion and benefits reaching $440 billion. FDA estimates that banning trans fats could prevent 1,620 to 23,350 coronary heart disease deaths annually.

It is difficult to examine the full extent of FDA’s economic considerations. Despite receiving “over 6,000 comments” (three-fourths were “form letters”), this order does not fall under regular notice-and-comment rulemaking. Thus, this order escapes a review by the Office of

Information and Regulatory Affairs (OIRA) and analyses as required under the Congressional Review Act and Unfunded Mandates Reform Act .

The result: an "economic analysis" that takes up less than a page based on an apparently as-of-yet not-publically-available memo dated June 11, 2015 – less than a week ago. At least FDA is consistent in utilizing economic analysis within such a short time window. The corresponding memo for the "Tentative Determination" is dated November 5, 2013 – three days before the agency published that determination.

At one point, FDA parenthetically notes:

> *As a general matter, we no longer affirm the GRAS status of substances through notice-and-comment rulemaking. In April 1997, we proposed to replace the voluntary GRAS affirmation petition process with a voluntary GRAS notification program, which would not involve rulemaking.*

Perhaps FDA is technically within its bounds to make such a determination, but this stands as a high-profile example of flawed regulatory policymaking. A regulatory order that, within hours of its release, grabs dozens of headlines and admits to affecting the economy by billions of dollars annually ought to undergo a more rigorous, standardized, and transparent process than this action. Finishing such evaluations within days of final publication calls into question how much the agency truly considered the economics of regulating.