Interagency Peer Review Evaluation

Final Regulatory Impact Analysis of a Nutrition Labeling Rule for Meat Products
Food Safety and Inspection Service
U.S. Department of Agriculture

Evaluated by
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16 May 2006

Overall, I believe that this analysis is thorough. The justification for government intervention (i.e., consumers do not receive the optimal amount of nutritional information) was discussed thoroughly. The baseline was defined and the logical regulatory options were identified and considered. The sensitivity of the findings to changes in some key variables (e.g., the discount rate, rate of compliance, effectiveness of POP information) was assessed. The bases for the estimates of the costs and benefits were explained and the sources of the data were identified. Additionally, the major sources of uncertainty in the analysis were identified and discussed in the paper. For the most part, the analysis is transparent.

FSIS response: The analysis has been significantly revised in response to the comments of the two reviewers and hopefully the transparency of the analysis has been improved.

I do have a question concerning the calculation of the decreased intake of fats due to increased label usage (Table 16, with supporting data in Tables 14 and 15). The intake prior to mandatory labeling appears to include the intake of fats and cholesterol that could be attributed to those consumers that do not buy meat. This is appropriate. However, their intake does not appear to be accounted for in the intake after adjusting for increased label usage. It seems to me that their behavior would not be affected by meat labeling and they would, therefore, consume the same amount of fats and cholesterol after the labeling change as before. Is it possible that the percentages of consumers that use nutrition facts panels reported in Table 14 should be adjusted for the roughly 2 percent of consumers that do not buy meat? In other words, is it possible that although 26.7 percent of men "often" use the nutrition facts panel, only 26.1 percent of men (.267 * 97.8) will use the nutrition facts panel on meat, because 2.2 percent of men do not buy meat? Similarly, would 46.7 percent (instead of 47.7 percent) of men "rarely or never" use the nutrition facts panel on meat?

(My calculations, based on the above discussion, suggest that the total fat intake for men could decrease by 1.7% instead of 1.3%.)

FSIS response: The reviewer makes a good point and the revision would result in greater reductions in fat and saturated fat intake. Fat and saturated fat intake also decrease for women. The authors of the article from which this information was taken supplied analysis showing the outcomes if the 2.2 percent of men and 2 percent of women who report not buying meat, poultry,

or fish continue to refrain from purchasing these products after the introduction of nutrition labeling. These results are shown in footnote 40.

I was able to recreate Table 16 from the information supplied in the report. I was not able to do the same for Table 17. It would make the analysis more transparent if the reader were provided with more information on how these values were calculated.

FSIS response: The reviewer is correct. The authors of the article from which this information was taken supplied additional information that enables the reader to derive the changes in intakes due to increased label use. The additional information is contained in a new table, Table 17. .

In addition to the above comments here are some minor editorial comments or suggestions.

Summarize the alternatives in a chart or a table: As someone not familiar with the nutritional labeling requirements, I had some trouble following the text at first. I think it would be easier to follow if a summary of requirements by alternative for each of the products was provided in a table.

FSIS response: The agency agrees and Table 6 has been added to the document which summarizes the regulatory alternatives. Other revisions have been made to improve the flow and readability of the document.

On page 39, the last full paragraph, the text states "For retail stores, consistent with the cost analysis of the chosen alternatives, the average cost of the nutrition analysis is $7.87 million…" *Is this really the total cost of the nutrition analysis (instead of the average)?*

FSIS response: Yes, the industry average, one-time compliance cost for nutrition analyses of major and non-major cuts is 7.87 million. The text has been modified to make this clarification. A footnote has also been added which explains why a nutrition analysis is required for these products.

On page 40, in the partial paragraph at the top, the text reads "… then retail stores will incur an added average cost of about $33.68 million." Should *average* be *annual*, consistent with Table 7?

FSIS response: The test was modified to show that the cost is an annual average. Table 7 (new Table 8) was modified to show that the reported costs are averages.

On page 49, the present value of the cost of purchasing and installing posters when discounted at 7% over 20 years is reported as $20.33 million. I believe this should be $31.07 million (as reported in Table 13, Row 1).

FSIS response: The text has been revised to correspond to the correct amount shown in the table.

On page 72 of the report there is a discussion of the elasticity of the market for meat products. I believe the discussion in that paragraph is referring to the elasticity of the demand faced by any individual firm, rather than the elasticity of supply.

FSIS response: The reviewer is correct. This paragraph has been deleted as it is confusing and repeats a discussion on the previous page.

On page 73, in the discussion of the research by Kim, et.al. there is a reference to their finding that improved dietary patterns could result in a reduction of medical costs by $43 billion. Is this an annual reduction?

FSIS response: Yes this is an annual reduction in medical costs. FSIS has added explanation of the research by Elizabeth Frazao of USDA's Economic Research Service in 1995, which was updated in 1999. The explanation notes that the reduction in medical costs is not related to the potential decline in fat, saturated fat, cholesterol, and sodium referred to by Kim, et al. It is also noted that Frazao, 1999, revises the potential reduction in medical costs to slightly over $33 billion, annually.

I have some minor editorial comments on page 78. In the last paragraph, in the sentence beginning "Examining the behavior of nutrition label or POP nutrition information users and non users before and after a significant change…" is probably better described as "research" rather than a "research method." There is an "is" missing later in that sentence between "preferences" and "significant."

FSIS response: The revisions have been made as suggested.

On page 86, in the first paragraph, "was not available" is missing from the sentence that begins "Since separate data for polyunsaturated (P) fat, …."

FSIS response: The revisions have been made as suggested.

On page 134, I think the number in first sentence of the first full paragraph is $46,000 or $0.046 million.

FSIS response: The reviewer is correct and the text has been revised accordingly.

Peer Review of
Economic Analysis of
the Nutrition Labeling of Single-Ingredient Products
and Ground or Chopped Meat and Poultry Products Final Rule

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May 17, 2006

The opinions expressed are only my own as a professional economist and regulatory analyst and not those of my employer.

The analysis is very difficult to follow and to evaluate, especially at the beginning. The organization is confusing (for example, estimates are given without explanations or justifications come many pages later or very enlightening cost-effectiveness analysis at the end of the document doesn't seem to have influenced the discussion of alternatives in the first pages). As far as I could tell without having access to the regulation and with very limited time for such a lengthy document the major issues that an analysis should address appear to be covered. If anything, the analysis would be improved by shortening it to remove lengthy discussions about matters that do not have much bearing on the results of the analysis (for example, the multiple values of statistical life).

FSIS response: FSIS has attempted to improve the flow and eliminate the possible sources of confusion found by the reviewer. For example, in the Baseline section, selected paragraphs were moved to where the information was used in the analysis. Some text materials were converted to footnotes. The amount of product affected by the rule is now presented in the Baseline. Other changes were made to present calculations close to points in the discussion where the calculations were used.

FSIS agrees that cost-effectiveness analysis provided insightful comparisons of the regulatory alternatives and labeling measures that were not available earlier in the analysis. FSIS has provided a summary of the major conclusions of the cost-effectiveness analysis at the close of the discussion of the regulatory alternative. The placement of the cost-effectiveness analysis was based on its use of information in the cost analysis and benefits analysis sections. It was thought that this would aid the reader. In hindsight, it may have been a greater benefit to present the entire cost-effectiveness analysis at the close of the section discussing the regulatory alternatives, sparing the reader of the grizzly details in the 100 pages, or so, that would then follow. The agency will strongly consider doing so in subsequent economic analyses, naming this somewhat unique approach after its progenitor—the Zorn Maneuver.

A table summarizing the provisions of the final rule and regulatory alternatives was added to the regulatory alternatives section. Pointers were added to the discussion of the alternatives to

show where the cost analysis of the final rule would be found and the relationship between the costs of Alternatives 4 and 5.

The discussion of alternative values of a statistical life and the justification for the value chosen by the agency has been shortened in response to the comment by the reviewer. The discussion justifying the value of a statistical life has been shortened somewhat and concludes that the amount of discussion is consistent with the impact of the value of a statistical life on the analysis.

Much of the early discussion is cluttered so as to make it difficult to keep track of the point being made. For example, the length of the phrase and the frequent repetition of "major cuts identified in §§ 317.344 and 381.444 (including ground beef and ground pork) and on all other ground or chopped products not covered in §§ 317.344 and 381.444" is at least distracting.

FSIS response: In addition to the changes mentioned in the paragraph above, FSI has attempted to reduce the "clutter" referred to by the reviewer. The text was revised to eliminate references to statutory definitions when simpler definitions would be sufficient. Repetitive calculations were stated in terms of a formula and moved to a footnote or condensed on several occasions is estimating the number of products subject to the labeling provisions of Alternative 5.

In a number of places estimates are given for minimum, maximum, and most-likely without any justification for the estimates of each, without any clear explanation of the reason for the uncertainty, without carrying the uncertainty thru to the industry-wide estimate and without a clear sense that the uncertainty is meaningful. For example, are $97.50 and $102.50 really different enough from $100 that it is worth the clutter? The extensive use of tables is helpful. In fact, much of the readability problems could probably be improved by taking estimates and calculations out of the text and putting them into tables.

FSIS response: In most cases, the minimum, maximum, and most-likely or mid-points are to be found in the tables of Appendix B. The text has been modified to more clearly identify the estimates of the input costs. In general, the values used represent information collected by RTI for the FDA Labeling Model, or other studies such as the NCBA surveys. Other values were assumed to be around a point-value that was collected by RTI, NCBA, or other referenced studies. Assumptions are made and tested for their effect on average cost of the alternatives considered. The results are in tables of Appendix B and in Appendix D, Table 1.

For purposes of the FRIA, the estimated costs are represented in a probability distribution, such as a triangular distribution (minimum, most-likely, and maximum values). The economic analysis is stochastic to the extent that an effort has been made to address the randomness of values or events. The cost model uses @RISK (Version 4.5, Palisade Corporation) to examine the effects of variability, volatility, or uncertainty. The cost model is a stochastic economic model with a simulation to determine sensitivities of variability, volatility, or uncertainties. The model structure, equation specification, statistical properties, assumptions, documentation, and results are presented in the tables of Appendix B. Other tables of Appendix D have the summary of costs by alternative (Table 1), and the detailed framework and results of the preferred Alternative 3 (Tables 2 and 3).

For example, for Alternative 2, the estimated distribution (minimum, most-likely, and maximum values) of costs represent assumed quantity discounts for the publication (book), and expected differences in shipping costs to the retail stores or establishments. Also, the shipping costs are assumed to vary by weight, distance shipped, and method of shipping. In addition, a distribution of labor was also assumed around the value of the 0.5 hours. The distributions of input values (book and labor time) allow for an assessment of the sensitivity or relative degree of resulting change in output values. In addition, there is a relatively large number (or multiplier) of retail stores (74,910 stores) that are affected by Alternative 2. Therefore, the distributions of input values that were used resulted in an average annual (or annualized) cost of $8.28 million. This average had a range of variability of $8.03 million at the 5th percentile and 8.53 at the 95th percentile (see Appendix D, Table 1). The relative small difference in the spread ($8.03 million to $8.50 million) represents 90 percent of the results of the analysis. Therefore, the assumed variability, volatility, or uncertainty of the input factors of the cost of the book and labor time, did not greatly affect the reported average annual cost of Alternative 2.

The explanation of the number of firms and establishments was very unclear. It seems a distinct possibility that too many small firms are assumed to be exempt.

FSIS response: Table 1 indicates that small and large federally-inspected establishments would be affected by the preferred alternative 3 (the final rule). The assumption was that each firm owns three large or small federally-inspected establishments. Table 2 indicates that 41 state-inspected establishments that are small would be affected, and that this represents 41 small firms. Further, Table 3 indicates the number of retail firms and establishments (stores) affected by one part of preferred alternative 3 (the final rule): nutrition labeling for major cuts. In addition, Table 4 indicates the number of retail firms and establishments (stores) affected by another part of preferred alternative 3 (the final rule): nutrition labeling for ground or chopped products. FSIS assumed that all of the very small and small establishments or firms would be exempt from the nutrition labeling requirements for ground or chopped products—

The discussion of the alternatives needs the most work. One of the alternatives should have been the proposed rule. This is the most obvious choice and would have helped show the changes made in the final rule. Alternative 1 was not completely evaluated. The costs and benefits of the decision to call ground or chopped products that do not have nutrition information misbranded should be estimated.

FSIS response: The proposal is largely consistent with the final rule. FSIS compared significantly different alternatives, as opposed to subtlety different alternatives. Among the alternatives, Alternative 3 is the preferred alternative and the final rule. This has been made clear in the section on Regulatory Alternatives. Alternative 3 evaluates the costs and benefits of requiring nutrition labeling for ground or chopped products. Under this alternative, these products would be misbranded without nutrition labels, unless they qualify for an exemption. Alternative 1 is continuing with the existing voluntary program. FSIS did not choose this alternative because this option would not ensure that nutrition information is provided for the major cuts of single-ingredient, raw meat and poultry products. In addition, FSIS did not choose this alternative because the Agency has determined that ground or chopped products that do not

bear nutrition information would be misbranded under section 1(n)(1) of the FMIA and section 4(h)(1) of the PPIA.

In the "Estimating Benefits of Preventing Premature Death" section, FDA did not really assume that one-third of the chronic-cases of heart disease would be fatal. The proportion of fatal cases of CHD comes from literature on medical statistics.

FSIS response: The text has been modified to respond to the comment by the reviewer. The discussion to which this comment was addressed was moved to the preamble.

I agree with the decision not to estimate benefits from cancers.

FSIS response: The agency appreciates the valued concurrence of the reviewer.

It is not clear to me why the approach in "Effects of Current Compliance Levels" is not applied from the beginning. I would think that this would be the baseline from which any regulatory impacts are measured.

FSIS response: FSIS thought it was appropriate to estimate the total costs of the new requirements. The impacts of current compliance levels are shown in Appendix C. Therefore, FSIS did not reduce the cost estimates to account for existing voluntary nutrition labeling of major cuts or ground or chopped products. FSIS recognizes that its cost estimates may be high because they estimate total costs. However, FSIS preferred to overestimate rather than underestimate the costs of the rule.

I thought that the best parts of the document were the cost-effectiveness sections starting with "Cost-Effectiveness Analysis" thru the end of the document. Once this analysis publishes I intend to point others to it as an example of state of the art cost-effectiveness analysis as far as I have seen it.

FSIS response: The agency appreciates the valued opinion of the reviewer.