DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Labeling: Health Claims;

Soy Protein and Coronary Heart Disease

Docket No. FDA-2017-N-0763

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

The Food and Drug Administration (FDA or we) has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). This proposed rule is a significant regulatory action under Executive Order 12866. Executive Order 13771 requires that the costs associated with new regulations shall "be offset by the elimination of existing costs associated with at least two prior regulations." It has been determined that this proposed rule is an action that does not impose more than de minimis costs as described below and thus is not a regulatory or deregulatory action for the purposes of Executive Order 13771.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because up to 40 small businesses could be required to relabel one or more products, we find that the proposed rule may have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in any 1-year expenditure that would meet or exceed this amount.

We invite comments on this Preliminary Regulatory Impact Analysis.

B. Summary of Costs and Benefits

This proposed rule would, if finalized, require changes to the labeling of products making health claims about the relationship between soy protein and coronary heart disease (CHD). As described in the preamble, we have tentatively concluded that there is no longer significant scientific agreement among qualified experts that a health claim regarding the relationship between soy protein and reduced risk of coronary heart disease is scientifically valid. All such claims would have to be removed from the labels of food packages that bear the claim and in labeling. However, if this proposed rule is finalized, but there is some credible evidence for the use of a qualified health claim about soy protein and a reduced risk of CHD, we intend to issue a statement of enforcement discretion for the use of a qualified health claim. Firms may then choose to include such a qualified claim on the food label.

The costs of this rule are learning about the rule, and relabeling the estimated 200 to 300 products currently making the health claim. We estimate total annualized costs of $37,000 to $84,000, when the costs are annualized over 20 years at a 7 percent discount rate. The initial, one-time costs are $400,000 to $890,000. Because all costs are incurred in the first year, this is also the present value of the rule costs.

The benefit of this rule is better information for the consumers who are considering purchasing products with soy protein. This may generate an unknown amount of increased consumer surplus. Some consumers are likely to react to this new information by switching their consumption to products that they enjoy more, or products that still have an authorized CHD health claim. By basing their consumption decisions on more recent and accurate scientific information, they will get more consumer surplus, in the form of enjoyment and/or potential health benefits, from the bundle of products they consume.

Table 1. Cost and Benefit Overview, USD, Annualized over 20 years

	Low Estimate	Mean	High Estimate
Costs, 7 percent discount rate	$37,000	$57,000	$84,000
Costs, 3 percent discount rate	$27,000	$41,000	$60,000
Benefits	Consumer Enjoyment and/or potential Health Benefits		

II. Preliminary Regulatory Impact Analysis

When presenting our estimates of input values, we use average values for readability. In the "Costs of the Proposed Rule" section, all results presented are for average values of inputs, rounded to two significant figures in the text. The "Uncertainty and Sensitivity Analysis" section presents the Monte Carlo simulation that we use to form our final estimates.

A. Background

In general, a food is not allowed to bear a health claim indicating that the food or an ingredient in the food is useful in reducing the risk of a disease or health-related condition, unless the food comports to a regulation promulgated by FDA authorizing the use of the claim.[1] A food that bears such a claim that is not authorized by FDA is deemed to be misbranded.[2] When we determine that a health claim is supported by the totality of the publicly available scientific evidence[3], we issue a regulation to authorize the use of the claim on the label of foods that we determine are eligible to bear the claim.

Alternatively, when the publicly available scientific evidence about the relationship between a substance and the risk of a disease does not meet the standard required under the FD&C Act ("significant scientific agreement"), we may consider the use of our enforcement discretion for a qualified health claim. (Ref. (1))

In the past, as described in the Preamble (Ref. (2)), we determined that there was evidence to justify a claim that soy protein could reduce the risk of coronary heart disease (CHD) and we issued regulations to authorize the use of this substance/disease relationship on food labels. We therefore allowed foods with specific levels of soy protein to state on their labels that soy protein could reduce the

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[1] See section 403(r)(3)(A) and (B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 343(r)(A) and (B)).

[2] See section 403(r)(1)(B) of the FD&C Act (21 U.S.C. § 343(r)(1)(B)).

[3] The determination requires a finding that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such a claim, that the claim is supported by the evidence. See section 403(r)(3)(B)(i) of the FD&C Act (21 U.S.C. § 343(r)(3)(B)(i)).

risk of heart disease. More recent research has shown that the scientific evidence for the health claim is inconsistent. We have tentatively concluded that the scientific evidence no longer supports our previous determination of significant scientific agreement among qualified experts for the relationship between soy protein and reduced risk of coronary heart disease. However, we are considering the exercise of our enforcement discretion for the use of a qualified health claim for soy protein and a reduced risk of CHD on certain foods.

B. Need for Regulation

Without this rulemaking, consumers would continue to see information that overstates the health benefits of soy protein. This inadequate information would keep the demand for soy protein above its socially optimal level. Consumers would continue to eat soy protein rather than foods they enjoy more or foods that have other authorized health claims, in hopes of obtaining health benefits. This excess consumption would result in a loss of consumer surplus, in the form of enjoyment and/or health benefits, as the quantity of soy protein consumed remains above the optimal level, and the marginal benefits of this excess consumption will be lower than the marginal costs.

C. Purpose of the Proposed Rule

The purpose of the proposed rule is to ensure that consumers see a health claim about soy protein and risk of coronary heart disease that reflects the more recent and accurate information about this substance/disease relationship on the label of food product packages and in labeling, allowing them to make informed decisions about the foods they consume.

D. Baseline Conditions

The baseline for this estimate is the continuation of the current market for soy protein, with continued use of the soy protein health claim, and a similar number and mix of products bearing the health claim.

E. Costs of the Proposed Rule

The estimated costs of removing this health claim come from food producers

1) learning about the rule, and

2) relabeling products currently bearing the claim.

We searched the LabelInsight database (Ref. (3)), a survey of all foods sold in supermarkets, for products with the soy protein and CHD health claim, and found 234 such products

1. Learning

We estimate that, for each of the 234 products covered by this proposed rule, executives at food producers will spend one hour learning about the rule. We request comments on this estimate. With an average wage of $55.08 (Ref. (4), doubled for benefits and overhead, (Ref. (5)) this results in a one-time cost of about $26,000 (55.08 x 2 x 234 = 25,777). When annualized over 20 years at a seven present discount rate, the cost is about $2,400 per year.

2. Relabeling

We used the FDA Labeling Cost Model (Ref. (6)) to estimate the average relabeling costs for each package type. Products must be relabeled by the Uniform Compliance Date for the time period in which the final rule is issued. Solely for the purpose of this economic analysis, we estimate that this final rule will publish in late 2017, and that the Uniform Compliance Date for that time will be in January 2020, meaning that producers will have slightly more than two years to comply with the rule.

The estimated cost is not the full cost of relabeling the package. When producers have two years to comply, most of them can coordinate the label change with an already-planned label change, meaning that the additional cost to change the claim is small. The average cost includes some full label changes made just to comply with this rule, and some where the claim change is added to an already-planned label change. Different industries have different schedules for planned relabeling, which means a different proportion of new and already-planned label changes. Additionally, different packaging types have different relabeling costs based on the printing technology used (Ref. (6)). Both the schedule difference and the printing cost difference lead to the cost differences in package type shown in Table 2.

We combined the average costs per unit and the number of units with the claim to produce a one-time relabeling cost of about $520,000, as shown in Table 2:

Table 2. Estimated Relabeling Costs, 2-Year Compliance Time

Type	Number	Package Type	Avg Cost	Total Cost
Soy Milk	128	Gable top carton	$ 1,233	$ 158,000
Protein Supplements	35	Plastic-sheet	$ 7,620[4]	$ 267,000
Tofu	25	Paperboard-sleeve	$ 1,498	$ 37,000
Frozen Soybeans	11	Plastic bag-opaque	$ 2,798	$ 31,000
Canned Soup	6	Paper-label	$ 2,324	$ 14,000
Snacks/Other	29	Foil-bag	$ 363	$ 11,000
Total	**234**			**$ 518,000**

When annualized over 20 years, this is about $49,000 at a 7 percent discount rate and $35,000 at a three percent discount rate.

The FDA Labeling Cost Model also provides low and high estimates of average relabeling cost. In the Uncertainty and Sensitivity Analysis section, we use the full range of cost estimates, and include uncertainty about the number of products affected, to produce a range of possible costs of the rule.

Total Cost

Combining the learning cost and the relabeling cost yields total one-time costs (and present value costs) of about $544,000 (518,000 +26,000 = 544,000). When annualized over 20 years, this is about $51,000 at a 7 percent discount rate and $37,000 at a three percent discount rate.

F. Benefits of the Proposed Rule

The benefit of this rule is better information for the consumers who are considering purchasing products with soy protein. This may generate an unknown amount of increased consumer surplus. Consumers are likely to react to this new information by readjusting their consumption to products that better fit their needs. Some consumers will switch to foods in the same category that they prefer more, for example switching from soy milk to almond milk or soy protein powder to whey protein powder.

[4] Protein supplements require more expensive relabeling on average because the labels are more complex, and they are less likely to be coordinated with existing label changes.

Other consumers will switch to other foods that still have a heart disease claim, for example whole grain foods. We do not know how many consumers are in each group. However, in both cases, by basing their consumption decisions on more recent and accurate scientific information, consumers will get more consumer surplus, in the form of enjoyment and/or potential health benefits, from the bundle of products they consume.

We are not able to monetize this increase in consumer surplus. However, given the costs of the rule, we believe that the benefits justify the costs.

G. Distributional Effects

We do not expect any significant distributional effects as a result of this rule. Consumers will spend slightly less money on products containing soy protein, and slightly more on substitutes for those products, but likely not enough to have a meaningful impact on markets.

H. International Effects

We do not expect any significant effects on international trade. Almost all soy consumed in the US is produced domestically, and the likely substitutes are also primarily produced domestically, so we do not expect any significant change in agricultural commodity imports. Foreign firms selling packaged food products in the United States will have to make the same label changes that domestic firms are making, but this is a minor change to existing labeling laws.

I. Uncertainty and Sensitivity Analysis

We find the 90 percent confidence interval of costs by running a Monte Carlo simulation. In each simulation run, we do the following:

1. Randomly choose the total number of affected products from a uniform distribution of 200-300, to reflect uncertainty in products affected, and update the number of products in each category, keeping the proportions the same.

2. Choose the relabeling cost from a triangular distribution defined by the low, average, and high costs in the FDA Labeling Cost Model, shown in Table 3.

Table 3. Average Relabeling Costs, 2-Year Compliance Time

Type	Low	Mean	High
Soy Milk	$ 665	$ 1,233	$ 2,047
Protein Supplements	$ 1,484	$ 2,798	$ 4,722
Tofu	$ 810	$ 1,498	$ 2,507
Frozen Soybeans	$ 1,484	$ 2,798	$ 4,722
Canned Soup	$ 1,268	$ 2,324	$ 3,933
Snacks/Other	$ 189	$ 363	$ 544

The results of the 10,000 simulation runs, rounded to two significant figures, are shown below:

Table 4. One-time (and Present Value) Costs, USD, 2-Year Compliance Time

Low Estimate	Mean	High Estimate
$ 400,000	$ 610,000	$ 890,000

We annualize these values at three and seven percent for the values shown in Table 1 in the Summary.

J. Analysis of Regulatory Alternatives to the Proposed Rule

For the purpose of this economic analysis, we examine the costs of 1- and 3-year compliance periods, even though these options are not viable. Mandating compliance at any time other than the Uniform Compliance Date, if FDA were to require this, may subject products to more than one required labeling change, resulting in greater costs because changes cannot be coordinated as described in the Labeling Cost Model documentation (Ref. (6)). We repeat the analysis as described above, by using the FDA Labeling Cost Model to generate 1- and 3-year cost estimates instead of 2-year cost estimates, adjusted to reflect the fact that more label changes would be uncoordinated. The results, which do not include second-order learning and adjustment costs related to disruption of accepted practice, and should be considered a minimum estimate rather than an expected result, are shown in Tables 5 and 6:

Table 5. Annualized Costs (20 years at 7%), 1-Year Compliance Time

	Low Estimate	Mean	High Estimate
Seven percent discount rate	$114,000	$177,000	$260,000

Three percent discount rate	$81,000	$126,000	$185,000

Table 6. Annualized Costs (20 years at 7%), 3-Year Compliance Time

	Low Estimate	Mean	High Estimate
Costs, 7 percent discount rate	$75,000	$117,000	$172,000
Costs, 3 percent discount rate	$54,000	$83,000	$122,000

III. Initial Small Entity Analysis

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, the Office of Management and Budget (OMB) has determined that this proposed rule is not a major rule for the purpose of Congressional review.

A. Description and Number of Affected Small Entities

As described above, this proposed rule will require approximately 200-300 food products to be relabeled. We reviewed the list of products likely to be affected (Ref. (3)) and found that the majority of them are brand names owned by large food manufacturers. However, between 20% and 40% of the products are brand names that may belong to small manufacturers, with the typical small brand having three products, so we estimate that up to 40 (300 x 40% / 3) small businesses may be affected. We request comment on this estimate.

B. Description of the Potential Impacts of the Rule on Small Entities

As described above, the average annualized cost of this proposed rule per affected product is about $230 ($57,000 / 250 = $228). The typical small business sells three products that must be relabeled, for a total annualized cost per business of $690 and a total first-year cost of about $6,500 (($544,000 / 250) * 3 = $6,528). These are the cost numbers found using a 7 percent discount rate, which is closer to the borrowing costs of small entities. Some small entities will have only one product, while others may have several. According to Dun & Bradstreet data (Ref.4), the average annual sales of food manufacturing companies with less than 500 employees are about $14 million. However, there is a large variance in form sizes. According to the US Census Bureau (Ref. (7)), approximately 44% of small

food manufacturing companies have annual revenues of less than $500,000.[5] This rule's first-year costs of about $6,500 for a three-product business would be more than 1% of revenues for any business with less than $500,000 in annual revenues. We do not know what percentage of these costs may be passed on to consumers in the form of higher food prices, but even when all costs are passed on to consumers, small entities will have to pay many of the up-front costs themselves before the costs can be recovered in later years, which could impact their cash flow and short-term profitability.

C. Alternatives to Minimize the Burden on Small Entities

For the purpose of this economic analysis, we examine the costs and benefits of exempting small business from the proposed rule, even though this option is not viable. We also examine the costs and benefits of establishing a delayed compliance date for small businesses as compared to other businesses.

An exemption for small businesses would reduce annualized costs to each small business by about $690. Annualized costs to all small businesses combined would be reduced by about $27,000.

When producers have four years to relabel instead of two, as would happen if small business compliance was pushed back to the subsequent Uniform Compliance Date average expected relabeling costs fall to about $156 per product. Therefore, delaying the costs of compliance by two years would reduce the annualized cost per small business by about $190 (660 - (156x3) = 192). Annualized costs to all small businesses combined would be reduced by about $7,700.

Any exemption or delay for small businesses would also reduce the benefits of this rule, and would also have the negative side effect of reducing overall consumer confidence in product labeling, because the rules and standards would no longer be uniform. We believe these reduced benefits and additional costs outweigh the small savings that could be obtained by an exemption or delayed compliance date for small businesses.

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[5] After subtracting the 959 firms with more than $100 million in revenues, which are probably not small businesses, there are 20,662 firms listed for NAICS code 311. Of these, 9,145 have revenues less than $500,000. 9,145/20,662 = 44.3%

IV. References

1. **FDA CFSAN.** Guidance for Industry: FDA's Implementation of "Qualified Health Claims": Questions and Answers; Final Guidance. [Online] http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053843.htm.

2. —. Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease, Notice of Proposed Rulemaking.

3. **Label Insight.** LabelInsight. [Online] https://www.labelinsight.com/.

4. **Bureau of Labor Statistics.** Occupational Employment Statistics. [Online] 2017. https://www.bls.gov/oes/current/oessrci.htm.

5. **Health and Human Services.** *Guidelines for Regulatory Impact Analyses.* 2016.

6. **RTI International.** *Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration.* 2011.

7. **US Census Bureau.** 2012 SUSB Annual Data Tables by Establishment Industry. *Data by Enterprise Receipt Size.* [Online] https://www.census.gov/data/tables/2012/econ/susb/2012-susb-annual.html.