

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Labeling: Health Claims; Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease

Regulatory Impact Analysis for Interim Final Rule

Regulatory Flexibility Analysis

Unfunded Mandates Reform Act Analysis

FDA-2013-P-0047

Office of Planning
Office of the Commissioner
December 2016

SUMMARY: The Food and Drug Administration (FDA or we) is issuing an interim final rule to amend the regulation authorizing a health claim on the relationship between dietary saturated fat and cholesterol and risk of coronary heart disease (CHD) (21 CFR 101.75) by permitting its use on raw fruits and vegetables that are currently ineligible to bear the claim. These raw fruits and vegetables do not meet the “low fat” definition (21 CFR 101.62(b)(2)) and/or the minimum nutrient content requirement (21 CFR 101.14(e)(6)) in order to be eligible to bear the CHD claim. FDA is issuing this interim final rule in response to a petition submitted by the American Heart Association. The analysis of benefits and costs included in this document is the basis for the Economic Analysis of Impacts section included in the Food Labeling: Health Claims; Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease interim final rule [FDA-2013-P-0047].

Table of Contents

I.	INTRODUCTION AND SUMMARY	4
A.	Introduction	4
B.	Summary of the Impact of the Interim Final Rule	5
II.	REGULATORY IMPACT ANALYSIS	6
A.	Background	6
B.	Need for the Regulation	7
C.	Purpose of the Interim Final Rule	8
D.	Coverage of the Analysis	8
III.	COSTS AND BENEFITS OF REGULATORY OPTIONS	
A.	Baseline: No New Regulation	11
B.	Option 1. The Interim Final Rule	11
C.	Costs of the Interim Final Rule	11
D.	Benefits of the Interim Final Rule	12
E.	Summary of Costs and Benefits for Option 1	14
IV.	REGULATORY FLEXIBILITY ANALYSIS	15
V.	REFERENCES	16

I. INTRODUCTION AND SUMMARY

A. Introduction

We have examined the impacts of the interim final rule under Executive Order 12866, Executive Order 13563, 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 us 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). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the interim final rule. We believe that this interim final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the interim final rule concerns voluntary claims, we certify that the interim final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “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 \$146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This interim final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of the Impact of the Interim Final Rule

This interim final rule amends the regulation authorizing health claims on the relationship between dietary saturated fat and cholesterol and risk of CHD by expanding their use to raw fruits and vegetables that do not meet the “low fat” definition (21 CFR 101.62(b)(2)) and/or the minimum nutrient content requirement (21 CFR 101.14(e)(6)). This includes, but is not limited to, such raw fruits and vegetables as avocados, bamboo shoots, beets, cucumbers, grapes, huckleberries, iceberg lettuce, mushrooms, plums, sea buckthorn berries, sweet corn, and scallions.

This Regulatory Impact Analysis (RIA) qualitatively discusses the economic impacts of this interim final rule, including costs and benefits. We have some data on how many businesses may be affected by the interim final rule, but very little data on the current consumer usage of CHD claims on labels and labeling, how these practices would change in response to this interim final rule, or how the consumers will respond to new CHD claims on raw fruits and vegetables that were previously ineligible for such claims. Because of this data gap, we acknowledge that we do not have sufficient evidence at this point to quantify the costs and the benefits of this interim final rule.

The costs of this interim final rule include administrative and labeling costs, but only for those firms choosing to add the CHD health claim to labels and labeling of fruits and vegetables that will become eligible for such claims. We believe that a business will only incur the additional costs associated with analyzing the health claim requirements and relabeling a previously ineligible product if the additional revenue it anticipates to generate by attracting more customers to its products is greater than these additional costs. This implies zero net costs from this interim final rule to such businesses, as well as to any businesses that decide not to

include new CHD health claims on previously ineligible fruits and vegetables. Industry will only use a new CHD health claim on the labels and labeling of previously ineligible product if it believes consumers are willing to pay more for such product or buy more of it due to the new CHD claim. If consumers value such new CHD health information, we expect there to be changes in consumer behavior that would result in public health benefits from the reduced annual number of CHD cases.

II. REGULATORY IMPACT ANALYSIS

A. Background

The authority to issue this regulation is found in section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), which specifically provides that any person may petition the Secretary to issue a regulation relating to a claim on the label or labeling of a food intended for human consumption that either characterizes the level of any nutrient or the relationship of any nutrient to a disease or health-related condition.

The American Heart Association submitted a petition, dated September 28, 2012, to FDA. This petition requests that FDA amend the dietary saturated fat and cholesterol and CHD health claim regulation. Specifically, it asks us to permit raw fruits and vegetables, as well as single-ingredient or mixtures of frozen or canned fruits and vegetables that contain no added fat or sugars, which do not meet the “low fat” definition (21 CFR 101.62(b)(2)) and/or the minimum nutrient requirement (21 CFR 101.14(e)(6)), to be eligible to bear the CHD health claim.

In addition, the petition requests that FDA issue an interim final rule by which these fruits and vegetables could be eligible to bear the claim prior to publication of a final rule. Section 403(r)(7) of the FD&C Act authorizes us to make proposed regulations issued under section

403(r) of the FD&C Act effective upon publication pending consideration of public comment and publication of a final regulation, if FDA determines that such action is necessary for public health reasons. The petition states that based on the scientific evidence, consuming fruits and vegetables as an integral part of a healthful diet, regardless of the specific nutrient or total fat content of these fruits and vegetables, is likely to reduce the risk of CHD. Authorizing the use of the CHD health claim on all raw fruits and vegetables has the potential to encourage fruit and vegetable consumption, which is important for public health.

B. Need for Regulation

Inadequate information about a product for consumers is a well-established type of market failure. When individual consumers find collecting information costly and/or time-consuming, the revealed private demand for information may differ from the socially optimal demand and level of information. Without this rulemaking, consumers have less readily-available information for their decisions about purchasing raw fruits and vegetables impacted by this rulemaking and incorporating them into their diets. For consumers that are trying to follow a heart-healthy diet, having clear, non-misleading labels and labeling with CHD information for previously ineligible raw fruits and vegetables decreases the search cost of obtaining that information ahead of time of purchase. We believe that these consumers value the CHD information on the labels and labeling for previously ineligible raw fruits and vegetables because it saves them time and effort when it comes to searching for heart-healthy products for their individual diets.

C. Purpose of the Interim Final Rule

FDA is issuing this interim final rule to amend the regulation authorizing health claims on the relationship between dietary saturated fat and cholesterol and risk of CHD by expanding their use to raw fruits and vegetables that do not meet the “low fat” definition (21 CFR 101.62(b)(2)) and/or the minimum nutrient content requirement (21 CFR 101.14(e)(6)). Prompt issuance of an interim final rule that reflects the current Dietary Guidelines for Americans 2015-2020 recommendations is necessary for consumers to be able to have the most current information on a healthful diet [1]. Thus, exempting raw fruits and vegetables from meeting the minimum nutrient content requirement and/or the “low fat” definition for the CHD health claim would be socially beneficial as it would help ensure that scientifically sound nutritional and health information, as well as important new knowledge regarding CHD, is provided to consumers as soon as possible to help consumers develop and maintain healthy dietary practices. Issuing this interim final rule would help achieve the socially optimal level of information related to the link between healthful diet and CHD.

D. Coverage of the Analysis

This interim final rule would apply only to those domestic and foreign businesses that label raw fruits and vegetables previously ineligible for this CHD health claim and will now be eligible to bear this claim. Although the petition requests that a “single-ingredient or mixture of frozen or canned fruits and vegetables that contains no fats or sugars in addition to the fats or sugars inherently present in the fruit or vegetable product” also be exempt from the low fat and minimum nutrient content requirements, we are not including these types of products in the exemptions at this time. Please see further discussion in section III.D of the interim final rule.

Although any business entity that is a part of the raw fruit and vegetable supply chain, including farms, produce processors, wholesalers, importers, retail establishments, etc., can potentially decide to label previously ineligible raw fruits and vegetables with a CHD health claim, for the purposes of this regulatory impact analysis, we assume that such health claim labeling is primarily done by fresh produce wholesalers. Because the interim final rule will impact only certain raw fruits and vegetables, we are unable to determine the exact number of businesses that will be impacted by this interim final rule because the exact firm-level production and processing data for each such business is currently unavailable to us.

Table 1 – The Estimated Number of Firms Impacted by This Interim Final Rule¹

	Number of firms	Number of these firms that are small businesses
Domestic	2,150	2,000
Foreign	21,695	20,176
Total	23,845	22,176

We use Dun and Bradstreet (D&B) global business database for estimating the number of domestic firms that may be potentially impacted by this interim final rule [2]². According to D&B database, there are 4,300 firms that operate about 4,701 domestic facilities in the U.S. that are primarily engaged in the wholesale distribution of fresh fruits and vegetables; about 93 percent of them employ fewer than 100 employees and therefore are small businesses according to the Small Business Administration [3]. We recognize that not all of these domestic firms and

¹ A single firm may operate multiple facilities. We do not have the data on the number of foreign firms that would be impacted by this interim final rule. Therefore, we assume that on average the number of foreign facilities per foreign firm is the same as the number of domestic facilities per domestic firm.

² The same dataset was used for the economic analysis for the FDA Food Safety Modernization Act rule titled “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food” (Docket No. FDA-2011-N-0920). From this data set we selected only those fruits and vegetables that are classified under the Standard Industrial Classification (SIC) code 5148.

facilities, however, process at least one raw fruit or vegetable that was previously ineligible for a CHD health claim and will become eligible for such claim under this interim final rule. We use a uniform distribution and estimate that the number of domestic facilities that may be impacted by this interim final rule is between 235 and 4,466 facilities³, with the best estimate of 2,351 facilities. We also estimate that the number of impacted domestic firms is between 215 and 4,085 firms, with the best estimate of 2,150 firms (Table 1).

In addition, we estimate the number of potentially impacted foreign fresh produce manufacturing facilities using the Operational and Administrative System for Import Support database (OASIS)⁴, FDA's internal data query. OASIS collects information on all importers (foreign manufacturers) of FDA-regulated products that supply the U.S. market [4]. Using the 2015 OASIS data, we estimate that on average 47,436 foreign facilities produce raw fruits and vegetables for the U.S. market. We believe, however, that not all of these facilities produce at least one raw fruit or vegetable that will become eligible for a new CHD claim under this interim final rule, and not all of these manufacturing facilities are processors that typically perform the labeling step of these raw fruits and vegetables. Therefore, we use a uniform distribution and estimate that the number of foreign facilities that may be impacted by this interim final rule is between 2,371 and 45,064, with the best estimate of 23,718 facilities. We also estimate that the number of foreign firms that may be impacted by this proposed rule is between 2,169 and 41,220, with the best estimate of 21,695 foreign firms (Table 1).

³ We use Monte Carlo simulations to estimate ranges.

⁴ To be registered in OASIS, a foreign facility must have physically shipped goods into the U.S. We use the OASIS database rather than the D&B database to estimate the number of foreign facilities, because D&B does not identify where a facility's final products are sold. Although the D&B database is comprehensive, we cannot know from the D&B database whether a foreign facility actually manufactures, processes, packs or holds food that will be exported to the U.S. The OASIS database only has the information by foreign manufacturer (foreign facility), but does not link each facility to a specific firm. In order to estimate the number of impacted foreign firms we assume that the share of facilities that foreign firms operate is the same as for domestic firms.

In sum, we estimate that this interim final rule may potentially impact about 23,845 firms (range 2,384 to 45,305 firms) and that 22,176 of these firms are small businesses (Table 1). These numbers include only those firms that typically perform the labeling processing step of the impacted raw fruits and vegetables; it does not include any new facilities that may join the market for the impacted fruits and vegetables in the future. We acknowledge the uncertainty in these estimates and request comment on the number and size of facilities and firms potentially impacted by this interim final rule.

III. COSTS AND BENEFITS OF REGULATORY OPTIONS

A. Baseline: No New Regulation

This baseline option is no new regulation. We include it here because OMB cost-benefit analysis guidelines recommend discussing statutory requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity cost of legal constraints that prevent the selection of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866. It is assumed that there are zero costs and benefits associated with this option and it serves as the baseline against which other options will be measured for assessing costs and benefits.

B. Option 1. The Interim Final Rule

Costs of the Interim Final Rule

Because this interim final rule does not require firms to re-label their products, we expect there to be zero net costs associated with this interim final rule. We believe that if a business

decides to learn about this interim final rule and re-label previously ineligible raw fruits or vegetables to include a CHD health claim, it will do so on a completely voluntary basis during the next re-labeling or marketing cycle. A business has an incentive to only use these CHD health claims on the labels and labeling if it believes that consumers value the information communicated by these claims, meaning that consumers are willing to pay more or buy more of the fruits and vegetables impacted by this interim final rule because of the CHD claim. Such businesses will only decide to bear the additional costs of learning about this interim final rule and relabeling fruits and vegetables impacted by this interim final rule if they anticipate generating additional revenues greater than these additional costs. Therefore, we estimate that this interim final rule has zero net cost to any business regardless of whether a change in the label or labeling of previously ineligible raw fruits or vegetables takes place.

Benefits of the Interim Final Rule

This interim final rule will allow businesses to expand the use of CHD health claims on labels and labeling of certain raw fruits and vegetables that were previously not eligible for such health claims under the “low fat” definition (21 CFR 101.62(b)(2)) and/or the minimum nutrient requirement (21 CFR 101.14(e)(6)). We are not aware of any clinical studies that produce measurable reduction of the number of CHD incidents resulting from consumption of any specific raw fruit or vegetable. Thus, we lack sufficient data to quantify the potential benefits of this interim final rule.

We believe, however, that the scientific studies provided to us by the petitioner as a part of the 2012 petition package sufficiently demonstrate that intake of fruits and vegetables as a group or category of foods is associated with reduced risk of cardiovascular disease and other

chronic diseases, including CHD. The studies submitted by the petitioner include studies of fruit and vegetable intake and the reduced risk of CHD (e.g., [5], [6], [7], [8], [9], [10], [11], [12]). In addition, some scientific studies provided by the petitioner suggest that there is no scientific basis for certain fruits or vegetables to be excluded from bearing a CHD health claim (e.g., [13], [14], [15]).

Based on this current scientific evidence and the official recommendations from the Dietary Guidelines for Americans by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture [1], we agree with the petitioner that fruits and vegetables as a group contribute to reduced risk of CHD as a part of a healthful diet and that previously ineligible raw fruits and vegetables should be allowed to bear a CHD claim. These health claims will provide consumers with important, scientifically sound nutritional and health information regarding fruit and vegetable intake that we agree is not misleading.

The value of CHD information to consumers will be demonstrated, in part, by the extent to which individual consumers shift their consumption towards a heart healthier diet by being willing to pay more for or buy more of relabeled raw fruits and/or vegetables previously ineligible and now eligible for a CHD health claim. If consumers respond to this CHD health information by increasing consumption of previously ineligible raw fruits and vegetables, there will be a gain in consumer welfare associated with substitution towards these raw fruits and vegetables. Having the CHD information readily available on a larger number of labels and labeling for raw fruits and vegetables also reduces consumers' search cost for that information ahead of time of purchase.

While there are studies that in general demonstrate consumers' willingness-to-pay for nutrition information on food labels (e.g., [16]) and changes in purchasing behavior caused by

the health information on the labeling of specific foods (e.g., [17]), currently there are no studies conducting such estimates for CHD health claims on the labels and labeling of fruits and vegetables. The literature exists, however, on consumers' willingness-to-pay for reduction in general risk and symptoms associated with chronic heart disease and heart attacks (e.g., [18], [19], [20]). For the purposes of quantifying benefits of this interim final rule, it is difficult to estimate changes in the amount of consumed raw fruits and vegetables impacted by this rule or to translate these changes into equivalent health and longevity welfare effects without knowing the impact of CHD-associated labeling on the total daily diet.

After the publication of this interim final rule, those consumers who are trying to eat a heart-healthy diet will have an easier time recognizing relevant fruits and vegetables that reduce the risk of CHD because of the information provided on labels and labeling. Therefore, we expect there to be changes in behavior that would result in public health benefits from people eating more fruits and vegetables impacted by this interim final rule. We cannot fully quantify these health benefits, but we expect that there will be a lower number of annual CHD cases because of consumers' positive response to CHD health claims on labels and labeling of the impacted fruits and vegetables.

Summary of Costs and Benefits for Option 1

In sum, we estimate that for firms, private costs will be outweighed by private benefits because the additional revenues received by firms will be equal to or greater than the sum of administrative and relabeling costs. A portion of these costs may be passed on by the industry to consumers in a form of increased prices on relabeled products. Social benefits, however, will necessarily outweigh these costs to consumers. The benefit to consumers from new CHD

information on labels and labeling includes the reduced risk of CHD and the reduced search cost for fruits and vegetables for their heart-healthy diet. If the consumer values these benefits more than the price increase passed on by the industry to consumers because of additional administrative and relabeling costs, the consumer has an incentive to purchase the previously ineligible fruits and vegetables with new CHD information on labels and labeling. Otherwise, the consumer will decide that the price increase is too high for this new CHD information and the industry will have no incentives to re-label previously ineligible raw fruits and vegetables, resulting in zero net costs and benefits from this interim final rule. Thus, the benefits will only be realized, and labels will only be changed, if the new CHD information on labels and labeling increases consumer demand for the previously ineligible and now eligible for a CHD health claim fruits and vegetables; otherwise, the firms will not use the CHD health claim on their labels for these fruits and vegetables.

IV. REGULATORY FLEXIBILITY ANALYSIS

We have examined the economic implications of this interim final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612). The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this interim final rule does not require that businesses of any size make changes to any existing labels or labeling to include new CHD health claims, we certify that the interim final rule will not have a significant economic impact on a substantial number of small entities.

V. REFERENCES

The following references have been placed on display in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. We have verified all the Web site addresses in the References section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.

- [1] U.S. Department of Health and Human Services and U.S. Department of Agriculture, "Dietary Guidelines for Americans 2015-2020, 8th edition," 2015. [Online]. Available: http://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf. [Accessed 29 June 2016].
- [2] D&B, *Dun & Bradstreet Global Business Database 2014*, purchased by FDA, 2014.
- [3] U.S. Small Business Administration, "Table of Small Business Size Standards Matched to North American Industry Classification System Codes," 26 February 2016. [Online]. Available: http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf. [Accessed 30 June 2016].
- [4] OASIS, *FDA's Operational and Administrative System for Import Support database*, 2015.
- [5] P. Knekt, R. Jarvinen, A. Reunanen and J. Maatela, "Flavonoid intake and coronary mortality in Finland: a cohort study," *BMJ*, vol. 312, pp. 478-481, 1996.
- [6] S. Liu, I. M. Lee, U. Ajani, S. R. Cole, J. E. Buring and J. E. Manson, "Intake of vegetables rich in carotenoids and risk of coronary heart disease in men: The Physician's Health Study," *International Journal of Epidemiology*, vol. 30, pp. 130-135, 2001.
- [7] K. J. Joshipura, F. B. Hu, J. E. Manson, M. J. Stampfer, E. B. Rimm, F. E. Speizer, G. Colditz, A. Ascherio, B. Rosner, D. Spiegelman and W. C. Willett, "The effect of fruit and vegetable intake on risk for coronary heart disease," *Ann Intern Med*, vol. 134, pp. 1106-1014, 2001.
- [8] L. M. Steffen, D. R. J. Jacobs, J. Stevens, E. Shahar, T. Carithers and A. R. Folsom,

- "Associations of whole-grain, refined-grain, and fruit and vegetable consumption with risks of all-cause mortality and incident coronary artery disease and ischemic stroke: the Atherosclerosis Risk in Communities (ARIC) Study," *Am J Clin Nutr*, vol. 78, pp. 383-390, 2003.
- [9] K. L. Tucker, J. Hallfrisch, N. Qiao, D. Muller, R. Andres and J. L. Fleg, "The combination of high fruit and vegetable and low saturated fat intakes is more protective against mortality in aging men than is either alone: the Baltimore Longitudinal Study of Aging," *J Nutr*, vol. 135, pp. 556-561, 2005.
- [10] L. Dauchet, P. Amouyel, S. Hercberg and J. Dallongeville, "Fruit and vegetable consumption and risk of coronary heart disease: a meta-analysis of cohort studies," *J Nutr*, vol. 136, pp. 1193-1197, 2006.
- [11] F. J. He, C. A. Nowson, M. Lucas and G. A. Macgregor, "Increased consumption of fruit and vegetables is related to a reduced risk of coronary heart disease: meta-analysis of cohort studies," *J Hum Hypertens*, vol. 21, pp. 717-728, 2007.
- [12] F. L. Crowe, A. W. Roddam, T. J. Key, P. N. Appleby, K. Overvad, M. U. Jakobsen, A. Tjonneland, L. Hansen, H. Boeing, C. Weikert, J. Linseisen, R. Kaaks, A. Trichopoulou, G. Misirli, P. Lagiou, C. Sacerdote, V. Pala, D. Palli, R. Tumino, S. Panico, H. B. Bueno-De-Mesquita, J. Boer, C. H. Van Gils, J. W. Beulens, A. Barricarte, L. Rodriguez, N. Larranaga, M. J. Sanchez, M. J. Tormo, G. Buckland, E. Lund, B. Hedblad, O. Melander, J. H. Jansson, P. Wennberg, N. J. Wareham, N. Slimani, I. Romieu, M. Jenab, J. Danesh, V. Gallo, T. Norat and E. Riboli, "Fruit and vegetable intake and mortality from ischaemic heart disease: results from the European Prospective Investigation into Cancer and Nutrition (EPIC)-Heart Study," *European Heart Journal*, vol. 32, pp. 1235-1243, 2011.
- [13] K. Khatun, H. Mahtab, P. A. Khanam, M. A. Sayeed and K. A. Khan, "Oyster mushroom reduced blood glucose and cholesterol in diabetic subjects," *Mymensingh Medical Journal*, vol. 16, no. 1, pp. 94-99, 2007.
- [14] P. S. Larmo, B. Yang, S. A. Hurme, J. A. Alin, H. P. Kallio, E. K. Salminen and R. L. Tahvonen, "Effect of a low dose of sea buckthorn berries on circulating concentrations of cholesterol, triacylglycerols, and flavonols in healthy adults," *European Journal of Nutrition*, vol. 48, pp. 277-282, 2009.

- [15] E.-J. Park and D.-Y. Jhon, "Effects of bamboo shoot consumption on lipid profiles and bowel function in healthy young women," *Nutrition*, vol. 25, pp. 723-728, 2009.
- [16] J. Abaluck, "What Would We Eat if We Knew More: The Implications of a Large-Scale Change in Nutrition Labeling," *Working paper*, 2011.
- [17] P. M. Ippolito and A. D. Mathios, "Information, advertising and health choices: a study of the cereal market," *Rand Journal of Economics*, vol. 21, no. 3, pp. 459-480, 1990.
- [18] C. R. Sunstein, "Bad death," *Journal of Risk and Uncertainty*, vol. 14, pp. 259-282, 1994.
- [19] F. R. Johnson, M. R. Banzhaf and W. H. Desvousges, "Willingness to pay for improved respiratory and cardiovascular health: a multiple format, stated preference approach," *Health Economics*, vol. 9, pp. 295-317, 2000.
- [20] T. A. Cameron, J. R. DeShazo and E. H. Johnson, *Willingness to Pay for Health Risk Reductions: Differences by Type of Illness*, 2008.